A reasoned proposal for shared approaches to ethics assessment in the European context

Compiled by: Philip Jansen, Wessel Reijers,
David Douglas, Faridun Sattarov, Agata Gurzawska,
Alexandra Kapeller & Philip Brey (University of Twente),
Rok Benčin (Scientific Research Centre
of the Slovenian Academy of Sciences and Arts),
Zuzanna Warso (Helsinki Foundation for Human Rights),
Robert Braun (Institute for Advanced Studies Vienna)

Contributors: Listed on following page

May 19, 2017 (revised version)
(Original report completed December 7, 2016)

Deliverable D4.1

This deliverable and the work described in it is part of the project *Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation – SATORI –* which received funding from the European Commission's Seventh Framework Programme *(FP7/2007-2013)* under grant agreement n° 612231

Contact details for corresponding author(s):

Prof. dr. Philip Brey, Project Coordinator, University of Twente
p.a.e.brey@utwente.nl

Full List of Contributors

Stakeholder Analysis	Rok Benčin (ZRC SAZU), Sudeep Rangi (UNESCO), Zuzanna Warso (HFHR)
Ethical Principles and Issues in Ethics Assessment	Philip Brey, Philip Jansen, Faridun Sattarov, David Douglas & Wessel Reijers (UT), Göran Collste (LIU), Gregor Strle (ZRC-SAZU), Sudeep Rangi (UNESCO)
Ethics Assessment Procedures	David Douglas (UT), Johanna Romare (Centre for Applied Ethics, Linköping University), Raija Koivisto (VTT), Rowena Rodrigues (Trilateral Research), Lise Bitsch (DBT)
Ethical Impact Assessment	Philip Brey, Wessel Reijers & Philip Jansen (UT), Rowena Rodrigues & David Wright (Trilateral Research), Raija Koivisto & Anu Tuominen (VTT), Lise Bitsch (DBT)
Standards, Tools and Best Practices for: Policy-Oriented Assessment and Guidance of New Developments and Practices in R&I	Doris Wolfslehner (Austrian Bioethics Committee), Wessel Reijers (UT), Sudeep Rangi (UNESCO)
Standards, Tools and Best Practices for Guiding, Assessing and Supporting Ethical Professional Behaviour by Scientists and Innovators	Rok Benčin & Gregor Strle (ZRC SAZU), Sudeep Rangi (UNESCO), Dubravka Vejnović (CPN)
Standards, Tools and Best Practices for the Ethics Assessment of Innovation and Technology	Philip Jansen & Agata Gurzawska (UT)
Models for Ethics Assessment and Guidance in Higher Education	Philip Brey, David Douglas & Alexandra Kapeller (UT), Rok Benčin (ZRC-SAZU), Daniela Ovadia (EUSJA), Doris Wolfslehner (ABC)
Models for Ethics Assessment and Guidance at Civil Society Organisations	Zuzanna Warso (Helsinki Foundation for Human Rights), Dalibor Petrović (Center for the Promotion of Science)
Models for Ethics Assessment and Guidance in Industry	Agata Gurzawska (UT), Andrea Porcari (Associazione Italiana per la Ricerca Industriale, AIRI), Johanna Romare (Linköping University), Rossella Cardone (Ericsson)
Models for Ethics Assessment at Research Funding Organisations	Doris Wolfslehner (ABC), Philip Brey & Philip Jansen (UT)

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INITIALS AND ACRONYMS

CR:	Corporate Responsibility
CSO:	Civil Society Organisation
CSR:	Corporate Social Responsibility
EA:	Ethics Assessment
EAU:	Ethics Assessment Unit
EI:	Ethical Impact
EIA:	Ethical Impact Assessment
EG:	Ethics Guidance
EU:	European Union
ICT:	Information and Communication Technology
IRB:	Institutional Review Board
NEC:	National Ethics Committee
NGO:	Non-Governmental Organisation
NSA:	National Science Academy
OECD:	Organisation for Economic Cooperation and Development
PDCA:	Plan-Do-Check-Act
QA:	Quality Assurance
REC:	Research Ethics Committee
RFO:	Research Funding Organisation
R&D:	Research and Development
R&I:	Research and Innovation
TRL:	Technology Readiness Level

1 INTRODUCTION

This report presents a comprehensive proposal for a common ethics assessment framework for research and innovation (R&I) in the European Union member states. It details recommendations for good practices for ethics assessment, which includes the development of ethics assessment units and the protocols of these units. More specifically, the report presents a general toolkit for ethics assessment of R&I, as well as specialised tools and toolkits for specific types of organizations that deal with ethics assessment, and for different scientific fields. In addition, the report offers recommendations for the general institutional structure of ethics assessment in the EU and its member states. Due to the length of this report, a summary of its findings and recommendations is available.[1] There are also several annexes that expand on particular sections of the report. These annexes are also available on the website of the SATORI project.

In chapter 2, we analyse the stakeholders' expectations about the intended outcome of the SATORI project: a shared European framework for ethics assessment of R&I. This analysis is based on 153 interviews with different kinds of stakeholders, including both ethics assessors and non-assessors. Both benefits and obstacles were identified and are listed in this chapter. Furthermore, three main challenges are identified: the differences in ethics/values, the need for stakeholder buy-in, and the need for the ethics assessment framework to be a long-term process. Nonetheless, it is found that a significant majority of interviewees were positive or conditionally positive towards the desirability of a common approach to ethics assessment in R&I.

In chapter 3, we propose a framework of ethical issues and principles, which are applicable to a broad array of types of scientific R&I. The research areas discussed in depth are the natural sciences, the engineering sciences, and the medical and life sciences, information and communication technology (ICT), Internet research, the social sciences, and the humanities. It provides a basis of ethical issues and principles that apply to all types of research. It also specifies the principles and issues that apply to specific research contexts. This chapter also includes a section on how potential conflicts between ethical principles may be resolved.

In chapter 4, we outline recommendations for best practice in Ethics Assessment Units (EAUs). These recommendations are structured around a series of parameters common to all EAUs that review R&I activity. These parameters include the appropriate composition of an EAU, the appointment, training, and expertise of its members, the procedures for performing assessment, and how to assess the quality and efficiency of the EAU's work. The cultural and organisational factors that may affect the work of an EAU are also briefly considered. The chapter concludes with a summary of the recommendations presented within it.

In chapter 5, we offer a short overview of the Common Framework for Ethical Impact Assessment (EIA) that is described further in Annex 1. This chapter can be used by governance bodies to set up new regulations with regard to ethics assessment in R&I, research funding organisations to set up new procedures for conducting EIAs in the projects they fund, and by local research organisations and companies for establishing internal procedures for conducting an EIA of the R&I projects they organise.

[1] Ingrid Callies, Philip Jansen, Wessel Reijers, David Douglas, Agata Gurzawska, Alexandra Kapeller, Rok Benčin, Zuzanna Warso, *SATORI Deliverable D4.2 Outline of a Common Ethics Assessment Framework*, September 2016.

In section 6, we present recommendations for specialised forms of ethics assessment and guidance. Specifically, we outline standards, tools and best practices for (1) policy-oriented assessment and guidance of new developments and practices in R&I (with a focus on governmental organisations, national ethics committees, and civil society organisations); (2) guiding, assessing and supporting ethical professional behaviour by scientists and innovators; and (3) the ethics assessment of innovation and technology development plans.

In chapter 7, we discuss ethics assessment (EA) and ethics guidance (EG) in the context of four specific types of organisation: universities, civil society organisations, industry and research funding organisations.

In chapter 8, we outline proposals for the institutional structure of ethics assessment in eight types of organisations that perform ethics assessment in the EU member states: universities, national science academies, RFOs, RECs, NECs, academic and professional organisations, CSOs, and companies. In addition, we present recommendations for the institutionalisation of ethics assessment in selected European countries.

In chapter 9, we assess the compatibility of existing ethics assessment frameworks with the SATORI framework. This covers international regulations and guidelines as well as the approaches to ethics assessment in the United States and China.

Finally, in chapter 10, we present a summary of the recommendations contained in this report, and conclude in chapter 11 with a list of the annexes to this report.

2 ETHICS ASSESSMENT ORGANISATIONS' EXPECTATIONS ABOUT A JOINT FRAMEWORK

2.1 Introduction

This chapter is an overview of the work completed in WP 4.1.1 and analyses the opinions on the desirability and possibility of a shared European approach to ethics assessment of research and innovation as expressed by the stakeholders identified by SATORI. The analysis is based on 153 interviews (completed in WP 1) with different kinds of stakeholders (ethics assessors and non-assessors).

The first two sections explain the purpose and approach to the stakeholder analysis. In the third section, general observations are presented along with observations specific to a particular type of stakeholder. The final section presents the conclusions.

2.2 Purpose

The purpose of this task is to analyse the stakeholders' views on the intended outcome of the SATORI project: a shared European approach to ethics assessment of research and innovation (R&I). As the approach was not yet developed at the time the interviews with stakeholders were conducted, the questions posed focused on the desirability and possibility of such a framework.

The analysis of interviewees' responses will show:

- whether this framework would be welcomed by the stakeholders,
- what would be the benefits and negatives of a common approach to ethics assessment,
- what kind of obstacles to the development and implementation of such an approach SATORI can expect,
- how the framework should be structured to be useful for the stakeholders, and
- how it fits with other approaches to ethics assessment.

The conclusions of this analysis can be used by SATORI to further reflect on the construction of its ethical assessment framework.

2.3 Methodology

Stakeholder analysis comprises a set of methods and tools for gathering and analysing knowledge about stakeholders, i.e. individuals or organisations that have an interest in or are affected by the implementation of a policy, reform, regulation, programme, project or framework.[2] In R&I

[2] Precise definitions vary according to what is being implemented; see Schmeer, Kammi, *Guidelines For Conducting a Stakeholder Analysis*, Partnerships for Health Reform, Abt Associates Inc., Bethesda, MD, 1999; The World Bank, "Stakeholder Analysis",

stakeholder analysis can be seen as a participatory process which helps make innovations more fit for purpose and more likely to be accepted. (In SATORI, a stakeholder analysis on non-assessor stakeholders was performed in Deliverable 2.2. See p. 17 for a brief analysis of the responses on the possibility and feasibility of a shared ethics assessment framework.)

The analysis was performed on 153 interviews with stakeholders carried out in WP 1, which included the following question:

> *Do you think it would be desirable to have a shared European approach for ethics assessment of research and innovation, with a certain amount of shared standards, procedures, and protocols for all European countries, and all organizations that engage in ethics assessment?*
>
> - *Do you believe it is possible?*
> - *What would be the obstacles to such an approach? What would be the benefits?*
> - *Would it be desirable for such an approach to have shared ethical values and principles, or only protocols and procedures?*

Several types of stakeholders were considered, following the general SATORI taxonomy: accreditation organisations, civil society organisations (CSOs), government organisations, impact assessment organisations (IAOs), industry, national ethics committees (NECs), research ethics committees (RECs), research funding organisations (RFOs), science academies and professional organisations, universities and university organisations.

In the first level of analysis, the general positions of the stakeholders' on the prospect of a common approach to ethics assessment in R&I was estimated. The scale of the positions is as follows:

- positive
- conditionally positive (i.e. the stakeholder would welcome such an approach if it would be designed or implemented in a certain way)
- undecided/inconclusive
- negative

The second level looks deeper into the semantics of the responses. Tags were used to develop an abbreviated mechanism to identify major themes and points provided by interview respondents. Tagging allowed us to compare responses and identify recurrent themes. Tags were divided into five categories, corresponding to the purpose of the analysis:

- *benefits*: why a common ethics assessment approach would be beneficial;
- *advice*: how should such an approach be designed to make it fit for purpose;
- *obstacles*: stakeholders' views on the obstacles SATORI is likely to face in developing this approach;
- *negatives*: why this kind of an approach would not be welcome;

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http://www1.worldbank.org/publicsector/anticorrupt/PoliticalEconomy/stakeholderanalysis.htm; *Guidance Note on How to Do a Stakeholder Analysis of Aid Projects and Programmes*, Overseas Development Administration, 1995.

- *continuation*: how do SATORI's efforts fit in with other initiatives and approaches in the field.

The observations made based of this analysis are presented in the following section.

2.4 Stakeholder Analysis

This section is divided into general observations, presenting frequent themes (those indicated by frequent tags) and observations specific to the types of stakeholders.

2.4.1 General Observations

Preliminary Analysis
The general positions of the stakeholders on the prospect of a common approach to ethics assessment in R&I was estimated based upon the responses given by interview subjects. Each of the responses was categorized according to a scale developed by the authors:

- positive [78 respondents]
- conditionally positive [46 respondents]
- undecided/inconclusive [15 respondents]
- negative [14 respondents]

78 of the 153 (51.6%) were positive on the desirability, representing the largest single total population. An additional 46 respondents (30.0%) were conditionally positive.[3] Together, these two categories represent a significantly greater than majority desirability for a common approach to ethics assessment in research and innovation. 15 responses (9.2%) indicated an undecided/inconclusive response by the interviewee. For these, there was not enough information in the response to indicate the interviewee's preference on the desirability of a common approach to ethics assessment in R&I or the interviewee did not share their opinion on the matter. The remaining 14 responses (9.2%) were negative.[4]

CSOs, government organisations, RECs, RFOS, science academies, and universities and university organizations were predominantly positive or conditionally positive. However, impact assessment organisations and industry were more tepid. Tellingly, no categories of respondents were primarily negative.

Secondary Analysis
Each of the responses was then "tagged" according to themes that were present. The goal was to determine if any recurring themes were present and the frequency with which they recurred.

[3] Common factors cited by respondents in the conditionally positive classification are addressed in secondary analysis.
[4] The authors do not assume the sample size to be a completely representative sample of all stakeholders concerning the ethics assessment of R&I but do believe the figures to be illuminating of overall trends.

Additionally, the authors were interested in seeing if any of the recurring themes were ascribed to a particular category of stakeholder. The most common themes are presented below.

Benefits
The most common "benefits" themes cited are unification, harmonisation, convergence, and commonality as a benefit to having a shared approach to ethics assessment of R&I. These themes emerged 12 times. These themes were often present in stakeholders who engage in ethics assessment processes in multinational settings, where different standards can affect research and innovation activity. Additionally, the themes of unification, harmonisation, etc. were also cited by organisations who sought to use universal rights doctrine as a basis for the ethics assessment. While a number of respondents fear an additional common approach would increase bureaucracy, many think that a common approach would make things simpler: it would harmonise/converge different existent protocols and approaches, and make standards more comparable.

A platform for discussion was the second most recurrent theme, being cited 6 times. These respondents indicated desirability for a common ethics assessment framework to facilitate a larger discussion forum for consolidating the numerous approaches and practices taking place in ethics assessment on different levels. They believed it could provide a forum for "best-practices" to be shared between actors, as opposed to adding to complicated structures that exist as well as establishing a minimum "ethical floor" for all to use in evaluation.

Promotion of ethics, awareness raising, and ethics over economics, particularly in countries where a central approach is still being developed or in organisations that do not articulate their activity in ethical terms (CSOs), was cited 4 times. The use in international projects and efficiency, expedition, and streamlining was shared especially by those concerned with ethics review approval, namely in clinical research.

Obstacles
National/political/legislative/health system differences were the single most cited theme throughout all responses, and were accounted for in 21 separate responses. These differences could be categorised as:

- national: cultural & political & legislative,
- ethical: norms, values, approaches, philosophies,
- scientific: fields & disciplines.

Almost all interviewees point out the existing differences between countries. They stress the framework should account for them, and according to some interviewees it may help to overcome the differences. At the same time, according to some respondents, ethical principles are in fact the same, but interpretations are different.

Closely linked, cultural differences were cited in 14 responses as a potential obstacle. Differences in ethics/values; the need for stakeholder buy-in; and the need for the ethics assessment framework to be a long-term process each emerged 4 times. With respect to a long-term process, respondents indicated that any new framework would need time to be implemented as well as have a revision mechanism, once implemented.

Many respondents also followed this pattern: there are differences between member states, thus the framework should be general. If it is too general, however, it may be useless. A possible solution is that states should have the option to accommodate the general rules with some room for manoeuvre due to cultural differences, similar to the "margin of appreciation" doctrine found in human rights law.[5]

Respondents, particularly those from government organisations, also noted the problem of the enforceability of such a framework.

Negatives

The most pressing negative theme involved the concern for a common approach to be reduced to a check box formality emphasising procedural concerns over ethical considerations. There is also trepidation that attempting to create a common approach could produce a lowest common denominator effect, whereby ethical considerations are comprised to achieve consensus.

Advice

Various respondents gave advice as to how a potential common approach should be structured. The most common of these were: the need for stakeholder inclusion; transparent discussion throughout the process; and an inclusive and not top-down negotiating process with a tool for mutual recognition. This theme was recorded in 12 responses.

Additionally, themes regarding the room to manoeuvre; opportunity, not requirement; not mandatory; not a list of demands; not prescriptive; common sense, not formalistic; flexible; and self-regulation were cited 9 times.

Eight respondents gave advice on the need to account for sector/field/discipline specifics as well as to be very targeted and issue/context specific.

Five respondents encouraged that a common approach should be human rights based, like a constitution, and aim to exist on an aspirational level.

Continuation

Eleven respondents thought that a common approach would be redundant, as the frameworks already exist.

[5] The "margin of appreciation" doctrine, as known to international human rights law, refers to the space for manoeuvre that the Strasbourg organs are willing to grant national authorities, in fulfilling their obligations under the European Convention on Human Rights (see Greer, Steven, *The Margin of Appreciation: Interpretation and Discretion under the European Convention on Human Rights*, Council of Europe, 2000 [p. 5].), Also see for example: http://www.ucl.ac.uk/european-institute/analysis-publications/britain-europe/appreciation .

Four respondents indicated that it would be a natural progression as the common approach is already trending in the EU, and already happening to some extent globally and would be a continuation on existing international instruments.

2.4.2 Observations by Stakeholder Type

Civil Society Organisations
CSO representatives highlight that the process of establishing a framework should be a participatory effort. Moreover the framework itself, in terms of its scope, should also be inclusive, meaning that in the process of ethics assessment interests of different groups should be taken into consideration.

A few interviewees pointed out the existing differences between countries and societies. They referred to some controversial issues, for instance in the area of reproductive rights, as an example of questions where it would be difficult to establish common ground. They stressed that the framework should account for these existing discrepancies. Interestingly, according to some interviewees a framework could be useful in overcoming differences. By being an inclusive "living instrument" it could simultaneously assist in establishing common standards. Guidance on common ground could be offered by human rights based approach.

For some respondents the existence of differences would entail that the framework could not be too detailed in terms of defining the principles, but instead should focus on protocols and procedures.

Concerns mainly had to do with the fear of increased bureaucracy. Interviewers also pointed out that it could be a challenge to encourage stakeholders to use the framework.

Government Organisations
Representatives of different governmental bodies pointed out that with regard to some countries, e.g. in east-central Europe, a common framework could help in "catching up" in terms of research ethics standards.

One challenge would be to make a framework compatible with all laws that are in force throughout EU member states. In order to do so it should not be too prescriptive. Moreover, the development and implementation would be a lengthy process that should be open to the "needs" of all countries.

A few interviewees pointed to religious, political and cultural differences between countries, and according to some these discrepancies would constitute a serious obstacle in coming up with a framework that could be used by different stakeholders.

Some respondents feared that a framework would stifle innovation. Moreover, the potential benefits were not clear to them.

Impact and Technology Assessment Organisations

Most representatives of impact and technology assessment organisations pointed out that the field of assessment is too large to allow a uniform approach. Harmonisation of approaches is not necessarily feasible nor desirable as there is no best approach for all situations. One must always consider national, cultural and other circumstances and differences.

However, it would be beneficial to identify common ethical grounds, minimal standards or principles on a general level.

Industry
Representatives of industry pointed to the standardisation potential of a shared framework. While they supported the framework, they also highlighted it would be a lengthy process and were cautious on how to achieve "buy in."

They stressed a need for inclusiveness and participation of representatives of different states in the course of establishing a common tool.

In order to overcome existing differences they stressed a need for a strong political will. At the same time, others highlighted that a mix of bottom-up and top-down approach should be employed.

National Ethics Committees
National ethics committees' responses predominantly focus on the application of ethics assessment within biomedicine, which has a long-standing tradition within the European community. When presenting responses, NECs generally formulate responses taking into consideration shared international background as presented by international texts in biomedical research.

Those in favour of a shared framework cited the existence of international texts as a potential foundation for a shared framework. Others appeal to processes already in place for the examination of emerging ethical issues that currently exist within the European Union, such as directives on embryonic stem cell research.

There are differences of opinions about whether or not there are common values, and if not, the best way to reconcile differences within a shared framework. Disparate cultural values are the most cited example of differing values that would need to be taken into consideration. There is no consensus whether it is best to do it with a list of issues of ethical concern, shared protocols, or with inputs from national committees on emerging issues – each of which were suggested by NECs.

Research Ethics Committees
Research ethics committees present highly polarised responses with, sometimes very specific critiques or encouragements. The highly detailed responses may be partially explained by their familiarity with the ethics assessment process.

On the one hand, certain respondents focused on the culture of ethics assessment and ethical research and innovation. For these respondents, the idea of a shared framework was a natural continuation of an existing European movement that would serve to highlight gaps that may exist

in peoples' knowledge of ethics culture and history on more local levels. Differences exist on how to achieve the shared ethics culture. Some believed the standardisation of protocols would be sufficient, which in turn allows for quicker review that could lead to higher quality research. Others emphasised that the culture should be driven but supra-legal or protocol procedures, with an emphasis on education and training on general population levels.

REC respondents consistently presented concerns about local, national, and international levels and the perception of activities done on each of them. There is disagreement about which level provides the strongest foundation to build upon.

On the other hand, there is a great emphasis on shared standards, protocols, and mechanisms. Within this theme, there are conflicting perspectives, with a great emphasis the notion of "policing" vs. "protecting." All were concerned with "protecting," but presented disparate accounts on whether a shared framework achieves greater protection or simply greater policing.

Research Funding Organisations

Interestingly, many interviewed research funding organisations were worried that the framework would be too strict or too formalistic. A desirable framework would be flexible, allowing for nuances and should not be a check-box exercise.

Funding organisations also pointed out the benefit of a common European framework when it comes to international research collaboration.

Science Academies and Professional Organisations

Many academies and professional organisations see the benefit of common standards and approaches. Some of them are in favour of harmonising and converging approaches to ethics assessment. However, finding common grounds should be balanced by nuances in the consideration of differences between scientific fields and disciplines.

Some have pointed out a common framework would be very useful in international research projects. A few of the respondents emphasised the importance of enhancing public understandings of ethical position of science and of integrating ethics into the education of scientists.

Universities and University Associations

Universities stress the importance of making the framework clear and usable. It would also have to include a way to allow the users (the assessed) to demonstrate their implementation of the framework.

Some respondents expressed the concern that a new framework would be too strict and organised in a top-down manner. It should consider differences between disciplines, different ethical principles and cultures.

A few interviewees pointed out the benefits of a common framework for international research projects. One emphasised that ethics should be integrated into the education process.

2.5 Conclusions

A vast majority of interview subjects were favourable towards the prospect of a common approach to ethics assessment in R&I. Specifically, CSOs, government organisations, RECs, RFOs, science academies, and universities and university organisations would welcome it for a variety of reasons. At the same time, impact assessment and industry organisations were more reserved. No categories of respondents were primarily negative.

Interviews showed that many stakeholders shared the view that a common approach would have a harmonising potential and, in general, considered it a positive opportunity. Simultaneously, they pointed to the existence of a variety of differences that could constitute a major challenge in reaching a consensus.

The awareness of the differences often led to the conclusion that a shared approach should be general and flexible in nature, and leave space for manoeuvre. At the same time the stakeholders were acutely aware that the framework that does not strive at providing concrete answers could become useless or at least impractical. One way of tackling these issues seems to be a conscious concession to the employment of a “margin of appreciation” in the implementation of the approach in cases where the differences are most vivid and cannot be overcome. That would mean that different stakeholders would have the option to accommodate more general rules to a specific situation. At the same time, the added values of the framework should be to provide guidance on how to achieve that in a structured and considered manner (e.g. by providing a list of criteria that should be considered). More specifically, a catalogue of good practices could offer insight into the practicalities of adjusting general rules to specific cases. This would also render the approach more useful and assist in obtaining buy-in, which is of crucial importance, especially since a few stakeholders pointed out that achieving a wide acceptance for the framework could be a major challenge.

3 ETHICAL PRINCIPLES AND ISSUES

In this chapter, we discuss ethical issues and principles that apply to the different scientific fields included in the SATORI project and propose a harmonised framework for shared ethical issues and principles. Both the discussions and the reasoned proposal are based on findings from WP 1, which includes the results of the SATORI interviews and documents relevant to the ethical issues and principles of the organisations active in different scientific fields.

Scientific research is a conscious and systematic approach to acquire knowledge, based on theories, methods and standards that have been developed through the history of scientific disciplines. The terms 'research integrity' and 'good research practice' refer to ideals for how research ought to be performed. Scientific misconduct and fraud are deviations from the ideals of science and good research practice. The purpose of principles of research ethics are to guide the researcher in how to conform to the ideals of good research practice and how to perform responsible research with respect to the consequences for human beings, animals and the environment.

Ethical issues and ethical principles are generally strongly related to one-another. A research-ethical issue refers to an ethically significant category of situations that might occur in a research context. An example is the breach of research integrity by committing fraud. An ethical principle, on the other hand, refers to an ethically preferred state of affairs. Again, research integrity is an example of an ethical principle because one could state that it *ought to be the case* that scientists conduct their research in a manner that demonstrates integrity.

In order to justify the application of ethical principles, one generally invokes an approach in normative ethics. The most well-known approaches in this canon are the *utilitarian calculus, Kantian deontology* and *virtue ethics*. For instance, the principle of human dignity is often justified by means of Kantian deontology, which asserts that a human being ought never to be treated merely as a means, but always as an end in itself.

However, these ethical principles in research always arise from a particular research context that is grounded in practice, not *a priori* reflection. The field of *applied ethics* deals with the ethics of such practical contexts, by investigating the existence of specific ethical issues and principles that might apply to one field of research but not to another. For this reason, we need to first investigate the specific ethical issues and principles as they apply to specific research contexts, for instance in the humanities or in the engineering sciences.

Our reasoned proposal of shared ethical issues and principles is based on the empirical data gathered and analysed by the SATORI project and published in the *Deliverable 1.1: Ethical Assessment of R&I: A Comparative Analysis* and its 47 Annexes. The main report provides a comparative analysis of ethics assessment in the scientific fields, organisations and countries investigated. The annexes consist of detailed studies of ethics assessment in different scientific fields, types of organisations and countries, in addition to reports on major principles, issues and approaches in ethics assessment. The deliverable is based on over 230 interviews with representatives of organisations that engage in ethics assessment and guidance, and experts in the field, in Europe, the US and China. It is also based on extensive desk research and literature surveys. The added value of our approach is that it is firmly based in the practice of R&I

throughout different fields, countries and institutions that we empirically examined. Our approach, therefore, will lead us to a good approximation of ethical issues and principles as they are used and recognised in everyday practices of research and innovation in the different institutions and within the different countries that the SATORI project focuses on.

Inasmuch as the proposal is based upon practices that currently exist within R&I, the ethical issues and principles found within the proposal have been largely developed within the context of the relevant legal doctrines built upon a conception of universal human rights. Deliverables 3.1-3.4 of the SATORI project examine these legal contexts extensively, which range from regional to international instruments. This examination is considered here not only to situate the principles within the legal paradigm, but also to understand how laws work to create the environments in which R&I activity takes place. Indeed, some of the principles speak to the conflict that may exist between ethical obligations and legal obligations, showing the two may not always go hand in hand. As presented, the proposal does not attempt to override any existing legal precedents, but could be used as a basis for addressing conflicts that may arise.

In the following sections, we will first of all discuss ethical issues and principles as they apply to each specific scientific field as established in the SATORI project. For each field, we provide overviews of the ethical issues and principles, discussions of these overviews and a short specific case study that illustrates the relevance of specific issues and principles for the respective field. Secondly, we will provide a discussion of ethical conflict resolution in which we evoke the different approaches in normative ethics that can be used for conflict resolutions of ethical principles. Thirdly, we present the reasoned proposal for shared ethical issues and principles consisting of a 'terms & definitions' section and a reasoned overview of the shared ethical issues and principles.

3.1 Natural Sciences

Ethical assessment in the natural sciences mostly deals with issues in areas of academic/research and professional ethics. The main ethical principle is the principle of scientific integrity and proper scientific practice based upon *observation, measurement and objective analysis*, the *testing of hypotheses through experimentation*, *replication of findings*, and *peer review* through public lectures and published works. Additionally, researchers and scientists have a strong ethical obligation to society and environment, and should act in the public's interests by conducting responsible research and promoting discussions on science related issues.

3.1.1 Ethical Principles

- Scientific integrity
    - Scientific honesty
    - Intellectual freedom and openness
    - The principle of scientific credit
    - The practice of experimental control and
    - Reproducibility of results (as two fundamental aspects of establishing reliable scientific practice and credibility of results)

- Advancement of sciences
- The principle of care and social responsibility
- Serving public interests
- Privacy

A comprehensive and representative set of guidelines can be found in *The Chemical Professional's Code of Conduct* of the American Chemical Society, which acknowledges responsibilities of the chemist towards the public (serving public interest and safety), the science of chemistry (advancement of science, respect for truth), the profession ('remain current with developments in their field, share ideas and information, keep accurate and complete laboratory records, maintain integrity in all conduct and publications, and give due credit to the contributions of others'), the employer ('perform work honestly, competently, comply with safety policies and procedures'), employees, students, colleagues, clients and the environment ('responsibility to understand the health, safety and environmental impacts of their work, to recognise the constraints of limited resources, and to develop sustainable products').[6]

The abovementioned ethical principles draw from more general principles and are not limited to the field of natural sciences. For example, physics and chemistry are continuously used in the wider world where decision-making typically also involves ethical choices of other stakeholders outside the domain of science and scientific professions, e.g. those of politicians/policy makers, economists and general public/consumers. Similarly, in the earth sciences, much focus in the last decades has been on climate change and global warming observations, the impact of regional variations on natural systems (of wildlife, marine systems, ice layers, and the timing of vegetation lifecycles), and the ways in which these changes have substantially accelerated during the twenty-first century. The amount of uncertainty in making informed conclusions is reflected in variations in results from research studies on these issues. Most reports related to policy making focus on the assumptions regarding economic growth, technological developments, and population growth, which are arguably the three most critical variables affecting the uncertainty over future climate change and policy options.[7]

3.1.2 Ethical Issues

Main ethical issues in natural sciences arise from scientific practice itself. Moreover, as many areas of natural sciences have an effect on the environment and society, the ethical decision-making also covers a range of issues related to societal responsibility. These are presented and shortly discussed below.

- Scientific misconduct
  - Plagiarism
  - Improper authorship
  - Data fabrication and falsification
  - Misappropriation of the ideas of others

[6] American Chemical Society, *The Chemical Professional's Code of Conduct*, http://www.acs.org/content/acs/en/careers/career-services/ethics/the-chemical-professionals-code-ofconduct.html.
[7] Schneider, Stephen H., "Climate Policy". http://stephenschneider.stanford.edu/Climate/Climate_Policy/Policy.html.

- Non-disclosure of information, which can have harmful side effects (e.g. laboratory trials)
- Misrepresentation of scientific experiments, funds or other resources (e.g. for personal/career gain)
- Misrepresentation of qualifications, experience, or research accomplishments (e.g., to obtain research programmes, external funding, professional career advancement)
- Violations involving the use of funds, care of animals, human subjects, or radioactive, biological, or chemical materials
- Violations of generally accepted research practices in carrying out research (e.g. manipulation of experiments to get desired results, statistical or analytical manipulation of results, improper reporting of results)

Individual judgment is a fundamental aspect of all scientific practice and a first step towards handling scientific misconduct. Openness and transparency are means to avoid scientific misconduct, implying regular and open seminars, public motivations for peer-reviews regarding publications, research funding, etc.

- Conflict of interest

Conflicts of interest arise when researchers have interests that may compromise their ability to fulfil their duties to others.[8] For example, consider the strong links between chemical research and chemical industries, and the issues of conflict of interest may arise (as a scientist, member of public, commercial interests). 'These concerns involve the funding of academic research by private corporations; the increasing pressure, both internal and external, on university scientists to patent and commercialise the results of their research; and the large-scale privatisation of knowledge in commercial databases'.[9]

- Research on human participants or animal testing

Research on human participants or animal testing is usually a part of interdisciplinary research involving biology and medicine. Historically, the most famous cases of unethical experiments with human subjects specific to chemistry and physics have been the ones linked to radiation and chemical weapons development. Toxicology is another discipline in which experiments on live subjects are more common. There is a risk of poisoning, explosions and pollution when dealing with chemical substances - professional codes of conduct usually prescribe responsibility for health, safety and environmental impacts.

- Societal responsibility, sustainability and safety
  - Human risks (health); climate change & environment; weapons industry

Defining responsibility is a particularly complicated issue as new theories and inventions can have potential further developments and uses that are sometimes very hard to predict and are out of the scope of influence of the initial researcher. There are moral issues related to chemistry, such as chemical weapons research, environmental pollution, chemical accidents, unintended bad

[8] Shamoo, Adil E., and David B. Resnik, *Responsible Conduct of Research*, 2nd ed., Oxford University Press, Oxford, 2009 [p. 189].
[9] Kovac, Jeffrey, "Gifts and Commodities in Chemistry", *HYLE: International Journal for Philosophy of Chemistry*, Vol. 7, No. 2, October 2001, pp. 141-153 [p. 142].

'side-effects' of chemical products, etc. Some of these examples are dual use research and technologies, as described above in section 3.2.4.

Moreover, there are significant potential risks linked to applications of new knowledge. As Hartmut et al. states '[s]ometimes the original purpose of a process or a substance may be lost and other applications are adopted that are completely different from the original intention, sometimes with catastrophic consequences.'[10] In chemical science, where approximately 900,000 new substances are published every year, there is an on-going debate about the extent to which 'chemists, as free creators of new substances, are generally responsible for all possible harms caused by their creations'.[11] In general, safety is a major ethical concern in natural sciences and engineering, much more so than in the social sciences or humanities, and underlies the technical standards and codes of ethics.

Discussions on climate change show the complexity of the relationship between science, ethics and climate policy, especially with regard to the assessment of ecological and economic impacts of human-induced climate change, and the need to create viable climate policies and technological solutions.

- Privacy

Privacy issues may arise in the publication of results,[12] but this aspect is not so prominent in natural sciences as is, for example, in social sciences or medicine.

3.1.3 Ethical Case Study in the Natural Sciences

To illustrate how these issues may emerge from research in the natural sciences and how these ethical principles relate to them, we will briefly describe the historical example of using a lead compound as an additive to petrol.

The issue: Internal combustion engines may suffer from 'knocking' if part of the fuel mixture ignites within the engine cylinder at the wrong time in the combustion cycle.[13] This reduces the engine's efficiency as part of the energy created during combustion is wasted. In 1921, researchers at General Motors in the US discovered that adding lead alkyl compounds to petrol made fuel combustion smoother, which reduced engine knocking by ensuring that the fuel mixture ignited at the appropriate time in the combustion cycle.[14] Despite the well-known poisonous effects of lead and lead vapour, leaded petrol was introduced onto the US market in

[10] Frank, Hartmut, Luigi Campanella, Francesco Dondi, Jan Mehlich, Erich Leitner, Giuseppe Rossi, Karine Ndjoko Ioset, Gerhard Bringmann, "Ethics, Chemistry, and Education for Sustainability", *Angewandte Chemie (International Edition)*, Vol. 50, Issue 37, September 5, 2011, pp. 8482–8490 [p. 8487].
[11] Schummer, Joachim, "Ethics of Chemical Synthesis", *HYLE: International Journal for Philosophy of Chemistry*, Vol. 7, No. 2, October 2001, pp. 103-124 [p. 108].
[12] Doss, Heide, and Gabriel Popkin (eds.), "Ethics Case Studies – Teacher Edition", *APS Task Force on Ethics Education*. http://www.aps.org/programs/education/ethics/upload/Ethics-Case-Studies-Teacher-Edition.pdf [p. 21].
[13] Berwick, I. D. G., "The Rise and Fall of Lead in Petrol", *Physics in Technology,* Vol. 18, No. 4, 1987, pp. 158-164 [p. 159].
[14] Ibid.

1923 to commercial success.[15] In the 1960s it was discovered that lead levels in the atmosphere were reaching levels dangerous for human health, and lead from car emissions was a major contributor.[16] Unleaded petrol was introduced and the use of lead as fuel additive began to be phased out globally.[17]

The decision-making process: The head of the research division at General Motors, Thomas Midgley, responded to public health concerns about adding lead compounds to petrol by stating that the issue had been 'given serious consideration', while also acknowledging that 'no actual experimental data has been taken'.[18]

Principles involved: The principles of care and social responsibility, and serving public interests are relevant to this example. The researchers who discovered the useful properties of lead compound additives to petrol did not investigate the potential health risks, despite the concerns raised by outside researchers and the US Public Health Service.[19] At the time the research was performed and leaded petrol was released onto the market, there was also a lack of awareness of the environmental impact that released lead into the atmosphere would cause. The researchers were also dismissive of safer alternative additives that would also address engine knocking.[20]

Specificity of the Example for the Natural Sciences:

- *Societal responsibility, sustainability and safety:* The researchers did not take seriously enough the concerns of other researchers and public health authorities about the risks of lead poisoning. Thomas Midgley held a press conference downplaying the health risks of lead poisoning.[21]
- *Conflict of interest*: The investment in adding lead compounds to petrol by General Motors, Standard Oil, and DuPont created a conflict of interest for their researchers who worked on developing these compounds, especially when the health risks to workers involved in the manufacturing process were recognised.[22] While the researchers were aware of alternative additives that would also reduce engine knocking, Midgley claimed publicly that there was no effective alternative to the lead compounds.[23]

[15] Kovarik, William, "Ethyl-Leaded Gasoline: How a Classic Occupational Disease Became an International Public Health Disaster", *International Journal of Occupational and Environmental Health,* Volume 11, No. 4, October 2005, pp. 384–397 [pp. 385-386].
[16] Berwick, I. D. G., "The Rise and Fall of Lead in Petrol", *Physics in Technology,* Vol. 18, No. 4, 1987, pp. 158-164 [p. 160-161].
[17] Ibid.
[18] Ibid.
[19] Kovarik, William, "Ethyl-Leaded Gasoline: How a Classic Occupational Disease Became an International Public Health Disaster", *International Journal of Occupational and Environmental Health,* Volume 11, No. 4, October 2005, pp. 384–397 [p. 385].
[20] Ibid. [p. 388]
[21] Ibid. [p. 387]
[22] Ibid. [pp. 386-387]
[23] Ibid. [pp. 388-389]

3.1.4 Summary

Like the engineering sciences, researchers in the natural sciences have professional standards and codes of ethics that guide their work. It also relies on the accepted norms of research practice, including scientific integrity and academic freedom.

The application of research performed in the natural sciences may have significant environmental and societal impacts. New chemicals developed through research may have unanticipated environmental and health effects, and may be open to malicious use. Anticipating and reducing risk are important for reducing the potential harm caused by the applications of research into the natural sciences. The historical example of the addition of lead compounds to petrol illustrates the potential health and environmental risks of failing to properly recognise these risks.

3.2 Engineering Sciences

In this section, we discuss ethical issues and principles that apply specifically to the engineering sciences. With *principles* in the engineering sciences, we refer to specific ethical principles that ought to play a role in decision making during research and innovation activities. With *issues* in the engineering sciences, we refer to general categories of actions or events that might follow from research and innovation activities in the engineering sciences that are ethically significant.

The engineering sciences include a great variety of scientific methods to design and develop systems, structures, and devices that pertain to practical ends.[24] They can be divided according to four sub-fields: chemical engineering, civil engineering, electrical engineering and mechanical engineering, although other divisions are possible (e.g. naming bio-engineering as a sub-discipline). Because the results of research in the engineering sciences are to be applied in practical contexts, ethical issues concern the impacts of applications resulting from the engineering sciences on humans, on society, and on the environment. A distinction can be made between ethical issues that are linked to the research design (for example, scientific integrity and human subject research), and ethical issues that are linked to the innovations that result from the engineering sciences, which can have positive ethical impacts such as improvements of health and security and negative ethical impacts such as environmental damage or impediments on human safety.

3.2.1 Ethical Principles

Research ethics approaches in the engineering sciences typically relate to professional ethics approaches, for they relate to the professional roles and responsibilities of engineers. Moreover, applied ethics is the dominant type of ethics used in the engineering sciences context because the ethical analysis of specific applications usually calls for empirical analysis. Presented below are the main ethical principles that are argued to apply in the engineering sciences.

- Autonomy
    - Individual rights and liberties

[24] For additional information, refer to Annex 2.b-Engineering Sciences of Deliverable 1.1.

  - Integrity
  - Informed consent
  - Authenticity
- Avoiding harm and doing good
  - Humanism
  - Respect for others
- Sustainability
  - Ecological restoration
  - Responsible waste management
- Justice and equality
  - Accessibility
  - Just war
  - Fairness
- Safety
- Precaution
- Social responsibility
  - Accountability
  - Social engagement
  - Social awareness
- Sufficiency

3.2.2 Discussion of Ethical Principles

Ethical assessment in the engineering sciences is generally based on the formulation of certain virtues that people ought to live up to in their professional roles as engineers. In the WFEO (World Federation of Engineering Organisations) code of ethics, it is argued that 'a code of professional ethics is more than a minimum standard of conduct; rather, it is a set of principles which should guide professionals in their daily work'.[25] Fleddermann shows that this approach fits within the professional ethics paradigm, for ethical problems frequently involve 'relationships between two corporations, between a corporation and the government, or between corporations and groups of individuals'.[26] It concerns not merely a set of rules to govern personal behaviour, but rather a set of guidelines to shape the relationships one encounters in professional life.

However, ethical principles in the engineering sciences also apply to 'social ethics', 'concerning socio-political decisions about technology'.[27] That is, even if the behaviour of engineers accords to the professional ethics in shaping the social relations with which they are dealing, technology design decisions on a higher level might still cause ethical impacts to society and the environment. For instance, the ethical principles of justice and equality, sustainability, social responsibility and sufficiency partly fall outside of the scope of professional behaviour and refer instead to socio-political decisions. Although an engineer working in petro-chemical research and innovation might behave strictly in accord with professional ethics, the fruits of his or her labour

[25] WFEO Code of Ethics. http://www.sustainable-design.ie/fire/WFEO-UNESCO_Model-Code-Ethics_2001.pdf.
[26] Fleddermann, Charles B., *Engineering Ethics*, 4th ed., Pearson, Upper Saddle River, 2012 [p. 4].
[27] Herkert, Joseph R., "Ways of thinking about and teaching ethical problem solving: Microethics and macroethics in engineering", *Science and Engineering Ethics*, Vol. 11, Issue 3, September 2005, pp. 373-385 [p. 374].

might nonetheless contribute to ecological destruction. For this reason, ethics in engineering sciences is highly contextualised: it plays a role in the professional work of engineers, but also in technology design decisions at political and economic levels.

3.2.3 Ethical Issues

Many ethical issues in the engineering sciences relate to societal and environmental impacts. This relation is due to the focus of the engineering sciences of translating scientific findings into applications that are appropriated by society at large. An overview of ethical principles and issues in the engineering sciences is presented below, organised into three categories: 1) scientific practice, 2) research involving human participants, and 3) societal/environmental impact.[28]

- Issues concerning scientific practice
  - Conflicts of interest
  - No use-context present in the lab
  - Tunnel vision of researchers
  - Unpredictability of models
- Issues involving human participants
  - Health risks during nanotechnology research
  - Human subjects in safety research
- Societal/environmental impacts
  - Accessibility issues for different stakeholder groups
  - Complexity of effects from climate engineering
  - Consumption of natural resources for chemicals
  - Design of spaces for torture or imprisonment considered inhumane
  - Destruction of cultural heritage
  - Development of nuclear weapons
  - Difficulty in establishing long-term effects of exposure to chemicals
  - Environmental impact and safety
  - Ethical impacts concerning technological singularity
  - Health risks of nanotechnology applications
  - Impacts of geo-engineering
  - Impacts on future generations
  - Just distribution of benefits and risks of nanotechnology applications
  - Military applications of robotics
  - Privacy risks of Nanotechnology applications
  - Reduction of human social contact due to robots
  - Responsibility for actions by robots and AI
  - Risk of nuclear catastrophes
  - Safety issues of domestic and care robots
  - Safety of built structures
  - Utility of built structures for different stakeholder groups
  - Waste disposal

[28] For additional information, refer to Annex 2.b-Engineering Sciences of Deliverable 1.1.

3.2.4 Discussion of Ethical Issues

Some ethical issues in the engineering sciences are manifested as problems resulting from personal or professional decisions of engineers. For instance, an engineer with tunnel vision and conflicts of interest are two clear examples of unethical personal and professional behaviour. However, ethical issues in the engineering sciences often manifest themselves as 'design problems', which pertain to ethical issues at the social, rather than the individual, level. Technology design can lead to environmental and societal problems that need to be dealt with in the research and development stages of emerging technologies. Herkert argues that these concerns motivate distinguishing between 'microethics' and 'macroethics' in the engineering sciences.[29] Microethics is concerned with issues resulting from personal and professional behaviour, while macroethics is concerned with issues resulting from socio-political decisions (e.g. whether or not a technology ought to be developed and marketed). It is especially the dominance of macroethical issues that cause the engineering sciences to be different from other scientific fields such as the humanities or the natural sciences. We now turn to five categories of macroethical issues for a brief discussion.

1. Environmental issues

Since the engineering sciences deal with the research and innovation of existing and emerging technologies that are meant to be part of the human life-world, they often have a direct impact on the environment. Many technologies developed in the engineering sciences have contributed to contemporary environmental problems, including the major issue of global climate change.[30] It is therefore an increasingly vested practice to take environmental impacts of research and innovation in the engineering sciences into account while subjecting the activities to an ethics assessment. Lynn and Salzman argue that the increasing importance of environmental issues in engineering sciences relates to the increasing globalisation of the engineering field.[31] For instance, since the engineering sciences are involved in R&I in the area of the global energy supply industries, the direction of R&I practices directly impacts global use of energy resources (fossil fuels, renewables, etc.).

2. Uncertainty

Some technologies developed in the engineering sciences are increasingly complex, and therefore it can be difficult to foresee or predict the impacts of these technologies. This difficulty in prediction in itself causes the ethical issue of uncertainty, since uncertainty is a factor that decreases people's ability to make rational ethical judgements (for such judgements, adequate knowledge is required). Technological complexity is thus an issue that engineers need to take into account by trying to reduce it or to deal with it in a prudent manner. Wulf argues that uncertainty can result from the growing complexity of systems that might show emergent properties. Such systems may exhibit chaotic behaviour that cannot be predicted using mathematical models due

[29] Herkert, Joseph R., "Ways of thinking about and teaching ethical problem solving: Microethics and macroethics in engineering", *Science and Engineering Ethics*, Vol. 11, Issue 3, September 2005, pp. 373-385.
[30] Fleddermann, Charles B., *Engineering Ethics*, 4th ed., Pearson, Upper Saddle River, 2012 [p. 125].
[31] Lynn, Leonard, and Hal Salzman, "Engineers, Firms and Nations: Ethical Dilemmas in the New Global Environment", in Colleen Murphy, Paolo Gardoni, Hassan Bashir, Charles E. Harris Jr., and Eyad Massad (eds.), *Engineering Ethics for a Globalized World*, Springer, Heidelberg, 2015, pp. 15-33.

in part to the growing difference between the magnitude of inputs and the outputs of those systems.[32]

3. Risk for harm

Due to the fact that the public often directly interacts with the technologies that result from research and innovation in the engineering sciences (robots, bridges, machines), the safety of such technologies is an important issue. Lack of safety, for example in cases in which technologies fail to work properly, can lead to major incidents or even deaths. For this reason, engineers have the duty to ensure the safety of the technologies they design.[33] The issue of risk (the probability that a potentially harmful event will occur) is directly related to the issue of safety, for higher levels of risk correspond to lower levels of safety. Coeckelbergh argues that vulnerability in systems can amount to higher levels of risk for harm. For instance, when the vulnerability of energy systems increases due to increased complexity, the risk for harm (e.g. large populations being deprived of energy supplies) increases as well.[34]

4. Dual use

'Dual use' forms of research and innovation refers to technological developments that face the explicit risk of being used for a different purpose than that intended by their designers, with possible harmful consequences. Nuclear energy technology is a clear example, for it can be used both to provide energy to people and to create nuclear weapons. Dual use issues often arise in the case of technologies that are created for civil use.[35] Forge argues that dual use issues arise at three distinctive stages of the R&I process: at the research stage, the technology stage and the artefacts stage.[36] To distinguish between these, he argues that 'bad' uses of technological knowledge differ from the 'bad' uses of actual technological artefacts. For instance, the know-how gained from certain research and technology areas that may be used to create a purpose-built (not an improvised) weapon, can count as dual use knowledge; whereas the supply of certain elements or resources of this weapon, concrete artefacts, amounts to the dual use of artefacts.

5. Ethics of emerging technologies

Some issues in the engineering sciences do not pertain to actual states of affairs but to possible states of affairs that might occur in the future. These are for instance certain health risks of nanotechnology applications, the effects of geo-engineering and the implications of strong artificial intelligence. Such issues fall under the general category of the ethics of emerging

[32] Wulf, Wm A., "Engineering ethics and society", *Technology in Society,* Vol. 26, Issues 2-3, April-August 2004, pp. 385-390 [p. 387].
[33] Whitbeck, Caroline, *Ethics in Engineering Practice and Research*, Cambridge University Press, New York, 2011 [p. 101].
[34] Coeckelbergh, Mark, *Human Being @ Risk: Enhancement, Technology, and the Evaluation of Vulnerability Transformations*, Springer, Dordrecht, 2013.
[35] Molas-Gallart, Jordi, "Which way to go? Defence technology and the diversity of 'dual-use' technology transfer", *Research Policy*, Vol. 26, Issue 3, October 1997, pp. 367–385.
[36] Forge, John, "A note on the definition of 'dual use'", *Science and Engineering Ethics,* Vol. 16, Issue 1, March 2010, pp. 111-118.

technologies.[37] For identifying and understanding these issues, forecasting techniques are used such as scenario studies or Ethical Delphi studies.[38]

3.2.5 Ethical Case Study in the Engineering Sciences

In order to show how an ethical issue is discussed in practice and how ethical principles are applied in the engineering sciences, we now discuss an ethical case that is specific for the engineering sciences: the case of the explosion of the space shuttle *Challenger*.[39]

The issue: In January of 1986, the space shuttle *Challenger* exploded shortly after launch. The cause of the explosion was determined to be a sensitivity of the technology to the weather conditions. The cold weather conditions triggered an error in the combustion process, leading to the explosion of the space shuttle.

The decision-making process: Before the launch, engineers raised the concern that the cold weather conditions amounted to a safety risk. Although engineers advised against the launch of the *Challenger* due to the weather conditions, the political interests were fixed on launching the space shuttle nonetheless. Because the data that would support a delay of the launch were inconclusive, the managerial team decided to continue the launch procedure.

Principles involved: Two principles seem to be involved in this case: the principle of safety (reducing the risk to cause harm) and the principle of sufficiency (not doing more than necessary for reaching the aim of the launch). Different interpretations of these principles conflicted with each other. While the engineers thought that it would be sufficient to delay the launch in order to avoid safety risks while still attaining the goal of the project, the managers argued that delay would violate the goals of the project.

Specificity of the Example for Engineering Sciences:
The *Challenger* disaster shows certain specific aspects of ethical issues in the engineering sciences:

- *The importance of empirical data*. The data that were meant to show the danger of the weather conditions for the technology design were said to be inconclusive since this was the first time a space shuttle would be launched in these conditions.
- *The importance of anticipation*. Ethical issues pertaining to technology design are often hidden until a calamity occurs. Anticipating future ethical issues is therefore an important aspect of ethics in engineering sciences.
- *The social embeddedness of ethical issues*. Ethical issues often arise out of conflicts between researchers and political actors (managers, politicians). This conflict is due to the practical nature of applications of knowledge coming from the engineering sciences. Often, these applications are valuable for economic and political processes.

[37] Brey, Philip A. E., "Anticipatory Ethics for Emerging Technologies", *NanoEthics*, Vol. 6, Issue 1, April 2012, pp. 1–13.
[38] Millar K. et al., "Developing the Ethical Delphi", *Journal of Agricultural and Environmental Ethics,* Vol. 20, No. 1, 2007, pp. 53-63.
[39] Fleddermann, Charles B., *Engineering Ethics*, 4th ed., Pearson, Upper Saddle River, 2012 [pp. 6-15].

3.2.6 Summary

Ethics in the engineering sciences has usually focused on the professional ethics of engineers themselves, including their responsibilities to clients and to society generally. Work in the engineering sciences has significant societal and environmental impacts, which justifies distinguishing between 'micro-ethical' concerns of professional behaviour and the 'macro-ethical' concerns raised by the decisions made in engineering projects. Some of these 'macro-ethical' concerns include environmental issues, uncertainty over the impact of new technology, the possibility of malicious uses of engineering research and products (i.e. 'dual use'), the risks of harm due to technological failure, and the ethical issues raised by emerging technologies, such as nanotechnology, geo-engineering, and artificial intelligence. As the example of the *Challenger* disaster illustrates, political pressures and uncertainty may have a catastrophic effect on the work of engineers.

3.3 Medical and Life Sciences

This section provides a survey of the ethical principles and issues that have been traditionally identified to play a role in the medical and life sciences within the context of research and innovation. The work here builds upon the findings of Annex 2.c-Medical and Life Sciences of Deliverable 1.1[40] of the SATORI Project and presents ethical principles and issues that have been identified within canonical texts addressing the medical and life sciences. The term 'medical and life sciences' is used as it was in the aforementioned Annex 2.c.

3.3.1 Ethical Principles

The three most prevalent action guiding principles governing research within the medical and life sciences are: *respect for persons* (autonomy), *beneficence*, and *justice*. Variations on these three principles are enshrined within specific traditions of the biomedical sciences. For example, the highly influential *Belmont Report*[41] and the CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects*[42] both identify these three basic principles as action-guiding ethical principles for research. While the Declaration of Helsinki presents a list of twelve general principles, they can be classified as more specific examples of these three basic principles.[43] From these principles, a greater number of ethical concepts have been identified as greater reflection has been given to research and innovation activities. However, these are the most widely cited principles across a series of texts since the development of contemporary ethics assessment practices within the biomedical sciences.

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[40] Annex 2.c-Medical and Life Sciences of Deliverable 1.1 of the SATORI Project, http://satoriproject.eu.
[41] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report". 1979. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.
[42] Council for International Organisations of Medical Sciences (CIOMS). "International Guidelines for Ethical Review of Epidemiological Studies".
http://www.cioms.ch/publications/guidelines/1991_texts_of_guidelines.htm.
[43] World Medical Association, "Declaration of Helsinki".
http://www.wma.net/en/30publications/10policies/b3/index.html.

The following outline lists the most broadly considered ethical principles within the medical and life sciences, as identified in Annex 2.c-Medical and Life Sciences of Deliverable 1.1 of the SATORI Project.

- Respect for Persons
  - Medical confidentiality[44]
  - Respect for autonomy
  - Respect for cultural diversity and pluralism
  - Voluntary and informed consent
- Beneficence
  - Contribute to general welfare
  - Improve or maintain quality of life
  - Minimise harm to research subjects
  - Prevent risks to the researchers
  - Protect the environment, biosphere, and biodiversity
  - Reduce the risks of research and new technologies
  - Responsiveness of research to health needs and priorities
- Justice
  - Access to new treatments for the underprivileged
  - Protect against discrimination
  - Treat participants fairly and equally
  - Underrepresented groups should have appropriate opportunities to participate in research[45]

3.3.2 Discussion of Ethical Principles

Differentiation on the three basic principles can be found within specific contexts. For example, the widely-cited *Principles of Biomedical Ethics* by Beauchamp and Childress[46] expands on these three foundational principles and identifies *respect for autonomy, beneficence, non-maleficence,* and *justice* as the core ethical principles. This approach to biomedical research is called the *principlism* model. In it, these four principles are considered in specific contexts and evaluated in order to determine an ethically appropriate or desirable outcome. Alternative models such as *casuistry* endeavour to identify ethically relevant principles in specific cases by categorising the case within the context of ethically similar cases, 'mining' the similar case for the most ethically relevant principles, and using the now considered principles identified from previous cases to guide the ethical deliberation process.

[44] De Bord, Jessica, Wylie Burke, and Denise M. Dudzinski, "Confidentiality", *Ethics in Medicine, University of Washington School of Medicine*. March 6, 2014.
https://depts.washington.edu/bioethx/topics/confiden.html.
[45] World Medical Association, "Declaration of Helsinki".
http://www.wma.net/en/30publications/10policies/b3/index.html.
[46] Beauchamp, Tom L. and James F. Childress, *Principles of Biomedical Ethics*, 7th ed., Oxford University Press, New York, 2013.

Notably, the use of ethical principles considers ethics as a part of a deliberative decision making process. That is to say, the legitimacy of the ethical principles is subject to an ethically grounded deliberation process. The principles do not exist in a vacuum outside of historical and political contexts, which are to be considered in the deliberation process. This commitment to deliberation suggests that while it has not been named as an explicit ethical principle, the concept of *ethical review* is a principle enshrined by the use of ethical principles within the medical and life sciences. It is within this context that *justice* is most often understood, placing it within a more specific tradition of *distributive justice*. The principles can also be well considered within the predominant human rights model.

The principles identified here are also inextricably linked to a concept of *health*. The principles and issues that arise in the development of the contexts in which the medical and life sciences are performed also inform the use of the ethical principles. For example, the nature of the relationship between researcher and subject affects the application of certain principles. In principlism, it can be argued that the nature of the relationship between a researcher and subject is most often understood to be a physician-patient relationship. Such a relationship may not parallel the relationship, for instance, that a botanist has towards the subject of her research. Additionally, the concept of *autonomy* has to be situated within the context of the research or clinical practice – where different prioritisation can be given to individual versus family autonomy.

3.3.3 Ethical Issues

The following issues are based on the lists of issues presented in Annex 2.c-Medical and Life Sciences of Deliverable 1.1.

- Issues concerning scientific practice
  - Medical confidentiality[47]
  - Privacy of medical records
  - Respect for cultural diversity and pluralism
  - Trustworthiness of the researchers[48]
  - Unpublished results potentially relevant for risk assessment
  - Use of animals in research
  - Use of placebos and deception
- Issues involving human participants
  - Adverse side-effects
  - Challenges to personal identity
  - Informed consent
  - Mental competence
  - Moral status of human embryos
  - Potential misunderstanding of research as therapeutic treatment
  - Privacy

[47] De Bord, Jessica, Wylie Burke, and Denise M. Dudzinski, "Confidentiality", *Ethics in Medicine, University of Washington School of Medicine*. March 6, 2014. https://depts.washington.edu/bioethx/topics/confiden.html.
[48] Ibid.

  - Quality of life
  - Respect of autonomy
  - Risks of new treatments
- Societal/Environmental impacts
  - Access to new medical treatments
  - Animal welfare
  - Cloning of animals (and potentially humans in the future)
  - Commodification of life
  - Creating artificial cells and organisms
  - Dual use of research and therapies
  - Environmental impact of agriculture
  - Farming innovations
  - Genetic testing
  - Human enhancement
  - Impact on existing cultural norms
  - Ownership of genetic information
  - Responsiveness of research to health needs and priorities
  - Toxicity of new materials
  - Unfair exploitation of local medicinal knowledge

3.3.4 Ethical Case Study in the Medical and Life Sciences

To demonstrate how these issues can emerge in medical and life science research, and how these ethical principles are applicable to them, we will briefly describe an example where the first trial of a potential new treatment for autoimmune and immunodeficiency diseases on human subjects had harmful effects on the participants.[49]

The issue: In March 2006, eight healthy volunteers entered a phase I trial (the first trial of a medical treatment on humans) for a new drug intended to treat autoimmune and immunodeficiency diseases. Six participants received the drug while the remaining two received a placebo. Within an hour, the participants given the active drug complained of minor aches and pains, which quickly escalated into more serious symptoms.[50] Their symptoms became life threatening over the next few days, requiring all of them to be placed in intensive care.[51] All six eventually survived, although with significant injuries, including the amputation of fingertips and toes that had become necrotic.[52]

[49] Goodyear, Michael, "Learning from the TGN1412 Trial", *British Medical Journal,* Vol. 332, Issue 7543, March 23, 2006, p. 677.
[50] Goldacre, Ben, *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*, Fourth Estate, London, 2012 [p. 8].
[51] Ibid. [pp. 8-9].
[52] Kenter, Marcel J. H., and Adam F. Cohen, "The Return of the Prodigal Son and the Extraordinary Development Route of Antibody TGN1412 - Lessons for Drug Development and Clinical Pharmacology", *British Journal of Clinical Pharmacology,* Vol. 79, Issue 4, April 2015, pp. 545–547.

The decision-making process: Researchers had previously tested the TGN1412 antibody in animals without signs of severe toxicity.[53] Based on the available evidence, the researchers believed it would be safe to perform a phase I trial on healthy human participants to determine whether there were significant side-effects. The dosage tested with the human participants was only 0.2% of the maximum dosage administered to cynomolgus monkeys during the animal trials.[54]

Principles involved: This case study features the principles of *respect for persons* and *beneficence.* The participants gave informed consent and were given £2000 for taking part in the study.[55] The trial was conducted in a research unit that was located within a hospital, so that emergency treatment was readily available.[56] The trial was intended to help develop a new treatment for immunodeficiency and autoimmune diseases, which would be beneficial to society.

Specificity of the Example for the Medical and Life Sciences:

- *Adverse side-effects:* The drug caused unexpected inflammation within the bodies of the participants, which began to be felt as nausea, headaches, and back pain, and led to 'a loss of function of several vital organs, including the lungs and kidneys.'[57] Blood also stopped flowing to the participants' peripheries, which led to the need to amputate some of their fingers and toes.[58]
- *Informed Consent/Use of placebos and deception*: Of the eight participants, two received a placebo. However, the participants were not told in the consent form what the probabilities were for receiving the active treatment or the placebo.[59] Providing this information might have affected their willingness to participate. One of the information brochures provided to the participants was also intended for participants in treatment intervention trials rather than healthy participants.[60] As a result, some of the information provided to the participants may have been inappropriate.
- *Risks of new treatments:* This study was a phase I trial, meaning that it was the first time that the drug was tested on humans. These trials measure the pharmacological and toxicological effects of the drug, and require healthy human participants.[61] While phase I trials are necessary to determine the risks associated with new drugs, they possess a significant risk to the healthy participants that needs to be carefully managed. In this case, instead of giving the drug to all the participants at the same time, it would have been

[53] Goodyear, Michael, "Learning from the TGN1412 Trial", *British Medical Journal,* Vol. 332, Issue 7543, March 23, 2006, p. 677.
[54] Kenter, Marcel J. H., and Adam F. Cohen, "The Return of the Prodigal Son and the Extraordinary Development Route of Antibody TGN1412 - Lessons for Drug Development and Clinical Pharmacology", *British Journal of Clinical Pharmacology,* Vol. 79, Issue 4, April 2015, pp. 545–547.
[55] Ibid.
[56] Shamoo, Adil, and Elizabeth Woeckner, "Ethical Flaws in the TeGenero Trial", *The American Journal of Bioethics,* Vol. 7, No. 2, March 2007, pp. 90–92.
[57] Ibid. [p. 546]
[58] Ibid.; Goldacre, Ben, *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*, Fourth Estate, London, 2012 [p. 9].
[59] Shamoo, Adil, and Elizabeth Woeckner, "Ethical Flaws in the TeGenero Trial", *The American Journal of Bioethics,* Vol. 7, No. 2, March 2007, pp. 90–92.
[60] Ibid.
[61] Shamoo, Adil E., and David B. Resnik, *Responsible Conduct of Research*, 2nd ed., Oxford University Press, Oxford, 2009.

better to administer the drug gradually among the participants so that the trial could be halted if the first participant has a negative response.[62]

- *Unpublished results*: It later emerged that a similar trial with a different antibody that affected the same receptor had been performed ten years before the TGN1412 trial on a single human subject. However, this study had not been published, so the TGN1412 researchers could not have used it to better understand the potential risks to the participants in their own trial.[63]
- *Use of animals in research:* While non-human animals were not involved in this study, it does show the limits of applying results from animal experimentation to human medicine. The researchers had previously tested the TGN1412 antibody in cynomolgus monkeys, which has a very similar receptor to that in found in humans. As these trials did not produce significant side effects in these monkeys, the drug was then prepared for human trials.[64]

3.3.5 Summary

The medical and life sciences can directly affect people's lives by developing treatments and gaining a better understanding of the environment, animal life, and human life. The focus of these sciences on living things and the environment itself means that this research may cause harm if not performed with care and responsibility. As biological research may cause harm and distress to animals, it is important to recognise this harm and to minimise it as much as possible.

It is also important for medical research to recognise that the subjects of study have rights and interests of their own, which researchers must respect in their work. There are also physical risks for those who participate in the research necessary for new treatments to be developed. The example of the TGN1412 antibody trial shows the serious risks that may emerge from testing new drugs and treatments on human participants.

3.4 ICT Research

This section discusses ethical principles and issues associated with research and development in information technology, or IT. (It is also referred to as information and communication technology, or ICT.)

3.4.1 Ethical Principles

Information technology involves developing and applying electronic means of collecting, manipulating, and analysing data. As much of this data is about people or their activities, the use

[62] Ibid.
[63] Goldacre, Ben, *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*, Fourth Estate, London, 2012 [pp. 9-10].
[64] Kenter, Marcel J. H., and Adam F. Cohen, "The Return of the Prodigal Son and the Extraordinary Development Route of Antibody TGN1412 - Lessons for Drug Development and Clinical Pharmacology", *British Journal of Clinical Pharmacology,* Vol. 79, Issue 4, April 2015, pp. 545–547.

of this technology has the potential to affect people's lives. The ethical principles that guide IT research seek to ensure that the impact of this technology on individuals and society is beneficial.

Ethical principles for IT research are reflected in the codes of ethics and conduct produced by organisations representing IT practitioners, such as the Code of Ethics and Professional Conduct of the Association of Computing Machinery (ACM) and the British Computer Society (BCS) Code of Conduct.[65] The ACM Code of Ethics is noteworthy for explicitly describing the broad ethical principles that should the actions of their members. The 'general moral imperatives' it describes are:

- 'Contribute to society and human well-being'
- 'Avoid harm to others'
- 'Be honest and trustworthy'
- 'Be fair and take action not to discriminate'
- 'Honour property rights including copyrights and patent'
- 'Give proper credit for intellectual property'
- 'Respect the privacy of others'
- 'Honour confidentiality'[66]

Another general account of principles for IT research ethics is described in the Menlo Report, which presents a series of moral norms to guide research in information technology.[67] It deliberately reflects the moral norms found in the influential Belmont Report on the treatment of human participants in research: respect for persons, beneficence and justice.[68] In addition to these three norms, the Menlo Report adds an additional norm it calls 'respect for law and public interest'. This addition highlights the role that national and international law plays in determining what uses of information are acceptable.[69] The major features and principles of the Menlo Report are listed below.

- Respect for Persons
  - Informed Consent
- Beneficence
  - Identification of Potential Benefits and Harms
  - Balancing Risks and Benefits

[65] Association of Computing Machinery (ACM), "ACM Code of Ethics and Professional Conduct". October 16, 1992. http://www.acm.org/about/code-of-ethics; BCS, The Chartered Institute for IT., "Code of Conduct for BCS Members". June 8, 2011. http://www.bcs.org/upload/pdf/conduct.pdf.
[66] Association of Computing Machinery (ACM), "ACM Code of Ethics and Professional Conduct". October 16, 1992. http://www.acm.org/about/code-of-ethics.
[67] Dittrich, D., and E. Kenneally, "The Menlo Report: Ethical Principles Guiding Information and Communication Technology Research". *U.S. Department of Homeland Security*, August 2012. http://www.caida.org/publications/papers/2012/menlo_report_actual_formatted/menlo_report_actual_formatted.pdf.
[68] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report". 1979. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.
[69] Dittrich, D., and E. Kenneally, "The Menlo Report: Ethical Principles Guiding Information and Communication Technology Research". *U.S. Department of Homeland Security*, August 2012. http://www.caida.org/publications/papers/2012/menlo_report_actual_formatted/menlo_report_actual_formatted.pdf [p. 5].

    - Mitigation of Realised Harms
- Justice
    - Fairness and Equity
- Respect for Law and Public Interest
    - Compliance
    - Transparency and Accountability[70]

The general principles of the ACM Code of Ethics closely align with those presented in the Menlo Report. Contributing to society and avoiding harm are covered by the principle of beneficence. Honesty, trustworthiness, and respect for confidentiality are aspects of showing respect for persons. Fairness and non-discrimination reflect the principle of justice. Respecting property rights (both physical and intellectual) fall under the principle of respect for law.

3.4.2 Discussion of Ethical Principles

The Menlo Report is intended to provide ethical guidelines for academic and non-academic researchers working in computing and information technology.[71] This covers researchers who develop these technologies and researchers who use information gathered through using these technologies (such as data gathered through social media, for example). The Menlo Report is therefore also relevant to researchers who interact with research participants via the Internet and who use data collected from Internet use for social science research. These cases are described in section 3.3, which focuses on Internet research.

A necessary pre-condition for applying the principles of the Menlo Report is identifying the stakeholders who may be affected by a research project.[72] This identification allows the possible effects for each group to be considered and determines whether specific ethical issues (such as dual use) may arise. The report lists several groups of potential stakeholders:[73]

- ICT Researchers
- Human Subjects, Non-Subjects, and ICT Users
- Malicious Actors
- Network/Platform Owners and Providers
- Government: Law Enforcement
- Government: Non-Law Enforcement
- Society

The Menlo Report follows the Belmont Report in conceiving of respect for persons as recognising people as autonomous individuals and ensuring that people with diminished autonomy are given protection against exploitation.[74] It also extends respect for persons to

[70] Ibid.
[71] Ibid.
[72] Ibid. [p. 3]
[73] Ibid. [pp. 6-7]
[74] Ibid. [p. 7]

include 'consideration of the computer systems and data that directly interface, integrate with, or otherwise impact persons who are typically not research subjects themselves'.[75]

3.4.3 Ethical Issues

The following list of issues is based on the overview presented in annex 2.b.1 on ethics assessment in information technology in SATORI Deliverable D1.1. The issues are divided into three categories: issues concerning research practice, issues involving human participants, and social/environmental issues.

- Issues concerning Research Practice
  - Freedom of speech
  - Intellectual property
  - Safeguarding of information
  - Social biases in software and systems design
  - Software piracy
- Issues involving Human Participants
  - Informed consent
  - Monitoring and controlling infrastructures
  - Privacy
  - Rights violations
  - Safeguarding of information
- Social/Environmental Impacts
  - Accessibility of computer systems and services for various social groups
  - Accountability for system failures and errors
  - Autonomous machines
  - Bias in IT systems
  - Censorship methods
  - Computer fraud
  - Cracking (bypassing computer security measures)
  - Cyber vandalism
  - Cyber warfare
  - Digital divide between industrialised and developing countries
  - Effects of IT in education
  - Effects of IT on behaviour and relationships
  - Energy consumption
  - Freedom of speech
  - Freedom to access information
  - Hazardous waste
  - Healthcare applications of AI and robotics
  - Impact on democracy
  - Individual privacy
  - Intellectual property
  - Internet privacy

[75] Ibid.

- Military applications of AI and robotics
- Monitoring and controlling infrastructures
- Public, commercial, and governmental privacy
- Software piracy

3.4.4 Ethical Case Study in IT Research

To demonstrate how these issues can emerge in information technology and how these ethical principles are applicable to them, we will briefly describe an example where software distributed on music CDs made changes to users' computers without their knowledge.

The issue: In 2005, Sony-BMG began including software (XCP and MediaMax) on some of its audio CDs that prevented the music contained on the CD from being copied onto a computer. This software acted as a special music player for the music contained on the CD, and prevented other software from accessing that music. It installed itself automatically onto any Windows computer that ran the CD, and hid itself from the user to prevent it from being removed. It was later discovered that the changes made to the user's computer system could also be exploited by malicious software, which could use the same methods to hide itself from the user to prevent removal. The software also contacted a web site when the CD was inserted into a computer to obtain new advertisements to display when the music was played.[76]

The decision-making process: The audio CD producers sought to protect the intellectual property in the music contained on their CDs from unauthorised copying. The audio CD standards do not include copy protection mechanisms, and it was important to maintain compatibility with existing CD players. The software developers addressed this problem by including digital data on the CD that is ignored by regular CD players but is automatically executed by Windows computers.[77]

Principles involved: The principles of respect for persons, beneficence, and justice were disregarded in this case. Installing the software onto the user's computer without their knowledge (and even when the user explicitly declined to do so) did not respect the user's ability to make decisions.[78] The changes made to the user's computer increased the risks of malicious software exploiting these changes, placing the user at a greater risk of harm. Finally, the software prevented the user from making copies of the audio CD that are permitted by law.

Specificity of the Example for IT:

- *Informed Consent*: Software usually requires the user to accept a EULA (End-User Licence Agreement), which defines the terms and conditions for using the software. If a user does not accept these terms, she can refuse to install and use the software. However, both XCP and MediaMax ran on the user's computer before these terms were accepted. The EULA also did not describe in sufficient detail the function of the software contained

[76] Felten, Edward W., and J. Alex Halderman, "Digital Rights Management, Spyware, and Security", *IEEE Security & Privacy Magazine*, Vol. 4, No. 1, February 2006, pp. 18–23.
[77] Ibid. [p. 19]
[78] Ibid. [p. 20]

on the audio CD. MediaMax also installed itself onto the user's computer, even if the user declined the terms of the EULA.[79]

- *Intellectual Property*: The producer's goal of protecting their intellectual property led them to overlook the potential impact their software would have on users. The users' interests in maintaining the integrity of their systems against unknown changes, their rights to choose what is installed on their computers and their rights to choose what is sent about their activities across the Internet were all ignored in favour of protecting the audio CD against unauthorised copying.
- *Privacy*: Contacting a web site when the audio CD was inserted into a computer sent information about the IP address of the computer accessing the CD as well as the time that accessed that web site.[80] The user was unaware that this information about her use of the CD was being transmitted.
- *Rights Violations*: The user's control over her own computer was overridden by the producer's goal of protecting their intellectual property against unauthorised copying. The integrity of the user's computer was deliberately undermined by the producer's software. The user was also prevented from making copies of the audio CD that are permitted by copyright laws in some jurisdictions (such as the fair use provision in US law that allows copying of portions of a work for particular purposes).

3.4.5 Summary

ICT research shares with the engineering sciences an emphasis on the professional ethics of computing professionals. It also shares with the engineering sciences the potential for significant societal impact. As ICT has a significant role in how people now interact with each other, how it affects this interaction are important ethical issues. The ability of information technology to collect, store, and analyse data also raises concerns about privacy, fair access to data, and the abuse of intellectual property. The complexity of balancing the rights of users to privacy and to control their own computers against the need to protect intellectual property is demonstrated by the case of the hidden software Sony-BMG included on some of their audio CDs in 2005.

3.5 Internet Research

As the Internet is a particular instance of information technology, there is considerable overlap between the principles and issues relevant to IT and Internet research. The major difference between Internet research and IT research in general is that Internet research is primarily concerned with investigating the uses and users of the Internet rather than developing the technology it uses. The principles and issues relating to Internet research therefore focus on the protection of human research participants and the use of the data collected about them.

[79] Ibid.
[80] Ibid. [p. 21]

3.5.1 Ethical Principles

The ethical principles that influence Internet research are inspired by the principles that guide research involving human participants generally, such as the Belmont Report.[81] The Menlo Report, described in the chapter on information technology, also covers Internet research, and is based on the Belmont Report's principles of respect for persons, beneficence, and justice.[82] The recommendations of the Association of Internet Researchers (AoIR) Ethics Working Committee also state these three moral norms as the basis for ethical research.[83] As the Menlo Report was described in the previous chapter, the focus here will be on the principles described by the AoIR Ethics Working Committee.

The major principles proposed by the AoIR Ethics Working Committee for evaluating Internet research can be summarised as follows:

- An obligation to protect the vulnerable: the vulnerability of the research subjects should determine the scale of the researcher's obligation to protect them.
- Exercising ethical judgment in each individual case: researchers should consider the context of their particular research in their ethical decision-making.
- Consider the potential human impact of using Internet research data: principles of human subject research may apply even if people are not directly studied.
- Balancing the rights of subjects against the benefits of research.
- Ethical consideration of the entire research process, including the study design and conduct, and in publishing and disseminating results.
- Deliberation and wide consultation in ethical decision-making.[84]

3.5.2 Discussion of Ethical Principles

The guidelines described by the AoIR Ethics Working Committee are intentionally broad so that they may be used in a variety of institutional and situational contexts.[85] The rapid changes in Internet use are another reason to avoiding definite rules that may no longer reflect the realities of how the Internet is used. The AoIR Ethics Working Committee also emphasise that researchers are responsible for the ethical decisions they make within their specific projects, and that these guidelines serve as a tool to assist them in making these decisions during the various stages of their projects.[86] Ethical reflection is needed at all points of the project, rather than just at the

[81] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report". 1979. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.
[82] Dittrich, D., and E. Kenneally, "The Menlo Report: Ethical Principles Guiding Information and Communication Technology Research", *U.S. Department of Homeland Security*, August 2012. http://www.caida.org/publications/papers/2012/menlo_report_actual_formatted/menlo_report_actual_formatted.pdf [pp. 3-5].
[83] Markham, Annette, and Elizabeth Buchanan, "Ethical Decision-Making and Internet Research: Recommendations from the AoIR Ethics Working Committee (Version 2.0)". *Association of Internet Researchers*, 2012. http://www.aoir.org/reports/ethics2.pdf.
[84] Ibid.
[85] Ibid.
[86] Ibid.

planning and approval stages. Further discussion of the principles of the Menlo Report can be found in section 3.2.2 on information technology.

3.5.3 Ethical Issues

The ethical issues that Internet research raises depend on the types of information collected and the sources from which it is obtained. The AoIR guidelines lists broad types of information collected in Internet research:

- Interactions, behaviours, transactions
- Production, presentation, performance
- Locations and movements
- Archived information[87]

These guidelines also list the various types of sources that may provide information for Internet research:

- Direct communication
- Special interest forums
- Social networking sites
- Personal spaces and blogs
- Avatar-based environments (virtual worlds, online games, social spaces)
- Commercial web services
- Databanks and repositories[88]

Different combinations of collected information and sources raise different ethical concerns. For instance, users may have a greater expectation of privacy for some information (such as location information) than for others. Similarly, the information shared on some sources might be publicly accessible, and so users will have different expectations about who has access to it.

The following list of issues is based on the overview presented in the annex 2.d.2 on ethics assessment in Internet research in the SATORI Deliverable D1.1. The issues are divided into three categories: issues concerning research practice, issues involving human participants, and social/environmental impacts.

- Issues concerning Research Practice
  - Adapting methods of informed consent to Internet research
  - Data storage and transmission
  - Distinguishing between private and public information
  - Institutional Review Board (IRB) awareness of issues in Internet research
  - Necessity of obtaining informed consent
- Issues involving Human Participants
  - Anonymity and confidentiality

[87] Ibid.
[88] Ibid.

- Informed consent
- Privacy
- Protection of identity

- Social/Environmental Impacts
  - Cloud computing
  - Data storage and transmission
  - Privacy

3.5.4 Ethical Case Study in Internet Research

To demonstrate how these issues can emerge in Internet research and how these ethical principles relate to them, we will briefly describe an example where information was gathered from the users of an Internet social networking site.

The issue: With the permission of Facebook and 'a diverse private college in the Northeast U.S.' (later identified as Harvard College), the 'Tastes, Ties, and Time' project collected the information posted on Facebook by a freshmen class of college students over a four-year period (2006-2009).[89] The purpose of the study was to examine how the relationships and tastes students recorded changed over time. The anonymised data was also made available to other researchers on request. However, it was quickly discovered that the data could be de-anonymised and traced back to individual students fairly easily.[90]

The decision-making process: The researchers stated that '[s]tudent privacy was assured by converting all names to numerical identifiers and promptly removing or encoding all other information that could be traced to individual students.'[91]

Principles involved: The principles of respect for persons (from the Menlo Report) and the balancing of the rights of subjects against the benefits of research and ethical consideration of the entire research process (from the AoIR Ethics Working Committee guidelines) are relevant to this example. The researchers in this case overestimated the difficulty of de-anonymising the dataset so that individual students could be re-identified.

Specificity of the Example for Internet Research:

- *Distinguishing between private and public information*: The researchers acted under the assumption that the data shared by Facebook users was publically accessible. However, users are able to choose whether content they post on Facebook is publically accessible or accessible only to other Facebook users they have already designated as friends, some of

[89] Lewis, Kevin, Jason Kaufman, Marco Gonzalez, Andreas Wimmer, and Nicholas Christakis, "Tastes, Ties, and Time: A New Social Network Dataset Using Facebook.com", *Social Networks*, Vol. 30, Issue 4, October 2008, pp. 330-342 [p. 331].
[90] Zimmer, Michael, "'But the Data Is Already Public': On the Ethics of Research in Facebook", *Ethics and Information Technology*, Vol. 12, Issue 4, December 2010, pp. 313–325.
[91] Lewis, Kevin, Jason Kaufman, Marco Gonzalez, Andreas Wimmer, and Nicholas Christakis, "Tastes, Ties, and Time: A New Social Network Dataset Using Facebook.com", *Social Networks*, Vol. 30, Issue 4, October 2008, pp. 330-342 [p. 331].

whom may have been collecting data for this study.[92] If publicly posting content is implied consent for it to be accessible to anyone, the use of content shared only with friends lacked this implied consent.

- *Anonymity and confidentiality*: Withholding the name of the college and anonymising the names and personal details of the students was insufficient to disguise their identities. Other details that remained unanonymised in the dataset (such as a student's hometown, ethnicity, and the major they were studying) could be used in conjunction with other publically available information to identify individual students.[93]

3.5.5 Summary

Like ICT, Internet research raises concerns about privacy and fair access to data. For researchers, the quantity of information available on the Internet itself and about how it is used creates ethical issues about what information is appropriate to collect. Like the humanities and the social sciences, it raises concerns about the confidentiality of information collected by research participants, and how to obtain consent from those whose activities are recorded in the research data. As the 'Tastes, Ties, and Time' study that used Facebook data illustrates, researchers and users may have widely differing views on the appropriate access to data available on the Internet.

3.6 Social Sciences

At the core of the social sciences is the relation between the researcher and human beings. This relation, however, differs from the one in the medical sciences, since it does not involve medical interventions but instead involves behavioural experimentation with and observation of humans, collection of personal information, and the representation of and intervention into the lives of individuals, social groups and society at large. This leads to ethical issues, e.g. the proper treatment of human subjects, privacy of data, and issues such as bias and unequal treatment (in theory and intervention). It involves ethical principles such as informed consent, equality, anonymity, confidentiality, privacy, fairness, non-discrimination, human rights, avoidance of cultural and social bias, and respect. In addition to having a focus on human beings, the social sciences also have a strong concern for proper methodology so as to ensure the quality and objectivity of research. There is therefore also a focus on ethical issues and principles concerning data integrity, research integrity, freedom from methodological bias, objectivity, and others.

The following discussion is based on the SATORI report on ethics assessment in social science (D1.1, Annex 2.d), an empirical study of guidelines and practices. In the European context, the most significant ethical guidance was provided by the RESPECT project, funded by the European Commission. RESPECT's *EU Code of Ethics for Socio-Economic Research* is a comprehensive guide to ethical principles and issues in social sciences.[94] Other highly relevant documents, already mentioned in the Humanities chapter, include *Guidelines for Research Ethics in the*

[92] Zimmer, Michael, "'But the Data Is Already Public': On the Ethics of Research in Facebook", *Ethics and Information Technology*, Vol. 12, Issue 4, December 2010, pp. 313–325 [p. 318].
[93] Ibid. [pp. 318-319]
[94] Dench, Sally, Ron Iphofen and Ursula Huws, *An EU Code of Ethics for Socio-Economic Research*, The Institute for Employment Studies, Brighton, 2004.

Social Sciences, Law and the Humanities by NESH and the European Commission's *Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research*. In the field of psychology, the European Federation of Psychologists' Associations (EFPA) provides thorough ethical guidance.[95]

3.6.1 Ethical Principles

- Freedom and autonomy of research
- Scientific integrity
  - Respecting and crediting work of others
  - Honesty in acquiring and analysing data
- Avoiding harm
  - Voluntary and informed consent
  - Privacy and confidentiality
  - Respect for cultural differences and diversity
- Social responsibility
  - Responsiveness to the needs and problems of vulnerable or underrepresented groups or communities
  - Care for publication and responsible dissemination of research results and participating in public debates

The literature suggests that the scope of ethical assessment in the social sciences would benefit from the inclusion of socio-political principles such as *liberty*, *equality*, and *justice*. Social research takes place in social contexts; therefore, socio-political concepts might be more effective than the traditional approach stemming from biomedicine.

While ethical principles in social sciences are similar to the ones in biomedicine and other fields, there are differences in regard to the ethical issues, which often differ significantly. Due to their dominance in shaping the practice of ethical assessment in general, biomedical approaches have had a major influence on thinking about ethics in social sciences.[96] This influence has, however, often been contested among social science researchers.[97] Different objects and methods of research in the social sciences generate significant differences in the nature of potential risks and benefits research may have for research participants and society.

3.6.2 Ethical Issues

Below is an overview of the main ethical issues in social sciences.[98]

- Voluntary and informed consent
  - The right to withhold or withdraw consent

[95] The European Federation of Psychologists' Associations, *Meta-Code of Ethics*. http://ethics.efpa.eu/meta-code/.
[96] Israel, Mark, and Iain Hay, *Research Ethics for Social Scientists*, Sage Publications, Thousand Oaks, London and New Delhi, 2006 [p. 23].
[97] Ibid.
[98] The selection of issues follows Israel & Hay 2006, combined with other literature.

- Unpredictability of social sciences research
- Scope of observation
- Covert research, deception
- Cultural differences

Obtaining consent from all participants is difficult when research involves observation of people in public spaces and the participation of crowds in large events or when investigating large institutions. Depending on the study, the practical difficulties and the fact that those observed are in a public space may reduce the ethical requirement to obtain consent from these participants. Cultural differences also need to be taken into account when approaching potential participants for informed consent and alternatives to written and signed consent need to be sought in cases where such consent is culturally foreign to participants.[99] There is an on-going debate in social sciences regarding the acceptability of covert research or research involving deception–such practices violate the principle of informed consent, but might be justifiable in some cases. For example, psychological research may require deception to obtain honest reactions from the participants. In such cases, the participants are debriefed about the true nature of the study as soon as it is completed.

- Confidentiality and privacy
  - Voluntary disclosure of identity
  - Public vs. private

Confidentiality-related risks are one of the main potential harms that can affect the participant: 'While in some instances, the research activity itself could produce psychological discomfort or harm, in most cases the biggest risk in SSH [Social Science and Humanities] research relates to the disclosure of a person's identity and insufficient protection of private information which may then lead to discrimination or stigmatisation.'[100] Researchers have to be wary of the changing demarcation between public and private in different cultures and through time. This could especially be an issue in Internet research and research into the impact of contemporary cultural phenomena, such as social media.

- Avoiding harm and doing good
  - Risks of harm
  - Misuse of psychological expertise
  - Classifications/designations

Risks of harm encountered in social science research differ from those in biomedical research: 'Indeed, in social science, research harm is generally more likely to involve psychological distress, discomfort, social disadvantage, invasion of privacy or infringement of rights than physical injury.'[101] In many cases research itself is not the source of risk, but rather the use of acquired information, when 'issues of expectation, interpretation, and representation' come to the

[99] Israel, Mark, and Iain Hay, *Research Ethics for Social Scientists*, Sage Publications, Thousand Oaks, London and New Delhi, 2006 [pp. 63-64].
[100] European Commission, Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research (Draft), 2010 [p. 10].
http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-scienceshumanities_en.pdf.
[101] Israel, Mark, and Iain Hay, *Research Ethics for Social Scientists*, Sage Publications, Thousand Oaks, London and New Delhi, 2006 [p. 96].

fore;[102] e.g. issues related to the participant's expectations of the outcomes and benefits of his or her participation, and how individual participants or communities are represented and their statements interpreted in the research outcomes. When interviewing financial or political elites, researchers themselves can be put under pressure. In some cases 'research may be deliberately and legitimately opposed to the interest of the research subjects', since social science may be 'critical of public personalities or organisations'.[103]

- Peers and research integrity
  - Fabrication
  - Falsification and plagiarism
  - Redundant publications
  - Bias in peer review
  - Conflict of interest
  - Methodology
  - Responsible dissemination

Concerns issues regarding cases of fabrication, falsification and plagiarism, redundant publications, bias in peer review, conflict of interest, relations within research teams and between researchers and their families are also discussed and issues related to the selection of methodology and responsible dissemination of results.[104] In psychology, the European Federation of Psychologists' Associations (EFPA) Meta-Code stresses the need for researchers and other professionals to recognise 'the boundaries of their particular competencies and the limitations of their expertise' as the most important integrity-related principle.[105]

- Social Innovation
  - Fraud, misrepresentation, and misappropriation of assets
  - Conflict of interest
  - Inadequate accountability and transparency
  - Conflict of interest
  - Compensation
  - Publications and solicitation
  - Financial integrity
  - Investment policies, accountability and strategic management

Various definitions of social innovation exist, depending on the social purpose (e.g., microfinance, distance learning, etc.) or social process (e.g., open innovation). The Open Book of Social Innovation defines this notion as 'as new ideas (products, services and models) that simultaneously meet social needs and create new social relationships or collaborations. In other words, they are innovations that are both good for society and enhance society's capacity to act.'[106] Despite its noble goal, social innovation may entail ethical issues related to trust,

[102] Jacobson, Nora, Rebecca Gewurtz and Emma Haydon, "Ethical Review of Interpretive Research: Problems and Solutions", *IRB: Ethics & Human Research*, Vol. 29, No. 5, September-October 2007, pp. 1-8 [p. 3].
[103] Interagency Secretariat on Research Ethics, *Ethical Conduct for Research Involving Humans*, Ottawa 2005 [p. i.7].
[104] For a discussion, see Chapter 8 in Israel, Mark, and Iain Hay, *Research Ethics for Social Scientists*, Sage Publications, Thousand Oaks, London and New Delhi, 2006.
[105] European Federation of Psychologists' Associations. http://ethics.efpa.eu/meta-code/.
[106] Murray, Robin, J. Caulier-Grice, Geoff Mulgan, *The Open Book of Social Innovation*, NESTA, London, 2010. http://www.nesta.org.uk/publications/open-book-social-innovation [p. 3].

cooperation and commitment relations such as fraud, misrepresentation, and misappropriation of assets, conflicts of interest, misallocation of resources, or inadequate accountability and transparency (public and private sector).[107]

The success factors of social innovations require in-depth analysis, taking into consideration different aspects of innovation:[108]

- Impact: How will the innovation improve the well-being of individuals and community?
- Appropriateness: Will the intervention be affordable, robust and adjustable to the settings in developing countries, and will it be socially, culturally and politically acceptable?
- Burden: Will the innovation address the most pressing societal needs?
- Feasibility: Can the innovation be developed and deployed in a realistic time frame?
- Knowledge gap: Does the innovation improve the situation of individuals and communities by creating new knowledge?
- Indirect benefits: Does the innovation address issues such as environmental improvement and income generation that have direct or indirect positive effects on people's wellbeing?

3.6.3 Ethical Case Study in the Social Sciences

To demonstrate the ethical concerns raised by research in the social sciences, we will consider some of the issues raised by Kassin and Kiechel's (1996) experiments on false confessions.[109]

The issue: In their experiment, Kassin and Kiechel demonstrated that the presentation of false evidence could lead individuals to confess to an act they did not commit.[110] The 'results suggest that false evidence can cause people to internalise blame and alter memory for their own actions.'[111] The experiment showed that participants confessed to things they did not do, simply by being presented with false evidence. Furthermore, some participants believed in their own guilt. The results challenge criminal justice systems, as false evidence and false witnesses are common during police interrogations and accepted in many courts.[112]

Principles involved: This study highlights the principles of *voluntary and informed consent*, *avoiding harm* and *social responsibility*. While deception was necessary as a part of the study, all of the participants were fully debriefed about the study's true purpose once the experiment was

[107] Rhode, Deborah L., Amanda K. Packel, "Ethics and Nonprofits", *Stanford Social Innovation Review*, Summer 2009. http://www.ssireview.org/articles/entry/ethics_and_nonprofits.
[108] Based on the model of ethical social innovation in the area of health, presented by Unite for Sight, "Ethics of Innovation". http://www.uniteforsight.org/global-health-university/ethics-of-innovation.
[109] Kassin, Saul M., and Katherine L. Kiechel, "The Social Psychology of False Confessions: Compliance, Internalization and Confabulation", *Psychological Science,* Vol. 7, No. 3, May 1996, pp. 125-128.
[110] Ibid.
[111] Hritz Amelia, Michal Blau, and Sara Tomezsko, "*False Confessions*", http://courses2.cit.cornell.edu/sociallaw/student_projects/FalseConfessions.html.
[112] Ibid.

complete.[113] The researchers also developed a safe method of testing their hypothesis that false evidence may prompt false confessions that did not place the participants at any risk. The research also demonstrates social responsibility by examining whether confessions in criminal cases should necessarily be accepted at face value.

Specificity of the Example to the Social Sciences:

- *Informed consent:* The problem of using deception is that participants are typically not aware of the true nature of the experiment. This leads to the issue of the informed consent as certain aspects of the experiment are being omitted.
- *Deception*: Deception by its nature conflicts with informed consent, as parts of the information are withheld or participants are being misinformed about an aspect of the research.[114] Despite the increased attention given to problematic use of deception in research within the social sciences over the past couple of decades, its use has not declined and remains a popular research strategy.[115] However, deception is often necessary as some psychological phenomena are impossible to research directly as participants may react differently if they are aware of the researchers' purpose.
- *Avoiding harm and doing good:* The research provided evidence of highly problematic nature of police interrogations. This evidence has positive social value, as it allows for evidence obtained through confessions to be evaluated more critically. The proper use of the outcomes of this study may help to reduce miscarriages of justice due to misleading or inaccurate evidence.

3.6.4 Summary

As social science research directly investigates society and human behaviour, it has the potential to have significant social impact and to directly affect the lives of those who participate in this research. The effects that social science research may have means that this research must play close attention to how it affects those who provide information, and how the researchers' work might be used by others.

The methods of performing this research also raise important ethical issues, such as the need to gain informed consent versus the need for deception to gain accurate results. The case of the study into false confessions shows how some of these issues can be effectively addressed.

3.7 Humanities

The humanities concern the study of human culture. Thus, a special focus is given to interpretation, narrative, imagination, and art, as well as to the documentation and preservation of cultural heritage. Ethical issues therefore concern the proper conduct of the interpretation and

[113] Kassin, Saul M., and Katherine L. Kiechel, "The Social Psychology of False Confessions: Compliance, Internalization and Confabulation", *Psychological Science,* Vol. 7, No. 3, May 1996, pp. 125-128 [p. 127].
[114] Shaughnessy, John J., Eugene B. Zechmeister, and Jeanne S. Zechmeister, *Research Methods in Psychology*, 10th ed., McGraw-Hill, 2015 [ch. 3].
[115] Sharpe, D., Adair, J. G. and N. J. Roese, "Twenty years of deception research: A decline in subjects' trust", *Personality and Social Psychology Bulletin*, Vol. 18, No. 5, October 1992, pp. 585-590.

construction of narratives, the proper role of works of imagination and art in society and our evaluation of them, and our responsibilities in the preservation of cultural heritage. In addition, because the humanities may include human subjects in their research, they share some of ethical issues and principles on human subjects' research with the social sciences.

The following discussion of ethical principles and issues is based on the SATORI report on ethical assessment in humanities (D.1.1, Annex 2.e), as a part of which an interview with an expert in the field was conducted. In the report, three documents of ethical guidance were identified as particularly relevant due to their scope and thoroughness: the Norwegian National Committee for Research Ethics in the Social Sciences and the Humanities' (NESH) *Guidelines for Research Ethics in the Social Sciences, Law and the Humanities*,[116] the European Commission's *Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research*[117] and the *EU Code of Ethics for Socio-Economic Research*,[118] written as a part of the RESPECT project,[119] which is also relevant for research within humanities. The following discussion synthesises these guidelines. It also emphasises the specificities of ethical principles and issues in humanities research as they are discussed in relevant literature.

3.7.1 Ethical Principles

- Freedom, autonomy and independence of scientific pursuit
- Scientific integrity
  - Quality of research
  - Scientific honesty
  - Safeguarding of research
  - Intellectual freedom and openness
  - Fair treatment of colleagues
  - Fair treatment of rival theoretical or methodological approaches (the coexistence of different approaches and theories is of a high importance in humanities)
- Social responsibility
  - Benefit of research for society
  - Responsiveness to the needs and problems of vulnerable or underrepresented groups or communities
  - Care for publication and responsible dissemination of research results and participating in public debates
- Human dignity, avoiding harm and doing good

[116] De nasjonale forskningsetiske komiteer, *Guidelines for Research Ethics in the Social Sciences, Law and the Humanities*, 2006. https://www.etikkom.no/Documents/Publikasjoner-som-PDF/Guidelines%20for%20research%20ethics%20in%20the%20social%20sciences,%20law%20and%20the%20humanities%20(2006).pdf.
[117] European Commission, *Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research (Draft)*, 2010. http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-sciences-humanities_en.pdf.
[118] Dench, Sally, Ron Iphofen and Ursula Huws, *An EU Code of Ethics for Socio-Economic Research*, The Institute for Employment Studies, Brighton 2014.
[119] The RESPECT project was funded by the European Commission's Information Society Technologies (IST) Programme to draw up professional and ethical guidelines for the conduct of socio-economic research. http://www.respectproject.org/main/index.php.

  - Respect for persons, communities and cultures
  - Voluntary and informed consent
  - Privacy and confidentiality
  - Excluding bias in terms of differences of gender, age, race, religion etc.
  - Respect for cultural differences and diversity
- Responsible treatment of cultural heritage (specific to humanities)

3.7.2 Discussion of Ethical Principles

Ethics assessment in humanities and social sciences is based on the adaptation of principles well-established in other fields (such as biomedicine, for example), based on the bottom-up approach grounded in research practice, rather than extensively elaborating on general frameworks specifically for the humanities. The difficulties of simple application of protocols and procedures based on medical and natural sciences have been discussed extensively.[120] Some have even argued that 'extending the ethical clearance regime of a biomedical research model into a new range of previously unaffected disciplines including history, literary studies, and cultural or media studies, with quite different models of research practice, is dangerous and may well have significant negative effects.'[121]

More appropriate guidelines for ethical assessment of humanities research were first crafted in the social sciences, but the general principles pertaining to the scientific practice are common to all scientific fields. The principles listed below are accompanied by commentaries on the specificity of their role in the humanities, according to three major categories: 1) standards of scientific practice, 2) responsibilities towards individuals and communities directly participating in research, and 3) considerations of societal impact of research.[122] These principles also represent a value system of the four R's: *Relevance*, *Responsibility*, *Respect* and *Reciprocity*.[123] The principles noted below should be included in the formulation of all research projects.

1) Standards of scientific practice

- Freedom, autonomy or independence of scientific pursuit
  - As the humanities often address topics that challenge accepted beliefs within society, researchers can find themselves under pressure from political, cultural or religious groups.
- Scientific integrity

[120] Cf. Schrag, Zachary M., "The Case against Ethics Review in the Social Sciences", *Research Ethics*, Vol. 7, No. 4, December 2011, pp. 120-131, and Schrag's blog on the topic: http://www.institutionalreviewblog.com; also Jacobson, Nora, Rebecca Gewurtz and Emma Haydon, "Ethical Review of Interpretive Research: Problems and Solutions", *IRB: Ethics & Human Research*, Vol 29, No. 5, September-October 2007, pp. 1-8.
[121] Parker, Malcolm, Jim Holt, Graeme Turner, and Jack Broerse, "Ethics of research involving humans: Uniform processes for disparate categories?", *Monash Bioethics Review*, Vol. 22, Issue 3, July 2003, pp. S50-S65 [p. 59].
[122] This kind of categorisation can be found in the mentioned EU Code of Ethics for Socio-Economic Research as well as in the Guidelines for Research Ethics in the Social Sciences, Law and the Humanities.
European Commission, Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research (Draft), 2010. http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-scienceshumanities_en.pdf.
[123] De Wet, Katinka, "The Importance of Ethical Appraisal in Social Science Research: Reviewing a Faculty of Humanities' Research Ethics Committee", *Journal of Academic Ethics*, Volume 8, Issue 4, December 2010, [p. 312].

- Fair treatment of rival theoretical or methodological approaches. The coexistence of different approaches and theories is of a high importance in the humanities. The criteria for quality and verifiability of research in the humanities differ from quantifiable criteria used in the natural sciences and sometimes even in the social sciences (see sections 3.5 and 3.6 below). The co-existence of different approaches and theories must be accounted for without sacrificing means of evaluation.

2) Responsibilities towards individuals and communities directly participating in research. Some disciplines within the humanities include research involving human participants, especially disciplines involving field work, such as cultural and social anthropology, ethnology, etc., where issues of disclosure and intrusion are also often brought up. In such cases, the following values and principles apply:

- Human dignity (in relevant cases in performance arts, this principle can also apply to the performers involved)
- Avoiding harm (e.g., in studying indigenous people, social, economic, cultural and political minorities)
  - Voluntary and informed consent
  - Confidentiality and anonymity
  - Respect for cultural differences and regard for vulnerable participants

3) Considerations of societal impact of research in the humanities and general scientific principles linked with responsibilities towards society.

- Social responsibility
  - This includes addressing concerns of relevant stakeholders and recognizing the impact of research results on individuals and communities. The context, whether historical, cultural, social, or other, is important – the research should account for imbalances in the representation of people of different social classes, genders and ethnicities. The principle of benefit for society can draw on the long-standing tradition of reflecting on the role of the intellectual in society within the humanities. There is the need, however, to balance this principle with the principle of autonomy of scientific pursuit.
- Equality of participation in conducting research
  - Excluding bias in terms of age, race, ethnicity, gender, class and sexuality.
- Regard for vulnerable, disadvantaged or underrepresented individuals and groups or communities

A specific principle in the humanities is

- Responsible treatment of cultural heritage (insofar that these are the objects of research (e.g. archived texts))

This includes tangible versions of cultural heritage and natural heritage as well as intangible heritage, understood as 'practices, representations, expressions, knowledge, skills – as well as the instruments, objects, artefacts and cultural spaces associated therewith – that communities, groups and, in some cases, individuals recognize as part of their cultural heritage.'[124]

[124] Convention for the Safeguarding of the Intangible Cultural Heritage, UNESCO, 2003, http://unesdoc.unesco.org/images//0013/001325/132540e.pdf.

International instruments have identified the importance of incorporating considerations of aspects of human culture into the impacts of research.[125]

3.7.3 Ethical Issues

An overview of ethical issues in the humanities is presented below, organised according to the three categories mentioned in the previous chapters: 1) scientific practice, 2) research involving human participants, and 3) societal impact. A list of issues in each category is followed by a brief discussion on specificities of issues in the field of humanities.

- Ethical issues concerning scientific practice
  - Plagiarism and improper authorship
  - Data fabrication and falsification
  - Misappropriation of the ideas of others
  - Misrepresentation of scientific experiments, funds or other resources (e.g. for personal/career gain)
  - Misrepresentation of qualifications, experience, or research accomplishments (e.g., to obtain research programs, external funding, professional career advancement)
  - Violations involving care of research participants
  - Conflicts of interest
  - Violations of generally accepted research practices in carrying out research, e.g. manipulation of data and materials to get desired results, statistical or analytical manipulation of results, improper reporting of results
  - Issues of ideological bias or political pressures
  - Unfair treatment of rival theoretical approaches in quality assessment, peer review, etc.

A major issue in regard to scientific practice is the method of assessing the quality of research in the humanities. From an ethical point of view, the coexistence of several theoretical approaches must be acknowledged according to *the principle of good faith*. Since research in the humanities is often very interpretive, reviewers are often faced with 'the conflict between the ideal of remaining objective in reviewing and critiquing papers and performances and the inherently subjective nature of these products'.[126] Furthermore, as the humanities often address topics that can be politically controversial or sensitive for various groups within society, researchers are often faced with pressure from political parties or religious organisations.

- Ethical issues involving human participants
  - Issues concerning avoidance of harm and human dignity
  - Issues concerning voluntary and informed consent

[125] See Council for International Organisations of Medical Sciences (CIOMS). "International Guidelines for Ethical Review of Epidemiological Studies", http://www.cioms.ch/publications/guidelines/1991_texts_of_guidelines.htm; European Parliament and the Council, Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012

[126] Stenmark, Cheryl K., Alison L. Antes, Laura E. Martin, Zhanna Bagdasarov, James F. Johnson, Lynn D. Devenport, Michael D. Mumford, "Ethics in the Humanities: Findings from Focus Groups", *Journal of Academic Ethics*, Volume 8, Issue 4, December 2010, [p. 296].

    - Issues concerning anonymity, confidentiality and control over material (e. g. interviews)
  - Issues concerning respect for cultural differences, vulnerable participants and groups
  - Issues concerning reverse power relations and risk of harm to the researchers
  - Issues concerning covert research and deception

Issues concerning human participants that do arise in humanities research are very similar to those in social sciences, and substantially different from those in biomedical research. In contrast to biomedical science, the potential harm for participants in social sciences rarely relates to health risks or physical wellbeing, even when human participants are included in the research (e.g. anthropological studies, oral history). Rather, the issues are of a more psychological nature or linked to the problem of how cultures and behaviours of certain individuals or groups are represented in the community (risk of discrimination, stigmatisation).

This difference also entails that unlike in medical sciences, which assume 'an all-powerful investigator and a vulnerable participant', the investigator and the participant are 'engaged in a mutual process of constituting knowledge'.[127] A different relationship between the investigator and participant has significant impact on the way consent is obtained and also on how issues of anonymity and confidentiality are perceived. The signed informed consent form may be at odds with cultural norms of the participants' community or might provoke suspicion with certain vulnerable groups. Alternative ways of obtaining consent should be considered in these cases. While many ethics review procedures require interview questions to be known in advance, in projects within the humanities new significant topics can arise during interviews that can change the direction of the research. This variability suggests that consent should be an on-going process in which the research participants are continuously consulted over the use of materials they hand over to the researcher. In some types of interviews, participants do not want to be anonymised and want to have their stories told. Such research can give a voice to marginalised groups, although researchers should present sensitive materials with care to avoid generalisations that can lead to stigmatisation.

When the researched groups are powerful elites, power relations can be reversed and the researcher is exposed to pressures. Such research is often critical of the interests of the research participants. Some types of research can present significant risk to researchers themselves, e. g. research conducted in war zones.

- Ethical issues in regard to societal impact
  - Issue of balancing the autonomy of scientific pursuit with its aim to benefit society
  - Ideologically sensitive topics (potential impact on public policy and affect on society)
  - Issues related to research involving vulnerable groups, cultures, developing countries (e.g. discrimination)
  - Issues related to societal responsibility and sustainability
  - Issues related to preservation of cultural heritage (specific to the humanities)

[127] Jacobson, op. cit., 2007, pp. 4, 2.

The humanities often deal with sensitive topics that have potential impact on society. Often, research is critical towards societal or political structures and is engaged in advocating rights of vulnerable groups, which can be controversial for some parts of society.

Preserving cultural heritage for future generations and researchers is also a specific issue for the humanities.

3.7.4 Ethical Case Study in the Humanities

To demonstrate how these issues can emerge in the humanities and how the ethical principles are applicable to them, we will briefly describe an oral history project collecting confidential testimonies on a sensitive period in recent history, which were later subpoenaed by the authorities in a criminal investigation.

The issue: From 2001 to 2006, researchers from Boston College conducted a series of interviews with people heavily involved in the Northern Irish 'Troubles' on both sides of the conflict.[128] Due to the sensitive topics discussed, including criminal activities, the project was carried out in secrecy and the agreement with respondents was that the testimonies were to remain sealed until after their death. The project started in the aftermath of the peace agreement and its aim was to provide a valuable archive for historians studying the conflict. However, after the first interviews and the existence of the project were made public, several issues emerged. The Northern Ireland police demanded the interviews to be handed over to them via the US justice system as a part of a murder investigation.

The decision-making process: The subpoenas resulted in a protracted legal battle, which also caused a split between the Boston College and project researchers themselves.[129] Boston College and the researchers based their case on academic freedom and the confidentiality agreement they had with the interview respondents. Researchers also argued that the police investigation is political, since the interview material led to the arrest of Gerry Adams, leader of Sinn Féin, in an election period. Boston College offered to return the files to the respondents. Some interviews were eventually handed over to the police. There was no ethical assessment of the project before it took place. Secrecy of the project was argued as necessary to protect the interviewees from danger of being perceived as "touts" (informers) within their communities. In the informed consent agreement with the respondents, there was no mention of the legal limits to confidentiality. Researchers argued that this omission would make the interviews impossible. Some have argued that the choice of the respondents was biased towards a certain view of the conflict and the way it was resolved. Some have also argued that the project, although designed with good intentions, eventually caused damage to the Northern Ireland peace process.

[128] This account is based on the website documenting the case: https://bostoncollegesubpoena.wordpress.com.
[129] The following information is extracted from two articles: McMurtrie, Beth, "Secrets from Belfast: How Boston College's oral history of the Troubles fell victim to an international murder investigation", *The Chronicle of Higher Education*, January 26, 2014, http://www.chronicle.com/interactives/belfast; Cullen, Kevin, "BC Exercise in Idealism Reopens Old Wounds", *The Boston Globe*, July 06, 2014, http://www.bostonglobe.com/news/world/2014/07/05/belfast-the-shadows-and-gunmen/D5yv4DdNIxaBXMl2Tlr6PL/story.html.

Principles involved: This complex case involves several ethical principles: freedom and autonomy of academic research, informed consent, confidentiality, social responsibility, avoiding harm, excluding bias and regard for vulnerable groups. The applications of these principles to the issues raised by the case are described below.

Specificity of the example for the Humanities:

- *Freedom and autonomy of research*: The project sought to collect materials that can help humanities and social science scholars study various aspects of a historical conflict situation and the people directly involved in it. The appeals against handing over the materials to police were based on the protection of academic freedom.
- *Informed consent*: The case shows that researchers should consider all legal aspects of their actions and fully transmit this awareness to the participants.
- *Confidentiality*: The project researchers argue that it is the duty of academics to protect the materials collected in confidentiality at all costs. However, there are legal issues that restrict the domain of confidentiality.
- *Social responsibility*: One of the aims of the project as described by the researchers was to 'enhance public understanding of the conflict' and therefore benefit the 'people involved in conflict resolution and policy making'.[130] The actual societal effects, however, were argued to be different, since 'the project has instead, at ground level in Belfast and beyond, engendered the sort of paranoia, furtive whispering and fevered accusations that got people killed here for years'.[131]
- *Avoiding harm, excluding bias and regard for vulnerable groups*: Risk of harm stems from the sensitive nature of narrations disclosed, since they could, when made public, incriminate or stigmatise and put in danger the narrator or third persons. Where the conflicts as objects of historical research are recent and not yet completely resolved, bias in collecting and interpreting materials should be avoided (the project interviewed people from both sides, however, there are strong internal divisions within each side). The case also shows how the notion of vulnerable groups can prove to be complicated in humanities and social science, e.g. when researched groups have been involved in criminal activity and their stories can help resolve conflicts (as was the initial aim of the project).

3.7.5 Summary

Work in the humanities is largely guided by the accepted norms of research practice, including academic freedom and the proper attribution of sources. While there have been attempts to impose ethical frameworks based on those used in the social sciences and in medical research, the significant differences in both the methodology and subject matter of the humanities mean that adopting ethical frameworks designed for other fields may be detrimental.

[130] McIntyre, Anthony, "The Belfast Project and the Boston College Subpoena Case", https://bostoncollegesubpoena.wordpress.com/2012/10/07/the-belfast-project-and-the-boston-college-subpoena-case/.
[131] Cullen, Kevin, "BC Exercise in Idealism Reopens Old Wounds", *The Boston Globe*, July 06, 2014, http://www.bostonglobe.com/news/world/2014/07/05/belfast-the-shadows-and-gunmen/D5yv4DdNIxaBXMl2Tlr6PL/story.html.

As the humanities study recorded human experience, ideas, and culture, it raises ethical concerns about the treatment and representation of other cultures, the use of data collected in confidence, and the privacy of those who provide information to researchers. As the case of the Boston College study into the conflict in Northern Ireland demonstrates, research into the past can have a significant impact on current events.

3.8 Moral Decision Making

A reasoned moral decision must be based both on a consideration of relevant facts, i.e. an assessment of the consequences and probabilities of the outcomes of alternative decisions and on value judgements. Moral decision makers, for example in research ethics committees, must both be well-informed and have reflected on the ethical principles, values and norms that are relevant for the moral problems at stake. We have good reasons for a moral decision if we have thoroughly examined the possible consequences of alternative courses of action, examined the likelihood of those consequences and if we have reflected on the ethical principles, norms and values that form the basis of the decision.

Ethical principles, such as the four principles of non-maleficence, beneficence, respect for autonomy and justice suggested by Beauchamp and Childress[132] are action-guiding to the extent that they inform the moral decision maker of relevant moral aspects of a decision. He or she is reminded of, for example, how to involve affected individuals as the principle of respect for autonomy recommends, or how to fulfil reasonable justice claims in accordance to the principle of justice.

What should be done when ethical principles suggest divergent courses of action? In what follows, some suggestions on how to solve this problem are presented. They are related to the following case of a disagreement taken from the discussions in research ethics.

In some large sociological research projects, information about people's health status and lifestyle is used to gain knowledge of health risks and causes of illnesses. To get a comprehensive and a sufficient database, researchers in some projects have accessed privacy sensitive information about individuals without asking the individuals for consent. The reason for doing so is that these kinds of large quantitative research projects would be impossible to accomplish if individual consent was required. Critics argue that such research projects violate individual privacy and individuals' right to decline to participate. According to their view, an individual has a right to consent to the use of information about him or her. In response, those who are in favour of the research argue that this kind of research is impossible if one has to obtain informed consent from every individual. They suggest that this is the price we have to pay in modern society in order to gain sufficient knowledge to track public health risks. They maintain that the positive consequences for public health outbalance the potential privacy intrusions. The principle of beneficence thus outweighs the principle of informed consent.

[132] Beauchamp, Tom L. and James F. Childress, *Principles of Biomedical Ethics*, 7th ed., Oxford University Press, New York, 2013.

Sociological research projects of this kind illustrate a conflict between two ethical principles: on one hand the principle of beneficence supports research that increases our knowledge of factors behind public health and illnesses. On the other hand, the principle of informed consent suggests that an individual who is a research subject should have a right to consent. There are good reasons to implement the project because it will contribute to public health and there are good reasons to reject it because it will involve research done without the research subjects' informed consent. So how can we come to a decision? Should the project be implemented or not?

3.8.1 Resolving Conflicts between Ethical Principles

In what follows, four ways or methods to resolve conflicts between ethical principles are presented. These methods are the *utilitarian calculus*, *libertarian side-constraints*, *prima facie principles* and *specification*.

Utilitarian calculus

The 18th century British philosopher Jeremy Bentham summarises utilitarianism in the following words: 'By the principle of utility is meant that principle which approves or disapproves of every action whatsoever, according to the tendency which appears […] to promote or to oppose […] happiness'.[133] The goal for utilitarianism is a world with as much utility (or happiness) as possible. Actions that maximise utility (or minimise harm) are morally right and actions that minimise utility (or maximise harm) are morally wrong.

So in principle (but not in practice) utilitarianism offers a simple and straightforward way to resolve conflicts between ethical principles. One only has to calculate how the different alternatives will maximise happiness and minimise suffering, and choose the alternative with the best outcome regarding the balance of happiness and suffering. According to this way of thinking, ethical principles, for example the four principles mentioned above, point at relevant moral aspects of moral decisions, but ultimately there is only one principle that should guide our decision: namely, the principle of utility (which in the Beauchamp and Childress scheme matches the principle of beneficence). Hence, in order to resolve the conflict regarding base research into sociological data, one has to estimate the amount of utility/happiness that results from research without consent, on the one hand, and research satisfying the principle of informed consent, on the other.

A benefit of the utilitarian approach is that it requires all of those affected by an action to be considered in deciding whether an act is morally justified. Utilitarian philosopher Richard Hare distinguishes between different roles and purposes of ethical principles. In everyday moral life, the purpose is learning. Principles point towards the morally relevant consideration when facing moral problems and moral dilemmas. However, when two principles require incompatible actions, 'critical thinking' leads us to evaluate the outcomes of the different alternatives from the point of view of the preferences or happiness of all persons affected and the alternative option that tends to maximise preferences should be chosen.[134]

[133] Bentham, Jeremy, *The Principles of Morals and Legislation*, Prometheus Books, Amherst, 1988 [p. 2].
[134] Hare, Richard M., *Moral Thinking: Its Levels, Method and Point*, Oxford University Press, Oxford, 1981.

The utilitarian method is simple in theory: one just has to apply one basic principle—the principle of utility—in order to come to a decision. In practice, though, the kind of utility-estimations that decision-making requires seems to be both very difficult and uncertain. It has been criticised for basing decisions on uncertain predictions of consequences, for pertaining to simplistic estimations of value (happiness vs. suffering) and for sacrificing individual rights for the happiness of the many.[135]

Libertarian side-constraints

Libertarian philosopher Robert Nozick developed an opposing view to the utilitarian calculus.[136] Individual rights are central in Nozick's theory. According to Nozick, individual rights to life, liberty and property are 'side constraints' for actions. No action that violates a person's life, liberty or property is justified according to this theory. The violations of these rights imply violating a person, or, in Immanuel Kant's words, to 'use a person only as a means'.

When one applies the idea of side constraint to the discussion of how to balance principles in moral decision making, there are some principles that have precedence. According to Nozick, the principle of human dignity (right to life) and the principle of respect for autonomy (right to liberty) would have this status. The priority of dignity and autonomy suggests a solution to the conflict between performing research without informed consent, which is motivated by the principle of beneficence, and the principle of informed consent, which is motivated by the principle of autonomy. The right to liberty, which in this case is protected by the right to informed consent, takes priority. It is then not morally justified to carry out the research while it violates people's right to liberty. Of course, the idea that a right to liberty in this way always take precedence over competing principles is controversial and in need of further justification.

Prima facie *principles*

The British philosopher W. D. Ross[137] proposed a method for solving conflicts between duties. According to Ross, moral decisions are guided by moral duties but no duty is absolute or (to use Nozick's terminology) a side-constraint. Instead, duties are valid *prima facie*. *Prima facie* duties are the fundamental and binding duties that we refer to when confronted with a moral dilemma. Fidelity, non-injury, beneficence and justice are among the prima facie duties that Ross himself proposes. Duties are understood by Ross as guidelines for moral decision-making and have a similar meaning as ethical principles in the way we use the term here. Let us therefore instead use the term '*prima facie* principles'.

Ross recommends the following way to act when we have to make a decision and the *prima facie* principles point in different directions by recommending different alternatives. In such a situation, one of the conflicting *prima facie* principles will take precedence and become the *actual* duty. According to Ross, in the specific situation we will recognise which principle to follow, i.e. our moral intuition tells us which *prima facie* duty will become the actual duty. In

[135] Sinnott-Armstrong, Walter. "Consequentialism", in *The Stanford Encyclopedia of Philosophy*, Edward N. Zalta (ed.), Winter 2015. http://plato.stanford.edu/archives/win2015/entries/consequentialism/.
[136] Nozick, Robert, *Anarchy, State and Utopia*, Basil Blackwell, Oxford, 1974.
[137] Ross, W. David, *The Right and the Good*, Indianapolis, Hacket, 1988.

addition to our moral intuition, we should also consult the views of the 'thoughtful and well-educated', which are influenced by 'the moral reflection of many generations'.[138]

If one wants to base morality on reasons, Ross' reference to intuition is unsatisfactory. On the other hand, perhaps Ross' theory is an illustration of the likely possibility that moral argumentation sooner or later will reach a point when we have to refer to intuitions or some other basic point of reference. Ross' theory is helpful in the sense that it conceptualises how conflicts of duties could be interpreted and handled.

So, what *prima facie* principles are relevant in the case of sociological research without consent? Here two *prima facie* principles come into conflict. The principle of beneficence guides us to make the research in order to better understand reason for health and illnesses. In contrast, the principle of autonomy guides us not to do the research without consent from the research subjects. Which *prima facie* principle is in this conflict the actual principle? We would need to reflect on the particular details of the study and whether our intuition is that autonomy or beneficence is the most important principle to follow. Examining previous cases whether ethics assessors have had to choose between these two principles and whether we find their decisions acceptable would also help to inform our decision making in this case. Through doing this, we can draw on both our moral intuitions and the views of the 'thoughtful and well-educated'.

3.8.2 Specification

Henry Richardson has developed a theory of specification as a way to handle conflicting norms.[139] Compared to both Nozick's and Ross' approaches, the main difference is that specification recognises that moral norms are revisable. Following Richardson, the reasons for modifying and specifying moral norms – in our case ethical principles – can be articulated in relation to conflicting principles. In the example above the principle of beneficence supporting the sociological research comes into conflict with the principle of informed consent, demanding that each research subject has a possibility to consent or not consent to the research. Which principle has priority?

The process of specification starts with a moral dilemma. In our case we have two *prima facie* principles, a principle of beneficence and a principle of informed consent and we face a conflict between them. They generate conflicting norms for actions: following the principle of beneficence the research can continue, but following the principle of informed consent the researcher has to obtain consent before the research can continue.

In the discussion of research ethics there are various suggestions of how to resolve the conflict between informed consent and research that benefits public health. Here are some examples. One should secure that it is highly probable that the research will benefit public health extensively;

[138] Skelton, Anthony, "William David Ross", in *The Stanford Encyclopedia of Philosophy*, Edward N. Zalta (ed.), Summer 2012. http://plato.stanford.edu/archives/sum2012/entries/william-david-ross/.
[139] Richardson, Henry S., "Specifying Norms as a Way to Resolve Concrete Ethical Problems", *Philosophy & Public Affairs*, Vol. 19, No. 4, Autumn 1990, pp. 279-310; Richardson, Henry S., *Practical Reasoning about Final Ends*, Cambridge University Press, Cambridge, 1994; Richardson, Henry S., "Specifying, Balancing, and Interpreting Bioethical Principles", *Journal of Medicine and Philosophy*, Vol. 25, No 3, 2000, pp. 285-307.

one should look for other possible ways to do the research that does not conflict with the principle of informed consent; finally, one should look for possible ways to obtain presumed consent.

Now, specification of the general principles becomes relevant. Specification is based on some assumptions. Firstly, norms and principles are generally not absolute but instead they implicitly begin with a 'generally speaking' or 'in most cases' sense that means that norms and principles are open for modification.[140] Secondly, different norms and principles may not necessarily have the same weight. Some norms and principles are more important and basic than others. This leads to possible specifications of the principles. A possible specified principle of informed consent has the following formulation:

In research on individuals, one should always obtain informed consent from the research subject, but only if it is not an obstacle to the possibility to do research that is of great value for public health.

One could also specify the principle of beneficence in a similar way. A possible specified principle of beneficence has the following formulation:

One should do research that is of great value for public health, if it does not come into conflict with the research subjects' right to informed consent.

The specified principles are action-guiding but they avoid the problem of conflicts between principles. Instead the two conflicting principles are integrated in the new formulations.

Which specified principle should then be applied this time? The answer depends on the particulars of the situation. Could the basic research aims be achieved without sidestepping the principle of informed consent? The specific aspects of the case have to be weighed against the principles back and forth until a balanced decision has been found. When a well-balanced and justified specification is reached, the decision is in a *reflective equilibrium.*[141]

3.8.3 Conclusion

This overview presents different theoretical methods to resolve conflicts between ethical principles. We can notice that the first two alternatives are based on ethical theories, i.e. conflicts between ethical principles are resolved by reference to more basic ethical views: maximising utility (utilitarianism) and respecting individual rights (libertarianism). The two latter alternatives, *prima facie* duties/principles and specification, are methods that are more open to different ethical approaches while they can entail both right-based and consequential considerations.

In practice, e.g. in deliberations in ethical committees, theoretical reasoning of the kind presented in this chapter probably rarely happens (see WP 1). Instead, the conflicts are resolved by the

[140] Richardson, Henry S., "Specifying Norms as a Way to Resolve Concrete Ethical Problems", *Philosophy & Public Affairs*, Vol. 19, No. 4, Autumn 1990, pp. 279-310 [p. 292].
[141] Rawls, John, *A Theory of Justice*, Harvard University Press, Harvard, 1971; Daniels, Norman, *Justice and Justification: Reflective Equilibrium in Theory and Practice*, Cambridge University Press, Cambridge, 1997.

committee members' moral intuitions – in the specific situation it seems clear which alternative is the most non-contentious – or by compromises. We recommend that EAUs adopt the methods for resolving ethical dilemmas described above, either singly or in combination. The most appropriate method will depend on the activity the EAU reviews. For example, appealing to libertarian side-constraints is more appropriate to evaluating research activity involving human participants than to research in the natural sciences. Using one or more of these methods will assist ethics assessors in making decisions that can be explained and justified to researchers and other stakeholders.

3.9 A Reasoned Proposal: A Framework for Shared Ethical Issues and Principles

This chapter provides an overview of ethical issues and principles that are meant to be applicable to a broad array of types of scientific research and technological innovation. The provided overview is based on the previous sections on ethical principles and issues that were identified in the earlier stages of the SATORI project, as well as on additional literature that specifically deals with ethical principles in research and innovation. First, it provides a framework of ethical principles and issues that apply to all types of research and innovation. Second, it specifies the principles and issues that apply to specific fields of research and innovation, such as the natural sciences, the engineering sciences, the medical sciences, the life sciences, the computer and information sciences, and the social sciences and humanities.

There are already several general sets of principles for the ethical conduct of research and innovation. Examples include the Singapore Statement on Research Integrity,[142] the European Code of Conduct for Research Integrity,[143] the Helsinki Declarations and the Oviedo Convention on Human Rights and Medicine.[144] Many of these sets of principles have been mentioned in the earlier discussions of research fields as sources for each field's particular principles. The account of principles described below builds on these sets of principles by bringing them together in a framework that integrates diverse research fields.

The reason for developing this proposal for shared ethical issues and principles in the SATORI project, rather than adopting an existing proposal from current literature (for instance, the principlist approach[145]) is to have a comprehensive overview of shared issues and principles that reflects actual research practices as far as we have been able to examine them empirically within the SATORI project. The list therefore also better reflects European values and ethical principles than the existing ones. While the framework strives to be as comprehensive as possible, the presented list is certainly not exhaustive. Rather, it is a fair approximation of the ethical issues

[142] "Singapore Statement on Research Integrity", 2010. http://www.singaporestatement.org/statement.html.
[143] European Science Foundation (ESF), and All European Academics (ALLEA), "The European Code of Conduct for Research Integrity", 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf.
[144] European Parliament and the Council, Convention for the Protection of Human Rights and Dignity of the Human Being in regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.4.1997.
[145] Beauchamp, Tom L. and James F. Childress, *Principles of Biomedical Ethics*, 7th ed., Oxford University Press, New York, 2013.

and principles as they are already applied and understood in the research and innovation context that the SATORI project investigates.

Ethical issues and principles in different disciplinary fields have already been discussed in the earlier deliverables of the SATORI project, namely Deliverable 1.1 and its relevant annexes (1.b-1.h and 2.a-2.e). For example, the deliverable discusses the role of ethics in fields and disciplines such as *natural sciences, engineering sciences, information technology, nanotechnology, medical and life sciences, neurosciences, pharmaceutics, social gerontechnology, biobanking, public health, genetics, stem cell research, agricultural research, social sciences, psychology, internet research ethics and humanities*. In addition to this, the deliverable has presented a number of ethical principles resulting from empirical data; principles such as *research integrity, institutional transparency, precaution, safety, sustainability, human dignity, justice and social responsibility*.

Ethical principles for research and innovation come in three kinds, only one of which is normally considered by ethics committees:

- *Professional principles and codes of conduct*. These are ethical principles that specifically concern the behaviour and practices of individual researchers and innovators and the way they treat others. Assessment of this behaviour is not normally the responsibility of ethics committees, but rather is the responsibility of research integrity boards, professional ethics boards or disciplinary committees.
- *Ethical guidelines for institutional responsibility and integrity*. These are ethical principles that concern the way in which the institutional setting for research and innovation ought to be constructed so as to support ethically sound research and innovation practices. These principles are not normally applied by ethics committees, although ethics committees sometimes address them in their work.
- *Ethical guidelines for the conduct of research and innovation*. These are ethical principles for the assessment of plans, procedures, and practices in research and innovation. This latter category of principles is normally considered by ethics committees and is therefore central to their functioning as ethics committees.

As can be seen, ethical issues relating to research integrity typically do not fall within the remit of ethics committees. Research integrity is about possessing and adhering to the scientific and professional standards that govern the conduct of research. These standards, which are often specific to particular fields or disciplines, are provided by professional organisations in *codes of conduct*, and sometimes by the government or the public. In general, they call for the avoidance of data fabrication, manipulation, plagiarism and conflicts of interest, and for collegiality, among other things. Since research integrity is about the behaviour and conduct of the researcher rather than the research plans and activities themselves, matters of research integrity are generally handled by other committees than those that perform ethics assessment of research and innovation projects, proposals and practices; namely, they are handled by scientific integrity boards or professional ethics committees. Nevertheless, research integrity can be assessed by ethics committees to the extent that there are potential individual or institutional conflicts of interest that are apparent in research and innovation proposals and activities. It is in the interest of good research ethics that ethics committee members are at least aware of the core principles of research integrity, and ethics committees could take it upon themselves to inform researchers of

research integrity standards, and to observe and identify flaws in research plans and activities that could provide evidence of scientific misconduct.

Also, note that ethical principles and protocols are sometimes stated as voluntary guidelines, but may also be encoded in legislation (directives passed by a government or governing body that must be legally complied with) and regulations (rules by regulatory bodies and government executives that specify how laws are to be implemented). Especially in the medical field, ethical issues are heavily regulated. In addition, regulations and legislation exist in many countries for issues concerning privacy and data protection, health and environmental risks and dual use, among other things. Ethics committees should be aware of the relevant legislation and regulations to which research and innovation is subject, and should assess if the research or innovation plan or activity is compliant.

The ethical principles under consideration by ethics committees can be divided into:

- General ethical principles that potentially apply to every major field of scientific research and innovation;
- Ethical principles that apply only to specific fields of research and innovation – including the natural sciences, the engineering sciences, the medical sciences, the life sciences, the computer and information sciences, and the social sciences and the humanities. These principles primarily concern the context of the research, such as how experiments are performed or which research participants are involved, and the (future) impacts of the research, such as the environmental consequences of technological innovations resulting from research in the chemical sciences (See Figure 1 for a diagram of the presented framework).

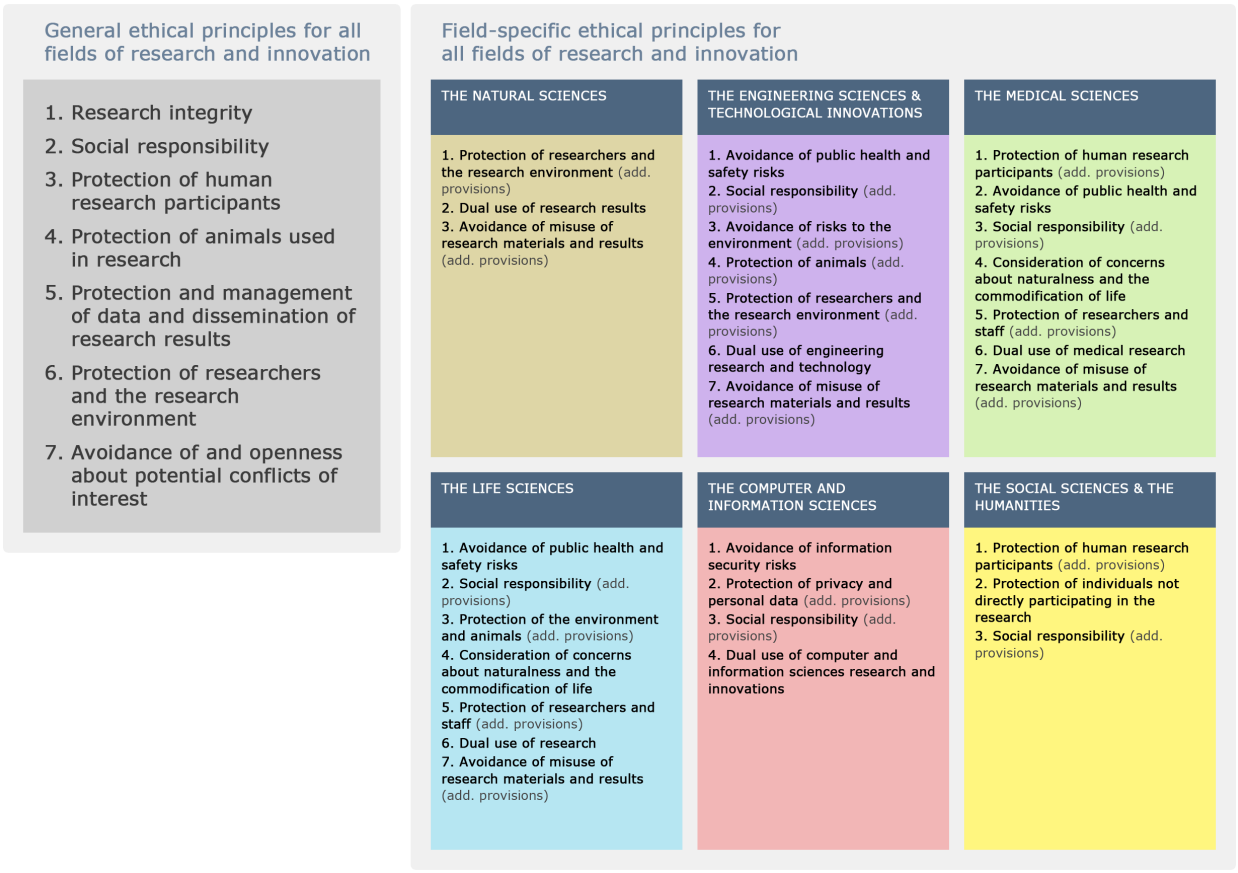

Figure 1: Framework of ethical principles and issues in research and innovation

In what follows, Subsection 3.9.1 presents the general ethical principles and issues for all fields of research and innovation, while Subsections 3.9.2 – 3.9.7 discuss ethical principles and issues that apply to specific fields of research and innovation, such as the natural sciences, the engineering sciences, the medical sciences, the life sciences, the computer and information sciences, and the social sciences and the humanities.

3.9.1. General ethical principles for all fields of research and innovation

Certain ethical principles and issues apply to all fields of research and innovation, principles such as (1) social responsibility; (2) protection and management of data; (3) dissemination of research results; (4) protection of researchers and research environment; and (5) avoidance of conflicts of interest.

This set of principles can be expanded by making a few additions. First, the list can be extended by including *"research integrity"* as a principle applicable to all fields of research and innovation. Certainly, as mentioned above, research integrity is usually handled by scientific integrity boards rather than ethics committees, since research integrity is about the behaviour and conduct of the researcher rather than the research plans and activities themselves. However, research integrity can be assessed by ethics committees to the extent that there are potential individual or institutional conflicts of interest that are apparent in research and innovation proposals and activities.

Second, the list can also be extended by adding the following two principles: (1) *protection of and respect for human research participants*; and (2) *protection of and respect for animals used in research*. Although these two principles do not apply to *all* fields of research and innovation, they still can play a significant role in all fields (more frequently in some than in others), and therefore should be included in the list of general ethical principles for research ethics committees.

Overall, the resulting framework consists of 8 main ethical principles that are applicable to all fields of research and innovation:

(1) Research integrity;
(2) Social responsibility;
(3) Protection of and respect for human research participants;
(4) Protection of and respect for animals used in research;
(5) Protection and management of data;
(6) Dissemination of research results;
(7) Protection of researchers and research environment;
(8) Avoidance of and openness about potential conflicts of interest.

In outlining these ethical principles for assessment of research and innovations, we make use of Shamoo and Resnik's *Responsible Conduct of Research*[146] for presenting the listed principles. That is, we present a principle, followed by a number of bullet points specifying the meaning of the principle and short commentaries to clarify the use of the respective principle.

1. *Research integrity*[147]

- Ensure careful and honest presentation of data and research findings.
- Practice universalism (hold research to equal standards, regardless of where and by whom it was performed) and disinterestedness.
- Ensure that institutions act according to their purpose, in a transparent and accountable way.

Researchers should follow adequate and well-grounded research methods and carefully declare sources and biases. The prime mover behind research is a quest for new knowledge and the main reason for publication is to make research results available for the public and for fellow researchers. Also, the institutional setting in which research and innovation takes place should be organised in a fair and accountable way.

2. *Social Responsibility*

[146]Shamoo, Adil E., and David B. Resnik, *Responsible Conduct of Research*, 2nd ed., Oxford University Press, Oxford, 2009.
[147]European Science Foundation (ESF), and All European Academics (ALLEA), "The European Code of Conduct for Research Integrity", 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf.

- Raise awareness of the societal impacts of research, and take appropriate remediate actions if deemed necessary.

The principle of social responsibility in a very broad sense designates the responsibility of researchers towards society as a whole, situating research in the broad context of institutional and cultural life. As such, researchers are expected to be aware of the possible societal ramifications of their work, to be transparent about these ramifications and to take appropriate actions if necessary. In assessing the societal impacts of research, the concept of justice[148] suggests the obligation to treat others in accordance to what is morally right and proper. It includes the preservation of the rights and welfare of the individuals and communities involved and ensuring the research is responsive to the needs and desires of those involved or to be impacted by the outcomes of the research.

3. *Protection of and respect for human research participants*

- Ensure that research participants are provided with adequate information about the research, including its purpose, its funder(s), who will use its results, the consequences for them of participation in it, and policies regarding privacy and confidentiality;
- Obtain consent from research participants that is informed, given freely, and provided in an explicit form (informed consent);[149]
- Treat human participants with due consideration for their dignity, autonomy and personal integrity;
- Ensure that research participants are not exposed to serious physical or psychological harm or strain as a result of the research;
- Ensure that any risks or burdens to research participants are balanced by benefits to the participants or to society; Ensure that the privacy of research participants is protected and that identifiable information about them is kept confidential;
- Respect cultural diversity and pluralism, meaning that the cultural background, values and viewpoints of research participants are respected, as well as the cultural values and norms that apply in research settings;
- Ensure that one's pool of human research participants adequately represents society or the social group being investigated, with respect to categories such as gender, age, race, ethnicity, social class, religion, culture and disability; or discuss and, where possible, compensate for limitations in one's selection.

Researchers should recognise and take measures to maintain the autonomy and dignity of human research participants (whether as individuals or collectives) involved and impacted by the research and innovation. In this sense, individuals and communities are to be considered in their broadest conception, including notions of gender, cultural, ethnic, and geographic identities.

[148] Partly drawn from: Rawls, John, *A Theory of Justice*, Harvard University Press, Harvard, 1971.
[149] European Science Foundation (ESF), and All European Academics (ALLEA), "The European Code of Conduct for Research Integrity", 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf.

4. *Protection of and respect for animals used in research*

- Consider all possibilities for replacing animal experiments with research methods that are less harmful to animals;
- Make an effort to minimise the number of animals involved in the experiment;
- Minimise the suffering of animals during the experiment and in the context of animal keeping and breeding.

Ensuring protection of and respect for animals used in research can be described as the principle of 'three Rs' (i.e. replacement, reduction, and refinement).

5. *Protection and management of data and dissemination of research results*

- Store all research data securely, and render them difficult to access or hard to use for unwanted third parties;
- Be aware of all actual and potential data flows;
- Ensure that all personal data that researchers plan to collect are necessary for the research;
- Obtain informed consent from research participants for the collection and use of their personal data, or verify that such consent has been given;
- Ensure that data related to identifiable participants are stored securely, and that such data are not stored any longer than is necessary to achieve the objective for which they were collected;
- Ensure that, for any secondary use of data, the data in question are openly and publicly accessible or that consent for secondary use has been obtained;
- Consider and anticipate the effects that gaining access to personal information could have on third parties (e.g., persons related to the data subject).
- Consider whether publicly available information should actually be considered sensitive personal information and treated as such;
- Take precautions when merging multiple data sources to ensure that anonymity and or pseudonymity are maintained;
- Inform participants in open online forums about systematic registration or reporting of information when possible;
- Researchers should not disguise their identity when communicating with research subjects electronically. This contravenes ethical principles concerning informed consent and openness about the nature and purpose of the research.

6. *Dissemination of research results*

- In the absence of compelling reasons to act otherwise, make research results publicly available. Openness regarding research findings is essential for ensuring verifiability, returning benefit to research participants, providing benefit to society and ensuring a dialogue with fellow researchers, stakeholders and the public;

- Wherever possible, strive towards open access publications, which provide free online access to any user;
- Where possible, make research results available to different audiences that may have an interest in them, using different formats and media. Aim to include the general public, if results may be of interest to them, and aim to include regions that are otherwise excluded for reasons of economic disadvantage.

7. *Protection of researchers and the research environment*

- Ensure that researchers and staff involved in conducting the research are not exposed to serious risk of physical or psychological harm or strain as a result of the research;
- Take special precautions regarding the health and safety of (local) researchers and staff if (part of) the research is conducted in lowincome or lower-middle income countries;
- Avoid harm to the local community as a result of any field work or experiments;
- Minimise harm to the local environment (including animals, plants and natural and cultural heritage) caused by any field work or experiments, and ensure that any harm done can be justified by the (potential) benefits of the research.

8. *Avoidance of and openness about potential conflicts of interest*

- Be aware of and as far as possible avoid actual or perceived conflicts of interest of the researchers and/or organisations performing the research;
- Disclose information about relevant financial ties (especially direct funding of the research, funding of the salaries of participating researchers, or funding of organisations participating in the research) that are relevant to judging potential conflicts of interest;
- Be transparent about and disclose relevant professional positions or other work that researchers have done in political, religious or other value-based organisations that could potentially negatively affect (the perception of) those researchers' objectivity in conducting the research;
- Ensure that, in the event of a potential conflict between different roles, it is clear whether a participating researcher is speaking as a researcher or in a different capacity.

It must be noted that the following shared list of issues and principles is not intended to *replace* field specific lists of issues and principles that are often used in specific institutional contexts (for instance in faculties of science and engineering, social sciences, humanities or medicine), because these lists might be more detailed and appropriate. This list is mainly intended to be a benchmark for setting the *minimum* requirements for ethical issues and principles that need to be considered in research and innovation projects; some of which should apply to all research endeavours and some of which should apply to specific types of research. As such, this list can be used as a basis for drafting institution-specific ethical issues and principles, or to guide ethics assessors in establishing the minimum requirements for research and innovation projects.

For multidisciplinary projects, general professional principles, presented herein, apply. These principles include scientific integrity, responsible conduct of research, and good research practice. Additionally, depending on the nature of the multidisciplinary project, field-specific

principles apply. Codes of ethics and guidelines of professional research need also be considered to address potential issues adequately. Furthermore, in cases of international collaboration, partners should agree on common standards of research integrity and, ideally, adopt a formal collaboration protocol.[150] Both multidisciplinary projects and international collaboration add additional responsibilities due to the complexity of the roles, interests, and methodological and cultural differences among partners.[151]

3.9.2. Additional field-specific ethical principles for research and innovation

In addition to these general ethical principles, the ethics committee should thus include ethical principles that apply to special conditions that may come up in research and innovation that raise ethical issues. The presence of human research participants and animals in research are two such special conditions. Other examples of special conditions include the involvement of personal data, the involvement of human stem cells, the involvement of objects of cultural heritage, the potential of particular social and environmental impacts, the possibility of dual (civilian and military) use, the utilisation of particular research methods, and others. The presence of such special conditions triggers the need for special ethical principles and protocols or special reflection on how to apply ethical principles.

1. *The Natural Sciences*

- Take special precautions to ensure that researchers and staff involved in conducting the research are not exposed to serious physical harm or strain as a result of working with harmful biological, chemical, radiological, nuclear, or explosive materials;
- Take special precautions to minimise any potential harm to the environment, animals, or plants caused by the use of harmful biological, chemical, radiological, nuclear, or explosive materials during the research;
- Consider whether the results of the research might have military applications, and whether the results of the research might contribute to the proliferation of weapons of mass destruction;
- Take special precautions to prevent or counter the effects of potential misuse of security-sensitive chemical, radiological, or nuclear materials and knowledge (e.g., the appointment of a security advisor, limiting dissemination of the research results, and training for staff).

Research in natural sciences often involves environmental risks of various kinds (although such risks are also prominent in the areas of engineering and life sciences). Within these fields, research results are continuously applied in practical contexts and thus have a strong impact on the society and the environment. For this reason, the ethical issues related to the environment are beyond the scope of the professional behaviour of a scientist and a part of a wider context of economic and socio-political decision-making.

[150] European Science Foundation (ESF), and All European Academics (ALLEA), "The European Code of Conduct for Research Integrity", 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf [p. 7].
[151] See the SATORI report on Task 4.2.2, Section "Ethical standards for professional researchers", and also OECD Global Science Forum reports and recommendations on international collaboration: http://www.oecd.org/sti/sci-tech/globalscienceforumreports.htm.

2. *The Engineering Sciences & Technological Innovations*

- Ensure that the technology to be developed does not pose risks of harm to public health and safety in terms of both its production and societal use;
- Ensure that the technology does not harm, or pose inherent risks to, individual freedom, autonomy, and privacy, human dignity or bodily integrity, as well as the well-being and interests of individuals and groups;
- Anticipate potential risks and harms to the environment resulting from the uses of the technology, and ensure the prevention of environmental harms caused by the use of bio-chemical, radiological and explosive materials;
- Ensure that the technology does not pose any unnecessary risks of harm to animals;
- Ensure that researchers and staff involved in research and development are not exposed to physical harm resulting from harmful biological, chemical, radiological, nuclear, or explosive materials;
- Anticipate and avoid the dual-use (e.g. for military purposes) or misuse of the technology.

The engineering sciences and technological innovations can have a significant effect on the lives of those who use them and on those affected by the social and environmental consequences of their use. Reflecting on how the principles, such as safety, precaution, and justice, can apply to technological innovations offers a way of considering these effects before they occur. Although these issues should not be considered in isolation (as almost all technologies can have dual or malicious uses, an emphasis on safety and precaution should be balanced with the potential benefits of the new technology, keeping in mind that technologies often have unforeseeable social impacts), as general issues to consider they offer a useful means of identifying potential concerns and identifying how these concerns may be addressed.

3. *The Medical Sciences*

- Take special precautions to ensure respect has a full understanding of all the risks associated with participating in the research;
- Take special precautions to ensure respect for the for the participant's dignity, bodily integrity and long-term quality of life;
- Adhere to rules and regulations concerning public health and safety, and those concerning the use of stem cells and tissues in medical research;
- Have consideration for concerns about the commodification of life in relation to (aspects of) human genetics research and human reproductive technologies;
- Ensure that medical research and innovation do not pose inherent risks to human dignity, individual freedom, autonomy, authenticity, identity (and sense of self) or individual privacy;
- Ensure that researchers and staff involved in medical research are not exposed to serious physical harm resulting from harmful biological, chemical, or radiological materials;
- Anticipate and avoid the dual-use (e.g. for military purposes) and/or misuse of medical research.

Medical sciences research often involves human research participants. Whether they are direct participants in research or are the sources of analysed data, should be respected through the research process. This respect is best demonstrated by aiming to reduce unfavourable outcomes for subjects, either through physical or psychological harm caused by participating in the study, or by embarrassment and humiliation through the exposure of personal information collected during research. To protect participants in medical research, the Charter of Fundamental Rights of the European Union[152] requires 'the free and informed consent of the person concerned, according to the procedures laid down by law' in medicine and biological research.[153] Individual rights over the collection and use of personal data are also included within the Charter. It states that *'[e]veryone has the right to the protection of personal data concerning him or her'*, and that *'[s]uch data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.'*[154]

4. *The Life Sciences*

- Ensure that the research, regardless of its potential applications, does not pose any direct or long-term risks of harm to public health and safety (e.g., by taking adequate precautionary measures against accidental release of hazardous biological agents);
- Consider how the research might lead to innovations that could harm human and civil rights, interests or the well-being of individuals and groups in society, or the common good, and how the research and innovation activity might be directed to enhance rights, well-being and the common good;
- Anticipate, assess and communicate how the research and innovations based on this research might pose risks to or harm biodiversity, the integrity of natural ecosystems, and the welfare of animals;
- Consider concerns about naturalness (authentic generation by nature without human interference) in relation to research into animal and plant breeding, cloning, and the (genetic) modification of biological organisms;
- Ensure that researchers and staff involved in conducting the research are not exposed to serious physical harm resulting from working with harmful biological, chemical, or radiological materials;
- Consider whether the research results might have military applications;
- Prevent or counter the effects of the potential misuse of security-sensitive biological, chemical, or radiological materials or knowledge (e.g., through the appointment of a security advisor, limitation of dissemination of the research results, training for staff).

Research involving animals is predominantly used in medical and life sciences, parts of natural sciences (e.g. chemistry), and parts of social sciences (e.g. experimental psychology). Animal testing within laboratory settings is invasive and often causes suffering and a reduced quality of life. The general discussion of ethical issues on this topic typically revolves around harm vs. benefit, whether potential benefits outweigh harm caused to the animals (e.g. developing new

[152]European Parliament and the Council, Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012
[153] Ibid. [Chapter I, Article 3]
[154] Ibid. [Chapter II, Article 8]

medicines, safety testing of chemical compounds, etc.). Hence, one of the criteria involves the consideration of alternatives and justifications for the research involving animals.[155] In the laboratory setting, the 'three Rs' principle of replacing, reducing and refining the use of animals in experiments (see below) has been put forward in EU legislation.[156] In general, the ethical principles of avoiding harm, proper treatment, care and respect for animal research subjects apply.

5. *The Computer & Information Sciences*

- Ensure that new research and innovations offer reasonable protection against any potential unauthorised disclosure, manipulation or deletion of information and against potential breaches of data security (e.g., protection against hacking, denial of service attacks, cracking, cyber vandalism, software piracy, computer fraud, ransom attacks, disruption of service);
- Ensure that new research concepts and innovations do not pose any unjustified inherent risks to the right of individuals to control the disclosure of their personal data;
- Ensure respect for freedom of expression, intellectual property rights, and other individual rights and liberties;
- Consider how new research concepts and innovations might harbour or counter unjust bias in terms of age, gender, sexual orientation, social class, race, ethnicity, religion or disability;
- Consider how the research or innovation activity might harm or promote the general well-being of individuals and groups in society (e.g., effects on the quality of work or quality of life), the common good, and environmental sustainability;
- Consider whether the research in computer and information sciences, and innovations in ICTs might have military applications.

6. *The Social Sciences and the Humanities*

- Take into account cultural differences when approaching potential participants for informed consent, and seek alternatives to written and signed consent when such consent is culturally foreign to participants;
- Avoid conducting covert research unless it is the only method by which information can be gathered to fulfil a research aim of high societal importance;
- In conducting research, ensure respect for individual rights and liberties, as well as local traditions and cultural differences of research participants;
- Ensure that the research is conducted with respect for all groups and communities in society, regardless of age, gender, sexual orientation, social class, race, ethnicity, religion, culture, and disability;

[155] The Nuffield Council on Bioethics, *The Ethics of Research Involving Animals*, May 2005. http://nuffieldbioethics.org/wp-content/uploads/The-ethics-of-research-involving-animals-full-report.pdf [p. 49].
[156] 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, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063.

- Protect and promote *'the legacy of physical artefacts and intangible attributes of a group or society that are inherited from past generations, maintained in the present and bestowed for the benefit of future generations.'*[157]

In fields that specifically has society or culture as the object of research, such as the social sciences and the humanities, additional ethical considerations should be in place. Issues concerning the protection of research participants differ from the ones in the biomedical field, since the risk of harm is rarely physical but rather psychological, linked to the problem of how cultures and behaviours of individuals or groups are represented in the community (risk of discrimination, stigmatisation). The reversal of power relations should also be considered in some types of research: since social science and humanities are often critical towards established practices in society, researchers can find themselves under political pressure.

3.9.3. Shared Ethical Principles and Issues: Possible Conflicts and Limitations

Possible conflicts may arise in several ways. First, there may be theoretical conflicts. In these, there may be conflicts of values in which principles are shared but the values and weight given to certain principles may differ. For instance, some may find communitarian principles to outweigh individualistic principles and vice-versa. A discussion on the reconciliation of these principles and on resolving moral conflicts can be found in section 3.8.

Secondly, there may be conflicts in practice. For example, while autonomy may be a principle shared between cultures, assumptions about what constitutes autonomy and where agency lies can vary between cultures. For some cultures, it is the individual that exercises autonomy at all times. For others, it is the head of the family or cultural unit of relevance. These conceptions can all be said to be understandings of autonomy, but the differences lie within the practical understanding of autonomy.

Thirdly, with regards to the limitations of the foregoing exercise, we need to ask: are ethical principles really relevant for ethical decision-making? Are not values contextual and bound to a particular tradition? Obviously, morality has developed within different cultural traditions such as the Confucian, Muslim, Christian, liberal and so forth.

While different traditions emphasise different values, there is also a universal basis underlying the differences. Human beings have certain needs and interests in common. For example, as human beings we all need both community and autonomy in order to flourish, although the former value is perhaps more emphasized in the Confucian tradition and the latter in the liberal tradition.

Some would argue that a particular moral case is the best starting point for moral communication and moral discussions. According to moral particularism, each moral situation is unique and communication should be case-based.[158] According to this view, ethical communication is best achieved through considering narratives of specific cases.

[157] UNESCO, "Cultural Heritage". http://www.unesco.org/new/en/cairo/culture/tangible-cultural-heritage/.

[158] Dancy, Jonathan, "Moral Particularism," in *The Stanford Encyclopedia of Philosophy*, Edward N. Zalta (ed.), Fall 2013. http://plato.stanford.edu/archives/fall2013/entries/moral-particularism/.

But is each moral situation really unique? Each situation is unique with respect to time and situation-specific characteristics but not regarding the ethical aspects. Let us illustrate this with two cases. In the first case a patient faces a choice of two different treatments for cancer. The patient is informed about the pros and cons of the treatments and she can then choose one. In the second case a person is asked to participate in a psychological experiment. She is informed about different aspects of the experiment and can, based on the information, choose whether to participate or not. These cases are very different but they both actualise the same ethical principle, namely the principle of informed consent. The patients are informed about the different treatments and have the right to choose one of them. The person facing the psychological experiment is similarly informed about the experiment and has the right to decide to participate or not. In conclusion, the situations are unique but the ethical principle of informed consent is relevant for both.

Is then communication of ethics across cultural borders easier regarding specific moral cases or regarding ethical principles? Let us assume that doctors in India, Africa, Saudi Arabia and Europe are to decide on the interruption of a lifesaving treatment. Should the conversation start with the case or with the relevant ethical principles? Perhaps, for pedagogical reasons, it is better to start with the particular case in order to get a common understanding and agreement. However, the discussants will immediately face the questions of the salient moral aspects of the case. Why is it a moral problem at all? The answer depends on views from other levels of the moral discourse; perhaps one decision-maker focuses on the dignity of the person, and another on the amount of pleasure or pain that the decisions will imply. For the first discussant, the question of life-saving treatment is a moral question because a human life is at stake, for the second it is a moral question because it is about a living creature's pain and pleasure. Hence, ethical principles, for example the principle of human dignity or the principle of utility, are inherent in ethical argumentation.

Finally, there are limitations that come from procedural considerations. Principles may be shared, but barriers may exist that preclude the realisation of the principles. Linguistic differences between relevant actors, fiduciary considerations, time constraints, all affect the practice of these principles. In addition, there are 'duty' considerations that may lead to conflicts. Employer or research sponsor considerations are prime examples of this. Having considered all these concerns with regards to conflicts and limitations, we argue that even though shared ethical issues and principles can function as a starting point for ethical deliberations, they should never be seen as being sufficient for guaranteeing the ethical conduct of research and innovation in all instances in which they are applied.

3.9.1 Conclusion

In this chapter, we sought to provide a reasoned proposal for shared ethical principles and issues in research and innovation. The discussion of the specific ethical issues and principles in the first parts of the text culminated in a list of shared issues and principles; some of which can be regarded as shared ethical issues and principles for all types of research and innovation whereas others only apply to specific fields of research and innovation.

The purpose of this text is to serve as a guideline for explicating effective proposals for shared ethical issues and principles. National research councils, academies of sciences, funding bodies and so forth, could adopt these. However, one ought to keep in mind the limitations of such explicated lists of issues and principles, such as the inevitable incompleteness of such an abstracted list, the conceptual ambiguities present in it and the possible incompatibility of this overview with different cultures of research and innovation.

4 ETHICS ASSESSMENT PROCEDURES

This chapter presents a series of recommendations for best practice in the composition and operation of *ethics assessment units*, or EAUs. As defined in SATORI Deliverable D1.1, ethics assessment is 'any institutionalized kind of assessment, evaluation, review, appraisal or valuation of practices, products and uses of research and innovation that makes use of primarily ethical principles or criteria.'[159] EAUs are the institutions that perform this assessment. They may assess 'research or innovation goals, new directions, projects, practices, products, protocols, new fields, etc.'[160], and their work may be performed before, during, and after the commencement of the projects they assess. EAUs may belong to a larger organisation (such as a hospital or university) or be independent. They are also distinct from groups that perform ethical guidance, which involves defining ethical standards and guidelines.[161] While some organisations may perform both ethics assessment and ethical guidance, this report focuses on how organisations conduct ethics assessment.

EAUs differ in size, scope, and in the research and innovation (R&I) activity they assess. To encompass the wide variety of EAUs, the recommendations presented in this report will necessarily be of a general nature. An EAU assessing medical research will require a different range of expertise among its members to perform effectively than an EAU that reviews environmental projects, for example. The general recommendations presented here can be tailored to the specific circumstances and the resources available to individual EAUs.

The content of this chapter is as follows. Section 4.1 discusses the aims and goals of EAUs. Describing the purposes of ethics assessment is necessary for establishing the objectives that EAUs are intended to meet. Section 4.2 introduces the various parameters for EAUs that are the subject of the following sections. These parameters are: the composition and expertise recommended for EAU members; the appropriate means of appointing, training, and supervising the work of EAUs; the procedures for the EAU to perform its work before, during, and after research and innovation projects; promoting the efficiency of the EAU's work; and how to address organisational and cultural factors that may affect the work of an EAU. Sections 4.3 to 4.10 discuss each of each parameters in turn and present recommendations for best practice for each of them. Section 4.11 concludes the chapter with a summary of the recommendations made for each of these parameters.

4.1 Aims and Goals of Ethics Assessment Units

The overarching aim of ethics assessment of R&I is to prevent the harm that the R&I activity may cause. The Nuremberg Code from 1947 is often considered to be the first systematic attempt

[159] 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. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf.
[160] Ibid.
[161] Ibid.

to formulate principles for assessing research.[162] The principles included in the Nuremberg Code are:[163]

- *Informed consent*: participation should be 'without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion'[164]
- *Beneficence*: experiments on humans should be expected to produce fruitful results beneficial for society
- *Nonmaleficence:* research involving humans can be conducted only if it is designed to avoid all unnecessary physical and mental suffering and injury

The Nuremberg Code was followed by the Declaration of Helsinki (1962 and on) and the Belmont Report in 1979, both of which had the aim of protecting research subjects against potential harm. However, they also included *weighing principles* – how risks could be weighed against the potential benefits of the research, as well as requirements to respect the *privacy* and *confidentiality* of individuals.[165] We also find in the Declaration of Helsinki the first requirements for research proposals to undergo *ethics review* in order to prevent unethical research practices more effectively.[166]

As the guidelines mentioned above indicate, research regulations were developed historically to prevent physical harm to research subjects. Today's ethics assessment of R&I comprises a broader range of issues than preventing physical and psychological harm to individuals. EAUs also assess R&I in order to prevent social harm, environmental harm, and harm to animals. Moreover, over the past 30 years there has also been 'a development of a more systematized approach to research, with greater emphasis on accountability, performance management, and quality assurance'.[167] Thus, the aim of EAUs also goes beyond the prevention of harm.

The following quotes from the interview summaries with EAU representatives conducted as part of WP 1 of the SATORI project show a diversity of aims and goals:

- 'The main purpose of carrying out ethic assessments is to ensure the safety of research subjects and the high quality of research.' (Research ethics committees)

[162] "The Nuremberg Code", in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, 2:181–82. Washington, D.C.: US Government Printing Office, 1949. http://www.hhs.gov/ohrp/archive/nurcode.html.
[163] Ibid.
[164] Ibid.
[165] US Department of Health & Human Services, "The Belmont Report". http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html ; World Medical Association, "Declaration of Helsinki". http://www.wma.net/en/30publications/10policies/b3/index.html.
[166] World Medical Association, "Declaration of Helsinki". http://www.wma.net/en/30publications/10policies/b3/index.html.
[167] Shaw, Sara and Geraldine Barrett, "Research Governance: Regulating Risks and Reducing Harm?", *Journal of the Royal Society of Medicine,* Vol. 99, No. 1, January 2006, pp. 14-19.

- 'To ensure that research, conducted at a university, is in line with national and international standards and regulations, as well as with publishers' and funders' requirements' (Universities and university associations)

- 'It aims to judge whether planned research is in accordance with the regulations and standards that were stated in the faculties' Protocol about Ethics and Research and to make recommendations to researchers for better adhering to ethical standards.' (Research ethics committees)

- 'To be recognized as a world leader in innovation for sustainable development through excellence in our people, our products, the environment and the community.' (Industry)

- 'A large part of our activity is bound to health care, the attention to ethical issues is part of the everyday routine. It is implicit in the company culture and in what the company do. We cannot avoid it to have access and succeed on the market. The bottom line of the company depends from a correct approach to this aspect.' (Industry)

From the quoted aims and goals of individual EAUs we again see that ethics assessment goes beyond the assessment of the risk of harm. A more general description of the aim of ethics assessment of R&I is that it aims to ensure that the R&I performed is ethically acceptable. In the context of the work of EAUs, the measure of ethical acceptability is that the R&I activity is consistent with national and international standards and regulations, as well as with research ethics guidelines (e.g. ethical codes). Moreover, in many cases EAUs also have the responsibility to ensure that the R&I activity performed is legal.

We can also see that EAUs within industry point to non-moral or prudential aims. In such cases the assessment of risks related to R&I does not only examine its ethical acceptability. Risk assessment serves as a means for the company conducting the assessed R&I activity to be recognised as a responsible agent in terms of accepting its responsibility for future actions, as well as being willing to respond to the duties that follow from such responsibilities.[168] The SATORI interviews with industry representatives identify various reasons for industry to perform ethics assessment, i.e. product improvement, value creation, competitive advantage, improve health and safety standards, reduce environmental impacts, improve community relations, motivate workers, etc.[169]

Within the scope of setting up and defining the mandate of an EAU, members should determine whether it is part of their mandate to assess the scientific quality and adequacy of proposals, including the methodology proposed in them. Reasons in favour of considering scientific adequacy are that bad science is unethical, is wasting resources, provides possibly false

[168] See Antonio Argandoña & Heidi von Weltzien Hoivik (2009) for a more thorough discussion on the definition of the concept of corporate responsible agency. Argandoña, Antonio and Heidi von Weltzien Hoivik, "Corporate Social Responsibility: One Size Does Not Fit All. Collecting Evidence from Europe", *Journal of Business Ethics*, Vol. 89, Supp. 3, November 2009, pp. 221-234.
[169] Gurzawska, Agata, Rossella Cardone, Andrea Porcari, Elvio Mantovani, and Philip Brey, "Ethics Assessment and Guidance in Different Types of Organisations: Industry", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.h-Industry.pdf.

information, and that there may not be another committee that assesses scientific adequacy. Reasons against it include the fact that some may not hold it to be part of the mandate of an EAU, and that an assessment of scientific adequacy may require extra effort and expertise.

4.1.1 Objects of Assessment

EAUs may review various types of R&I activity. These activities can be categorised as:

- *Proposals:* Detailed plans produced by researchers for conducting a new research project or for developing a new technology or product.
- *In-progress:* An R&I activity that is currently active.
- *Operational Use:* Research or technology being applied within society or within a particular context (such as internally by an organisation).
- *Field Assessment:* A new or emerging technology or field of research.

The proposal and in-progress stages apply to a single R&I project, while the operational use stage applies to both individual and multiple projects or technologies. These three stages represent the typical life cycle for a research project. The fourth activity, field assessment, covers multiple projects, multiple forms of a technology, or different technologies.

These activities are often assessed by different EAUs. EAUs associated with a specific institution, such as hospital research ethics committees (RECs), tend to evaluate research proposals and on-going projects being conducted by that institution. Civil society organisations (CSOs) may evaluate the impact of particular technologies that affect the causes promoted by that organisation. National ethics committees (NECs) may be called upon to assess individual projects of national significance and to evaluate broader trends in research and technology.

These differences mean that particular procedures will be more relevant to some activities than to others. Procedures for assessing a research proposal will be of little use in assessing the impact of an emerging technology that is already in use in society. As a result, the procedures presented here will be categorised by the R&I activities to which they apply. Procedures relevant to all R&I activities will be identified as such.

4.1.2 Potential Risks of Regulating Ethics Assessment

Research ethics has over time developed more and more into a regulatory system with ethics guidelines and protocols. The number of ethical guidelines and frameworks intended to guide research is constantly increasing, and most countries have also adopted legal frameworks regulating research and innovation.

The recommendations for best practices for EAUs that are presented here will provide both researchers as well as the assessors of research and innovation with yet another tool for ethics assessment. However, the move towards ethics review as a legal or extra-legal activity has been questioned. If the researchers and EAUs will adapt to legal regulations, to checkboxes, and to guidelines, there is a risk that they will cease reflecting on the ethical implication of R&I and start

to think in terms of what is legally forbidden or not. It has even been argued that ethics review and guidelines are not only insufficient to ensure responsible research, but that it may even obstruct morally responsible research.[170]

Johnsson *et al* identifies three particular risks that emerge from research ethics being developing into a regulatory system: (i) that research ethics will focus on some ethical aspects, distracting attention away from other ethical issues; (ii) that guidelines that are oriented towards rules rather than principles will 'encourage a checklist-like approach to ethics that makes individual moral deliberation appear redundant, eventually leading to heteronomy of action'; and (iii) fail to provide enough guidance when rules contradict.[171] The risks that Johnsson *et al* are discussing are primarily focusing on the researcher's perspective, but their discussion can also be transferred to an EAU perspective and that EAUs will be at risk of overseeing ethical issues that are not regulated in the guidelines or in the legal framework.

In this chapter we will take the above risks into consideration when suggesting recommendations for best practices for EAUs.

4.2 General Parameters for Best Practice in Ethics Assessment

All EAUs share several common features, despite their differences in goals, available resources, and in the R&I activity they assess. Based on the study of existing EAUs conducted in WP 1 of the SATORI project[172] and the academic literature on performing ethics assessment, we present recommendations for best practice in EAUs that are structured around a series of common parameters. These parameters are:

- Composition and expertise of ethics assessment units
- Appointment and training of ethics assessment unit members
- Procedures prior to assessment
- Procedures during assessment
- Procedures after assessment
- Supervision of ethics assessment units
- Quality assurance
- Efficiency considerations

[170] Johnsson, Linus, Stefan Eriksson, Gert Helgesson, and Mats G. Hansson, "Making researchers moral: Why trustworthiness requires more than ethics guidelines and review", *Research Ethics,* Vol. 10, No. 1, March 2014, pp. 29-46.
[171] Ibid [p. 31].
[172] 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. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf ; "Comparative Analysis of Ethics Assessment Practices." *SATORI*, June 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/.

The following sections examine each of these parameters in turn. In addition to these parameters, the organisational and cultural factors that should be considered in the operation of an EAU are also discussed in section 4.10.

Before proceeding to this discussion, it is important to recognise that legislation often places requirements on the structure and operation of particular kinds of EAUs, such as ethics committees that review human subject research. For example, the EU Clinical Trials Directive (Directive 2001/20/EC) defines an ethics committee as:

> *an independent body in a Member State, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent* […][173]

While this definition only covers research ethics committees that review biomedical research and focuses exclusively on the protection of human subjects, the scope of the EAUs considered in this report also covers animal research and technical research and development. The recommendations in the following sections are intended for any EAU that reviews R&I activities. Specific national legislation may impose additional requirements on EAUs that go beyond the general recommendations presented here.

4.3 Composition and Expertise of Ethics Assessment Units

An EAU should determine, monitor and maintain procedures for the appointment of the EAU and its members. The procedures by which ethics committee members are appointed and by which membership is renewed should be transparent and fair. The appointment process should establish the authority, independence and credibility of the EAU.

An effective EAU requires that its members are able to recognise the ethical concerns raised by R&I activity during its planning, development, and application. These concerns may emerge in a proposal for new R&I activity, while the activity is underway, and when others apply the results of the activity. These are the proposal, in-progress, and operational use stages mentioned earlier. It may also include considering the ethical concerns raised by a field of R&I activity itself, as performed during a field assessment.

As human subject research ethics committees are often the subject of national regulations and guidelines, they provide a good starting point for examining the current expectations about the appropriate membership of EAUs generally. The ethics committee definition in European Directive 2001/20/EC states that the committees reviewing clinical trials should be composed of expert and non-expert members. Non-expert members, especially those who are individuals from

[173] European Parliament and the Council, Directive 2001/20/EC of 4.4.2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ L 121, 1.5.2001.

the general public without connection to the research project or the institutions involved, are frequently referred to as 'lay persons'. While Article 6 of the Directive describes the tasks of the ethics committee in more detail, the composition and expertise is not elaborated any further than in the initial definition.[174] Other international and national regulations and guidelines go into more detail on composition and expertise. For example, the World Health Organization (WHO) has produced guidelines for the composition of health research ethics committees.[175] These guidelines list four factors:

1. *Members include individuals with scientific expertise, including expertise in behavioural or social sciences; health care providers; members who have expertise in legal matters and/or ethics; and lay people whose primary role is to share their insights about the communities from which participants are likely to be drawn.*
2. *Lay people and other members, whose primary background is not in health research with human participants, are appointed in sufficient numbers to ensure that they feel comfortable voicing their views.*
3. *In order to enhance independence, committee membership includes members who are not affiliated with organizations that sponsor, fund, or conduct research reviewed by the REC* […].
4. *Committees are large enough to ensure that multiple perspectives are brought into the discussion. To this end, quorum requirements provide that at least five people, including at least one lay member and one non-affiliated member, are present to make decisions about the proposed research.*[176]

Individual countries and professional organisations also produce their own guidelines for the appropriate composition of ethics committees in particular fields. In Denmark, for example, research ethics committees must contain at least seven members, have a maximum of fifteen members, and lay persons must always outnumber the expert members by one.[177] The guidelines of the British Economic and Social Research Council (ESRC) are another example.[178] These guidelines require RECs to be multidisciplinary, composed of both men and women, include members with expertise about the research under review, and members who are familiar with research ethics.[179] Finally, an example from outside the EU is the Australian National Statement on Ethical Conduct in Human Research, which states that human research ethics committees (HRECs) should have an equal number of male and female members, and that one third of the membership should not be affiliated with the organization that with which the HREC is affiliated.[180] Furthermore, the HREC should contain one chairperson, at least two lay people

[174] Ibid.
[175] World Health Organization, "Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants." *WHO*, 2011. http://www.who.int/ethics/publications/9789241502948/en/.
[176] Ibid.
[177] Hernandez, R., M. Cooney, C. Dualé, M. Gálvez, S. Gaynor, G. Kardos, C. Kubiak, et al., "Harmonisation of Ethics Committees' Practice in 10 European Countries", *Journal of Medical Ethics,* Vol. 35, Issue 11, November 2009, pp. 696–700 [p. 697].
[178] Economic and Social Research Council (ESRC), "Framework for Research Ethics", 2015. http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/.
[179] Ibid.
[180] "National Statement on Ethical Conduct in Human Research (2007) (Updated May 2015) | National Health and Medical Research Council". http://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research.

(male and female), at least one professional carer or health professional, at least one pastoral worker, at least one lawyer, and at least two people with current experience in the field of the research under assessment.[181]

For EAUs that are embedded in research performing organisations it is recommended that:

1. the chairperson should be elected by the members;

2. the members from outside the organisation (e.g.,. stakeholder- or civil society organisation (CSO) representatives) should be nominated by their organisations in a transparent way and selected because of their competency;

3. the lay persons should not be exclusively selected by scientific experts;

4. the chief executive of the organisation should not be a member of the EAU;

In cases where a newly elected member of the EAU is replacing an outgoing member, there should be a transition period during which the new member acts as a regular substitute for the outgoing member, and during which knowledge is transferred and training may take place. The term of office of EAU members, including the option of membership renewal, should be clearly prescribed, bearing in mind the need to maintain an appropriate balance between continuity of accumulated expertise and the appointment of new members. The position of chairperson of the EAU should rotate, over a fixed time period and through a democratic process, among members of the EAU with strong administrative competence.

The EAU should provide all members with adequate compensation (financial or equivalent non-financial) for their work as members of the EAU.

Members of the EAU can only be discharged from their position in the EAU by unanimous decision of the entire membership of the EAU.

4.3.1 Composition Discussion

The composition of the EAU is a means of reinforcing the trustworthiness of both the unit itself and of the decisions it makes. Trustworthy decisions are promoted by ensuring that the composition of the EAU does not allow a single perspective on R&I activity to be accepted without discussion and review. Without the possibility of disagreement and the opportunity to convince others of the morality or otherwise of the activity, an acceptable ethics assessment cannot be performed. The rigorous discussion of research proposals is fostered by an EAU membership that is *competent, independent*, *diverse*, and *representative*. Competence will be discussed in the following sections on expertise; here we will focus on independence, diversity, and representation.

Members who are independent of the researchers and organisations whose work they assess help to foster trust in the objectivity of the EAU's decisions. Independence is important for avoiding

[181] Ibid.

actual or potential conflicts of interest that may create the perception that the EAU is biased. Conflicts of interest may be individual or institutional, depending on whether the individuals themselves or the organisation for which they work has a bias or incentive to favour one outcome over another.[182] If an apparent or potential individual conflict of interest exists between an EAU member and the R&I activity under review, it should be disclosed so that the other members are aware of its potential to affect that member's judgment in the matter. EAU members who have a conflict of interest in a particular R&I activity should not be involved in the discussion and assessment of that activity to avoid the possibility (and perception) of their interest biasing the EAU's decision.[183]

Institutional conflicts of interest may be avoided if the EAU has no connection with the organisation conducting the research. This may be difficult if the EAU operates at the institutional level, as the EAU and the researchers are likely to belong to the same organisation (even if they belong to separate departments or branches). Distinguishing between different forms of independence can address this problem. EAU independence can be interpreted as being narrow or broad. Narrow independence requires the EAU not to be the principal investigators or members of the research team whose work is under assessment.[184] Broad independence requires that EAU members do not belong to the institution performing the activity under assessment.[185] The degree of independence possible may depend on the resources available to perform ethics assessment. Broad independence requires using an external EAU with no connection to the research institution.[186] An EAU associated with an institution will therefore have a narrower interpretation of independence. If an institutional connection between an EAU and the researchers is unavoidable, a useful compromise is to include members from outside organisations within the membership of the EAU or as advisory experts.

Including community members or lay persons as members is another way of broadening the composition of an EAU's membership. Schluppi and Fraser present seven justifications for including lay persons as EAU members:

1. Provide a perspective independent of institutional or research goals.
2. Broaden committee discussion and include public input.
3. Provide greater visibility of broader concerns and popular opinion.
4. Make R&I activity more accountable to the general public.
5. Serve as a connection between the research institution connected to the EAU (if any) and the general public.
6. Protect research subject interests (human or animal).

[182] Shamoo, Adil E., and David B. Resnik, *Responsible Conduct of Research*, 2nd ed., Oxford University Press, Oxford, 2009, pp. 193-196.
[183] DuVal, Gordon, "Institutional Conflicts Of Interest: Protecting Human Subjects, Scientific Integrity, And Institutional Accountability", *The Journal of Law, Medicine & Ethics,* Vol. 32, No. 4, December 2004, pp. 613–625 [p. 623].
[184] Macklin, Ruth, "How Independent Are IRBs?", *IRB: Ethics & Human Research,* Vol. 30, No. 3, 2008, pp. 15–19 [pp. 15-16] .
[185] Ibid.
[186] Ibid, [p. 16]

7. Raise ethical issues and promote ethical reflection by researchers.[187]

Including lay persons also diversifies the EAU membership. This diversity should cover beliefs and attributes that may influence the EAU's decisions. These attributes include gender, race, background (including education) and expertise, as well as political, social, and religious beliefs. The relevant beliefs and attributes may differ depending on the R&I activity assessed the EAU. Diverse views on animal welfare and research are more relevant to EAUs that review research involving animal subjects, while diversity in race, gender, and social and religious backgrounds will benefit EAUs that assess human subject research. Diversity also fosters trust by limiting the potential implicit bias that may emerge from an EAU membership that is predominately composed of people sharing the same gender or race, or similar backgrounds and expertise. The broader range of perspectives that a diverse EAU membership provides allows for the EAU's decisions to better reflect the diversity of views found in the broader community.[188]

However, including lay persons as EAU members may cause difficulties. Lay persons may lack the technical understanding necessary to evaluate R&I activity fairly and may be unwilling to disclose this ignorance, they may be deliberately obstructive or unwilling to be open-minded in debate and discussion, and with time and experience may begin to lose the 'outsider' perspective that makes their contribution to the EAU's decisions particularly valuable.[189]

These problems of irreconcilable differences and increasing familiarity and identification with researchers by lay persons can be addressed. Frank Green proposes these selection criteria for lay person EAU members: 'an informed interest, articulacy, evaluation capability, reasoned balance, personal commitment and committee experience.'[190] These characteristics assist in the EAU's practical functioning and in ensuring that it fulfils its goals of evaluating R&I activity. There is also no reason why these criteria should be limited to selecting lay persons. From Green's criteria, we can derive a general list of desirable characteristics for EAU members:

- Relevant expertise (professional members) or an informed interest (non-professional members/lay persons, experts from other fields) in the R&I topic
- Good communication skills, both written and interpersonal
- An ability to evaluate the benefits, risks, and burdens associated with specific R&I activities
- An ability to engage in reasoned debate and discussion to reach and accept a balanced view of R&I activities
- Personal commitment to the goals of ethics assessment

[187] Schuppli, C. A., and D. Fraser, "Factors Influencing the Effectiveness of Research Ethics Committees", *Journal of Medical Ethics*, Vol. 33, Issue 5, May 2007, pp. 294–301 [pp. 298-299].
[188] Edwards, Sarah J.L., "The Role, Remit and Function of the Research Ethics Committee — 1. The Rationale for Ethics Review of Research by Committee", *Research Ethics Review*, Vol. 5, No. 4, December 2009, pp. 147–150 [p.149].
[189] Legood, Giles, "The Recruitment and Role of Lay Members", *Research Ethics Review,* Vol. 1, No. 4, December 2005, pp. 135–138 [p. 138].
[190] Green, Frank A., "Further Thoughts on the Recruitment of REC Lay Members", *Research Ethics Review* Vol. 3, No. 1, March 2007, pp. 8–12 [p. 10].

Any potential EAU member who possesses these qualities, serving either in their professional capacity or as a lay person, would be a valuable asset for that organisation.

Placing a limit on the amount of time a lay person may serve as an EAU member can address the problem of losing the external perspective.[191] This restriction also promotes the addition of new perspectives to the EAU as new members are appointed to replace them, thus ensuring that the EAU's non-expert membership best reflects the current views of the general population.

The EAU's composition should also reflect the population affected by its decisions. These members will either represent the organisations associated with the EAU, or the general public. The organisations represented will relate to the level of the EAU's work, whether the level is institutional, regional, national, or international. At the institutional level, the organisation will be the institution that the EAU is associated with, such as a hospital or university. Regional governments and relevant organisations (such as regional associations of institutions) within the specific region will often be represented within EAUs operating at the regional level. Similarly, national and international EAUs may include representatives from governments and national or international organisations.

A final consideration for the EAU's composition is the appropriate number of members. While the sizes of EAUs often appear to be arbitrary, they are influenced by several factors, such as limiting the size so that it can serve as an effective decision-making committee while also being large enough to include the necessary range of expertise and viewpoints.[192] Legislation may also impose a minimum number of members for an EAU. For example, Denmark requires RECs to have at least 7 members and a maximum of 15.[193] Such regulations may also impose requirements for the number of expert and non-expert (including lay person) members of a REC.[194] The national legal requirements for the EAU assessing the particular kind of research will therefore impose constraints on the size of the EAU membership. If the proportion of lay persons as EAU members are not specified in law, the number appointed should also be sufficient to ensure that their views are not ignored in the EAU's decisions.[195] The appropriate number of EAU members therefore is that which best meets the various institutional, legal, and practical constraints that apply to it while maintaining the EAU's ability to make independent decisions that represent a wide variety of perspectives.

[191] Lidz, Charles W., Lorna J. Simon, Antonia V. Seligowski, Suzanne Myers, William Gardner, Philip J. Candilis, Robert Arnold, and Paul S. Appelbaum, "The Participation of Community Members on Medical Institutional Review Boards", *Journal of Empirical Research on Human Research Ethics,* Vol. 7, No. 1, February 2012, pp. 1–8 [p. 7].
[192] Edwards, Sarah J.L., "The Role, Remit and Function of the Research Ethics Committee — 1. The Rationale for Ethics Review of Research by Committee", *Research Ethics Review*, Vol. 5, No. 4, December 2009, pp. 147–150 [p.149].
[193] Hernandez, R., M. Cooney, C. Dualé, M. Gálvez, S. Gaynor, G. Kardos, C. Kubiak, et al., "Harmonisation of Ethics Committees' Practice in 10 European Countries", *Journal of Medical Ethics,* Vol. 35, Issue 11, November 2009, pp. 696–700 [p. 697].
[194] Ibid., p. 699.
[195] Schuppli, C. A., and D. Fraser, "Factors Influencing the Effectiveness of Research Ethics Committees", *Journal of Medical Ethics*, Vol. 33, Issue 5, May 2007, pp. 294–301 [p. 297].

4.3.2 Survey of Ethics Assessment Unit Member Expertise

EAUs consist of various types of members: a chairperson, field practitioners, ethics specialists, experts from other disciplines, institutional representatives, legal experts, public representatives and members of the public (including laypersons and end-user(s), or representative(s) of the end-user group(s) or organization(s)). These categories are described below. The information used to develop this categorisation is contained in the ethics assessment reports within Annex 3 of SATORI Deliverable D1.1.[196]

The Chairperson

The chairperson represents the EAU in official communications and is responsible for organising and arranging the meetings of the group's members. Chairpersons are also responsible for the smooth operation of the EAU's deliberations and the timely completion and reporting of the group's decisions.

The person selected for this task should possess strong administrative competence. This competence includes the interpersonal skills in fostering productive group discussions and in ensuring that the various members of the EAU are able to contribute to the group's deliberations effectively.[197] The chairperson should also be responsible for ensuring that members receive any training they may require to fulfil their role.[198]

The Secretary

The secretary of an EAU is responsible for the administrative and bureaucratic functions of the unit. Secretaries organise the practical details of the EAU's function, such as arranging meetings, receiving proposals and distributing them to members for assessment, and acting as a point of contact between the EAU and those outside of the unit. The secretary also makes notes of EAU meetings and decisions and distributes them to members so that there is a record of their deliberations.

Like the chairperson, the person selected to be the secretary should possess strong administrative competence. Good communication skills assist the chairperson in assuring researchers that the EAU's procedures are clear and unbiased. Similarly, the chairperson's communication skills contribute to explaining and justifying the EAU's decisions to researchers in a respectful manner. Good record keeping of the EAU's deliberations and decisions will assist in achieving these goals.

Field practitioners

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[196] 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. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf ; "Comparative Analysis of Ethics Assessment Practices." *SATORI*, June 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/.

[197] Ryan, Mary Kay, "General Organization of the IRB", in Robert A. Greenwald, Mary Kay Ryan, and James E. Mulvihill (eds.), *Human Subjects Research: A Handbook for Institutional Review Boards*, Plenum Press, New York and London, 1982, pp. 29–38 [p. 32].

[198] Ibid.

Field practitioners possess expertise relevant to the R&I activity the EAU reviews. The specific expertise is often connected with the role of the institution associated with the EAU. For example, physicians, pharmacists, and nurses may belong to a hospital EAU.

Ethics specialists
Ethical specialists have expertise in evaluating moral issues and who are sought after for moral advice. This category includes religious leaders or representatives as well as ethicists and philosophers.

Experts from other disciplines
Sometimes practitioners and experts from fields not directly related to the work under review are included in an EAU. They serve a similar function to lay persons on EAUs in that they bring an outside perspective (i.e. one from outside the particular R&I field) to the EAU's assessment. Unlike lay persons, however, experts from other disciplines are included primarily for their professional expertise that is *indirectly* relevant to the R&I activity being assessed. For example, sociologists may belong to a medical ethics committee to provide expertise on the relevant social factors associated with medicine and medical care.

Institutional representatives
Members of the institution associated with the ethics assessor are also common members. For example, university EAUs may include faculty members, administrative stuff, PhD candidates, and student representatives.

Legal experts
Lawyers and those with legal expertise are valuable for ensuring that the work reviewed by an EAU meets any legal requirements and legislation that affect it. Including legal experts is important for protecting the legal rights of human participants and for complying with the regulations concerning animal experimentations and other biological research. Legal expertise also helps to identify legal problems that might arise for the researchers and their institution if particular R&I activity is performed which does not comply with the relevant laws and regulations.

Public representatives/Members of the Public
R&I activity may affect the public directly (as research participants) or indirectly by the effects new developments have within society. Public representatives in EAUs represent the interests of non-experts in discussions. This representation may take the form of lay persons, patient or participant advocates, or members of civil society organisations and NGOs such as animal welfare or environmental protection groups. Lay persons may be considered as having expertise 'about the "community" of nonscientists in general'.[199] End- users, or representative of the end-user groups or organization, patient advocates represent the interests of those whose medical care is affected by the proposed research.

[199] Solomon, Stephanie, "Too Many Rationales, Not Enough Reason: A Call to Examine the Goals of Including Lay Members on Institutional Review Boards", *Accountability in Research,* Vol. 23, No. 1, January 2016, pp. 4–22 [p. 15].

Additional expertise may be included:

— the EAU may consult ad hoc experts when necessary.

Conflict of interest policy

The EAU should establish, monitor and maintain a conflict of interest policy to assess and manage the conflicts of interest of members of the EAU. Such a policy helps to preserve the independence of the ethics review process by establishing cultural norms and providing a framework for enforcing those norms. The policy should be publicly available and should include the following elements:

— clear definition of conflict of interest;

— acknowledgement of the different types and dimensions of conflict of interest, including:

- Financial and non-financial conflicts of interest (e.g., ownership of shares in a company funding the proposed research, or an interest in attracting scientists into the research programme with which one is affiliated with);
- Conflicts of interest due to protocol involvement, or personal and professional interests and relationships (e.g., personal involvement in the proposed research, or competing research proposals associated with the ethics assessor and another researcher);
- Institutional conflicts of interest (e.g., the research is proposed by the EAU's home institution or an institution with which an individual EAU member is affiliated); to particular institution that is proposing research);

- Specification of the general conditions under which these kinds of conflict of interest should be considered problematic (e.g., monetary threshold for financial interests, guidance on which relationships should be considered problematic);

- Specification of the people to whom the policy applies. The policy should chiefly apply to: EAU members, ad hoc reviewers, /consultants, /guests, and administrative staff;

- Conflict of interest disclosure procedure, consisting of:
  - Annual reports from the individual members and administrative staff of the EAU about their actual, possible orand perceived conflicts of interest;
  - Regular conflict of interest disclosure rounds at EAU meetings;
  - Submission, by the Chairperson of the EAU of conflict of interest reports to an audit subcommittee or other appropriate oversight body for review;

4.3.3 Expertise Discussion

The appropriate expertise of members for a specific EAU is best determined by considering the unit's intended purpose, and reflecting on the skills, experience, and background of individuals that best fulfil that objective. EAU members should be qualified to evaluate the relevant R&I activity, and should understand the perspectives and concerns of both the researchers and society about how (and what) activities should be performed. The expertise of EAU members should be selected with these goals in mind.

The expertise of EAU members should make them competent to assess the R&I activity that they are tasked with evaluating. This competence has three dimensions: technical, ethical, and administrative. Technical competence is the theoretical and practical understanding of the R&I activity that the EAU is responsible for assessing. This competence also includes expertise in areas related to the work being assessed, such as legal or social issues. Similarly, ethical competence is an understanding of ethical theories, the ethical issues raised by the work assessed by the EAU, and how to apply ethical theories to address these issues. Administrative competence is the ability to organise and perform the EAU's work efficiently, including reaching agreement on assessment and communicating these decisions quickly. While individual EAU members should not be expected to possess all three, the membership as a whole should be competent in all three areas for the EAU itself to perform effectively.

Having researchers active in the R&I fields that the EAU assesses is the most straightforward and effective way of ensuring that it is technically competent. Field practitioners are the best placed to understand the purpose, methods, and significance of R&I activity within their area of expertise. For example, in human research ethics committees, healthcare professionals provide knowledge of medical practice and of medicine itself as a science.[200] Animal carers and veterinarians serve a similar role in animal research ethics committees. It is important to recognise that 'field practitioners' should not be thought of solely as 'experts' in a particular field, as this can obscure relevant knowledge and experience that are useful to an EAU. For example, focusing on 'clinical expertise' may privilege doctors and physicians over nurses and carers, when in fact all of these groups have important experience in clinical procedure and patient care that should be taken into account.

The need to include active researchers within an EAU's membership means that these members cannot be expected to serve as full-time members. While it is desirable to have at least some full-time members of an EAU to make it more effective (since full-time members will be able to devote more time to both the assessment and administrative functions), the costs of doing so make it prohibitive for many organisations.

Those with theoretical or practical experience in applied ethics provide ethical competence to the membership of an EAU. This includes applied ethicists themselves, moral philosophers, and theologians with an interest or experience in applied ethics.[201] The concept of 'moral expertise' is controversial in the sense that such expertise gives such individuals a privileged moral

[200] Emmerich, Nathan, "On the Ethics Committee: The Expert Member, the Lay Member and the Absentee Ethicist", *Research Ethics Review,* Vol. 5, No. 1, March 2009, pp. 9–13 [pp. 10-11].
[201] Ibid. [p. 9]

authority.[202] However, accepting this claim is not necessary to recognise the benefits that knowledge and experience of applied ethics brings to the membership of an EAU. Those with applied ethics training and experience may recognise ethical issues that may otherwise be overlooked, and can draw on their experience and specialist knowledge to suggest possible solutions.[203] They can also be useful in discussions and deliberations by helping other members to clarify and justify their moral concerns with reference to ethical theory. This can promote the understanding of members' moral judgements to other members, and is useful in explaining and justifying the decisions by the EAU members to researchers.

Beyond the straightforward organisational tasks of arranging and conducting meetings, receiving requests for assessment, conveying decisions, and responding to queries, administrative competence also includes promoting *procedural* and *interactional justice*. Procedural justice involves using clearly explained procedures for performing assessment that are applied fairly so that the researchers involved understand how the decision was reached and are assured that it was unbiased.[204] Interactional justice is conveying the EAU's decision to those involved in a respectful way that justifies to them how the decision was reached.[205] Paying attention to these factors will foster trust in the EAU's work and improve its relationship with researchers who are affected by its decisions.[206]

In addition to competence, the concerns of researchers and the broader community can be addressed by seeking to fulfil three further requirements in selecting EAU members: *relevance*, *representation*, and *impartiality*. These requirements should be understood as ideal goals, and it may not always be possible to fulfil them completely given the resource constraints under which an EAU operates. Individuals are also unlikely to meet all of the requirements themselves. What is important is that the membership of an EAU as a whole meets these requirements as well as possible given the resources available to it.

Relevance means that the expertise of members should be sufficient to allow them to understand the R&I activity under consideration and to make a defensible judgment as to its research and ethical merits. Relevant expertise for the work of any EAU is research, ethical and legal. Those working in the same field as the R&I activity under review are the best placed to understand its methodology and potential risks. Similarly, those with expertise in identifying and evaluating moral issues have relevant skills and knowledge. Legal expertise is also helpful for recognising the legal implications of research and the legislation that imposes requirements and limitations of the work under review.

Representation means that the perspectives of the members should reflect those of the community to which the EAU belongs as much as possible. This requirement may be in tension with that of relevance as experts in research fields are often unrepresentative of their broader community.

[202] Ibid. [p. 10]
[203] Ibid. [p. 12]
[204] Keith-Spiegel, Patricia, Gerald P. Koocher, and Barbara Tabachnick, "What Scientists Want from Their Research Ethics Committee", *Journal of Empirical Research on Human Research Ethics,* Vol. 1, No. 1, March 2006 pp. 67–81 [p. 68].
[205] Ibid.
[206] Ibid.

Their status as privileged elites means that their perspective on appropriate R&I activity may not be shared by less privileged members of society. This is a particular concern for research involving human participants, as there may be concerns about exploiting participants who belong to vulnerable groups.[207] The inclusion of lay persons and patient or participant advocates within the EAU assists in countering this perception. Experts from other fields may also help to fulfil the requirement of representation if their expertise gives them a perspective on the assessed activity and its potential impact that would otherwise be missed by restricting membership only to those with relevant expertise. This motivation for including experts from other fields reflects the justifications for including lay persons in the composition of the EAU's membership.

Lay persons and members of the public are important for ensuring that outside perspectives are considered in the EAU's decisions. For them to be most effective in this goal, however, it is important that they are informed that introducing outside perspectives is a part of their role within the EAU.[208] This information assists lay persons in performing their role as both a person with an outside perspective on the R&I activity, and as a member of the community who may be asked to participate in it.[209] The experience of belonging to a group of people who are frequently involved in the activity reviewed by the EAU and how it affects them may be considered part of the particular 'expertise' that lay persons contribute to the group.

While the appropriate range of expertise will differ from EAU to EAU, there are some broad proposals that can be made. Frank Green suggests that the non-researcher members of an EAU should consist of at least:

- a person with ethical expertise or an ethics background (including counsellors, religious authorities as well as ethicists)
- a representative of significant social or ethnic groups in the relevant area
- a representative of a relevant patient's group
- a person working in local media or education
- a person with research expertise in an outside field
- a person with professional auditing experience, such as law or accountancy[210]

Green's proposal reflects many of the common sets of expertise found in the survey of European EAUs: experts from other disciplines, legal expertise, ethics specialists, and public representatives (social or ethnic group representatives, media and education workers, patient representatives). It can also be easily modified for EAUs that do not review R&I activity that involves human subjects. For example, the patient representative may be replaced by an animal welfare advocate for EAUs that deal primarily with R&I activity that involves animals.

Impartiality requires the members to assess R&I activity objectively. In this context impartiality has two dimensions: impartiality towards the researchers and their work, and impartiality towards

[207] Shamoo, Adil E., and David B. Resnik, *Responsible Conduct of Research*, 2nd ed., Oxford University Press, Oxford, 2009, pp. 267-270.
[208] Ibid.
[209] Ibid.
[210] Green, Frank A., "Further Thoughts on the Recruitment of REC Lay Members", *Research Ethics Review* Vol. 3, No. 1, March 2007, pp. 8–12 [p. 10].

the organisation performing it. A clear way of achieving this is for EAU members to be independent of both the researchers and the organisation conducting the activity. As discussed in the earlier section on composition, while having an EAU composed entirely of individuals with no connection to the relevant institution may be impossible, including members who are independent of the institution helps to protect the EAU from the perception of bias towards the associated institution.

As with the composition of an EAU, avoiding potential conflicts of interest should be an important factor in deciding the appropriate expertise for the EAU's members. Impartiality may conflict with expertise if there is a perception (justified or not) that experts within a particular field favour their own R&I field (and the benefits of performing activity in that area) and may not fully appreciate the concerns others have with their work.[211] Including outside perspectives, such as those of lay persons and of experts from other fields, can counter this potential bias.

4.3.4 Summary of Composition and Expertise Recommendations

The appropriate composition of and expertise within an EAU depends on the unit's goals, the scope of its work and the available resources. The objectives of the organisations and institutions whose R&I activity is reviewed will also have an influence on what the most appropriate membership of the ethics assessment unit should be. The recommendations given below should be interpreted with these requirements in mind. Given the overlap between the composition and expertise of the membership of EAUs, the key recommendations for both of these parameters are summarised here.

- The number of members in an EAU may depend on any legislative requirements for the size of an EAU, the available resources, and the need to include a number of diverse perspectives on research while maintaining a manageable size to allow for fruitful discussion and deliberation.
- The membership of an EAU should be arranged so that it encourages rigorous discussion and evaluation of R&I activity. This is best achieved by a membership that is *competent* (technically, ethically, and administratively), *independent* of the researchers and the institutions involved, *diverse* in backgrounds and expertise, and *representative* of the communities affected by its decisions.
- The EAU chairperson should possess strong administrative competence. This includes good interpersonal skills for managing group decisions and good communication skills to convey the EAU's decisions to researchers and supervisors.
- Those with expertise relevant to the activity under review should be included among the EAU's members. However, persons without directly relevant expertise should be an equally important section of the membership.
- EAU members should possess the following characteristics:

[211] Kaur, Sharon, and Sujata Balan, "Towards a Balanced Approach to Identifying Conflicts of Interest Faced by Institutional Review Boards", *Theoretical Medicine and Bioethics,* Vol. 36, No. 5, October 2015, pp. 341–361 [p. 354].

- Relevant expertise (professional members) or an informed interest (non-professional members/lay persons, experts from other fields) in the R&I activity under assessment
- Good communication skills, both written and interpersonal
- An ability to evaluate the benefits, risks, and burdens associated with the specific research projects assessed
- An ability to engage in reasoned debate and discussion to reach and accept a balanced view of the research projects assessed
- Personal commitment to the goals of ethics assessment

- Lay persons (persons without expertise relevant to the R&I activity, including members of the general public) should be included in the membership of an EAU. The number of lay persons included should be sufficient to ensure that their views cannot be ignored by the other members. They should also only be permitted to serve as EAU members for a limited time so that such members continue to provide an 'outside' perspective on research.
- Lay persons should be aware that their role is to view the R&I activity both as someone from outside the research community, and as someone belonging to a group of people who may participate in the activity.
- Ethical and legal expertise should be included among members of an EAU.
- EAU members with an apparent conflict of interest (based on a publicly available conflict of interest policy) should not participate in discussions or decisions where that interest may affect their judgement.

4.4 Appointment and Training of the Ethics Assessment Unit

This section describes the prevailing practices of appointing and training of EAU members based on the review of existing ethics assessors completed during the WP 1 of the SATORI project.[212].

4.4.1 Survey of Ethics Assessment Unit Member Appointment

National Ethics Committees

NECs typically offer ethics guidance and policy advice, although some of them also perform ethics assessment. NECs are usually established by law. Their term of office is tied to the term of office of the appointing authority, and the appointment procedures as well as the establishment of secretariats, which may be permanent, are usually provided for by law.[213] A government ministry

[212] 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. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf ; "Comparative Analysis of Ethics Assessment Practices." *SATORI*, June 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/.

[213] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: National Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.b-National-ethics-committees.pdf.

may appoint the members of a NEC associated with it.[214] In other cases, NEC members may be appointed by the national parliament and/or directly by the head of state.[215]

Research Ethics Committees

The organisation that the REC belongs to or is associated with often appoints individual committee members. Institutional directors may appoint the members of RECs that operate within that institution.[216] Similarly, the members of university RECs are typically appointed by the rector of the university. In some countries (such as Germany and the Netherlands), the appointment requirements and procedures may be stated in law.[217] Experts in a specific field may be appointed on an ad hoc basis to review particular projects within their field of expertise.[218]

Research Funding Organisations

The majority of RFOs rely on external ethics assessment provided for by the competent national body.[219] Often the EAUs of the institutions seeking research funding will provide the assessment.[220] Other RFOs form ad hoc review committees composed of experts relevant to particular proposals. These experts may be selected from national research organisations or from volunteers who have expressed interest in serving on such committees.[221]

Science Academies and Professional Organisations

Science academies typically form special committees or working groups to address ethical issues, such as the Permanent Working Group on Science and Ethics (PWGSE) at ALLEA[222] or the IAP-IAC Committee on Research Integrity.[223] Members of such committees or working groups may be elected academy members and may also include invited representatives of other relevant stakeholders (e.g. universities, research institutions, funding agencies).[224] New members of national academies are recruited by nominations from current members, usually based on the achievements of the nominees.[225] In some cases the nomination of science academy and professional organisation EAU members may also be formal government appointments.[226]

Universities/University Organisations

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[214] Ibid.
[215] Ibid.
[216] Díaz, Javier Arias, Mª Concepción Martín-Arribas, Laura Herrero Olivera, Leyre de Sola Perea, and Johanna Romare, "Ethics Assessment and Guidance in Different Types of Organisations: Research Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.a-Research-ethics-committees.pdf.
[217] Ibid.
[218] Ibid.
[219] Wolfslehner, Doris, "Ethics assessment and guidance in different types of organisations. Research Funding Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.c-Research-ethics-committees.pdf.
[220] Ibid.
[221] Ibid.
[222] ALLEA – ALL European Academies, "Permanent Working Group Science and Ethics". http://www.allea.org/Pages/ALL/19/228.bGFuZz1FTkc.html.
[223] IAP – Global Network of Science Academies, "Responsible Conduct in the Global Research Enterprise: A Policy Report", September 2012. http://www.interacademies.net/file.aspx?id=19789.
[224] Strle, Gregor, Rok Benčin, Jelica Šumič-Riha, and Rado Riha, "Ethics Assessment and Guidance in Different Types of Organisations: National Science Academies and Academic & Professional Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.d-National-academies-of-science-and-POs.pdf.
[225] Ibid.
[226] Ibid.

Ethics committees are becoming the central organisational form of ethical activities at universities. Depending on the national research regulations, some university research projects are reviewed by external ethical committees. Nevertheless, many universities establish their own RECs, guidelines and protocols to complement external review. Members of university research ethics committees are usually appointed by the universities' governance bodies and include professors and researchers at the university, and are chosen for their knowledge in the field and/or experience with ethical issues.[227]

Government/Government-funded Organisations

Government and government-funded organisations that perform ethics assessment are a very heterogeneous group and they engage in ethics assessment differently: some organisations have special ethics units, some have overall procedures, some have mandated ethics assessment, some not. Overall, the vast majority of organisations that provide ethics guidelines or perform ethics assessment do this internally, while only very few utilise external assessors.[228] The members of internal EAUs for these organisations are often government appointments.[229] In addition, external experts might be appointed to deal with specific topics.[230]

Civil Society Organisations

The majority of CSOs engaged in informal ethics assessment do not include a specialised division or formal structure that undertakes these activities. The vast majority of CSOs undertake ethics assessment voluntarily out of a sense of responsibility. The members of ethics committees within CSOs may be appointed from the organisation's members, with external experts appointed when necessary.[231]

Industry

The level of institutionalisation of ethics assessment in industry varies greatly across different countries and particular companies. The ethics assessment and ethical guidance in the context of industry is related to companies' Corporate Social Responsibility (CSR)[232] strategies. The assessment depends on the activities performed. Those in charge of company operations usually implement ethics assessment committees according to need.

[227] Benčin, Rok, Jelica Šumič-Riha, Gregor Strle, and Rado Riha, "Ethics Assessment and Guidance in Different Types of Organisations: Universities", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.e-Universities.pdf.
[228] Ibsen-Jensen, Jakob, and Anne Kirstine Lygum, "Ethics Assessment and Guidance in Different Types of Organisations: Government and Government-Funded Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.f-Govt-and-govt-funded-orgs.pdf.
[229] Ibid.
[230] Ibid.
[231] Warso, Zuzanna, and Marcin Sczaniecki, "Ethics Assessment and Guidance in Different Types of Organisations: Civil Society Organisations (CSOs)", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.g-Civil-society-organisations__.pdf.
[232] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2012) 492 final, Brussels, 12.9.2012. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0492:FIN:EN:PDF.

While large companies often do the assessment in-house, small and medium-sized enterprises (SMEs) typically do not have enough resources to have people dedicated solely to this task.[233] In large companies a specific corporate unit is often in charge of deploying and monitoring the company sustainability strategy and programs at a central level.[234] Such units may refer directly to the company's managing board.

4.4.2 Appointment Recommendations

Our recommendations concerning the appointment of the EAU members are presented in the following paragraphs.

The appointment process is one method of establishing the authority and credibility of the EAU.[235] In general, the chief executive of the organisation containing the EAU should appoint the EAU chairperson.[236] The chief executive, based on recommendations made by that organisation's research administrators, may also appoint the other members.[237] If the EAU is only responsible for reviewing the R&I activity of a specific branch of an organisation (such as a single faculty within a university), the chief executive of that branch should be responsible for appointing the EAU members.

One doubt presented within the interviews was that the experts in the assessment group may be biased.[238] Some of the recommendations on composition and expertise may be useful for addressing concerns about bias within the membership of EAUs.

The EAU chairperson should also be able to appoint temporary members with specific expertise if she believes that additional expertise is necessary to assess particular R&I activity fairly. The selection of these temporary or 'ad hoc' members may be performed by the chairperson in consultation with the EAU's supervisor. Temporary members may be treated as advisors to the EAU who present their informed opinion of the activity under review, or as temporary members who participate in the EAU's full decision-making process. Appointing temporary members based on their expertise or their independence from a particular institution may also help to overcome perceptions of bias.

National ethics committees (NECs) often have an expanded role in guiding research assessment in their country and in performing field assessment.[239] This influence means that greater attention

[233] Gurzawska, Agata, Rossella Cardone, Andrea Porcari, Elvio Mantovani, and Philip Brey, "Ethics Assessment and Guidance in Different Types of Organisations: Industry", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.h-Industry.pdf.
[234] Ibid.
[235] Ryan, Mary Kay, "General Organization of the IRB", in Robert A. Greenwald, Mary Kay Ryan, and James E. Mulvihill (eds.), *Human Subjects Research: A Handbook for Institutional Review Boards*, Plenum Press, New York and London, 1982, pp. 29–38 [pp. 29-30].
[236] Ibid. [p. 30]
[237] Ibid.
[238] Warso, Zuzanna, and Marcin Sczaniecki, "Ethics Assessment and Guidance in Different Types of Organisations: Civil Society Organisations (CSOs)", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.g-Civil-society-organisations__.pdf.

must be paid to appointing a representative and qualified membership. This is also true for other EAUs that can influence government policy and national research programmes, such as GOs, GFOs, and RFOs. In these cases, the board should be multi-professional and multi-disciplinary and the gender distribution of the members should be equal. Especially in NECs, consultation of citizens, experts and other groups could be improved. The interaction with other ethical assessment organisations could also be improved.

An additional challenge which has not been reported in the interviews is that the debate in NECs is still very much focused on areas which have traditionally produced ethical conflicts, such as new developments in the life sciences or in the field of environment (agriculture). New developments regarding emerging technologies (e.g. challenges to human identity and integrity by neurosciences; challenges of uncertainty and complexity raised by nanotechnology; and challenges to human autonomy and privacy by information and communication technologies)[240] are still not respected in the mandates of most NECs. A widening of NEC mandates is therefore a precondition in order to keep pace with ethical challenges in science and new technologies.[241]

4.4.3 Survey of Ethics Assessment Unit Training

This section discusses the training of EAU members based on the SATORI survey.[242] Generally, it appears that these organisations typically do not organise training but that it will be given by other organisations. This section gives examples on how and by whom the training is organised.

National Ethics Committees

Most NECs provide information, guidance and recommendations and promote discussion on ethics. They also typically monitor and publish international trends in ethics for national purposes. On the international level, examples of organisations that support NECs include:

- the NEC Forum sponsored by the European Commission[243]
- the European Commission's International Dialogue on Bioethics, which is a platform bringing together the National Ethics Councils of 97 countries[244]
- the European Conference of National Ethics Committees (COMETH) sponsored by the Council of Europe[245]

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[239] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: National Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.b-National-ethics-committees.pdf.
[240] Strand, Roger, and Matthias Kaiser, "Report on Ethical Issues Raised by Emerging Sciences and Technologies", January 2015. http://www.coe.int/t/dg3/Healthbioethic/Activities/12_Emerging%20technologies/BergenStudy%20e.pdf.
[241] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: National Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.b-National-ethics-committees.pdf.
[242] "Comparative Analysis of Ethics Assessment Practices", *SATORI*, June 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/.
[243] European Commission, "Policy Initiatives", *Research & Innovation: Science in Society*, 2012. http://demo.intrasoft.be/ssc/index.cfm?fuseaction=public.topic&id=1305
[244] European Commission, "The European Group on Ethics in Science & New Technologies", *Research & Innovation*, 2016. http://ec.europa.eu/research/ege/index.cfm.
[245] Council of Europe, "Bioethics at the Council of Europe", 2015. http://www.coe.int/t/dg3/healthbioethic/COMETH/national_ethics_committees/default_en.asp.

- the Global Summit of National Bioethics Advisory Bodies, supported by a secretariat at the World Health Organization (WHO)[246]

The instruments produced by the UNESCO International Bioethics Committee (IBC) also provide a basis for the work done by the UNESCO bioethics section, which assists in the establishment of bioethics committees, provides training in bioethics curriculum, and engages regularly with organisations that engage in ethics assessment/guidance. The IBC's advice and recommendations on specific issues are broadly disseminated by the Director General to member states, the Executive Board and the General Conference, as well as the wider global community.

NECs themselves, on the other hand, may participate in training other research ethics committees.[247]

Research Ethics Committees

In some countries, including Spain, the UK and Germany, there are associations or forums of RECs that organise training for their members or promote such training. RECs themselves typically are university committees. Examples include the Association for Research Ethics (AfRE) in the UK, the National Association of Research Ethics Committees (ANCEI) in Spain, and the Science Ethics Committee of the Chinese Academy of Sciences (CAS). [248]

Some RECs state that training would be needed for the new members of the group or if perhaps there is a new European framework for ethics assessment.[249] Organisations and institutions such as universities may already have ethics codes that describe the ethical conduct and assessment of research. In some cases there is a professional ethics committee that ensures that the Code of Ethics is honoured by the university's teachers, associates and students.[250]

Research Funding Organisations

As a general rule, RFOs' internal, external, and mixed models of ethics assessment rely on independent experts coming from different fields of research. Therefore, only a few examples related to training in RFOs were found.[251] One organisation has a new policy focusing on training of RECs. The aim is to ensure that the RECs themselves are aware of the issues and know how to deal with them.[252] Another organisation reports that training measures of internal staff as well as evaluators were necessary to raise understanding for gender issues and to find common understanding on implementation.

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[246] World Health Organization, "Ethics and Health: The Global Summit of National Bioethics Advisory Bodies". http://www.who.int/ethics/globalsummit/en/.
[247] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: National Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.b-National-ethics-committees.pdf.
[248] Díaz, Javier Arias, Mª Concepción Martín-Arribas, Laura Herrero Olivera, Leyre de Sola Perea, and Johanna Romare, "Ethics Assessment and Guidance in Different Types of Organisations: Research Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.a-Research-ethics-committees.pdf.
[249] Ibid.
[250] Ibid.
[251] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: Research Funding Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.c-Research-funding-organisations.pdf.
[252] SATORI Interview, 25.11.2014.

Science Academies and Professional Organisations

Academic and professional organisations develop discipline-specific guidelines and provide advice and training on research ethics. Associations encourage the use of their guidelines among their members by organising forums for discussions on ethical issues within the discipline, and by organising research ethics training courses. The training may be addressed to RECs, to researchers and other experts, and to (university) students. The training may also be addressed to a certain topic such as research involving humans or animals, or research on technological issues and engineering. One example is the TRREE (Training and Resources in Research Ethics Evaluation) course by the World Medical Association, which is designed for all those involved in collaborative research involving humans, including physician-investigators and other researchers, students, RECs and regulatory agencies.[253]

Universities/University Organisations

Many universities consider ethical assessment as a part of research and educational excellence and ethics committees are becoming the central organisational form of ethical activities at universities. In many countries the university ethics assessment committees are officially recognised research ethics committees. This is the case in Germany, Austria, Poland, Serbia and the US, for example.[254] Many of these committees also provide ethical training and advice at their universities. In some cases, a national body evaluates the training in educational programs as part of the quality evaluation.[255]

Civil Society Organisations

CSOs generally contribute to the training of EAU members in three ways: they provide recommendations on ethical issues in general, organise training/courses for experts, and organise ethics training at universities.[256] The recommendations may take different forms: generic guidelines, news, comments, discussions, webinars, opinions on legal or administrative acts, lobbying at the government or parliamentary level, initiatives of court proceedings, advices, opinions and lobbing in the course of the legislative process, facilitation of discussions, offering guidance and a platform for exchanging knowledge, and so on.[257]

Government/Government-Funded Organisations

GOs/GFOs provide guidance in different forms. Compared to the guidance by CSOs, GOs/GFOs' guidance more often includes official documents by different ministries and authorities. The beneficiaries are governments, national legislators and regulators, public and private research actors, and all other stakeholders including the general public.[258]

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[253] World Medical Association, "Research Ethics Course – TRREE". http://www.wma.net/en/70education/10onlinecourses/70trree/index.html.

[254] Benčin, Rok, Jelica Šumič-Riha, Gregor Strle, and Rado Riha, "Ethics Assessment and Guidance in Different Types of Organisations: Universities", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.e-Universities.pdf.

[255] Ibid.

[256] Warso, Zuzanna, and Marcin Sczaniecki, "Ethics Assessment and Guidance in Different Types of Organisations: Civil Society Organisations (CSOs)", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.g-Civil-society-organisations__.pdf.

[257] Ibid.

[258] Ibsen-Jensen, Jakob, and Anne Kirstine Lygum, "Ethics Assessment and Guidance in Different Types of Organisations: Government and Government-Funded Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.f-Govt-and-govt-funded-orgs.pdf.

Some GOs/GFOs also provide grants for developing or chairing training programs. The National Center for Ethics in Health Care (NCEHC) at the U.S. Department of Veterans Affairs (VA) developed standards for ethics consultations, as most ethics consultants do not have proper training or standards by which to preform ethics consultation. The model is continuously improved as new resource materials are added.[259]

Industry

The systematic assessment of the potential environmental, health and social impacts is a fundamental part of how companies design their projects or perform any changes. 'Ethics' in industry may be known as risk management, sustainability, or as Corporate Social Responsibility (CSR). Attention to ethical issues is portrayed as a part of the everyday routine by companies and therefore, training in good practice – including ethics – is part of the business.

CSR may also include ethics training within the company. One of the most efficient ways of training is by a good example given by managers and superiors. The other efficient type of training is through the analysis of real cases.

Business and industry associations (such as trade organisations and industry trade groups) support companies from particular industry sectors. This support may include providing information, training, and education programs concerning ethics assessment to companies.

4.4.4 Training Recommendations

While training EAU members is recognised as important, there was concern among the interviewees that currently it is insufficient. One problem expressed in interviews was that '[e]ducation and training of people who conduct research have been done, but not enough, training programs need to be improved, but the biggest problem is that the law is not obeyed.'

New technologies are also creating new challenges (neuroscience, big data, use of social networks, etc.) and it is necessary to be aware of the risks that they may generate, debate them, agree on procedures, and to train assessors on these issues.

Ethics training could be make more effective by making it more accessible and by incorporating it into other policies and procedures that require training. Universities and other organisations (including CSOs) might offer special training courses for ethics assessment. Quality is also now a well-established issue in all organisations, and training in dealing with ethical issues could be included in the quality assurance system.

Ethics assessment should be better integrated in political decision-making through providing information and training about ethical issues for decision makers and by including ethics assessment as a necessary part of decision-making procedures.

[259] Ibid.

4.5 Procedures Prior to Assessment

In this section we study the procedures that take place prior to the ethics assessment of R&I activity. By such procedures we here refer to the procedures running from the dissemination of policies and procedures for ethics assessment to scientists and others, to the actual submission of proposals or requested information to the ethics assessment unit as well as the procedures necessary for preparing the descriptions of R&I activity for ethics review. We will consider the results from the ethics assessor studies in WP 1[260] by looking for common procedures and joint approaches among the various ethics assessment organisations studied. The aim is to identify and propose best practices for these procedures.

We first summarise the identified procedures prior to ethics assessment of R&I activity. We then describe the procedures and what actions that are taken by which actor in the process. Common procedures and joint approaches for ethics assessment are identified and discussed. We assess the possibility of constructing a practice that can be supported and shared by all types of organisations engaged in the ethical assessment of R&I or whether there is a need for specialised tools and toolkits for specific types of organisations. The section ends with recommendations for best practice for procedures taking place prior to ethics assessment.

4.5.1 Identified Procedures Prior to Assessment

National Ethics Committees
NECs have primarily a deliberative and consultative function. The ethics assessment in which NECs engage is not related to individual research proposals. It is instead related to the assessment of ethical principles, polices, recommendations and guidelines that will later be disseminated to research institutions, researchers, and others, and thus serve as the basis for ethics assessment of research proposals.

The relevant procedures taking place prior to ethics assessment for NECs are highly characterised by the selection of relevant topics or questions that are in need of further assessment. The authorities under which NECs operate, such as individual ministries, research councils, research funders, research professionals, etc., are actors that can select topics or questions in need of further assessment. Most NECs also have the mandate to address projects on their own initiative.

The selection of relevant topics to address is initiated in many cases to explore the ethical implications of research involving new technologies, recent biomedical or biological advances (e.g. the Nuffield Council) or new or controversial research methods. Topics may also be selected where there is a need to examine issues raised by individual applications for ethics assessment made by other EAUs. In some cases, NECs interact with the public, health care professionals, and other relevant professionals or organisations (e.g. CSOs) in order to identify and define ethical issues to assess.

[260] 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. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf [Chapter 5].

The procedures are not described in detail in the interview material. Instead, identified procedures involve setting up a working group for the study or preparation of the issue selected. The working group can involve either the members of the committee or consist of external actors with or without the consultation of external experts, stakeholders and the public.

Research Ethics Committees

RECs provide evaluations that are in most cases addressed to researchers, research groups or institutions that have submitted research proposals for ethical review.

Many RECs have established SOPs (standard operating procedures) for ethics assessment. Studies on US hospital-based Institutional Review Boards (IRBs) have shown that despite variations in the structure of the different boards, the operating procedures are nevertheless similar.[261] This also holds for most of the RECs interviewed for the SATORI survey.

The SOP taking place prior to EA are basically directed towards procedures related to the submission of proposals for ethics assessment. The procedures involve the following steps:

- When the law requires ethical assessment of research proposals, or when the researcher wants advice or needs ethical approval for journal publication, the researcher will submit their research proposals to a REC.
- The responsible research body will complete the standard application form. The application typically includes:[262]
    - information on the person responsible for the conduct of the project
    - a description of the research/experiment including the scientific questions, and the overall aim and purpose of the research/experiment;
    - a detailed presentation of the proposed methodology;
    - the project plan;
    - the significance of the research and expected benefits achieved by the research project/experiment;
    - documentation ensuring the consent of the participants; and
    - information on documentation and data protection and/or information on how biological material is to be stored.
- In many cases the submission of the research proposal also includes the researcher's own description and assessment of the ethical considerations.
- Before the review committee will assess the submitted proposal, one or several members of the committee usually prepare a pre-assessment. The pre-assessor(s) will make a suggestion for a decision.

The procedure is similar for RECs dealing with animal experimentation (apart from procedures related to informed consent). In these cases a pre-assessment is added concerning whether the

[261] Sana Loue, *Textbook of Research Ethics: Theory and Practice*, Kluwer Academic, New York, 2002 [p. 93].
[262] Díaz, Javier Arias, Mª Concepción Martín-Arribas, Laura Herrero Olivera, Leyre de Sola Perea, and Johanna Romare, "Ethics Assessment and Guidance in Different Types of Organisations: Research Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.a-Research-ethics-committees.pdf.

experiment is in need of ethics assessment. If ethics assessment is deemed wanting, the research proposal will undergo ethics assessment (see CETEA, for example).

Research Funding Organisations

Most RFOs ask applicants to make a self-assessment of their research proposal. In some cases RFOs will do a pre-screening with the help of independent experts. The procedures are not described in detail, but the procedures regarding the researchers' self-assessment and the pre-assessment procedures seem to be similar to the RECs procedures presented above.

Proposals that have been declared to have no ethical concerns, or where ethical issues are adequately addressed, do not have to undergo further ethics assessment. If there are ethical issues that the researchers do not address in the self-assessment, the project will undergo a more thorough ethics review.

The pre-screening of a research proposal often assesses whether the proposal complies with national legislation on ethics review. In some cases, pre-screening will only occur if a large number of proposals are submitted. The aim of the pre-screen is to ensure that referees only receive proposals that have a good chance of being granted.

Universities

At some universities, an ethical approval is obligatory for certain kinds of research. Many universities establish their own RECs and guidelines for ethics assessment. In such cases the universities' research ethics offices will provide application forms, checklists, and general guidelines to help their researchers and students when submitting a proposal for ethics assessment.[263]

The interviews show that university RECs can have different roles in different institutional settings. In most cases university RECs only have an advisory role, and their advice is often non-binding. However, when the university REC acts as a replacement for external review committees, or when ethical assessment is officially assigned to university RECs, their assessment is often obligatory and binding.

Civil Society Organisations

Some interviews indicate that CSOs have as one of their objectives to discuss the social implications of innovation or to maximise the potential of R&I/R&D activities.[264] In that context, CSOs evaluate R&I/R&D activities for their impacts on civil rights such as privacy, protection of personal data, etc., and may evaluate new innovations for their consequences for the environment or society.

The CSOs that discussed their assessment methods briefly describe procedures such as asking relevant agents to submit documents necessary for the assessment process (e.g. for corporate

[263] Benčin, Rok, Jelica Šumič-Riha, Gregor Strle, and Rado Riha, "Ethics Assessment and Guidance in Different Types of Organisations: Universities", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.e-Universities.pdf.
[264] Warso, Zuzanna, and Marcin Sczaniecki, "Ethics Assessment and Guidance in Different Types of Organisations: Civil Society Organisations (CSOs)", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.g-Civil-society-organisations__.pdf.

compliance audit) or by receiving information about certain unsettling situations or practices that are submitted by external agents (e.g. from the public). One CSO (PRIM&R) refers to educational courses as important procedures that take place prior to assessment.[265]

Government Organisations/Government-Funded Organisations

The GOs/GFOs interviewed for the SATORI survey engage in ethics assessment in different ways. The procedures followed by the organisations prior to assessment are as a result diverse, stretching from relatively formalised processes to ad hoc procedures. The interviews show that organisations with specific ethics units have a more formalised process for ethics assessment.[266]

Some GOs/GFOs adopt formalised standard operation procedures. The EDCTP (European & Developing Countries Clinical Trials Partnership) adopts the *ERC Rules for Submission and Evaluation*, which requires that 'applicants should pay particular attention to the ethical aspects of the proposed work and must submit an ethics-ready proposal'.[267] The applicant must submit an ethics self-assessment consisting of (i) an ethics issue table, and (ii) a description of how the proposal meets national legal and ethical requirements of the country or countries where the research tasks raising ethical concern will be performed. If a national or local authority has assessed the proposal, the applicant should provide a copy of that assessment. The applicant should also (iii) provide a detailed discussion of how the ethics issues will be addressed in relation to the research objectives (e.g. vulnerable research subjects), research methodology and the potential impact of the research.

Other GOs/GFOs do not adhere to fixed procedures. The OECD Global Science Forum (GSF) sets up a working group to define the best onward action from case to case.[268] This could involve, for instance, a comparative analysis of practices in different countries. The National Center for Ethics in Health Care (NECHC) within the US Department of Veterans Affairs has an extensive program for managing ethics in health care organisations, known as IntegratedEthics (IE). The core function is an ethics consultation based on the CASES approach.[269] CASES is the acronym for a step-by-step approach standing for Clarify the consultation request, Assemble the relevant information, Synthesize the information, Explain the synthesis, and Support the consultation process. The purpose is to guide ethics consultants in order to resolve ethical concerns more effectively and to provide high quality ethics consultation. Clarifying the request and assembling relevant information are the first steps of the process, and can be regarded as procedures prior to the assessment.

Industry

[265] Ibid.
[266] Ibsen-Jensen, Jakob, and Anne Kirstine Lygum, "Ethics Assessment and Guidance in Different Types of Organisations: Government and Government-Funded Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.f-Govt-and-govt-funded-orgs.pdf.
[267] The European Commission, *Horizon 2020: ERC Rules for Submission and Evaluation, Annex A:* "Ethics Review Process". http://ec.europa.eu/research/participants/data/ref/h2020/sgl/erc/h2020-erc-se-rules-1617_en.pdf [p. 24].
[268] OECD, "What is the Global Science Forum?". http://www.oecd.org/sti/sci-tech/whatistheglobalscienceforum.htm.
[269] US Department of Veteran Affairs, National Center for Ethics in Health Care, "Ethics Consultation. Responding to Ethics Questions in Health Care" (2nd edition). http://www.ethics.va.gov/docs/integratedethics/ec_primer_2nd_ed_080515.pdf.

The procedures taking place prior to assessment involve the implementation of the CSR strategy and their code of conduct. This could include networking and education. In some cases, it also includes dialogue with its stakeholders at all its locations and in relevant markets. The most common assessment procedure that companies implement is impact assessment (IA). IA aims to predict and evaluate the impact of a current or proposed action. A number of the interviewed companies have developed their own IA tools.[270]

CSR is an established mechanism for self-regulation with the purpose to encourage corporations to behave in a socially responsible manner. It is usually defined in terms of voluntary measures to integrate social, environmental, consumer, and human rights concerns in business operations, but it does also refer to measures of how to integrate mandatory legal regulations. Though CSR tools (e.g. CR standards; global initiatives such as UNGC) for integrating CR principles are not only directed towards assessing corporate R&D, there are nevertheless cases where ethics assessment of R&D in companies is explicitly addressed. Examples of this are specific research areas where extensive regulation and guidelines are already in place, e.g. research on humans and animals, and research that is regulated by data protection and privacy concerns. Other areas that are particularly relevant are human rights issues, e.g. in biomedical research, scientific and professional integrity, excellence, innovations that have tangible effects on society, innovation management, and product responsibility, and in areas where companies R&D activities directly contribute to improve social, economic and environmental aspects.[271]

There are several CSR tools that provide companies with standardised procedures for ethics assessment, e.g. ISO International Standard for Social Responsibility (ISO 26000) provides procedures to assess impacts related to the principles and core subjects addressed by the standard; and the Global Reporting Initiative (GRI) provides procedures for the reporting procedures, assessment and monitoring of the companies' activities.

For companies subject to ethics assessment, the procedures for assessing their R&D activities vary. Some companies have their own audit committee or units, while others use external auditors. The auditors supervise application of CR throughout the organisation, and interact with the various functions in order to collect CSR initiatives and information. Within the biomedical field, larger companies often interact with ethical committees (e.g. research ethics committees, national ethics committees). There is also a difference between how large companies deal with ethics assessment and how the assessment is dealt with by SMEs: when large companies might set an autonomous supervisory board to ensure independent assessment and monitoring of their R&D activities, SMEs might face difficulties in doing it individually due to limited resources.[272] For the reasons such as those above it is difficult to make general claims on companies' ethics assessment procedures.

[270] Gurzawska, Agata, Rossella Cardone, Andrea Porcari, Elvio Mantovani, and Philip Brey, "Ethics Assessment and Guidance in Different Types of Organisations: Industry", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.h-Industry.pdf.

[271] See Agata Gurawska and Andrea Porcari, "Models for ethics assessment and guidance in industry", SATORI report 4.2.6, for a more extensive account of areas where ethics assessment of R&D in companies are explicitly mentioned.

[272] Høivik, Heidi von Weltzien, and Deepthi Shankar, "How Can SMEs in a Cluster Respond to Global Demands for Corporate Responsibility?", *Journal of Business Ethics*, Vol. 101, Issue 2, June 2011, pp. 175–195 [p. 185].

4.5.2 Common Procedures and Recommendations for Best Practice

The EAUs discussed here differ from each other in several aspects. One reason is that, while they share some aims for engaging in ethics assessment, some EAUs (or categories of EAUs) have additional aims that are not shared by all. Obviously, such diversity will influence ethics assessment procedures and the possibility for common procedures.

One of the identified challenges for most EAU types is the lack of clear procedures and the fact that there is some diversity (i.e. in the case of industry) in how to organise ethics assessment of R&I/R&D within the same EAU type. The basis from which organisations practice ethics assessment and guidance also varies in terms of institutional framework (whether ethics assessment is voluntary or mandatory) and objects of assessment, as well as the available resources (time, expertise, etc.) and willingness to conduct ethics assessment of R&I.

These factors create challenges for suggesting best practices and joint procedures for ethics assessment. However, the country studies in WP 1 showed that all 11 countries studied are currently expanding their ethics assessment infrastructure.[273] This expansion involves RECs but also all the other types of EAUs discussed here. Thus, there is some willingness to make amendments in how ethics assessment is conducted and to improve procedures.

Based on the summary of the relevant procedures taking place prior to ethics assessment, the most common procedures identified are those related to the submission R&I proposals for ethics assessment, or the ethics assessment/ethics audit of R&I activities.

The EAUs adapt either to standard operating procedures such as the ERC rules for submission, CASES, or to CSR tools in the case of industry. Alternatively, they may have developed their own procedures for submission. In the case of RECs, the operating procedures for submission of research proposals are quite similar. A noticeable commonality is that researchers are required to make a *self-assessment* of the proposal when submitting it for ethical review.

A second commonality for several of the discussed EAUs is that before the EAU assesses a proposal, it usually goes through a *pre-assessment* or *pre-screening* by one or more members of the committee. The *pre-assessment/pre-screening* may serve different purposes for different EAUs. One reason for adopting such a procedure is efficiency, often in terms of making the assessment procedure more time-effective. In many cases RFOs will only conduct a *pre-screening* of ethical issues if a large number of proposals are submitted. When it comes to the pre-assessment conducted by members of a REC, the committee member responsible of preparing the case will make a summary of the case, identify and reflect on the ethical considerations and suggest a decision. The pre-assessment or preparation of the case conducted by committee members before the ethics review by the committee is time-effective and probably enables a more thorough assessment than if all members of the committee immersed themselves in all research proposals that are submitted for assessment.

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

A third commonality (at least when it comes to RECs) regards the application form that researchers should complete when submitting the project proposal for ethics review. With few exceptions, the EAUs require very similar information from the researchers about the research proposal.

We saw that RECs in general have well-developed and well-established operating procedures. Other EAUs use similar procedures, but are in many cases not as elaborate. The operating procedures by RECs are time-effective and enable a thorough assessment of individual research proposals. Based on this observation, we recommend the following procedures as best practices for all types of EAUs:

- Use of a standard application form, including:
    - information on the person responsible for conducting the project;
    - a description of the R&I activity including the scientific questions, and the overall aim and purpose of the research/experiment;
    - a detailed presentation of the proposed methodology;
    - the significance of the R&I/R&D activity and expected benefits achieved;
    - documentation describing the procedures for obtaining informed consent;
    - information on the social impact and context of the R&I/R&D activity;
    - information on documentation and data protection and/or how biological material is to be stored; and
    - information on identified stakeholders.

  Some interviewed RECs criticised the existing standard application forms for not being sensitive to the ethical issues addressed by non-medical research. Often the application forms are formulated with medical research in mind, asking the researcher to report on how biological material will be sampled and stored, etc. This focus on medical research creates a risk that researchers within other fields will get the impression that ethics review is irrelevant for their work. Therefore, we suggest that either there should be different application forms for medical and non-medical research, or that the application form is worded in a more neutral way.
- Use of self-assessment: The research proposal should include the researchers' description and assessment of the ethical considerations. A benefit of self-assessment is that the researchers themselves have to reflect on the ethical issues of the project. Making researchers more aware of the ethical impact of their research is an important aim of ethics review.
- Use of pre-assessment/pre-screening: Pre-assessment and pre-screening make ethics review both time-effective and enable a thorough ethics assessment for R&I activities that require it. Pre-assessment will only deal with the question of whether there are any ethical issues that have not been adequately addressed. The EAU will conduct the full assessment of R&I activity where such assessment is needed, e.g. when there is a high-risk project. Pre-assessment is suitable for EAUs that receive large numbers of research proposals for ethics review while having limited resources. The pre-assessment of ethics proposals made by one or two persons of the ethics committee make the assessment more thorough by allowing more resources to be allocated to R&I activity that require more detailed assessment. The pre-assessment will involve:
    (i) a summary of the case,

(ii) a reflection on the ethical considerations that the researcher has identified as well as a reflection of how the researcher will deal with them,
(iii) an analysis of other ethical concerns that the researcher may have not addressed, and
(iv) suggest a decision (for which the pre-assessor could give reasonable arguments).

- Ethics assessment of R&I activity is proactive in most cases, i.e. it takes place before the research or innovation is conducted. However, there are cases when EAUs should assess on-going projects. At least two cases can be identified: (1) When an application already has been approved but have undergone essential changes that may affect the risk of harm or other relevant ethical aspects, or (2) when the application has not undergone ethics review but the researcher (or equivalent agent) identifies ethical issues that ought to undergo ethics review. In the first case the researcher (or equivalent agent) should submit a proposal for amending the former application. In the latter case the researcher (or equivalent agent) should submit a new application for ethics review. Any changes to the protocol must go to the EAU for approval.

The suggested best practices are procedures that could easily be adopted by most EAUs. However, the assessment infrastructure within industry differs to a great extent from the other types of EAUs. CSR policies are intended to function as self-regulating mechanisms for business to ensure compliance with legal regulations, with the spirit of the law, with ethical standards, and international norms. Except for compliance with law, this type of assessment is the result of a voluntary regulation of an industry by its own members. Voluntary regulation by means of self-regulation is more flexible than government regulations, which is preferred by the industry since regulatory agencies tend to slow business operations and thereby increase the costs for businesses. An effective self-regulatory framework will be less costly for businesses as well as reducing the risks for its stakeholders. Is it possible to include the above-suggested best practices within this framework? The request for applying for ethics review implies that ethics assessment is not voluntary, which could have a negative impact on companies' willingness to adopt such a framework for ethics assessment. It will be difficult in general to suggest procedures that will appeal to business unless they are based on the principle of self-regulation. Apart from this challenge it should be possible for industry to adopt a self-assessment procedure and a pre-assessment/pre-screening procedure similar to those suggested above.

However, there are several arguments against a voluntary self-regulatory framework for ethics assessment of companies' R&D activities. First, the effectiveness of voluntary/non-binding EA procedures and corporate responsibility (CR) tools have been challenged, both in regard to the companies' motivation to engage in CR activities, and in what is actually achieved by companies in terms of EA. Second, the great diversity in how companies define and understand CSR makes it difficult to measure the quality and the monitoring of the ethics assessment taking place.

This report focuses on organisations that perform ethical assessment. We have therefore not been recommending procedures for ethics guidance. However, the SATORI interviews in WP 1 indicate that many researchers in the humanities and social sciences are unaware that some of their research should be submitted to ethics review. For the recommended practices to become effective, the policies, regulations and guidelines must be known and adopted by the research community. To increase the awareness of R&I policies, regulations and guidelines, it is also important to consider best practices for dissemination procedures. Research ethics education

(courses, workshops, seminars, etc.) is another way of making researchers aware of ethics assessment. Many universities offer research ethics courses only for doctoral students (which in some cases are mandatory). Other universities also offer research ethics education for senior researchers.

4.6 Procedures During Assessment

In this section we study the procedures taking place during the ethics assessment of R&I activity. As in the previous section on procedures prior to assessment, we consider the results from the ethics assessor studies in WP 1 with the aim of identifying and recommending best practices for procedures during ethics assessment.

We first present a summary of identified procedures during the ethics assessment of R&I. We then describe the procedures and actions taken by different actors in assessment procedures. We also assess the possibility of constructing practices that can be supported and shared by all types of EAUs. The section ends with recommendations for best practice for procedures taking place during ethics assessment.

4.6.1 Identified Procedures During Assessment

National Ethics Committees
NECs engage in the assessment of ethical principles, polices, recommendations and guidelines for R&I as well as for ethics assessment.

After a topic or question in need of assessment has been selected, most NECs will establish working groups led by a chairperson. External experts can be consulted. They can be experts from scientific and education institutions, non-governmental organisations (NGOs), media and private citizens.

Working procedures involve reviewing work papers and giving presentations at work meetings. In general, there is a discussion and a decision is taken (e.g. if making an amendment of a policy). There are no rules on consensus, but recommendations are deemed to carry more weight if they are the result of an agreement.

Research Ethics Committees
As mentioned earlier, many committees have established standard operating procedures (SOPs). The SOPs during ethics assessment are primarily directed towards assessing individual research proposals. After the researcher has made a self-assessment of the proposal it is usually reviewed by one or several members of the REC, and is then presented to the rest of the committee together with a decision proposal. The REC will then discuss the proposal.

One EAU that differs from the other RECs is the National Committee for Research Ethics in the Social Sciences and the Humanities in Norway (NESH). Their ethics review system is built around the idea of self-assessment with extensive ethical guidelines that help researchers to

ethically assess their own research, as well as promoting good practice in research ethics. If the researchers need help to interpret the principles in the guidelines, or any other minor issue, they can get ethical advice by phone or email from NESH. If a researcher still believes that the principles in the guidelines do not give enough guidance in a particular case and it is of principal interest to further assess the issue, the researcher can bring the case to the committee for evaluation. The evaluation may conclude with a decision either to revise the guidelines, write a report clarifying the ethical issues related to the topic that initiated the evaluation, or make a comment on how certain principles can be interpreted and applied in the light of this new issue. NESH describes their method as being *casuistic* (i.e. uses case studies and analogous reasoning to reach ethical judgements).[274]

Despite the commonly shared SOPs, the assessment procedures vary between the different RECs. Some RECs discuss the proposal until a consensus is reached, while others use a voting procedure. In most cases RECs will make a top-down analysis, basing their decision on ethical principles such as human dignity, beneficence, etc. Some RECs have developed guidelines for this purpose, while other RECs use declarations or standards such as the Declaration of Helsinki or the CIOMS (Council for International Organisations of Medical Sciences) guidelines. In some cases, a top-down analysis is not sufficient to make a decision on the research proposal. Different values (e.g. harms and benefits) can come into conflict and therefore need to be weighed against each other or against the scientific value of the study.

Research Funding Organisations

The procedures of the different RFOs studied are rather diverse. Some RFOs describe the procedures as verifying compliance with national legislation on ethics review, with or without consulting external actors such as CSO panels representing relevant interest groups. One RFO consults a large number of experts and lay persons to determine whether the researchers have considered the possible benefits and harms toward the research subjects and other parties that may be affected by the research.

One RFO states that ethical issues are in principle only evaluated occasionally, e.g. where the research is particularly controversial, such as when experiments on humans are performed. In such cases the applicant can, as a part of the evaluation of the research proposal, be asked to inform the RFO about the ethical issues of the research.[275]

Universities

The review procedure depends on the identified level of risk. Only high-risk projects require a full review. The assessment process differs from country to country, and sometimes also between universities within one country. In Germany and Austria, the submitted research proposal is anonymised and sent to an external evaluator. The proposal is then assessed by applying the relevant principles from the Declaration of Helsinki. Whether the decision is the result of a voting procedure or consensus is not made clear in the responses.

[274] Beauchamp, Tom L., and James F. Childress, *Principles of Biomedical Ethics*, 7th ed., Oxford University Press, New York, 2013 [pp. 398-399].
[275] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: Research Funding Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.c-Research-funding-organisations.pdf.

Civil Society Organisations

CSOs do not assess individual research proposals. The assessment is primarily related to analysing data that has been gathered, and the writing of reports, guidelines and recommendations.[276] A Chinese CSO describes their process during ethics assessment (audit) in more detail:

> The audit has an on-site part and an off-site part. The off-site part is the document review, in which the enterprise submits relevant documents and the auditing company provided by NGOs audits the documents and writes the document review report. Afterwards the on-site audit is carried out. The auditing company chosen by the enterprise will lead the onsite document audit, on-site investigation and interviews and if necessary some sampling work. During this process, NGOs take part in all auditing activities by informing the auditing company of anything that could affect the normal auditing procedures. The auditing company will report on-site audit findings and NGOs will check the findings. The auditing company will write the preliminary audit report and NGOs check this audit report.[277]

Government Organisations/Government-Funded Organisations

Only one of the interviewed GOs/GFOs has established formal procedures for the ethics assessment of R&I activity. The procedures are described in terms of risk assessment, reaching agreement and providing a final recommendation.

The CASES approach mentioned in the earlier chapter on pre-assessment outlines the procedures for ethics assessment for one of the studied GOs. The last three letters of CASES give the keywords for the procedures taking place during assessment: *Synthesize* the information, *Explain* the synthesis and *Support* the consultation process.[278]

Industry

The concept of Corporate Social Responsibility (CSR) emphasises the impacts of corporate activities on society, the environment and stakeholder groups. CSR can be seen as a set of moral duties that a business organisation has voluntarily adopted. CSR includes guidelines, policies and principles by documents such as ISO 26000, GRI, OECD, UN-HR, etc. The guidelines and policies provide the tools for putting CSR into practice.[279]

The ethical assessment of industries' R&D activities can therefore be seen as an assessment of whether an industry complies with its voluntarily adopted moral duties. As mentioned in the earlier chapter on pre-assessment, the most common assessment procedure within industry is impact assessment (IA). IA is a prospective form of assessment that is used to identify and

[276] Warso, Zuzanna, and Marcin Sczaniecki, "Ethics Assessment and Guidance in Different Types of Organisations: Civil Society Organisations (CSOs)", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.g-Civil-society-organisations__.pdf.
[277] Ibid.
[278] US Department of Veteran Affairs, National Center for Ethics in Health Care, "Ethics Consultation. Responding to Ethics Questions in Health Care" (2nd edition). http://www.ethics.va.gov/docs/integratedethics/ec_primer_2nd_ed_080515.pdf.
[279] Argandoña, Antonio and Heidi von Weltzein Høivik, "Corporate Social Responsibility: One Size Does Not Fit All. Collecting Evidence From Europe", *Journal of Business Ethics*, Vol, 89, Supp. 3, November 2009, pp. 221-234.

evaluate the social (SIA), environmental (EIA) and economic impacts of a project or product before it is developed further. Other assessment tools used within industry are risk assessment and cost-benefit analysis.[280] One research company interviewed in the study describes their own developed assessment tool where the social impact of the company's R&I activities are evaluated from six dimensions: economic capital, social capital, cultural capital, well-being, ecological capital, and relational capital.[281]

4.6.2 Common Procedures and Recommendations for Best Practice

The EAUs studied have different assessment procedures depending on their aim of assessment as well as the object of their assessment. The procedures also depend on the institutional, organisational, legal and practical constraints faced by individual EAUs. Assessment procedures sometimes vary within the EAUs of the same type within the same country. Even though the assessment procedures in the latter case are not arbitrary, it may still be problematic with procedures for ethics assessment that are too diverse. Best practices recommended should be general enough to be reasonably adaptable to all types of EAUs but must be sensitive to the different institutional and organisational settings of EAUs.

We will here suggest best practices for assessment procedures and for decision procedures. The pre-assessment by a member of the EAU has already been discussed in section 4.5. However, this step could also be perceived as a part of the actual ethical assessment of R&I activity at the proposal stage.

As for the procedures taking place prior to ethics assessment we again find that the most detailed procedures are among the RECs. The procedures are quite similar among various RECs. The steps that a proposal submitted for ethical review goes through in terms of ethics assessment involves:

- pre-assessment of the research proposal which will be presented at the RECs committee meeting
- recommendation by the pre-assessor
- discussion by the committee members
- decision-making

Discussion by the members of the EAU and the decision making process can take different forms as we have already seen. The ethics committees have regular meetings where the research proposals are discussed. Usually the discussion takes its starting point from a pre-assessor's report where ethical issues have been identified and specified. In most cases, the pre-assessor has also suggested a decision: to approve, to refuse, or to ask for a revision. The decision is backed up by arguments that are supported by ethical principles, facts, etc.

[280] Gurzawska, Agata, Rossella Cardone, Andrea Porcari, Elvio Mantovani, and Philip Brey, "Ethics Assessment and Guidance in Different Types of Organisations: Industry", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.h-Industry.pdf.
[281] Ibid.

The procedures are generally the same regardless of whether the assessment is obligatory or non-obligatory. What differs is the decision, which in the latter case will result only in a recommendation or an advice.

We recommend the following general procedures as best practices for all types of EAUs:

- All EAUs should have an established decision procedure to prevent arbitrary decisions from being made. Established procedures promote transparency and prevent arbitrary decisions by the committee. We recommend a set of methods for resolving conflicts between ethical principles in section 3.10. Whether the method for assessing ethical issues is based on a top-down approach starting from ethical principles or if it is casuistic is less important. It is also of less importance whether the decision is reached by a voting procedure or by consensus. What is important is that a documented process exists for the EAU to reach its decision.
- EAUs should meet in person, if possible, to engage in joint ethics assessments. Discussions could also take place by modes of teleconference meetings. Meetings and exchanges through e-mail and other textual media are acceptable for routine issues, but should be avoided for issues that require extensive deliberation.
- The assessment procedure should be designed to ensure that the conducted R&I activity:
  (i) protects stakeholders (e.g. individuals participating in research) from undue risk and harm,
  (ii) ensures that participation in research, trials and similar activities related to the R&I activity is voluntary,
  (iii) determines if the research or innovation methods are appropriate, and
  (iv) aims to increase the awareness of the ethical impact of R&I.
  Some of these goals can be achieved by using a checklist for relevant and pressing issues.
- There should be a method for how to deal with the issue of weighing the benefits of the research against the risk and harm. The methods presented in section 3.8 describe several possibilities. However, before weighing the harms against the benefits of the research, it should be considered whether there are ways to redesign the research study or the product to reduce the risk. Such methods should not only consider weighing benefits against harms towards individuals, but also harms against society, the environment and animals.
- The decision-making procedure should be made public for the sake of transparency. However, regulatory requirements and confidentiality considerations should be considered whether decisions are made public or are only made available internally.
- In cases where the EAU finds information lacking, or where they identify ethical issues that can be avoided, they should ask the applicant to revise the application in accordance to their suggestions rather than reject the proposal.

4.7 Procedures After Assessment and Supervision of the EAU

In this section we study the procedures taking place after ethics assessment of R&I activity. As with the two previous sections, our aim is to identify and recommend best practices for procedures after an ethics assessment has been made. This section also covers the supervision of the EAU. An organisation that includes an EAU needs to ensure that it fulfils its intended purpose within that organisation. An independent EAU also needs to confirm that it achieves the

assessment standards that it claims to perform, so that those relying on its assessment can be confident in the quality of its work.

We first present a summary of identified procedures taking place after the assessment. Second, common procedures and joint approaches for ethics assessment are identified and discussed. We also assess the possibility of developing practices that can be supported and shared by all types of EAUs. We present recommendations for best practice regarding procedures that follow ethics assessment before moving onto the supervision of EAUs. Again we summarise how different types of EAUs are supervised, and present recommendations for EAU supervision.

4.7.1 Identified Procedures After Assessment

National Ethics Committees

After review and decision-making, the NECs will produce reports or revise already existing documents (e.g. guidelines, policy recommendations, etc.). The reports are submitted to relevant authorities and on the organisations' websites, making them available to the public, to researchers, and to other stakeholders. In most cases the documents are also translated in order to contribute to international ethics debate.

There is little information regarding following-up procedures. It is therefore not possible to draw any conclusions about that. The *Danish Council of Ethics* reports that they do not assess the influence of their recommendations.

Research Ethics Committees

After the decision, the submitter will receive a written judgment regarding the ethical issues. If approval cannot be given, the committee may ask the submitter to submit a revised proposal. The committee has the option of giving advice on how to amend the application to receive an ethics approval. If approval has been given a favourable report is issued.

If approval is not given and the decision is binding, it is possible in some cases for the researcher to submit the proposal to an appeal body. If the assessment result is merely a recommendation, the researchers can choose to ignore it and continue with their research.

There are only a few examples of monitoring compliance with a REC's decision. RECs generally do not monitor the results of their decision. In some cases there is an administrative follow-up, especially regarding biomedical research and clinical trials where inspectors make control visits, review logs, medical records, etc.

Research Funding Organisations

The interviews with EAUs within RFOs show in general that the phase after project implementation is poorly developed. After the project has commenced it is the researcher's responsibility to address any new ethical issues that arise. The researcher is also responsible for informing the funding organisation of any new ethical issues that emerge.

Universities

A guideline or a code of conduct comes into force as soon as it has been published. Follow-up procedures have shown that the published guidelines or codes sometimes are not acted upon, which is explained by 'lack of resources and the inertia of the existing institutional routines'.[282]

Civil Society Organisations
CSOs generally have extensive and well-functioning procedures for monitoring compliance. If non-compliance is identified during the assessment/audit process, the research will be further monitored by the auditing body. The progress of the follow-up actions of the enterprise will be tracked. A final report will be written, which in some cases is made public.

Government Organisations/Government-Funded Organisations
After completing the ethics assessment, the decisions are published or lead to a revision of existing guidelines and policies. Only a few organisations have following-up procedures that monitor compliance.[283]

Industry
After assessment (often impact assessment, risk assessment or cost-benefit-analysis), the company or industry will create and implement a strategy dealing with the issues identified, as well as measure and evaluate performance. The procedures after the impact assessment are basically related to social audit/social accounting, which can be perceived as a way of monitoring compliance.

What is special about EAUs in industry is that they are evaluating their own company or industry. In addition, the company that they assess often has mixed motives (non-moral as well as moral) for its CSR strategy. Moreover, they often include other aspects (business performance) in their assessment (see section 4.5 on pre-assessment). The companies will monitor and evaluate their compliance to the CSR strategy and publish it in their annual report. Transparent reporting is stressed by some EAUs within industry.[284]

4.7.2 Recommendations for Best Practice

Procedures after the assessment deal with communicating the result of the assessment process, the possibility to appeal, and monitoring compliance. We suggest the following general best practices for all types of EAUs:

- The decisions of the EAU should be recorded for internal access and for external reference if required by legislation or auditing.

[282] Benčin, Rok, Jelica Šumič-Riha, Gregor Strle, and Rado Riha, "Ethics Assessment and Guidance in Different Types of Organisations: Universities", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.e-Universities.pdf.
[283] Ibsen-Jensen, Jakob, and Anne Kirstine Lygum, "Ethics Assessment and Guidance in Different Types of Organisations: Government and Government-Funded Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.f-Govt-and-govt-funded-orgs.pdf.
[284] Gurzawska, Agata, Rossella Cardone, Andrea Porcari, Elvio Mantovani, and Philip Brey, "Ethics Assessment and Guidance in Different Types of Organisations: Industry", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.h-Industry.pdf.

- After the review/decision, the submitter should receive a written judgment regarding the ethical issues. The decision may vary depending on whether the assessment is obligatory or non-obligatory. If approval has been given (in the case of an obligatory ethics assessment), a favourable report is issued. If minor amendments are necessary, the committee will ask the researcher to submit a revised proposal. Ideally there should be a dialogue between the EAU and the submitter regarding the ethical issues and how to deal with them. In cases of non-obligatory assessment, the EAU will give a recommendation that the R&I activity should either proceed, be revised, or halted.
    - Most of the decisions made by the interviewed EAUs are final and give no possibilities for the researcher to appeal their decision. We recommend that the opportunity to appeal against the decision should be given. This is especially important if the decision of the EAU is binding. The right to appeal is necessary to correct mistakes made by an EAU and to uphold the integrity of the research ethics system.
    - There are several ways in which an appeal can be organised, and several grounds on which an applicant may appeal the EAU's decision.[285] When the applicant is notified of the EAU's decision, the procedure and timeframe for appeals should be specified. The timeframe should give the applicant reasonable time to make a formal appeal. What is a reasonable timeframe depends on the circumstances of the appeal, e.g. if the appeal body is to re-examine the original application or not, as well as the institutional framework that may regulate a specific appeal procedure.
    - The appeal should first be sent to the EAU that reviewed the R&I activity. If the appeal has been made within the appropriate timeframe the application will be sent to the appeal body that will re-examine the application.
- Monitoring compliance is an important tool for making researchers aware of the importance of ethics review of R&I activity. It is striking that few RECs have a follow-up procedure that includes monitoring compliance. This lack of a follow-up is also something that, according to the interviews, REC representatives find wanting. Industry and CSOs are the only identified assessor groups that actually have standard procedures for monitoring compliance.
- There should be QA monitoring of both whether the researchers followed the EAU's decision and whether the researchers found the EAU effective. Interviews from WP 1 indicate that when compliance has been monitored it has shown that the ethical guidelines are sometimes not acted upon. There are, therefore, good reasons for monitoring compliance, especially when the decision is binding: Without a follow-up procedure there is a risk that the trust towards ethics assessment organisations will be undermined. There are also good reasons to follow up non-binding decisions routinely since compliance or non-compliance will tell us something about whether the ethical guidelines are effective, and whether they have been institutionalised in the research community. To conclude, the current system for monitoring compliance is found wanting. However, due to the limited resources of many EAUs it is difficult to estimate how this could be realised in practice.

[285] Under what grounds a researcher may appeal the decision of an EAU will not be discussed here (e.g. if mere dissatisfaction with the EAU's decision is sufficient ground for appeal).

- If decisions (especially binding ones) are to be followed up, there should also be procedures for what measures to take in case of non-compliance. Different types of EAUs have different prospects to intervene in case of non-compliance:
    - RFOs can withdraw funding if the researchers do not comply.
    - CSOs have, as has already been mentioned, follow-up actions. The corporation or enterprise that does not comply will be tracked. Non-compliance can have a serious negative impact on the reputation of the corporation or enterprise.
    - One of the aims of some EAUs is to ensure that research is conducted according to national regulations, as well as to monitor compliance, and should report cases of non-compliance to the relevant authority.

4.7.3 Identified Forms of Supervision

National Ethics Committees
National ethics committees are often linked with national governments in an advisory role. For example, the German Ethics Council presents recommendations to the German Parliament (whose members can suggest subjects to be assessed), and holds regular meetings with various ministries to discuss their work.[286] Similarly, the US Presidential Commission for the Study of Bioethical Issues (PCSBI) advises the US President on bioethical matters.[287] Regulations and committees that supervise government advisors also affect NECs that advise the government.[288]

Research Ethics Committees
Research ethics committees associated with a particular organisation are usually supervised by that organisation.[289] Similarly, RECs operating within universities will be accountable to the university administration.[290] RECs may also perform quality assurance to ensure that their work is meeting the necessary requirements.[291]

Governments also play a role in supervising RECs through legislation that guide their work and the integrity systems they put in place to ensure compliance with it. RECs that operate within government research institutes also serve as a means for government supervision of research (and of the REC itself, since it is a means of ensuring that government-sponsored research is conducted ethically). For instance, the Institute of Health and Medical Research (IMSERM) operates under the joint authorisation of the French Ministry of Health and the Ministry of Research.[292] As IMSERM is responsible to these ministries in the government, the Ethics Committee of IMSERM is ultimately accountable to the government.

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[286] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: National Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.b-National-ethics-committees.pdf.
[287] Ibid.
[288] Ibid.
[289] Díaz, Javier Arias, Mª Concepción Martín-Arribas, Laura Herrero Olivera, Leyre de Sola Perea, and Johanna Romare, "Ethics Assessment and Guidance in Different Types of Organisations: Research Ethics Committees", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.a-Research-ethics-committees.pdf.
[290] Ibid.
[291] Ibid.
[292] Ibid.

Research Funding Organisations
As their task is to coordinate the most effective distribution of research funding, RFOs are accountable to the sources of the funds that they allocate. RFOs that distribute research funding on the government's behalf will report to that government.[293]

Science Academies and Professional Organisations
Science academies and professional organisations both serve as institutions that represent the interests and establish the standards expected of their members. As with research funding organisations, science academies often have a close connection with government, and may advise them on science policy and scientific issues.[294] The EAUs operating within science academies and professional organisations are ultimately accountable to the members of their organisation, as they are important for demonstrating the quality and trustworthiness of the work of their members. An ineffective EAU would reflect poorly on the members of the academy or the profession. As a result, the leadership of academies and professional organisations have a strong interest in supervising the work of their EAUs.

Universities/University Organisations
Government legislation may determine whether ethics assessment is performed by a university's own EAU or requires external review.[295] In some cases, the training in educational programs is evaluated by a national body, such as the Accreditation Organisation of the Netherlands and Flanders NVAO in the Netherlands, as a part of the quality evaluation.[296]

Beyond the integrity systems defined by government legislation, the administrations of universities and university organisations supervise their own EAUs. Like other organisations that operate their own EAUs (such as science academies and professional organisations), establishing and maintaining high ethical standards is important for the reputation of the institution. The work of EAUs is also important for attracting and maintaining research funding, so university administrations have a strong interest in maintaining the quality of the assessment performed by their EAU.

Civil Society Organisations
CSOs are ultimately accountable to their members. The members of CSOs are often motivated by a sense of social responsibility, and the operation of their EAU is a part of fulfilling that responsibility. The credibility of the proposals and statements made by the CSO on social, political, and scientific issues depends on the quality of the work they perform, including that of the EAU itself. The administrations of CSOs, and the members themselves, have a strong interest in the EAU performing work of a high standard. CSOs may also use external assessors and

[293] Wolfslehner, Doris, "Ethics Assessment and Guidance in Different Types of Organisations: Research Funding Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.c-Research-funding-organisations.pdf.
[294] Strle, Gregor, Rok Benčin, Jelica Šumič-Riha, and Rado Riha, "Ethics Assessment and Guidance in Different Types of Organisations: National Science Academies and Academic & Professional Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.d-National-academies-of-science-and-POs.pdf.
[295] Benčin, Rok, Jelica Šumič-Riha, Gregor Strle, and Rado Riha, "Ethics Assessment and Guidance in Different Types of Organisations: Universities", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.e-Universities.pdf.
[296] Ibid.

auditors to perform their ethical assessment.[297] As with internal EAUs, the CSO has a strong interest in supervising the work performed by external assessors and auditors to ensure that the work is of high quality and does not damage of the CSO's reputation.

Government/Government-Funded Organisations
Government organizations and government-funded organisations are both accountable to their government. The government department within which they operate or the government department that provides their funding will supervise the work of their EAUs.[298] External auditors may also be used to confirm the quality of the work performed by government or government-funded EAUs.[299]

Industry
EAUs that operate within companies are accountable to management.[300] External assessors may also audit internal integrity monitoring within companies.[301] This activity may also include the use of external auditors.

4.7.4 Recommendations for Best Practice in Supervision

Those responsible for the work performed by an EAU have the strongest interest in supervising that work. Institutional EAUs are commonly supervised by the institution for which they work. Regional and national EAUs will be overseen by regional and national governments respectively. While this situation creates the possibility of a conflict of interest if the EAU assesses the work of the organisation that operates it, the conflict can be addressed through using external auditors and by compliance with government regulation.

EAUs should be supervised by a high administrative or managerial level of the organisation within which they operate. This is important for several reasons. First of all, it ensures that the work of the EAU is respected within the organisation, since it has a direct connection with the management or administration. Second, it means that the EAU may be independent of other sections of the organisation that it assesses. This independence can reduce the potential conflict of interest that occurs from a section of an organisation assessing its own work. Finally, being supervised by a high level within the organisation makes it easier to authorise the external assessment of the EAU's work, as the supervisors of the EAU will likely have the authority within the organisation to approve this themselves and to make any recommended changes.

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[297] Warso, Zuzanna, and Marcin Sczaniecki, "Ethics Assessment and Guidance in Different Types of Organisations: Civil Society Organisations (CSOs)", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.g-Civil-society-organisations__.pdf.
[298] Ibsen-Jensen, Jakob, and Anne Kirstine Lygum, "Ethics Assessment and Guidance in Different Types of Organisations: Government and Government-Funded Organisations", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.f-Govt-and-govt-funded-orgs.pdf.
[299] Ibid.
[300] Gurzawska, Agata, Rossella Cardone, Andrea Porcari, Elvio Mantovani, and Philip Brey, "Ethics Assessment and Guidance in Different Types of Organisations: Industry", *SATORI D1.1*, June 2015. http://satoriproject.eu/media/3.h-Industry.pdf.
[301] Ibid.

The supervisor of the EAU's work should not be the person who appoints the EAU's members. This separation is intended to protect the independence of the EAU and its decisions while also maintaining its accountability. The EAU must make impartial assessments in order to perform its function well. Using external auditors and performing quality assurance of the EAU's work are both ways of demonstrating the quality of the EAU's work and that it is fair and unbiased. (Quality assurance practices are discussed in the next section.)

It is also important that the supervisors cannot ignore the EAU's work (for instance, if the EAU gives an unfavourable assessment for a proposal important to the institution or company for which it works). This concern can be addressed by implementing policies that require the EAU to assess R&I activity conducted by the relevant institution as well as policies requiring that the EAU's assessment must be considered by the administration in deciding whether to proceed with a project or research proposal. This requirement also prevents the EAU (and thus, ethics assessment) from being bypassed.

4.8 Quality Assurance

In ethics assessment, quality assurance refers to activities that (systematically) determine the effectiveness of ethics assessment process and procedures through studying, evaluating, monitoring, or measuring and comparing them with established standards. It may also make recommendations for improvement. These activities are undertaken either by ethics assessors themselves or their agents, and they may be administrative, procedural or have some other form.

One of the conclusions in the SATORI D1.1 deliverable on *Ethical Assessment of Research and Innovation* was that many organisations active in ethics assessment 'cannot point to a clear methodology or framework for doing it, and quality assurance and accreditation procedures are often lacking.'[302] This section will explain why this is a concern and how QA may be implemented by an EAU.

4.8.1 Why Quality Assurance of Ethics Assessment is Useful/Required

Quality assurance (QA) of ethics assessment processes helps ensure that the ethics assessment processes and procedures are contributing to the meeting of their goals and expectations. It is often not termed as such, or recognised as 'quality assurance', rather it is more often called a review of the ethics policy and procedure. Such measures help correct any misinterpretations or misapplications of ethics policies and procedures. QA activities also help foster communication between different agents involved in the ethics assessment process – i.e. those making the policy and those implementing it. QA can also help develop/strengthen best practices and help tailor ethical policies to meet different requirements (e.g. in relation to different scientific fields).

[302] 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. [p. 11].

QA of ethics assessment may be internal or external. Internal quality assurance of ethics assessment is conducted either by the ethics assessor herself, or by another individual or agent internal to the organisation. It may be a very simple review, or a very formalised process. External quality assurance of ethics assessment is conducted by third parties external to the organisation. There could be different forms of external QA of ethics assessment policy and processes (this is shown later in this report).

Ethics assessment can be either formal (in the case of ethics assessors with formally established policies and procedures) or highly informal (ad hoc, conducted often on a need-to basis). It is hard to determine exactly what QA means or how it manifests in cases of informal processes of ethics assessment, such as assessment by individual researchers prior to submission of the research proposal and prior to ethics assessment by CSOs. Difficulties arise, for example, where there is no specific unit or dedicated person responsible for the ethics assessment process (e.g. many SMEs face this problem and conduct ethics assessment only on a need-to basis). In such cases there might be no QA (or it might not even be feasible) for such ad hoc ethics assessment.

4.8.2 How Organisations Conduct QA/Review of their Ethics Policy and Procedure

We now present how QA manifests in different categories of ethics assessment organisations, i.e. how various ethics assessor categories engage in QA of their ethics assessment policies and procedures. This discussion is based on the SATORI interviews of different categories of ethics assessor organisations conducted as part of WP 1 of the project[303] and supplemented by desktop research.

National Ethics Committees

- The unique position of NECs does not make their activities amenable to QA in the strict sense of the term; NECs advise or make recommendations on ethical aspects of scientific developments; their advice is not generally subject to QA (internal or external).
- In a majority of the cases, there is no self-evaluation of NECs' practice and procedure; post-recommendation/post facto review is lacking.
- A lack of administrative and financial support and continuity of mandate may account for the lack of QA.
- Some NECs do report to parliamentary committees, perform annual self-evaluations and discuss their work.

Research Ethics Committees

- RECs do not generally assess the quality of their own ethical frameworks; however, if an organisation using their framework wants an external auditing of their research ethics arrangement, they may provide that based on the framework.
- RECs may have meetings with stakeholders to learn about how the framework is being used, and whether any amendments need to be made to the framework.
- Training (e.g. through working groups) is one means used to ensure quality assurance.

[303] SATORI interviewed 230 representatives of organisations that engage in ethics assessment and guidance, and experts in the field, in Europe, the US and China. The results are documented in Deliverable 1.1.

- In one analysed case, the organisation had established a system of quality management based on ISO 9001:2008 (Quality Management Systems).
- There may be a quality committee responsible for making decisions on quality and the overall supervision of the implemented quality management system, with annual evaluations and reviews.
- RECs may be accredited.[304]

Research Funding Organisations

- RFOs sometimes use external accreditation to evaluate whether their ethics assessment policies and procedures meet established standards.
- RFOs may conduct self-evaluation exercises and reviews of the ethical monitoring process (generally small-scale, periodic and/or focused on specific aspects).
- RFOs collaborate with other parties to identify critical problems.
- RFOs review and amend applicable regulations.
- RFOs may conduct annual meetings to review and discuss problems.

Science Academies and Professional Organisations

- SAs and POs may have Advisory Bodies or Boards to guide them.
- SAs and POs may carry out surveys on the usage of their guidance documents and the need for updating these documents, specifically with regard to any changes in legislation that may have to be considered.
- SAs and POs may review and amend Codes/Guidance (generally using a light-touch approach).
- If needed, SAs and POs may carry out further research on codes/guidance.
- SAs and POs may self-assess using standard evaluation protocols.

Impact Assessment Organisations

- IAOs may carry out engagement and training via seminars.
- IAOs define rules for internal procedures.
- IAOs use external reviews and evaluations of policy/guidance.
- IAOs review the underlying laws and regulations (legislative and policy fitness checks).
- IAOs involve or meet with stakeholders.
- IAOs co-operate with and participate in international networks.
- IAOs benchmark with (international) good practices.

Universities/University Associations

- In many cases, universities/university associations have no formalised QA process.
- Universities/university associations may have ethical policy reviews.
- Universities may conduct QA visits to units in order to check implementation of centrally established ethics policies.

[304] In the Netherlands, the Central Committee on Research Involving Human Subjects (CCMO) handles accreditation of MRECs. The CCMO checks whether an accredited medical ethical reviewing committee (MREC) meets obligations (accreditation) and oversees their operations. The CCMO can set up new guidelines with regards to the operations of accredited MRECs. The criteria for accreditation are laid down in the Medical Research Involving Human Subjects Act (WMO).

- Universities/university associations organise training workshops/events, where considered necessary.
- Universities create ethics policy committees to address slowness of addressing certain ethical issues by departments or sub-units.
- Universities/university associations use surveys to check/monitor the use of ethical guidance tools.

Civil Society Organisations

- CSOs use questionnaires/surveys to investigate the expectations and the actual behaviour, training, collaborative learning activities.
- CSOs use external people as trainers.

Government/Government-Funded Organisations

- Some organisations have established QA processes, e.g. the UK National Heath Research Authority (HRA) has a quality management system and has achieved (and continues to achieve) certification against ISO 9001:2008 for HRA Quality Assurance Activities.[305] Accreditation programmes for RECs ensure that RECs adhere to agreed or established standards. For example, the HRA also has a three-year rolling accreditation programme in order to audit UK RECs against agreed standards as detailed in Standard Operating Procedures (SOPs) and Governance Arrangements for Research Ethics Committees (GAfREC).[306]
- Some GOs/GFOs may review and update ethical frameworks on a regular or ad hoc basis (depending on factors such as technological progress, change in public values or expectations).
- GOs/GFOs may carry out consultations with stakeholders.
- Some organisations could be said to have a process continuously to assess their ethics assessment process. Every time a decision is made or an investigation is carried out the criteria established by the organisation are tested.
- GOs/GFOs may carry out organisational surveys to review ethical policies and processes.
- GOs/GFOs use ethical boards and advisory groups to consult with and agree changes to ethical policy and processes.

Industry

- Review activities in relation to corporate social responsibility (CSR) policies are often uncoordinated.
- Bigger companies might put more resources into evaluating CSR policies. Smaller ones might not have a CSR policy. If they do have such a policy, they may not have resources to evaluate it.
- Companies may subject themselves to third party evaluation/rating and certification to validate their ethical credentials, e.g. Bureau Veritas SA8000 social accountability certification or DS 49001 social responsibility certification.

[305] NHS Health Research Authority, "Quality Assurance". http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.
[306] Ibid.

- Some companies might review their ethical policies and procedures in liaison with regulatory authorities, e.g. review of data protection policy in liaison with a data protection authority.
- Some larger companies have boards that conduct annual reviews of their CSR strategy and performance. For example, BT has such a board.[307] Some companies, such as Alstom, conduct a 'materiality matrix' based on the evolution of stakeholders' expectations and Alstom's future strategy.[308]
- Companies may conduct internal audits and assessments of compliance to ensure policies and processes are working as expected. One tool used is called 'benchmarking' and involves 'reviewing competitor initiatives, as well as measuring and evaluating the impact that those policies have on society and the environment, and how others perceive competitor CSR strategy'.[309]
- Companies may update and revise their Code of Ethics.

4.8.3 General Observations/Gaps and Challenges

Based on the above, we can make the following general observations about QA of ethics assessment.

- QA activities are not streamlined or uniformly applied.
- QA is not conducted in a systematic way, even in the more formalised ethics assessment bodies.
- There is often no overarching policy of taking responsibility for quality assurance of the ethics assessment process; QA may not be built into the policy of the ethics assessment unit or the top-level management.
- For some, ethics assessment is a regular activity. For others, ethics assessment is not a regular activity, which makes QA much more difficult; post-ethics assessment review or reflections are not the norm.
- The outcomes sought of various types of QA activity vary.
- The focus is more on the ethics assessment itself (investigating ethical issues/designing ethical policies and guidance) than on improving the ethics assessment or any such follow-up.
- Flexibility in quality assurance activities such as those outlined in the preceding section may be desirable.
- The availability of resources (financial and human) is a determinative factor in whether QA of ethics assessment is conducted. For example, a lack of continuity in staff membership may result from lacking the resources needs to employ permanent staff.

[307] BT, "Our Commitment to Society". http://www.btplc.com/report/report05/Ourcommitmenttosociety/ .
[308] Alstom, "Corporate Social Responsibility (CSR) Materiality matrix methodology". http://www.alstom.com/Global/Group/Resources/Images/Signposts/Medium/Materiality%20Matrix%20methodology_UK_Final.pdf.
[309] Fontaine, Michael, "Corporate Social Responsibility and Sustainability: The New Bottom Line?", *International Journal of Business and Social Science,* Vol. 4, No. 4, April 2013, pp. 110-119 [p. 114].

4.8.4 Recommendations to Improve Quality Assurance of Ethics Assessment

Quality assurance of the ethics assessment process currently leaves much to be desired. However, the different types of ethics assessment activities and the divergent mandates of ethics assessment units or agents makes it necessary to have a flexible yet robust means of ensuring QA of the ethics assessment process. Considering the difficulty of having a harmonised approach for all ethics assessor categories, we propose a simple approach to facilitate quality assurance of the ethics assessment process. This approach could also be expanded to ensure the quality of ethics policies and procedures.

We recommend that EAUs consider using the **Plan-Do-Check-Act** (PDCA) process[310] used in the internationally well-recognised ISO 9001 'Quality Management Systems — Requirements' standard. This method is particularly relevant as it is a continuous improvement model. Using this approach could help all ethics assessors to better plan their ethics assessment processes and interactions. It would ensure the quality of ethics assessment by enabling assessors to ensure 'processes are adequately resourced and managed, and that opportunities for improvement are identified and acted on'.[311] The PDCA cycle can be used in any process. ISO 9001 describes the PDCA cycle as follows:[312]

- **Plan:** establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organisation's policies;
- **Do:** implement what was planned;
- **Check:** monitor and (where applicable) measure processes and the resulting products and services against policies, objectives and requirements and report the results;
- **Act:** take actions to improve performance, as necessary.

In relating this to the ethics assessment process, we can adapt it as follows with relevant elements from existing QA of ethics assessment practice, and the ISO 9001 approach:

- **Plan:** establish the objectives of the ethics assessment and its processes, and the resources needed to deliver results in accordance with ethical requirements and the organisation's policies;
- **Do:** implement what was planned;
- **Check**: monitor and (where applicable) measure ethics assessment processes and the results against policies, objectives and requirements and report the results;
- **Act:** take actions to improve performance, as necessary.

PLAN

Ethics assessors should adequately plan for QA of their ethics assessment processes and procedures. They should develop a quality assurance plan showing:

a) the objectives of the QA,

[310] Also called the 'Deming cycle', this is a widely used process improvement method.
[311] International Organization for Standardization, "ISO 9001: 2015 Quality Management Systems – Requirements", September 2015.
[312] Ibid.

b) the strategy and approach to QA,
c) the methods/techniques to be used and how performance shall be measured, and
d) who has the responsibility for QA.

EAUs also need good infrastructure and the resources necessary to deliver results in accordance with ethical requirements and the organisation's policies. This requires investment and commitment of dedicated resources. An ethics assessment organisation's by-laws could support QA and provide the impetus and framework for it.

DO

This part envisages the implementation of the QA plan and ensures that the arrangements therein are followed. This process includes support actions (the list below is largely based on section 7 of ISO 9001, adapted for use here) such as:

- Determining and providing the resources needed for the establishment, implementation, maintenance and continual improvement of the ethics assessment process (while considering the capabilities of, and constraints on, existing internal resources and also what needs to be obtained from external providers).
- Determining and providing the persons necessary for the effective implementation, operation and control of its ethics assessment processes and for the operation and control of its processes.
- Determining, providing and maintaining the infrastructure necessary for the operation of processes to achieve quality of ethics assessment.[313]
- Determining, providing and maintaining the environment necessary for the operation of its ethics assessment processes.
- Determining and providing the resources needed to ensure valid and reliable results in the ethics assessment process.
- Ensuring that the resources provided:
    - are suitable for the specific type of ethics assessment being undertaken;
    - are maintained to ensure their continuing fitness for their purpose.
- Retaining appropriate documented information as evidence of fitness for purpose of the ethics assessment process.
- Determining the knowledge necessary for the operation of its ethics assessment processes.
- Ensuring:
    - the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the ethics assessment process;
    - that these persons are competent on the basis of appropriate education, training, or experience;
    - and where applicable, taking actions to acquire the necessary competence, and evaluating the effectiveness of the actions taken;
    - the retention of appropriate documented information as evidence of competence.
- Ensuring that relevant persons working under the organisation's control (e.g. ethics assessors, other staff) are aware of:

[313] For example, buildings and associated utilities, any equipment, including hardware and software, transportation resources, and information and communication technology.

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) the implications of not conforming with the ethics assessment process requirements.

- Determining the internal and external communications relevant to the ethics assessment process (what, when, with whom, how).
- Maintaining documented information determined by the organization as being necessary for maintaining the effectiveness and quality of the ethics assessment process. This maintenance is important for transparency purposes.

CHECK

To help facilitate the CHECK aspect, we outline below some key questions (based upon and adapted from the *EC Better Regulation Guidelines on Evaluation and Fitness Checks,*[314] which is useful guidance) that could help assess the quality of ethics assessment policy, practice or procedure:

1. **What is the current situation?**

Typical example questions:

- What is the origin of the ethics assessment policy, practice or procedure and what were its objectives?
- What progress has been made over time?
- What is the current situation for different stakeholders and how are they affected by the ethics assessment policy, practice or procedure? (Include a consideration of how different elements of the ethics assessment policy, practice or procedure have worked in practice.)

2. **How effective has the ethics assessment policy, practice or procedure been?**

Typical example questions:

- To what extent have the objectives been achieved?
- What have been the (quantitative and qualitative) effects of the ethics assessment policy, practice or procedure?
- To what extent do the observed effects correspond to the objectives?

[314] European Commission, "Guidelines on Evaluation and Fitness Checks", *Better Regulation*. http://ec.europa.eu/smart-regulation/guidelines/ug_chap6_en.htm. These we find are highly relevant as in SATORI we are aiming to develop an EU-wide framework for ethics assessment. The EC Guidelines help evaluate whether EU activities are fit for purpose and deliver, at minimum cost, the desired changes to European businesses and citizens and contribute to the EU's global role. According to the EC, a Fitness Check assesses whether the framework for a given sector is fit for purpose by assessing the performance of the relevant framework with respect to its policy objectives; it pays particular attention to identifying any synergies, or inefficiencies and helps to identify the cumulative impact of the interventions covered, covering both costs and benefits.

- To what extent can these changes/effects be credited to the ethics assessment policy, practice or procedure?
- What factors influenced the achievements observed?
- To what extent did different factors influence the achievements observed?
- Did evaluation or review policies/procedures allow for the addressing of things affecting the achievement of the objectives of the ethics assessment policy, practice or procedure?

3. How efficient has the ethics assessment policy, practice or procedure been?

Typical example questions:

- To what extent has the ethics assessment policy, practice or procedure been cost effective?
- To what extent are the costs justified, given the changes/effects that have been achieved?
- To what extent are the costs proportionate to the benefits achieved? What factors are influencing any particular discrepancies?
- What factors influenced the efficiency with which the achievements observed was attained? How affordable were the costs borne by different stakeholder groups, given the benefits they received?

4. How relevant is the ethics assessment policy, practice or procedure?

Typical example questions:

- To what extent is the ethics assessment policy, practice or procedure still relevant?
- To what extent have the (original) objectives proven to be appropriate for the ethics assessment policy, practice or procedure in question?
- How well do the (original) objectives (still) correspond to the needs within the EU?
- How well-adapted is the ethics assessment policy, practice or procedure to subsequent technological, scientific, societal or other advances? (Note: issues related to the specify policy could be included here.)
- How relevant is the ethics assessment policy, practice or procedure to individuals or citizens?

5. How coherent is the ethics assessment policy, practice or procedure internally and with other external actions?

Typical example questions:

- To what extent is ethics assessment policy, practice or procedure coherent with other ethics assessment policy, practice or procedures that have similar objectives?
- To what extent is the ethics assessment policy, practice or procedure coherent internally?

- To what extent is the ethics assessment policy, practice or procedure coherent with wider EU or national policy?
- To what extent is the ethics assessment policy, practice or procedure coherent with international obligations?

6. What is the EU added value of ethics assessment policy, practice or procedure?

Typical examples of EU added value questions:

- What is the additional value resulting from the EU ethics assessment policy, practice or procedure), compared to what could be achieved by Member States at national and/or regional levels?
- To what extent do the issues addressed by the ethics assessment policy, practice or procedure continue to require action at EU level?
- What would be the most likely consequences of stopping or withdrawing the existing EU intervention?

The above list of questions is non-exhaustive and might be further adaptable.

In line with the Smart Regulation Guidance, '[e]valuation results should be assessed and, where relevant, be complemented by follow up actions to ensure maximum use of the results. Active discussion and debate on these findings should be encouraged'.[315] The evaluation results should be disseminated to all interested stakeholders (e.g. via publication of a report, presentation at events, briefing document). More importantly, follow-up actions should be taken to 'put into practice the lessons learned and feed the evaluation findings into the next cycle of decision making'.[316] The follow-up could take any number of forms (e.g. revision of guidance, further monitoring, setting up of a QA committee or Advisory Board).

ACT

This part envisages review and continuous monitoring to improve the performance, adequacy and effectiveness of the ethics assessment process. It entails taking all actions necessary to improve the ethics assessment process and also correct any undesirable effects (e.g. acceptance of a highly unethical project with detrimental effects on society). This process includes following type of activities:

- Learning from feedback about ethical policy or assessment procedure.
- Learning from other organisations.
- Revisiting plans, policy documents and the ethics assessment process to see if they need updating.
- Taking actions on lessons learnt (including from internal and external evaluations/QA exercises).

[315] European Commission, "Guidelines on Evaluation and Fitness Checks", *Better Regulation*. http://ec.europa.eu/smart-regulation/guidelines/ug_chap6_en.htm.
[316] Ibid.

4.8.5 Conclusion

Quality assurance of ethics assessment is a necessary but challenging and underdeveloped aspect of ethics assessment, even though it can help determine and ensure that the ethics assessment processes and procedures are meeting their goals and expectations.

Going forward, we recommend that all ethics assessor organisations should take responsibility for quality assurance of the ethics assessment policies and processes; QA should be built into the policy of the ethics assessment unit. Ethics assessor organisations should self-evaluate their ethics assessment policies and procedures on a defined, regular basis (either using the SATORI adapted PDCA approach outlined in this section or an alternative means). They should also gauge the views of relevant stakeholders on this (via surveys, etc.). Where possible, they should use external third party evaluation services and gain accreditation.

4.9 Efficiency Considerations

Similar to quality assurance of ethics assessment, few EAUs have procedures in place for evaluating their efficiency. Given that EAU units often operate with limited resources, efficiency considerations should be taken into account to ensure that the resources available are used effectively. Our discussion on efficiency in EAUs focuses on two issues: general recommendations for the most effective use of the EAU's resources, and how to measure and improve the efficiency of ethics assessment procedures.

4.9.1 Efficiency in Ethics Assessment

We can distinguish between three groups who are burdened by an EAU's work: EAU members themselves, the researchers who must complete reports and proposals for R&I activity for assessment and respond to questions from the EAU members, and the supervisors of the EAU who provide the resources. For the EAU and its work to be supported over the long term, the EAU itself needs to be efficient in order to minimise the burdens imposed on these groups by its operation.

The burdens imposed on each group can be generally classified as additional workload for EAU members, additional workload and delays for researchers, and operating costs for supervisors. An efficient EAU will minimise each of each burdens.

As discussed in section 4.5, pre-assessment by one or more EAU members helps to reduce the workload of the EAU as a whole by ensuring that their time and effort is devoted to the proposals that require significant ethical assessment. While this creates additional workload for researchers (as it requires them to complete a self-assessment of their project), it also benefits them by minimising delays because ethically sound R&I activity can be assessed more quickly in this way.

Delays for researchers can be minimised by having clear policies that describe the assessment process. The EAU should also keep the researchers informed about the progress of their assessment. Ensuring that the EAU meets regularly to assess R&I activity can also reduce delays.

Minimising delays and using pre-assessment to ensure that more time and effort is devoted to evaluating the R&I activity that does require detailed assessment helps reduce the burdens on those supervising the EAU. Ensuring that the EAU does not have more members than it needs to operate smoothly and to evaluate proposals effectively can also reduce the resource burden. As described in section 4.3.1, many national laws and regulations impose requirements on the size of research ethics committees. Having too many members may affect the EAU's ability to reach decisions quickly as well. Ensuring that these limits are met and that the EAU membership fulfils the requirements of competence, independence, diversity, and representation will suggest the appropriate size for the EAU's membership.

4.9.2 Measuring and Improving Efficiency

In section 4.8 on QA we developed recommendations for quality assurance based on the Plan-Do-Check-Act (PDCA) process described in the ISO 9001 'Quality Management Systems – Requirements' standard. According to the PDCA approach, planning for and ensuring efficient use of resources is already part of the quality assurance of a project. Following the adaption of the PDCA approach to ethics assessment practices, *Error! Reference source not found.* collects the aspects mentioned under the PDCA approach that directly mention or overlap with efficiency considerations.

Phase of the PCDA	**Efficiency considerations**
PLAN	• The objectives of the QA. • The strategy and approach to QA. • *The methods/techniques to be used and how performance shall be measured.* • Who has the responsibility for QA.
DO	• Determining and providing the resources needed for the establishment, implementation, maintenance and continual improvement of the ethics assessment process: persons, infrastructure, environment, knowledge. • Ensuring that the resources provided: are suitable for the specific type of ethics assessment being undertaken; are maintained to ensure their continuing fitness for their purpose. • Determining the internal and external communications relevant to the ethics assessment process (what, when, with whom, how). • Maintaining documented information determined by the organization as being necessary for maintaining the effectiveness and quality of the ethics assessment process.
CHECK	• *To what extent have the objectives been achieved?* • *What have been the (quantitative and qualitative) effects of the ethics assessment policy, practice or procedure?* • *To what extent do the observed effects correspond to the objectives?* • *To what extent can these changes/effects be credited to the ethics assessment policy, practice or procedure?*

Phase of the PCDA	Efficiency considerations
	• *What factors influenced the achievements observed?* • *To what extent did different factors influence the achievements observed?* • *Did evaluation or review policies/procedures allow for the addressing of things affecting the achievement of the objectives of the ethics assessment policy, practice or procedure?* • *To what extent has the ethics assessment policy, practice or procedure been cost effective?* • *To what extent are the costs involved justified, given the changes/effects that have been achieved?* • *To what extent are the costs proportionate to the benefits achieved? What factors are influencing any particular discrepancies?* • *What factors influenced the efficiency with which the achievements observed was attained? How affordable were the costs borne by different stakeholder groups, given the benefits they received?*
ACT	• *Learning from feedback about ethical policy or assessment procedure.* • *Learning from other organisations.* • *Revisiting plans, policy documents and the ethics assessment process to see if they need updating.* • *Taking actions on lessons learnt (including from internal and external evaluations/QA exercises).*

Table 1 Efficiency considerations for ethics assessment in the PDCA approach

What we learn from considering the PDCA approach in relation to efficiency is that it is an aspect that must be considered and planned from beginning to end. In the table we have highlighted aspects of efficiency considerations, where EAUs are particularly challenged. These issues are emphasized in italics in **Error! Reference source not found.**. Summarised challenges emerge particularly in terms of measuring impact, determining cost-effectiveness and risk benefit of the ethics assessment, as well as in terms of learning from the process of ethics assessment.

Part of the challenges experienced by PDCAs concerns the measuring and determination of impact. The questions from **Error! Reference source not found.** which relate to the determination and measurement of impact come down to three questions:

- *What are the methods/techniques to be used for measuring performance (impact)?*
- *What have been the (quantitative and qualitative) effects of the ethics assessment policy, practice or procedure?*
- *What factors influenced the achievements observed?*

The questions related to determining the efficiency of the ethics assessment procedures of the EAU comes down to three questions:

- *To what extent has the ethics assessment policy, practice or procedure been cost effective?*
- *To what extent are the costs involved justified, given the changes/effects, which have been achieved?*

- *To what extent are the costs proportionate to the benefits achieved? What factors are influencing any particular discrepancies?*

Finally, there are issues from the PDCA related to learning. These questions can be reduced to four key issues:

- *To what extent have the desired effects, as stated in the objectives, been achieved?*
- *What factors influenced attainment of the original objectives? Did the ethics assessment procedure allow for addressing those factors?*
- *What can be learned from the evaluation of the success of the ethics assessment?*
- *What actions can we take?*

In the following table we present an overview of how each type of EAU performs in terms of addressing goal of measurement of impact, cost-effectiveness and risk-benefit, and in terms of learning.

Organisation Type	**Measurement of impact**	**Evaluation of cost-effectiveness and risk-benefit**	**Structured learning on efficiency**
National Ethics Committees (NECs)	Not as a rule	Not strictly or by those terms	Most cases no self-evaluation of NECs practice and procedure; post-recommendation/ post facto review is lacking (there are exceptions)
Research Ethics Committees (RECs)	Rely on user feedback	Not strictly or by those terms	Not as a rule
Research Funding Organisations (RFOs)	Not as a rule	Not strictly or by those terms	RFOs may conduct self-evaluation exercises and reviews of the ethical monitoring process (generally small-scale, periodic and/or focussed on specific aspects)

Organisation Type	Measurement of impact	Evaluation of cost-effectiveness and risk-benefit	Structured learning on efficiency
Science Academies (SAs) and Professional Organisations (POs)	Some carry out surveys on the usage of their guidance documents and the need for updating of the documents, specifically with regard to any changes in legislation that may have to be considered	Not strictly or by those terms	May have advisory bodies or boards to guide them
Impact assessment organisations (IAOs)	Meet with stakeholders	Not strictly or by those terms	Use external reviews and evaluations of policy/guidance, partner with international networks, and use benchmarks for good practice. Have defined rules for internal procedures. Perform fitness checks
Universities/university associations	Use surveys to check/monitor the use of ethical guidance tools	Not strictly or by those terms	May have ethical policy reviews
Civil society organisations (CSOs)	Not as a rule	Not strictly or by those terms	Use questionnaires/surveys to investigate the expectations and the actual behaviour, training, collaborative learning activities
Government/government-funded organisations (GOs/GFOs)	Not as a rule	Not strictly or by those terms	Have established quality assurance processes that could include efficiency considerations

Organisation Type	Measurement of impact	Evaluation of cost-effectiveness and risk-benefit	Structured learning on efficiency
Industry	May conduct internal audits and assessments of compliance. Measure and evaluate the impact of policies on society and the environment, and measure impact on others perception of their performance	Not strictly or by those terms	May update and revise their Code of Ethics, (CSR) policies – happens more or less systematically and is dependent on available resources

Table 2 EAU performance on efficiency

4.10 Addressing Cultural and Organisational Factors

The circumstances under which an EAU operates will affect the shape that such a unit will take. The particular culture and society within which an EAU operates will influence its goals and composition. An EAU connected to a specific organisation must also reflect the purpose of that organisation. The following two sections will discuss how one can account for these cultural and organisational factors, and the third section will provide a set of recommendations based on these discussions.

4.10.1 Cultural Factors

'Culture' here is understood as the societal norms and expectations that affect research practice within a society. Individual members of an EAU may differ in their cultural backgrounds and expectations. This includes the proper treatment of research participants (human or animal), acceptable topics for research, and who has the appropriate expertise to evaluate moral issues.

Cultural factors should not be used as a justification for ignoring accepted research standards and practice, however. Accepted research standards for conducting research, such as the Declaration of Helsinki, should be regarded as absolute minimum standards that apply regardless of cultural factors.[317] Cultural considerations should be used only as a justification for imposing stricter requirements than those required by national and international laws and guidelines on research ethics, and not as an excuse for implementing weaker requirements.

Using cultural factors only to justify stricter protections for research subjects has additional benefits for EAUs as well. Following international guidelines in research ethics also has the benefit of countering claims of 'ethics dumping', where projects are deliberately conducted in

[317] World Medical Association, "Declaration of Helsinki". http://www.wma.net/en/30publications/10policies/b3/index.html.

countries with more permissive ethical standards than those of the country where the researchers are based.[318] The EAU's decisions will also be more acceptable to other ethics assessors as they will all be using the same minimum guidelines for ethical research. This practice will further increase trust in the EAU's decisions.

Cultural (and political) factors may also influence the acceptability of particular areas of research. An example of this influence can be found in the differences in the permissibility of embryonic stem cell research between European states.[319] In such cases, however, legislation often exists that describes the limits of acceptable research. Unless the EAU belongs to an organisation that is able to influence legislation (such as a national ethics committee or a national science academy), such legislation takes the problem of whether or not to approve culturally unacceptable research out of the EAU's hands.

It will not always be the case that controversial research will be illegal, and so an EAU may have to decide whether politically or socially controversial research should be approved. These situations reinforce the importance of the EAU's decisions coming as the result of discussion by members of diverse backgrounds and experiences that reflect the major perspectives about the research in society. The EAU's decisions may not necessarily reflect the prevailing view within society about the permissibility of the research, but they must be *defensible* to open-minded members of that society. This requirement is also important for the researchers whose work is reviewed, as the justification of the EAU's decisions will assist them in understanding why their work conflicts with the views of the broader community.

Culture is also significant in determining the appropriate source of ethical expertise. A more secular culture, for example, may favour an ethicist or bioethicist over a theologian while a more religious culture may favour a theologian of the dominant religion over an ethicist or a representative of a different faith. Ideally, the best response is to include a specialist in ethics (either a philosopher, ethicist or bioethicist) as well as a theologian from the religion that is most influential both in the EAU's society and in the community to which the research subjects belong. However, this is unlikely to be possible in practice, particularly in multicultural societies where a variety of faiths are represented within the population. A more practical solution is to ensure that the EAU members have training and experience in applied ethics and an awareness of the cultural factors that may influence the community perception of the research under consideration. This solution reinforces the importance of the EAU being ethically competent, as described in section 4.3.

4.10.2 Organisational Factors

The organisational factors that affect EAUs are the scope of the assessor's work, the legal requirements for ethical assessment, and, if the EAU is associated with another organisation, the goals of that organisation.

[318] European Commission, "Ethics", *Horizon 2020*. https://ec.europa.eu/programmes/horizon2020/en/h2020-section/ethics.
[319] Engeli, Isabelle, and Christine Rothmayr Allison, "Diverging against All Odds? Regulatory Paths in Embryonic Stem Cell Research across Western Europe", *Journal of European Public Policy,* Vol. 20, No. 3, March 2013, pp. 407–424.

The EAU's scope defines the range of projects and research for which it is responsible. The scope may be institutional, regional, national, or international. An institutional scope means that ethics assessment is limited to the work of a particular institution that the assessor is usually connected with. University and hospital ethics committees are ethics assessors with an institutional scope, for example. A regional scope means that an assessor may perform ethics assessment for a variety of researchers and organizations that operate within a specific geographic region. An assessor with a national scope may perform assessment of research performed anywhere within a given country, while assessors with an international scope may assess research within any country that recognizes the legitimacy of their work.

The type of organisation also affects the availability of people with particular expertise. Universities, for instance, may have philosophers, ethicists and bioethicists belonging to various departments. While appointing members belonging to the same organisation may reduce the appearance of the EAU's independence, this practice may be countered by appointing sufficient non-affiliated members (such as lay persons and outside experts) to provide balance.

The next factor is the legal requirements that affect the ethics assessor's work. As ethics assessment is a legal requirement for some forms of research, the ability to fulfil these requirements necessarily influences how an EAU operates. Legal requirements must take precedence over other considerations in the organisation and operation of an EAU.

Finally, the goals of the organisation associated with the EAU (if there is one) or the goals of the EAU itself should be considered. EAUs associated with medical research institutes, for example, should consider the social value (i.e. the possibility of reducing the disease burden to society compared to the potential risks to any human or animal participants) of the research under review.[320] EAUs associated with industry would need to take into account the corporate social responsibility goals of the industry and the research's potential impact to the business goals of the company. This consideration must not compromise the EAU's judgement by allowing it to approve research that it would otherwise reject as unethical. The presence of independent members within an EAU can help to protect against the goals of the EAU's organisation from having an undue influence on its decisions.

4.10.3 Recommendations for Cultural and Organisational Factors

The recommendations for accommodating cultural and organisational factors in the work of EAUs are summarised below.

- Cultural factors should only be used to justify stricter requirements than those imposed by national and international laws, and accepted international guidelines on research ethics.

[320] Edwards, Sarah JL., "The Role, Remit and Function of the Research Ethics Committee — 3. Balancing Potential Social Benefits against Risks to Subjects", *Research Ethics Review,* Vol. 6, No. 3, September 2010, pp. 96–100 [pp. 96-97].

- Having members of the EAU with training and experience in applied ethics can assist in identifying and addressing cultural factors that might affect how the general community perceives the research.
- Legal requirements must take precedence over other considerations in the organisation and operation of an EAU.
- The work of the EAU should recognise the goals of the organisation connected with the ethics assessor, but this should not undermine the independence of the EAU's decisions.

4.11 Summary of Recommendations

This section includes a summary of the general recommendations made for each of the various aspects of ethics assessment units that have been discussed. While these recommendations have already been presented through this chapter, they are gathered together here for convenience.

Composition and Expertise

- The number of members in an EAU may depend on any legislative requirements for the size of an EAU, the available resources, and the need in include a diverse number of perspectives on research while maintaining a manageable size to allow for fruitful discussion and deliberation.
- The membership of an EAU should be arranged so that it encourages rigorous discussion and evaluation of R&I activity. This is best achieved by a membership that is *competent* (technically, ethically, and administratively), *independent* of the researchers and the institutions involved, *diverse* in backgrounds and expertise, and *representative* of the communities affected by its decisions.
- The EAU chairperson should possess strong administrative competence. Such competence includes good interpersonal skills for managing group decisions and good communication skills to convey the EAU's decisions to researchers and supervisors.
- EAU members should possess the following characteristics:
    - Relevant expertise (professional members) or an informed interest (non-professional members/lay persons, experts from other fields) in the research under assessment
    - Good communication skills, both written and interpersonal
    - An ability to evaluate the benefits, risks, and burdens associated with the specific research projects assessed
    - An ability to engage in reasoned debate and discussion to reach and accept a balanced view of the research projects assessed
    - Personal commitment to the goals of ethics assessment
- Those with expertise relevant to the R&I activity under review should be included among the members of an EAU. However, persons without directly relevant expertise should be an equally important section of the membership.
- Lay persons (persons without expertise relevant to the research, including members of the general public) should be included in the membership of an EAU, and their views must be taken into consideration. They should be aware that their role is to view the R&I activity both as someone from outside the research community and as someone belonging to a group of people who may participate in the activity.

- Lay persons should only be permitted to serve as an EAU member for a limited time so that they continue to provide an 'outside' perspective on R&I activity.
- Ethical and legal expertise should be included among an EAU's membership.
- EAU members with an apparent conflict of interest should not participate in discussions or decisions where that interest may affect their judgement.

Appointment and Training

- In general, the chief executive of the organisation containing the EAU should appoint the EAU chairperson.[321] The chief executive, based on recommendations made by that organisation's research administrators, may also appoint the other members.[322] If the EAU is only responsible for reviewing the R&I activity of a specific branch of an organisation (such as a single faculty within a university), the chief executive of that branch should be responsible for appointing the EAU members.
- The EAU chairperson should be able to appoint temporary members with specific expertise if she believes that additional expertise is necessary to assess fairly particular R&I activity. The selection of these temporary or 'ad hoc' members may be performed by the chairperson in consultation with the EAU's supervisor. Temporary members may be treated as advisors to the EAU who present their informed opinion of the activity under review, or as temporary members who participate in the EAU's full decision-making process.
- Ethics training could be make more effective by incorporating it into other policies and procedures that require training. Training in dealing with ethical issues could be included in the quality assurance system.
- Ethics assessment should be better integrated in political decision-making through education and training in ethical issues for decision makers and by including ethics assessment in decision-making procedures.

Procedures Prior to Assessment

- EAUs should create a standard application form for project assessment that includes the following:
    - information on the person responsible for the conduct of the project;
    - a description of the R&I activity that includes the scientific questions as well as the overall aim and purpose of the activity;
    - a detailed presentation of the proposed methodology;
    - the significance of the R&I/R&D activity and expected benefits achieved;
    - documentation describing the procedures for obtaining informed consent;
    - information on the social impact and context of the R&I/R&D activity;
    - information on documentation and data protection and/or how biological material is to be stored; and
    - information on identified stakeholders.

  If the EAU assesses both medical and non-medical research, such forms should either be worded in a neutral way that makes them suitable for medical and non-medical research, or different forms should be used for different types of research.

[321] Ibid. [p. 30]
[322] Ibid.

- The report or proposal of R&I activity should include a self-assessment prepared by the researchers, which contains their description and assessment of the ethical considerations.
- Pre-assessment/pre-screening of R&I activity should take place, and it should only deal with the question of whether there are any ethical issues that have not been adequately addressed. The pre-assessment of R&I activity is made by one or two persons of the ethics committee, while the full EAU will conduct the full assessment of activities if such assessment is needed, e.g. when there is a high-risk project. The pre-assessment should involve:
  (i) a summary of the activity,
  (ii) a reflection on the ethical considerations that the researchers have identified as well as a reflection of how the researchers will deal with them,
  (iii) an analysis of other ethical concerns that the researchers may have not addressed, and
  (iv) a suggested decision (for which the pre-assessor could give reasonable arguments).
- EAUs should assess on-going R&I activity where either of the following situations has occurred:
  - The activity has already been approved but has undergone essential changes that may affect the risk of harm or other relevant ethical aspects. In these cases, the researchers should submit a proposal for amending the former application.
  - The activity has not undergone ethics review but the researcher (or equivalent agent) identifies ethical issues that ought to undergo ethics review. In these cases, the researchers should submit a new application to the EAU for review.

Procedures During Assessment

- All EAUs should have an established decision procedure to prevent arbitrary decisions from being made. Whether the method for assessing ethical issues is based on a top-down approach starting from ethical principles or it is casuistic is less important.
- The assessment procedure should be designed to ensure that the conducted R&I activity:
  (i) protects stakeholders (e.g. individuals participating in research) from undue risk and harm,
  (ii) ensures that participation in research, trials and similar activities related to the R&I activity is voluntary,
  (iii) determines if the research or innovation methods are appropriate, and
  (iv) aims to increase the awareness of the ethical impact of R&I.
  Some of these goals can be achieved by using a checklist for relevant and pressing issues.
- The decision-making procedure should be made public for the sake of transparency.
- There should be a method for how to deal with the issue of weighing the benefits of the activity against the risk and harm. However, before weighing the harms against the benefits of the activity, it should be considered whether there are ways to redesign the research or the product to reduce the risk.
- The EAU should ask the applicant to revise their application rather than reject it if they require more information or they identify readily avoidable ethical issues with an application.
- The decision-making procedure should be made public for the sake of transparency. However, regulatory requirements and confidentiality considerations should be considered with regard to whether decisions are made public or are only made available internally.

Procedures After Assessment

- The decisions of the EAU should be recorded for internal access and for external reference if required by legislation or auditing.
- After the review/decision, the submitter should receive a written judgment regarding the ethical issues. The decision may vary depending on whether the assessment is obligatory or non-obligatory. If approval has been given (in the case of an obligatory ethics assessment), a favourable report is issued. If there is a need of minor amendments, the committee will ask the researcher to submit a revised proposal. In case of a non-obligatory assessment the EAU will give a recommendation that the R&I activity should either proceed, be revised, or halted.
- If approval is not given and the decision is binding, the applicant should have the opportunity to appeal the EAU's decision.
- If resources permit, there should be monitoring for compliance with ethical guidelines and assessments even if the EAU's decisions are non-binding. If decisions (especially binding ones) are to be followed up, procedures should be in place that state what measures to take in case of non-compliance.
- There should be QA monitoring of both whether the researchers followed the EAU's decision and whether the researchers found the EAU effective.

Supervision

- Those responsible for the work performed by an EAU have the strongest interest in supervising their work and ensuring that it is of a high quality.
- EAUs should be supervised by a high administrative or managerial level of the organisation within which they operate.
- The supervision of EAUs should not compromise their ability to be independent in their decision-making. Using external auditors and performing quality assurance of the EAU's work are both ways of demonstrating the quality of the EAU's work and that it is fair and unbiased.
- Policies should be put in place that require the supervisors of EAUs to take the assessment of the EAU into account when deciding on whether to proceed with R&I activity.

Quality Assurance

- EAUs should take responsibility for performing quality assurance for their policies and procedures.
- QA should be incorporated into the EAU's policies.
- EAUs should self-evaluate about their ethics assessment policies and procedures on a defined, regular basis (either using the SATORI adapted PDCA approach outlined in this section or an alternative means). They should also gauge the views of relevant stakeholders on their assessment policies.
- Wherever possible, EAUs should use external third party evaluation services and gain accreditation in QA.

Efficiency Considerations

- Pre-assessment of research proposals should be used to ensure that the EAU's time and effort is focused on proposals that required detailed assessment.

- The procedures for ethics assessment should be clearly stated so that researchers have clear expectations about the time needed to perform assessment. The EAU should also keep the researchers informed about the progress of the assessment.
- The number of EAU members should be no larger than necessary to meet any national requirements for EAU membership and to fulfil the requirements for the EAU membership to be competent, independent, diverse, and representative.
- The PDCA approach (Plan/Do/Check/Act) can be used to evaluate the EAU's procedures to ensure that resources are used effectively.

Cultural and Organisational Factors

- Cultural factors should only justify imposing stricter requirements than those required by law and by relevant national and international research practice guidelines.
- Ensuring that the membership of the EAU includes those trained and experienced in applied ethics assists in identifying and addressing cultural factors that may influence public perceptions of the research under assessment.
- Legal requirements must take precedence over other considerations in the organisation and operation of an EAU.
- The work of the EAU should recognise the goals of the organisation connected with the ethics assessor, but this should not undermine the independence of the EAU's decisions.

5 ETHICAL IMPACT ASSESSMENT

This chapter is an extended summary of Annex 1 of this deliverable. It contains a shortened overview of the Common Framework for Ethical Impact Assessment (EIA).

An ethical impact is an activity (e.g. fraudulent conduct of research), event (e.g. environmental damage), outcome (e.g. knowledge about cloning humans) or an artefact (e.g. a nuclear weapon) in the context of research and innovation that can be identified as having normative implications. An ethical impact can be identified by moral intuition, consultation and participation. Ethical impact assessment (EIA) is a non-prescriptive[323] process of assessing the ethical impacts of R&I activities, outcomes and technologies. This assessment incorporates both means for contextually identifying and evaluating these ethical impacts, and translating them to be usable at a policy level, by providing guidance for implementing remedial actions or recommendations.

The need for EIA methods emerged from the increasing focus on responsible research and innovation in policy contexts and in collaborative efforts of researchers,[324] as well as from new legal regulations for research and innovation at the European level. Moreover, the increasing impact of research and innovation on society and the increasing pace of technological advancements call for a reflection on the impacts of these transformations, on society.

In this chapter, we present our own proposed framework for ethical impact assessment. This proposal may be used by the following organisations in the following ways:

- For governance bodies to set up new regulations with regards to ethics assessment in R&I;
- For RFOs to set up new procedures for conducting EIAs in the projects they fund;
- For local research organisations and companies for setting up internal procedures for conducting an EIA in the R&I projects they organise.

Our framework presents the EIA process as a series of six stages: the EIA threshold analysis stage, the preparation of the EIA plan, the ethical impact identification stage, the ethical impact evaluation stage, the remedial actions stage, and the review and audit stage. Below, we outline the functions, the essential elements and the specific procedural steps of each of these stages. Moreover, we formulate different recommendations for properly implementing each stage of the EIA process.

5.1 Ethical Impact Assessment Procedure Proposal

Our proposed procedure for EIA is presented in Table 3. Further details and recommendations on each stage of the procedure are given in the following sub-sections.

[323] Wright, David, "A Framework for the Ethical Impact Assessment of Information Technology", *Ethics and Information Technology*, Vol. 13, No. 3, September 2011, pp. 199–226.
[324] Owen, R., P. Macnaghten, & J. Stilgoe, "Responsible Research and Innovation: From Science in Society to Science for Society, with Society", *Science and Public Policy*, Vol. 39, No. 6, December 2012, pp. 751–760.

1. **Conduct an EIA threshold analysis** i. Complete the EIA questionnaire ii. Send the finished documentation to the ethics assessor or conduct a self-assessment iii. The threshold analysis is either accepted, rejected or there will be a request for amendments
2. Prepare and EIA plan i. Assess the scale of the EIA ii. Allocate a budget to the EIA iii. Compose a team for the EIA iv. Review and approval of the EIA plan v. (Optional) Repeat the threshold analysis at different stages of the project, critically when there are significant changes in the project vi. (Optional) Consult with relevant stakeholders to raise awareness of the project taking place and gather more details about possible ethical impacts
3. Set up and execute an ethical impact identification assessment i. Assess the Technology Readiness Level (TRL) of the R&I project's outcomes ii. Review existing work on ethical impact (EI) anticipation and determination in the relevant R&I field iii. Select appropriate methods for conducting the EI anticipation and determination based on the TRL and the threshold analysis iv. Gather relevant data (evidence based, by consulting experts, by interacting with stakeholders, based on creativity) v. Determine possible, probable and/or preferable ethical impacts vi. Document and present the ethical impacts
4. Evaluate the ethical impacts i. Decide which methods should be used (desk research, expert consultation or participatory method) ii. Conduct a contingency analysis to evaluate the likelihood of ethical impacts to occur iii. Assess the relative importance of ethical impacts iv. Identify potential or actual value conflicts and, if possible, aim at resolving these v. Formulate workable conceptualisations of the relevant ethical impacts vi. Document and present the ethical impacts evaluation
5. Formulate and implement remedial actions i. Gather relevant information about remedial actions proposed by other R&I projects ii. Formulate and implement design interventions iii. Formulate different types of recommendations iv. Document and present the remedial actions

6. Review and audit the EIA outcomes i. At the beginning of the EIA: set the milestones and criteria for the review and audit process ii. During the EIA: evaluate the EIA documentation and the agreed upon criteria and milestones iii. At the end of the EIA: ensure proper documentation, follow-up and signing off of the EIA iv. Document and present the review and audit outcomes

Table 3: Procedural steps of the Ethical Impact Assessment process

5.1.1 Threshold Analysis

The threshold analysis stage of an EIA is aimed at determining whether an EIA should be implemented in an R&I project.

Why conduct a threshold analysis?

- To assess the expected number and severity of ethical impacts.
- To determine whether or not an EIA is needed, according to the ethical impacts.

Who performs the threshold analysis?

- Third party organisation representative (e.g. independent consultant).
- Designated administrator for an institution.
- Researcher in the R&I team.

Who reviews the threshold analysis?

- Ethics committees (for public R&I at research institutes).
- Research funding organisations (for R&I funded by these organisations).
- Internal department, company associations, consultancies (for commercial R&I).

Essential elements for a threshold analysis:

- An overview of relevant ethical impacts.
- A questionnaire based on this overview.
- Communication of the outcomes of the threshold analysis.

Recommendations for the Threshold Analysis Stage

- Certain R&I projects could be exempt from conducting a threshold analysis, especially projects that are based on a research funding call that already includes substantive requirements for ethics.
- An occasional peer-review process should be institutionalised, which means that independent researchers review on an periodic basis the threshold analyses of their peers in order to guarantee the independence of the reviewing institution (the university, funding organisation, etc.).
- The requirement for a threshold analysis should be included in research funding calls.

5.1.2 Preparation of EIA plan

The EIA preparation is aimed at setting out the parameters of the EIA activities: including the budget and team composition for the execution of the EIA.

Why prepare an EIA plan?

- To make the EIA execution compatible with the overall R&I project.
- To allocate sufficient resources to the execution of the EIA.

Who sets up the EIA plan?

- The research team (e.g. a consortium), leading a public or private R&I project.
- Third party representative of an organisation (e.g. an independent consultant).

Who reviews the EIA plan?

- An ethics committee at the respective institution.
- The body funding the R&I project.
- Responsible entity in a company.

Essential elements of an EIA plan:

- Assessment of the EIA scale: small-scale, medium-scale or large-scale.
- Budget composition: taking into account the EIA scale and the budget of the overall R&I project.
- Team composition: taking into account the EIA scale and the experience and seniority of assessors.
- Review and approval of the EIA plan: reviewers accept the plan, ask for amendments or reject the plan.
- (Optional) Agreeing on periodic threshold analysis.
- (Optional) Setting up a preliminary stakeholder consultation.

Recommendations for setting up the EIA plan

- Public institutions should provide the necessary funds so that researchers can apply for a grant that covers their activities while working on the EIA plan. This would ensure that the EIA plan is not an unnecessary financial or resource burden for a project team working on an R&I project proposal.
- A ready-made format for EIA plans could be provided by R&I institutions, to speed up the process of setting it up.

5.1.3 Ethical Impacts Identification

In the EI identification stage, the persons involved in the EIA attempt to map the ethical impacts that might occur in the context of the R&I project and put them on a timeline (short-term, medium-term, and long-term impacts).

Why conduct the ethical impact identification?

- To describe probable futures regarding the ethical impacts of the R&I project.
- To describe the relevant research outcomes that can lead to ethical impacts.
- To identify ethical values and principles and relevant stakeholder interests regarding these impacts.

Who performs the ethical impact identification?

- Researchers working within the R&I project
- External experts

- Designated consultants

Essential elements for ethical impact identification stage:

- Conducting the TRL assessment, based on explicit criteria
- Select and use methods for EI anticipation:[325]
    - For small-scale EIA:
        - Horizon scanning
        - An expert consultation
        - Stakeholder consultation
    - For mid-range EIA:
        - Trend analysis
        - Stakeholder brainstorm/futures wheel
        - Roadmapping
    - For full-scale EIA:
        - Delphi interviews
        - Citizen panels
        - Scenario writing
- Select and use methods for EI determination:
    - Conceptual investigations:
        - Ethical checklist approaches
        - Use of ethical theories
        - Situational approaches
    - Empirical investigations:
        - Consolatory/consultative approaches (consulting stakeholders)
        - Techno-ethical scenario building (collaboratively come up with scenarios in which ethical impacts could occur)

Presentation of the ethical impact identification results

- Presentation of the results will involve:
    - Small scale EIA: A report with the EI anticipation and determination results
    - Mid-range EIA: Additionally, academic publications
    - Full-scale EIA: Additionally, public presentation of the EIA outcomes, especially of stakeholder engagement

Recommendations for the** ethical impact identification **Stage

- A repository of documentation of the ethical impact identification stages for R&I projects would be very useful to avoid duplication of the same activities.
- If the impacts of an R&I project remain uncertain, more resources of the EIA should be allocated to the foresight studies in the ethical impact identification stage.
- In the event that periodic reviews of the EIA take place, the assessor(s) may be requested or required to work on certain milestones with regards to the presentation of the EIA outcomes (e.g. a report, publications or public presentation of the results).

[325] For more detailed information, see EFP, *European Foresight Platform*, 2012. http://www.foresight-platform.eu/community/forlearn/what-is-foresight/.

5.1.4 Ethical Impacts Evaluation

The EI evaluation stage evaluates the relative severity of the potential impacts, the likelihood of their occurrence, and any potential value conflicts that may arise.

Why conduct the ethical impacts evaluation?

- To assess the relative importance of identified ethical impacts.
- To locate potential value conflicts and, where possible, to resolve them.
- To find workable conceptualisations of the ethical impacts and the applicable ethical values/principles.

Who performs the ethical impacts evaluation stage?

- Researchers working within the R&I project
- External experts
- Designated consultants

Essential elements for the ethical impacts evaluation stage:

- Select the appropriate methods:
    - Desk-research approaches
    - Expert consultations
    - Participatory approaches
- Evaluate the relative importance of the ethical impacts:
    - To evaluate the normative importance of ethical impact:
        - For basic EIA procedures: desk review and use of ethical theories.
        - For mid-range and full-scale EIA: Expert consultation and stakeholder engagement.
    - To evaluate the risk of violation of ethical principles/values involved:
        - For basic EIA: use outcomes of the contingency analysis.
        - For mid-range and full-scale EIA: consult experts for input on these outcomes.
    - To evaluate the severity of ethical impacts:
        - For basic EIA: Analyse factors of scale and intensity of ethical impacts.
        - For mid-range and full-scale EIA: consult experts for input on this analysis.
    - Identify and resolve (if possible) value conflicts:
        - Use five rules of thumb for determining appropriate procedures:
            1. Reference to ethical theories and/or widely acknowledged documents on human rights.
            2. Take the severance of ethical impacts into account.
            3. Construct an ethical argument to resolve the value conflict.
            4. (Only for mid-range and full-scale EIA) Consult stakeholders for balancing conflicting values.
            5. Formulate ways in which the ethical impact can be avoided if negative, and promoted if positive.
    - Construct workable concepts:
        - Conduct a literature review.
        - Construct a definition of the relevant value/ethical principle.

Presentation of the ethical impacts evaluation results

- Presentation of the results will involve:

- Small scale EIA: A report with the ethical impact evaluation results
- Mid-range EIA: Additionally, academic publications
- Full-scale EIA: Additionally, public presentation of the EIA outcomes, especially of stakeholder engagement

Recommendations for the Ethical Impacts Evaluation Stage

- Because of the controversial nature of deciding on the relative importance of ethical impacts, assessors should be required to be nuanced in conducting this evaluation.
- Since certain knowledge of ethical theories would be a prerequisite, it would be recommended to provide for sufficient training for the assessor in order to ensure the assessor's knowledge is sufficient in this area.
- A knowledge repository with documents relevant for the EI evaluation stage (such as widely acknowledged lists of ethical principles and human rights declarations) would be very useful for assessors to reduce the amount of time spend on activities such as desk review.

5.1.5 Remedial Actions

In the remedial actions stage, remedial actions may be designed and performed in response to the negative impacts found and analysed during EI anticipation & determination and EI evaluation stages.

Why conduct a remedial actions phase?

- To translate the earlier findings in the EIA into practical recommendations for the relevant stakeholders.
- To translate the earlier findings in the EIA into design interventions at the project level.
- To identify possible gaps between the earlier findings and practical possibilities for remedial actions and, if necessary, reiterate parts of the previous stages.

Who performs the remedial actions?

- For design interventions: project-wide collaboration between researchers and assessor(s).
- For societal and organisational recommendations: the R&I project's assessor(s).
- For regulatory and policy recommendations: the R&I project's assessor(s) in collaboration with legal or policy experts.

Essential elements of the remedial actions:

- Collect information about remedial actions proposed by related R&I projects.
- Formulate and implement design interventions by implementing value sensitive design:
  - Articulate the relevant values
  - Investigate the empirical context of technology deployment
  - Alter the technological design of R&I outcomes
- Formulate different types of recommendations:
  - Societal recommendations
  - Organisational recommendations
  - Regulatory recommendations
  - Policy recommendations

Presentation of the remedial actions:

- For design interventions: report with proposed interventions and/or conduct a stakeholder survey.

- For societal and organisational recommendations: a simple report, based on existing recommendations and project-specific ones.
- For legal recommendations: legal proposals.
- For policy recommendations: green/white papers.

Recommendations for the Remedial Actions Stage

- The value sensitive design approach needs to be developed further to make it fit with actual R&I practices. At this point, the framework offers only a fairly abstract groundwork on how to implement value sensitive design.
- Overall, recommendations should be viable and implementable. It would also be beneficial to have experts or other external stakeholders to review draft recommendations before their finalisation.[326]
- More concrete frameworks for the way in which recommendations can be drafted should be proposed, primarily with the aim of increasing the communicability of the EIA outcomes as well as giving reviewers of the EIA better criteria for assessing its effectiveness.

5.1.6 Review and Audit Stage

The review and audit stage of an EIA ensures independent evaluation of the EIA process and, if necessary, independent corrective intervention in it.

Why conduct a review and audit?

- To provide constructive feedback for improving the execution of the EIA process.
- To provide guidelines for successfully finalising the EIA process.
- To guard agreed-upon milestones and KPIs (key performance indicators) of the EIA process.

Who performs the review and audit?

- The local ethics committee
- The R&I funding organisation
- Internal or external commercial organisation

Essential elements of a review and audit:

- At the start of the EIA:
  - Set review and audit planning
  - Establish review and audit criteria
- During the EIA:
  - Intermediate review(s): monitoring, evaluation, management and communication of the EIA
  - Intermediate audit(s): review audit criteria and issue an opinion on the EIA progress
- At the completion of the EIA:
  - Conduct a final review, with final EIA and review reports

[326] Wright, David, "Ethical Impact Assessment", in J. Britt Holbrook and Carl Mitcham (eds.), *Ethics, Science, Technology and Engineering: A Global Resource, 2nd edition*, Macmillan Reference, Farmington Hills, MI, USA, 2015 [p 165].

- Conduct final audit, with financial statement, portfolio of publications and follow-up actions

Presentation of the review and audit:

- At the start of the EIA: a contract with review and audit criteria
- During the EIA: Intermediate review and audit reports
- At the finish of the EIA: Final EIA and review reports, financial statement and publication portfolio

Recommendations for the Review & Audit Stage

- RFOs should consider establishing a body that is responsible for conducting the review and audit of EIAs.
- An independent body may need to be installed for ensuring the independence of the review body. This might be a watchdog organisation at the EU level, for instance.
- Review and audit procedures should preferably be standardised as much as possible to decrease their administrative burden, perhaps by providing for an online entry system in which the assessor can present the necessary EIA outcomes, for example.

6 SPECIALISED FORMS OF ETHICAL ASSESSMENT AND GUIDANCE

In this section, we present recommendations for specialised forms of ethics assessment and guidance. Specifically, we outline standards, tools and best practices for (1) policy-oriented assessment and guidance of new developments and practices in R&I; (2) guiding, assessing and supporting ethical professional behaviour by scientists and innovators; and (3) the ethics assessment of innovation and technology development plans.

There are three annexes that expand on the three subsections of this section: Annex 2, Annex 3 and Annex 4.

6.1 Standards, Tools and Best Practices for Policy-Oriented Assessment and Guidance of New Developments and Practices in R&I

This subsection is a summary of Annex 2 of this deliverable (which has the same title as this subsection).

Ethical guidance has two major applications: (1) guidance for decisions, behaviours and practices in R&I, and (2) ethics assessment of R&I. This section presents recommendations for standards in policy-oriented assessment and guidance of new developments and practices in R&I. Policy-oriented assessment is understood here as the ethics assessment of (new) scientific fields, methods, techniques, technologies, devices or innovation areas. Proposals are made based on the literature review and codes of ethics discussed in SATORI deliverables.

To develop these proposals, we analysed how policy-oriented guidance, assessment and expertise is organised. We focused on policy-oriented assessment and guidance of three different types of stakeholders: government organisations, national ethics committees, and civil society organisations. Our recommendations for each stakeholder are listed below. Many of these recommendations presented here align with the recommendations for ethics assessment that are presented in chapter 4.

6.1.1 Governmental Organisations

- Recommendations for guidance:
  - Directly involve CSOs in the ethics guidance process
  - Regularly evaluate the ethics guidance procedures
  - Include community members and lay persons in ethics guidance processes
  - Create greater public visibility of ethics guidance
  - Ethical guidance must rest on ethical values and principles that are in line with society
- Recommendations for assessment:
  - Include non-ethicists in ethics assessment committees
  - Transparently align different law regimes
  - Diversify the ethics assessors according to country, gender, etc.
  - Prevent an “ethics creep” from happening; minimise bureaucracy
- Recommendations for the role of experts:

- Take into account the value of democratic decision making in the composition of ethics guidance and assessment bodies
  - Voting of committee members amongst peers
  - Allotment of lay people as representatives[327]
- Take into account the accountability of expert bodies
  - Follow strict rules of representation in appointing committees
  - Guarantee diversity in committees
- Experts should engage in public debates

- Recommendations for procedures:
  - Monitor the implementation of procedures
  - Take into account the sensitivity for intercultural differences

6.1.2 National Ethics Committees

- Recommendations for policy-oriented guidance:
  - NECs should respect the international regulatory frameworks as applicable to biomedical research and innovation.
  - NECs should develop reference principles according to the topic under scrutiny and should be transparent about the ethics framework applied.
  - NECs should aim at providing recommendations for the political level and at fostering debate, education and public awareness of, and engagement in, ethics assessment in R&I.
  - NECs should be established by law.
  - The work of National Ethics Committees should be supported by a permanent secretariat.
- Recommendations for the role of experts:
  - NECs should be established as independent, multidisciplinary and pluralist (representing different ethical traditions) ethics bodies.
  - The legal base of a National Ethics Committee should also provide for an equal gender distribution of members.
- Recommendations for procedures:
  - NECs should work on topics that are assigned to them by the authorities under which they are operating. They should, however, also be able to select topics that they deem necessary to evaluate in order to contribute to relevant national or international debates.
  - With regard to working methods, NECs should organise plenary discussions, which can be prepared by working groups or rapporteurs. Room should also be given for the discussion of dissenting opinions.
  - After the publication of an opinion, NECs should inform the responsible authority about their views and should actively disseminate their opinion to the public. Dissenting opinions should also be published in the same document as the majority opinion.

[327] See also Seyfang, Gill, & Adrian Smith, "Grassroots Innovations for Sustainable Development: Towards a New Research and Policy Agenda", *Environmental Politics*, Vol. *16, No.* 4, 2007, pp. 584–603.

- In order to foster international debate, NECs should attempt to provide their opinions in a language understood by the international community.

6.1.3 Civil Society Organisations

- Ensure the participation of CSOs in research projects.
- Strengthen the CSO's mandate to have representatives in research ethics committees; encourage CSO to participate in RECs.
- Ensure the participation of CSOs in institutionalised forms of ethics assessment or guidance and formal advisory panels; it would allow CSOs to develop expertise in the area of assessment and guidance. At the same time, it is necessary to make sure the functioning of any mechanisms is transparent and remains open to interested parties.
- Strengthen the CSO's right to participate in decision-making. CSOs should be able to comment on policies, plans, programmes and proposals for R&I projects that affect society. They should receive feedback on their involvement in decision-making.
- Engage CSOs in ethics capacity building and training to enhance their capacity to perform ethics assessment or guidance.
- Encourage CSOs' networking and creating working groups devoted to ethics assessment and guidance.

6.2 Standards, Tools and Best Practices for Guiding, Assessing and Supporting Ethical Professional Behaviour by Scientists and Innovators

This subsection is a summary of Annex 3 of this deliverable.

This section presents recommendations regarding standards for guiding, assessing and supporting ethical professional behaviour by scientists and innovators. Ethical professional behaviour is defined as a part of research ethics, specifically aimed at ethical principles, applicable to the conduct of individual scientists and innovators (engineers). Proposals are made based on the literature review and the codes of ethics discussed in SATORI deliverables.

6.2.1 Proposal of Ethical Standards

- For professional researchers:
  - *Objectivity & impartiality*
  - *Truthfulness & transparency*
  - *Honesty & openness*
  - *Respect & fairness*
  - *Conformity to regulation, guidelines and good practices*
  - *Integrity in international cooperation*
  - *Social responsibility*
- For professional engineers:
  - *Honesty & integrity*
  - *Accuracy & rigour*
  - *Holding paramount safety, health and welfare of the public*

- *Objectivity, impartiality and verifiability*
- *Transparency & fairness*
- *Promoting collaboration*
- *Promoting engagement with the and social responsibility*
- *Continuing learning and professional development*
- *Conformity to regulations and good practices*

6.2.2 Recommendations for Ethical Guidance of Professional Behaviour of Researchers

- Recommendations for the research community:
  1. The responsibility for ethical professional behaviour should be acknowledged by individual institutions that conduct research and employ researchers (universities, research institutes, companies), but also other stakeholders in the research process, such as RFOs, academic journals, governmental organisations responsible for research policies, integrity boards, science academies and professional organisations.
  2. Stakeholders should strive to cooperate to achieve a research environment that encourages ethical professional behaviour on all levels (national-international, funding, research process, publishing) by creating international guidelines, national governance systems, forums for discussion and exchange of information, etc.
  3. The initiative to raise awareness on ethical professional behaviour and develop guidelines in a particular country or scientific field should be taken up by independent and representative institutions, such as science academies, professional associations, university associations, science foundations, etc.
  4. In order to embed ethical professional behaviour in the research cultures, institutions should review the ways in which they evaluate researchers' work, e.g. preferring quality over quantity, etc.

- Recommendations for individual institutions:
  1. Individual institutions should establish a body (e. g. committee, office) with a mandate and resources to:
     a) develop a coherent and integral institutional research integrity policy, including the development of guidance and assessment procedures and strategies,
     b) provide information services, awareness raising and other activities aimed at encouraging the acceptance of developed guidelines and procedures and their integration into the research culture. If this is not possible due to the size of the institution or limited resources, institutions may refer to existing frameworks by professional associations, science academies or other institutions.
  2. To encourage ethical professional behaviour and prevent misconduct, universities should include ethics in their curricula and offer ethics classes and training sessions. Research institutions should offer training and organise workshops and conferences to raise awareness and discuss research integrity issues.

6.2.3 Recommendations for Ethical Assessment of Professional Behaviour of Researchers

- *Recommendations for the research community:*
    1. A national system of assessment of professional behaviour is recommended as it reduces the risks of internal institutional assessments (e.g. conflict of interest, covering up of misconduct, etc.) and allows for the development of more efficient assessment procedures and practices.

- *Recommendations for individual institutions:*
    1. Institutions that conduct research should establish fair and transparent procedures for assessment of ethical behaviour of scientists and innovators.
    2. Research institutions should take measures so that researchers and innovators are aware of what constitutes misconduct and are well informed of the assessment procedures.
    3. Each research institution should have a contact person for professional research behaviour whose contact details would be easily publically available and who could be contacted concerning any suspicions of misconduct (e.g. when findings from a journal article published by institutions' researchers could not be reproduced, for example).

6.3 Standards, Tools and Best practices for the Ethics Assessment of Innovation and Technology Development Plans

This subsection is a summary of Annex 4 of this deliverable.

This subsection outlines our proposals for the specific adaptation of the SATORI ethical impact assessment approach (as described in chapter 5 and Annex 1 of this Deliverable) to ethics assessment of innovation and technology development plans.

In innovation and technology development, three main stages can be distinguished: basic research, applied research and innovation and development. While *research* is understood as 'the conception or creation of new knowledge, products, processes, methods and systems',[328] *development* is a 'systematic use of knowledge or understanding gained from research.'[329] However, taking into account the chain-linked model of technological innovation (CLM) by

[328] Frascati Manual, OECD, "Proposed Standard Practice for Surveys on Research and Experimental Development", 2002.
[329] AAAS, "Definitions of Key Terms", http://www.aaas.org/page/definitions-key-terms.

Kline & Rosenberg[330], it should be emphasised that the innovation process has a non-linear character, as 'science is part of the process, but not necessarily the initiating step.' [331]

In the first main stage of the innovation and technology development plans, the basic research, research is conducted as an end to itself; without any plans of application. It can be described as 'pure science' and is not working towards any social improvements.[332] As the possible (later) applications are therefore not yet determined and hence even more applications are to consider, ethics assessment in this stage should contain a significantly expanded foresight stage. However, it should be kept in mind that EIA of basic research has its limits, as all predictions remain uncertain to some degree.

In contrast, the second main stage, applied research, is conducted to gain knowledge or understanding necessary for meeting a specific need.[333] Ethical impact assessment is similar to the one in the third stage, innovation - development. However, EIA in applied research should focus more on the foresight stage than the one of the third stage and therefore also resembles the EIA of the first stage, which is an indicator of the blurring line between basic and applied research. Two factors contribute to these blurred boundaries: First, limits in financial resources force scientists to research on topics with a profitable application, leading to a loss of "pureness" in basic research. Second, it is increasingly acknowledged that researchers do not only have the responsibility to conduct "good science" as in peer-reviewed and free from misconduct, but also as in considering social accountability.

Subsequently, EIA in the third stage, innovation – development, should focus less on foresight than EIA in the first stages, as it is already clear which end-products should be evaluated. The end-products of the third stage can be categorised into (1) structures and spaces, e.g. parks, squares, industrial buildings and artificial islands, (2) products, e.g. machines, tools, materials and services, and (3) applied systems and processes, meaning a set of interacting or interdependent component parts or activities forming a whole. Every category benefits from a different focus in the respective EIA. EIA of structures and spaces benefits from an increased stakeholder participation, as these goods have a large impact on communities. For products, the EIA can be based on the analysis of ethical principles, as it is more cost- and time-efficient. Even though stakeholder participation is helpful, it is not as necessary as for (1), since products are bought and used voluntarily. Thirdly, as product-type goods are produced by commercial businesses, EIA should be incorporated in strategies for corporate responsibility tools (CR). Next to these three categories, a third stage's end-product can also be a project that aims at developing and implementing plans and programs, such as environmental, land use, regional, urban and spatial plans; technology development programs; and product development programs. As these programs are developed on a very large scale, their implementation has a large impact on people

[330] Kline, Stephen J, and Nathan Rosenberg, "An Overview of Innovation", in Ralph Landau and Nathan Rosenberg (eds.), *The Positive Sum Strategy: Harnessing Technology for Economic Growth*, National Academies Press, 1986, pp. 275-305.
[331] Caraça, João, Bengt-Åke Lundvall, and Sandro Mendonça, "The changing role of science in the innovation process: From Queen to Cinderella?", *Technological Forecasting and Social Change,* Vol. 76, No. 6, July 2009, pp. 861-867 [p. 864].
[332] Briggle, Adam, and Carl Mitcham. *Ethics and Science: An Introduction*, Cambridge University Press, 2012.
[333] AAAS, "Definitions of Key Terms", http://www.aaas.org/page/definitions-key-terms.

and the environment. Just as the EIA of the first category, structures and spaces, the EIA of these programs calls for an increased stakeholder participation.

In addition to the different end products of the development stage, different sub-stages can call for a difference in EIA. These are (1) the conception, where research on a new future product is conducted, (2) the definition, where the feasibility is evaluated and eventually, a prototype is made, (3) the development, where the product is designed and engineered, and (4) the implementation, where the new product is constructed, manufactured or installed. Following the process of these sub-stages, the EIA should be adopted to the level of concreteness of the end-product. Similar to the larger scale of the main stages, more attention to foresight should be given in the earlier sub-stages. But as the product becomes more tangible in the last sub-stages, foresight loses importance again.

7 ETHICS ASSESSMENT AND ETHICS GUIDANCE BY SPECIFIC TYPES OF ORGANISATIONS

In this chapter, we discuss proposals for developing ethics assessment and guidance in the context of four specific types of organisations: universities, industry, research funding organisations (RFOs) and civil society organisations (CSOs). The first three types of organisations (universities, industry and RFOs) are the most important agents in the funding and performance of research and innovation; the latter (CSOs) is important in terms of stimulating public engagement with R&I.

The first subsection of this chapter presents best practices for developing ethics assessment and guidance of R&I in universities. The second subsection presents does the same for CSOs. The third focuses on industry. Finally, the fourth subsection details best practices for developing ethics assessment and guidance in RFOs.

The four subsections of this chapter are summarised versions of the full reports contained in Annex 5, Annex 6, Annex 7 and Annex 8.

7.1 Universities

This subsection is a summary of Annex 5 of this deliverable (Models for Ethics Assessment and Guidance in Higher Education).

Within the higher education sector, the major instruments for ethics assessment and guidance are codes of conduct and practice, and integrity boards. For simplicity, we will refer to codes of conduct and practice as *codes of ethics*. Codes of ethics offer guidance to university members on the expected standards of behaviour within their organisation, while integrity boards investigate reported instances of ethical failures and assess whether unacceptable behaviour has occurred.

7.1.1 Codes of Ethics

Codes of ethics can be divided into three categories:

1. Broad codes of ethics or mission statements: General ethical norms and standards of conduct that apply to all university staff.
2. Codes of ethics relating to R&I activity: Ethical and standards of conduct for all researchers working for the university.
3. Codes of ethics relating to R&I activity within a specific discipline: Ethical norms and standards of conducts for researchers working in a particular field for the university.

Codes of ethics in R&I activity offer several compelling benefits: they help increase the trust of state and society in researchers and their work, they draw attention to values and norms that

might otherwise remain implicit, and they are flexible policy instruments.[334] Codes of ethics also serve an important communicative function in making ethical norms and standards explicit.[335]

Our recommendations for university codes of ethics are listed below:

1. Individual universities should develop codes of ethics that explicitly addresses conduct in R&I.
2. A code of ethics in R&I should be general rather than focused on one specific discipline. This allows for a discussion by research ethics committees in diverse fields. However, if further clarifications are needed (e.g. in medicine), specific forms of conduct may be added to the general code of ethics.
3. Codes of ethics should be implemented in the curriculum and institutional strategies. Research integrity boards (described below) are helpful for enforcing these codes.
4. The code of ethics should be revised and updated on a regular basis. It should be regarded as a 'living document' that is open to change, to help identify problems with the code and allow them to be addressed.[336]

7.1.2 Integrity Boards

Integrity boards investigate alleged breaches of the codes of ethics by researchers performing R&I activity. These groups are often associated with research ethics committees, although the focus of integrity boards is largely on investigating and resolving allegations of misconduct rather than reviewing projects for ethical concerns.

Our recommendations for research integrity boards are presented below:

1. The structure and operation of an integrity board must encourage the trust of both the research community and the public in the fairness and accuracy of its decisions. The investigation of alleged misconduct must strive for fairness and credibility, so that the decisions made based on the evidence gathered during the investigation process will themselves be fair and credible.[337]
2. There must be clarity in the legal framework in specifying which organisations are responsible for particular aspects of the inquiry and investigation processes.[338] This is

[334] Boer, Harry de, and Leo Goedegebuure, "'Modern' Governance and Codes of Conduct in Dutch Higher Education", *Higher Education Research & Development*, vol. 26, no. 1, 2007, pp. 45–55 [p. 53].
[335] International Association of Universities, "IAU-MCO Guidelines for an Institutional Code of Ethics in Higher Education", 2012. http://www.iau-aiu.net/sites/all/files/Ethics_Guidelines_FinalDef_08.02.13.pdf. [p. 2]
[336] Anderson, M., & Shaw, M.,"A Framework for Examining Codes of Conduct on Research Integrity", In T. Mayer & N. Steneck (Eds.), *Promoting Research Integrity in a Global Environment,* World Scientific Publishing, Singapore, 2012, pp. 133-147 [p. 142-143].
[337] OECD Global Science Forum, "Best Practices for Ensuring Scientific Integrity and Preventing Misconduct". http://www.oecd.org/sti/sci-tech/40188303.pdf.
[338] Boesz, Christine C., "Developing Research Integrity Structures: Nationally and Internationally", in *Promoting Research Integrity in a Global Environment*, edited by Tony Mayer and Nicholas Steneck, World Scientific Publishing, Singapore, 2012, pp. 7–16 [p. 11].

important for transparency and consistency, as well as for avoiding potential litigation in response to irregularities in these processes.[339]

3. The independence of those investigating alleged misconduct should be guaranteed so that their investigation is fair and impartial. The integrity board should be separate from the research-performing sections of the university. Conflicts of interest (real and apparent) must be avoided, and the integrity board should have the necessary resources to perform its work without having to rely on other sections of the university.[340]
4. The processes for investigating, adjudicating, and appealing against allegations of misconduct should be distinct from each other, so that different parties are involved in each process. This separation is intended to promote fairness in each stage of the process.[341]
5. Collaboration agreements should clearly describe how any allegations of research misconduct would be addressed.[342] The text should include statements of what is considered research misconduct and the procedures through which such allegations will be investigated.[343]

7.2 Civil Society Organisations

This subsection is a summary of Annex 6 of this deliverable (Models for Ethics Assessment and Guidance at Civil Society Organisations).

CSOs face two basic sets of challenges that also affect their involvement in ethics assessment and ethical guidance:

- The lack of dedicated recourses (such as financial resources, work force, in some cases also expert technical knowledge), which is closely related to the ways in which independent CSOs operate and are financed.
- Weak recognition of their formal role in the decision-making process (an exception being, to some extent, environmental matters).

At the same time, the majority of CSOs interviewed during the course of the SATORI project were favourable towards the prospects of creating a common European framework of ethics assessment of research and innovation.[344]

CSOs typically are not a part of a system of practice for ethics assessment that occurs in an institutional setting. Only some CSOs perform activities that can serve as examples of their

[339] Ibid.
[340] Ibid,, pp. 11-12.
[341] Ibid., pp. 14-15.
[342] Ibid.
[343] Ibid.
[344] Out of 28 CSOs 18 were 'positive' towards the idea of creating a framework, 8 were conditionally positive. (see SATORI Deliverable 4.1.1. "Stakeholder analysis on the desirability and possibility of a shared European approach to ethics assessment of research and innovation.")

formal involvement in the process of ethics assessment. Examples include participation in research ethics committees, involvement in assessing research applications and proposals, or acting as independent ethics assessment agents.

With regard to the informal involvement of CSOs in ethics assessment, two basic types of activities can be distinguished: influencing R&I agendas, and monitoring the field of R&I policy and development. Currently many CSOs perform some kind of informal ethics assessment or guidance of R&I as an element of their other activities, such as advocacy, monitoring, preparing policy briefs, campaigning. Their activities however are rarely referred to as concerning ethics.

There are different aims behind the assessment and guidance performed by CSOs. Based on the types of aims, CSOs that are involved in ethics assessment and guidance can be grouped into the following categories:

- oriented towards the society, e.g. maximising the potential of R&I to deliver sustainable solutions, protecting fundamental rights and freedoms;
- oriented towards professional groups, e.g. engineers, science journalists;
- oriented towards (vulnerable) individuals e.g. patients, people living with rare diseases.

The following structures involved in (informal) assessment have been set up in the CSOs interviewed for the SATORI project:

- an informal group within the organisation
- a specific project with dedicated financing
- a sub-group of the board
- a dedicated science unit
- community advisory board, organized on a voluntary basis
- specific units that deal with fields directly related to R&I, such as bioethics, environmental issues and economic and human rights

Bearing in mind the great diversity of CSOs in terms of their focus, the type of expertise, their organisational structure and level or scale of their activity, it is difficult to establish a common set of recommendations that would fit all organisations. Since the vast majority of CSOs were not established as ethics assessors, most of them would lack resources, both in terms of staff and financing, as well as in terms of the ethics assessment related expertise that would be required to perform fully-fledged ethics assessment. Additionally, there may be a lack of trust in the opinions of CSOs as ethics assessors, since they may be seen as leaning towards a specific set of values that defines and shapes their agendas.

In the case of some CSOs, however, it seems justified to recommend their further involvement in research ethics committees as representatives of a specific vulnerable group (e.g. consumers or patients) or as spokespeople for a specific interest (e.g. animal welfare). This involvement would be legitimate if acting on behalf of these groups was defined in the CSO's statutes as one of their key objectives. Such a model ensures that the perspective of those affected by the research is taken into consideration, and contributes to a greater diversity of views within RECs. Moreover,

CSOs who are involved in R&I more directly should consider establishing structures (codes of conduct and procedures) for internal ethics assessment.

At the same time, CSOs that can be identified as those who perform informal ethics assessment in the course of their other activities, should be offered training, in order to increase the awareness of ethical issues, as well as tools such as checklists and general guidelines that can be easily used on an on-going basis in different types of projects.

Another way of strengthening CSOs' capacity to deal with ethical issues in R&I could be by building ethics assessment related CSO networks. Bearing in mind the disparity between different states with regard to the level of civil society involvement in ethics assessment of R&I (concerning, for example, the existence of dedicated organisations, or the level of public involvement in debates about the societal aspects of R&I), there is a need to exchange best practices between organisations and groups from different states.

7.3 Industry

This subsection is a summary of Annex 7 of this deliverable (Models for Ethics Assessment and Guidance in Industry).

Companies are increasingly using structured approaches to monitor the economic, environmental and social impacts of their activities, and taking into account ethical principles and values acknowledged by stakeholders and society. In several cases, as shown by analysis of the SATORI project, these approaches (or part of them) can be considered a form of ethical assessment. Ethics assessment by industry is closely related to the well-established concept in the business world of corporate social responsibility (CSR).

References for ethics assessment and corporate responsibility in the business sector derive from existing normative frameworks and regulations, as well as various types of voluntary initiatives, ranging from codes of practices, frameworks for corporate responsibility (CR), general and sectorial standards, and company specific initiatives.

The reasons to engage in ethics assessment are multifaceted, and relate to the following factors (this list is non-exhaustive):[345]

- Improve product sustainability, desirability and acceptability of products, product quality, safety and reliability, effect on quality of life and health of customers
- Create value, build corporate image and reputation, give competitive advantage
- Motivate workers, improve community relation, increase customer satisfaction and targets or needs

[345] SATORI WP1 analyses and: ISO 26000:2010(E): Guidance on social responsibility; Global Reporting Initiative, G4- Sustainability Reporting Guidelines, Reporting Principles and Standard Disclosure, 2013; Responsible-Industry: A Framework for implementing Responsible Research and Innovation in ICT for an ageing society, a report of the Responsible Industry project, November 2015; 5.6; UN-SDGs: The United Nations Sustainable Development Goals.

- Improve health and safety standards, reduce environmental impacts
- Reduce costs (e.g. use of resources, efficiency of the decision making process)
- Market penetration, profit, compliance with regulatory requests, access to financial support, minimises the risk of lower financial performances

Various barriers that can thwart ethics assessment are (again, this list is non-exhaustive):[346]

- Additional bureaucracy, eventual extra costs
- Heterogeneity in approaches & guideline implementation
- Lack of awareness of ethics issues & structured approaches
- Lack of resources (financial, human, time, knowledge, particularly for SMEs)
- Inability to implement non-binding/failures of self-regulation
- Problem accepting ethical criteria in the research community (beyond what is provided for by law)
- Possible slowdown of innovation
- Additional ethical constraints that might limit creativity
- Ethics is culture sensitive (requirement might change depending from context)

Nevertheless, the rising demand coming from society, the strengthening of laws and regulation, and the increasing awareness that CR is not a cost and it generates value for the company, are pushing industry to embrace ever more social responsibility.[347]

The specific concept of R&I is not addressed by CR tools in a comprehensive manner, with few or no actions designed explicitly for this issue. Therefore, the work of SATORI could provide an added value to these tools by introducing a strategic ethics assessment model explicitly devoted to R&I activities that would be integrated within a broader corporate responsibility framework.

Approaches may differ in terms of the scope and themes considered, but there are several common procedures, tools and experiences that emerged during our analysis. We want to emphasise the following common procedures, tools and experiences as good practices:

- Define the domains of influence and responsibility of an organisation over its impacts
- Identify the relevant topics and prioritize the most important ones for the organisation
- Apply a due diligence process in the evaluation of impacts
- Ensure the commitment of executives to ethics assessment
- Set a strategy for ethics assessment, based on a structured, step-by-step, procedure (e.g. the Plan, Do, Check, Act (PDCA) cycle described section 4.8).

[346] Ibid. and 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. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf [table pp. 75].
[347] "Currents of Change: The KPMG Survey of Corporate Responsibility Reporting 2015", KPMG, 2015. https://www.kpmg.com/CN/en/IssuesAndInsights/ArticlesPublications/Documents/kpmg-survey-of-corporate-responsibility-reporting-2015-O-201511.pdf.

- Ensure a flexible, modular, incremental process (tailored to the organisation type and needs)
- Define responsibility for ethics assessment along the entire hierarchy of the organisation
- Ensure credibility of actions:
    - ensure transparency and accountability of the ethics assessment process
    - engage with stakeholders to evaluate and review impacts and actions; adopt multi-stakeholder approaches
    - regularly communicate results on ethics assessment
    - provide ways for third part evaluation, external assurance of ethics assessment
- promote training and capacity-building on ethics assessment

7.4 Research Funding Organisations

This subsection is a summary of Annex 8 of this deliverable (Models for Ethics Assessment and Guidance at Research Funding Organisations).

The recommendations for ethics assessment by RFOs can be divided into three categories: those concerning the criteria for ethics assessment, those concerning the organisational structure of such assessment, and those on the procedures for conducting ethics assessment. Our recommendations for each category are presented below.

7.4.1 Criteria for Ethics Assessment

- RFOs should verify whether the research proposal meets the national legislation and ethics requirements of the country in which the research will be performed.
- RFOs should verify whether the research proposals indicates the timeframe in which possible ethics review of the research proposed as provided by law will be conducted.
- Ethical issues that go beyond the minimum standards provided by law should be evaluated by RFOs. Evaluation should include the following aspects with an eye on addressing possible vulnerabilities: human embryos/foetuses, human subjects, human cells/tissues, protection of personal data, animals, third country research, environmental protection and safety, misuse of materials, technology and information, and dual use. In addition, evaluation should be based on ethical principles that are specific to particular kinds of research such as research involving human subjects, research involving animals, and research involving possible environmental risks.
- Research conduct should be evaluated in a proactive manner. Evaluation should include the following aspects: research integrity, scientific misconduct, policy criteria such as usefulness of science, open-access strategies, gender issues, transparent communication, benefit sharing, and promotion of the social good.
- RFOs should verify whether the research proposal describes possible implications of results in a satisfactory manner relating in particular to individuals and the society as a whole.

7.4.2 Organisational Structure of Ethics Assessment

- RFOs should establish procedures for in-house ethics assessment going beyond ethics assessment provided by law.
- Ethics assessment should be included in regular project selection procedures in order to install ethics assessment as an overarching principle within their policies.
- RFOs should provide regular training activities in the field of ethics for staff members engaged in project selection procedures.
- Ethics panels should be organised for the full ethics review for all projects that have been identified as ethically problematic in a pre-screening phase by staff members involved in the RFO's project selection who have received prior training in the field of ethics.
- Ethics panels should be independent, multidisciplinary and pluralist by including members from different research fields and ethical traditions that are consistent to the goals of ethics assessment. They should include expertise in the field of research of the project that is proposed, and should also include expertise in the field of philosophy, law, sociology, and ethics (if ethics exists as a separate discipline in the national higher education system).
- RFOs should organise a permanent structured exchange with their national counterparts in order to discuss ethics in relation to new technologies.

7.4.3 Procedures for Ethics Assessment

- Transparent procedures for ethics review should be established.
- EA procedures should consist of different phases. Before the start of the project they should include a self-assessment phase, pre-screening phase, and a full ethics review, if applicable.
- During the implementation of the project, monitoring should also include aspects relating to research integrity, and scientific misconduct. Monitoring of ethics issues during project implementation, if necessary, should be organised through the inclusion of an ethics work package that involves monitoring/evaluation of ethics issues in the project at hand.
- RFOs should make available guides on their ethics assessment procedure, including forms for the self-assessment phase clarifying which ethical principles and issues will be regarded as being of particular importance.
- RFOs should hold a permanent structured exchange with their national counterparts in order to discuss ethics in regard to new technologies.
- RFOs should write regular reports on their deliberations regarding the permanent structured exchange with their national counterparts.
- The procedures, related guides, and the regular reports of their exchanges with their national counterparts should be published by RFOs on their official website.

8 PROPOSALS FOR THE INSTITUTIONAL STRUCTURE OF ETHICS ASSESSMENT IN THE EUROPEAN UNION AND ITS CONSTITUENT COUNTRIES

This chapter presents recommendations on the institutional setup of eight different types of ethics assessors on the EU level. These types of assessors are universities, national science academies, research funding organisations, research ethics committees, national ethics committees, academic and professional organisations, civil society organisations, and companies. Additionally, some recommendations are made regarding the national level of some EU countries. All recommendations are based on previous SATORI reports, especially the annexes of Deliverable 1.1 on the respective types of ethics assessors, and some subtasks of WP 4, concerning models for ethics assessment and guidance in some of the named types of ethics assessors. For many general recommendations (indicated by a numeral), actions (indicated by a letter) are listed that should be taken by specific actors.

This chapter is an extended summary of Annex 9 of this Deliverable.

8.1 Universities

The main instruments for ethics assessment in universities are scientific integrity boards and research ethics committees. For both instruments, the recommendations aim at transparency, consistency and effectiveness.

Scientific Integrity Boards

1. There must be clarity in the legal framework in terms of which organisations are responsible for particular aspects of the inquiry and investigation processes.[348] Different entities should handle the investigation, adjudication/sanctions and appeal phases of an allegation of misconduct.[349]
    a. The relevant body at the national level should establish clear guidelines on investigating scientific misconduct, including overarching principles and standard procedures. It should also decide upfront whether different organisations or bodies within or outside the research organisation are responsible for different categories of allegation of wrongdoing, to ensure that all are covered.[350]
2. The independence of those investigating alleged misconduct should be protected. Conflicts of interest (real and apparent) must be avoided, and the integrity board should

[348] Boesz, Christine C., "Developing Research Integrity Structures: Nationally and Internationally", in *Promoting Research Integrity in a Global Environment*, edited by Tony Mayer and Nicholas Steneck, World Scientific Publishing, Singapore, 2012, pp. 7–16 [p. 11].
[349] Ibid., p. 14.
[350] European Science Foundation and ALL European Academies, "The European Code of Conduct for Research Integrity", 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf [pp. 8–9, 12]..

have the necessary resources to perform its work without having to rely on other sections of the institution.[351]

   a. The relevant body should make the integrity body separate from the research-performing institution and to write out explicit rules aimed at avoiding conflicts of interest.[352]
   b. The relevant body should have all investigators and staff make a "Conflict of Interest Declaration" both when hired and thereafter on a yearly basis.[353]
   c. Investigators of alleged scientific misconduct should not report to the research management under investigation[354] and they should have an independent budget.[355]

3. In cases of severe fraud, it may be necessary to refer the case to integrity boards established outside the institution, e.g., at national science academies. This process should be specified by guidelines including the respective integrity board, the severity of fraud and the position occupied by the researcher who is suspected of misconduct.
4. In international research projects' terms of collaboration, it should be clearly described how allegations of research misconduct will be addressed. The text should include statements of what is considered research misconduct and the procedures through which such allegations will be investigated,[356] including a protocol that defines the authority structure, the scope and limits of an investigation, the rules for evidence and the source of resources.[357]
5. It is important to ensure that integrity boards have codified substantive protections for the parties involved in the case.
   a. The relevant body should publish investigating procedures (including jurisdiction, rules of procedures, timeline and potential sanctions) in a clear, easy-to-understand and accessible manner for all staff.[358]
   b. The relevant body should ensure that the entire staff understands what constitutes misconduct.[359]
   c. The relevant body should provide the accused with complete details of the alleged wrongdoing.[360]

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[351] Boesz, Christine C., "Developing Research Integrity Structures: Nationally and Internationally", in *Promoting Research Integrity in a Global Environment*, edited by Tony Mayer and Nicholas Steneck, World Scientific Publishing, Singapore, 2012, pp. 7–16 [pp. 11–12].
[352] European Science Foundation, 2000, p. 14.
[353] Hin, Lee Eng, "Research Integrity Challenges—A Singapore Perspective", in *Promoting Research Integrity in a Global Environment*, edited by Tony Mayer and Nicholas Steneck, World Scientific Publishing, Singapore, 2012, pp. 21–25 [p. 23].
[354] Boesz, Christine C., "Developing Research Integrity Structures: Nationally and Internationally", in *Promoting Research Integrity in a Global Environment*, edited by Tony Mayer and Nicholas Steneck, World Scientific Publishing, Singapore, 2012, pp. 7–16 [p. 11].
[355] Ibid., p. 11–12.
[356] OECD Global Science Forum, "Investigating Research Misconduct Allegations in International Collaborative Research Projects: A Practical Guide". http://www.oecd.org/sti/sci-tech/42770261.pdf.
[357] Boesz, Christine C., "Developing Research Integrity Structures: Nationally and Internationally", in *Promoting Research Integrity in a Global Environment*, edited by Tony Mayer and Nicholas Steneck, World Scientific Publishing, Singapore, 2012, pp. 7–16 [p. 13]; European Science Foundation and ALL European Academies, "The European Code of Conduct for Research Integrity", 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf, [p. 9].
[358] Ibid.
[359] European Science Foundation, 2000, p. 14.

d. The investigation process should allow sufficient time at each step of the process for the accused to fairly present his/her case.[361]
e. Witnesses should be allowed to seek advice from and be accompanied by counsel.[362]
f. All decisions should be subject to an appeal.[363]
g. As much as possible, no penalty should be levied against an accused person before a verdict.[364]

Research Ethics Committees

1. University associations and national academies of sciences should, with the help of professional organisations, establish and commit to a joint framework that would set general standards at a national level regarding research ethics committees in the higher education system.[365] For that framework, an official committee should be established.
2. Accreditation committees, in the course of evaluating teaching programmes, should assess whether research ethics are a part of the curricula and based on and reflective of the general standards adopted by the institution, ensuring their quality.
3. Ethics assessment in institutions of higher education should be organised into one or more research ethics committees. In order to address discipline-specific issues in project evaluation, the principle of interdisciplinarity and independence should be respected in committee membership.
    a. Each institution should decide, based on its size and volume of research, whether it should have multiple standing committees or one committee that has the authorisation to form sub-committees as needed.[366]
    b. Committees should consider appointing a chairperson who is not from the focus field for the committee or the institution, to ensure minimal bias.
    c. The governing body should periodically (at defined intervals) verify the continuing autonomy of the committee from the institution.
4. The members of research ethics committees should be appointed by the institutions' governing bodies. They should not be picked by current members of the committee, but rather be suggested by community leaders. When choosing members, persons with a potential conflict of interest should be avoided. Finally, the committee should be allowed to seek the advice from outside experts.

8.2 National Science Academies

The recommendations for ethics assessment at national science academies (NSAs) focus on the potential impact in science and society that NSAs have due to their influential positions.

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[360] European Science Foundation and ALL European Academies, "The European Code of Conduct for Research Integrity", 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf, [p. 15].
[361] Ibid.
[362] Ibid.
[363] Ibid.
[364] Ibid., p. 16.
[365] Eksioglu, Subhan, Hatice Beyza Mercan Sezer, and Fatma Gozalan Cicek, "Ethics Committees in Turkish Universities", *Procedia - Social and Behavioral Sciences*, Vol. 174, February 2015, pp. 2882 – 2890 [p. 2889].
[366] Economic and Social Research Council, 2015, p. 14.

1. In the majority of cases, there is no systematic monitoring of compliance with NSA recommendations. Therefore, monitoring and compliance programs should be incorporated into National Science Academies.
    a. NSAs should establish a compliance officer to monitor the number of mentions and citations of academy results by policy, decision, and public actors.
2. Too often, the decision-makers do not accept/follow recommendations established by academic committees or see the need to conduct ethics assessment, and try to avoid difficult topics.
    a. NSAs should try to develop closer connections, while retaining their autonomy, to work in conjunction with policy and decision makers by establishing liaisons or programs to work alongside decision-makers.
3. Another pressing challenge is the lack of necessary resources (administrative staff, budget) that would facilitate the work of NSAs. Whether a public or private funded model is utilized, effectively gauging the necessary resources and needs should be presented.
    a. The European Commission (EC) should encourage the establishment of National Science Academies as a part of its requirements for countries to receive funding for research and innovations projects.
    b. Governments (i.e. the EU, UN, OECD and potentially other organisations) should create a multi-stakeholder platform on a global level, in which the UN, OECD, and the EU could collaborate in pursuit of harmonized NSA objectives. This can build upon the existing work of established associations in this area.

8.3 Research Funding Organisations

Research funding organisations frequently ask those submitting research proposals for ethics assessment, but the ethics assessment itself is mostly outsourced and not based on a broad set of criteria. To secure the high quality of ethics assessment, in-house ethics assessment should be considered.

1. Large RFOs (spending more than 100 million Euros a year) should themselves be responsible for conducting ethics assessments of research proposals submitted to them. Smaller RFOs (usually privately funded NGOs) may continue to rely on external ethics assessment.
    a. Large RFOs should institute in-house ethics panels for conducting full ethics review of all project proposals that have been flagged as ethically problematic during a pre-screening phase. This pre-screening phase would be conducted by RFO staff members who are involved in project selection and who have received prior training in the field of ethics.
2. RFOs should organise a permanent structured exchange with their international counterparts to discuss (good practices in) ethics assessment in response to new and emerging technologies. They should also do more to raise awareness of ethics among researchers who submit research project proposals.

8.4 Research Ethics Committees

RECs are not only important in universities, but can operate on various levels outside universities. It is therefore crucial to clarify the legal conditions that RECs operate under.

1. It should be clear in a legal sense when RECs are to be included in the ethics assessment practice.
    a. Local and national governments should make the necessary legal provisions at the appropriate level (whether institutional, local, regional, or national) for when RECs are to be included in the ethics assessment practice.
2. For the sufficient funding of the REC, including any necessary secretariat or administrative staff, means of supplying funding should be established. They can be either directly funded by the government or a respective institution, or incorporated into the research project proposals.
3. RECs should have representatives that participate in (e.g. national) forums directed at the discussion and guidance of emerging ethical issues and guidelines. This is to ensure harmony with international trends, but also to provide input in their developments.

8.5 National Ethics Committees

NECs usually focus on bioethics and could benefit from broadening their focus. As they are supposed to advise national governments, stakeholders should participate in the ethics assessment process.

1. NECs should broaden their focus to encompass all other scientific fields besides the medical and life sciences. In order to do so, NECs should institute special sub-committees for different disciplines.
2. NECs should create an organisational structure that allows for the consultation of citizens, civil society organisations, external experts and possibly other external groups. To investigate how this might be achieved, individual NECs should institute a temporary sub-committee.
3. NECs should set up a special committee that monitors for compliance with the ethical guidance they offer to ethics assessors.
4. NECs should be more actively involved in ensuring the quality of the ethics assessments made by REC members and other ethics assessors, e.g. by offering training programs.

8.6 Academic and Professional Organisations

As academic and professional organisations often work together with NSAs, the three recommendations for NSAs are also applicable to them.

1. Academic and professional organisations should create forums for the consolidations of developments in ethics assessment, which produce unambiguous results that can be implemented and monitored by group members.

2. Academic and professional organisations should utilise their positions as membership-granted organisations to train members to instil responsible research and practices through developing partnerships with universities and other research conducting organisations that account for its membership group.
    a. The EC should recognise academic and professional organisations as potential conduit points for the implementation of training programmes for responsible research.

8.7 Civil Society Organisations

The recommendations for CSOs focus on making their two ways of participating in ethics assessment more effective: 1) participating in RECs, and; 2) cooperating with each other to build their own structures for ethics assessment.

1. CSO representatives should make efforts to be involved in research ethics committees as representatives of a specific vulnerable group (e.g. consumers or patients) or spokespeople for a specific interest (e.g. animal welfare).
    a. CSOs should draft a comprehensive list of potential vulnerable groups or specific interests to ensure no group is being unintentionally omitted.[367]
    b. CSOs should coordinate (e.g. through a network as described in #2 below) to ensure that multiple groups are not inadvertently representing the same vulnerable groups or specific interests while leaving others underrepresented.
    c. CSOs should consider potential conflicts of interest between the interests of different vulnerable groups and how to navigate those conflicts.
    d. When deciding which group to represent, CSOs should consider their relative expertise and knowledge about specific groups.
    e. If the CSO is representing specific individuals within a vulnerable group, it must make sure to obtain informed consent from the people themselves or, if they are unable to give it, those legally capable of providing consent on their behalf.[368]
2. There should be support at the EU level for the development and exchange of ethics assessment related CSO networks. These networks could vary in terms of structure, level of interdependence, aims etc. The purpose of networking would be to exchange information (knowledge and experience) and learn from each other (through sharing best practices, coordinating activities, obtaining common funding, organising advocacy campaigns, influencing the adoption of new regulative acts, etc.).
    a. To gain support for EU-level CSO networks for ethics, CSOs should emphasise the EU's acknowledgement of the importance of CSOs in the globalised world[369]

[367] British Psychological Society, "Code of Human Research Ethics," 2010. http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf [p. 31].
[368] Ibid., pp. 30–31.
[369] For example, Marchetti, Raffaele, "The Role of Civil Society in Global Governance: Report on the joint seminar organised by the EUISS, the European Commission/DG Research, and UNU-CRIS", 1 October 2010,. http://www.iss.europa.eu/uploads/media/Civil-Society_Report.pdf [p. 2].

as well as the importance of research ethics and of hearing different opinions in research ethics discussions.[370]

b. When advocating for or forming a network, CSOs should explicitly articulate the network's purpose.
c. CSOs should also decide the target membership, both in terms of size and scope (i.e. whether the network is attempting to connect CSOs across a particular field, e.g. medical ethics, or across a particular role, e.g. watchdog CSOs).[371]
d. To save resources, CSOs should consider whether ethics assessment related CSO networks could be formed within existing networks (e.g. CSO-Net[372] or Euclid network[373]).

3. Due to disparities between different states regarding the level of civil society involvement in ethics assessment of R&I (for example, the existence of dedicated organisations or the level of involvement of the public in debates about the societal aspects of research and innovation), there is a need to exchange best practices between organisations and groups from different states. This could be done at the EU level, for example by means of establishing dedicated working groups in the existing CSO networks (e.g. the Euclid network).
    a. CSOs should form a working list of all existing CSO networks at the EU level to determine which, if any, would be best fitted to the exchange of research ethics best practices.
    b. CSOs should examine existing EU-level groups that engage in the exchange of best practices in other fields to determine which have been most successful, and why.[374]
    c. If possible, CSOs should reach out to these existing groups to determine how they decided to affiliate with EU-level groups and the process through which they went to do so.
    d. CSOs should consider whether these exchanges of information would be more successful if they included either non-EU nations or only a subset of EU nations.[375]
    e. If the exchange networks are established at the EU level, the CSOs should determine the degree of autonomy the exchange needs from the governing EU structure. They should also consider how the exchange network would be funded.[376]

[370] European Commission, "European Textbook on Ethics in Research," 2010, p. 7; European Commission, "Ethics for Researchers," 2013.
[371] See World Economic Forum, "The Future Role of Civil Society", January 2013. http://www3.weforum.org/docs/WEF_FutureRoleCivilSociety_Report_2013.pdf [p. 9].
[372] CSO-Net, ECOSOC Civil Society Network. http://esango.un.org/irene/index.html.
[373] Euclid Network. http://www.euclidnetwork.eu/.
[374] For example, the Community of Practice on Partnership (http://partnership.esflive.eu/) and surgery practices (de Graauw, J. A., S. Mihály, O. Deme, H. S. Hofker, A. G. Baranski, O. P. Gobée, C. Krikke, et al., "Exchange of Best Practices Within the European Union: Surgery Standardization of Abdominal Organ Retrieval", *Transplantation Proceedings,* Vol. 46, No. 6, July 2014, pp. 2070–2074).
[375] For example, a "Civil Society Dialogue" operates between EU nations and Turkey. See http://civilsocietydialogue.org/us/.
[376] OECD, "Civil Society Empowerment", April 2013 (draft). https://www.oecd.org/cleangovbiz/CivilSocietyEmpowermentDraft.pdf [p. 7].

8.8 Industry

This section provides recommendations to meet the challenges in the institutional structures of ethics assessment in industry.

1. A broad institutional structure of corporate responsibility including R&I should be formed as a cross-sectorial approach based on collaboration.[377]
2. The institutional structures should enable engagement with stakeholders to evaluate and review impacts and actions. Multi-stakeholder approaches should be adopted.
3. CR (including R&I activities) should be based on appropriate mix of bottom-up and top-down approaches to promote CSR, while also taking into account local context and values.
4. The institutional structures for ethics assessment of R&I for industry should be incorporated with already existing general CR institutional structures, e.g. by businesses, the EU and the UN.
5. For the benefits of stakeholders, the institutional structures for ethics assessment of R&I should promote recognition of the companies as their members, e.g. via certificates and rewards.
6. The EU should enforce the currently existing legislation.
7. The membership of a company in the institutional structures should not be granted indefinitely. The adherence to the ethical requirements should be verified regularly (e.g. through annual or biennial verification).
8. The institutions for the ethics assessment of R&I in industry should respond to the needs of different types of businesses.

8.9 National Institutional Structures for Ethics Assessment

In this section, recommendations are given for ethics assessment on the national level, including national level coordination, networking between RECs, ethical guidance and training, ethics assessment in non-medical fields and institutional problems.

1. In countries that currently lack a NEC, governments should establish a NEC to coordinate RECs, and to develop ethics assessment and guidance procedures. The NEC should also provide a platform for discussion and cooperation.
2. While a national ethics committee can provide top-down coordination, REC networks can complement it by providing bottom-up solutions based on experience from day-to-day practices of committees. Therefore, RECs should consider establishing a platform for discussion and cooperation.
3. In non-medical fields, professional associations have proven to be best placed to provide common ethical guidance and platforms for discussion of ethical principles and issues. NECs should expand to include special sub-committees for different fields

[377] STM Electronics (WP1 interview): 'Compare and share experiences with other (external) organizations is generally useful and interesting at company level; (…) There is a need of an appropriate mix of bottom-up and top-down approaches to promote CSR, also taking into account local context and values.'

and disciplines, perhaps in cooperation with professional associations, which can provide insight into field-specific research practices and their ethical issues.

4. Institutions with the knowledge, experience and authority to provide ethical guidance are national ethics committees and REC networks as well as national academies and professional associations in specific fields and disciplines. These institutions, especially NECs, should provide training programs.
5. Governments should take action towards maintaining a functioning national system of ethics assessment, by providing the necessary funding and impetus to national-level institutions as well as to take measures to implement national regulations.

9 ASSESSING THE COMPATIBILITY OF EXISTING ETHICS ASSESSMENT FRAMEWORKS WITH THE SATORI FRAMEWORK

This chapter compares the proposed SATORI framework for ethical assessment with those in place in the United States (US), China, the various approaches found within developing countries, as well as with that established by various international rules, including both international regulations and international policies/guidelines.

This chapter is a summary of Annex 10 of this Deliverable.

9.1 International Regulations and Policies

The SATORI framework does not have any clear areas of conflicts with international regulations or guidelines. Generally, SATORI has shared approaches with these rules.

There is broad agreement across international rules and SATORI regarding issues and principles. General human rights guidelines helped guide the inauguration of formal ethics assessment. SATORI, along with its empirical basis, draws heavily on the notion of human rights issues and principles as a basis for ethics assessment and guidance. The convergence between the empirical, historical and theoretical human rights frameworks provides great compatibility with the SATORI framework. Therefore, there is an obvious synergy between them.

Because international regulations overall do not discuss ethics review committees or the specific scope of the procedures suggested by the SATORI framework, there is generally no potential for conflict.

Although other international regulations operate in different fields, the procedures they offer for their own implementation affirm the type of approach that SATORI suggests. Regulations such as the Cartagena Protocol outline a process including reviews of decisions, simplified procedures, risk assessments and public education and awareness.[378] There is an accepted importance of the need to train, monitor and follow through on initial recommendations.[379] SATORI's framework outlines a clear, standardized process including these same steps, as chapter 4 of this report demonstrates.

The organisational structures outlined in international regulations differ in subject matter from SATORI but show a shared approach. As with SATORI, multiple international regulations mandate the creation of a national-level action plan or committee to ensure the regulations are

[378] Cartagena Protocol on Biosafety to the Convention on Biological Diversity. https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf [Articles 12–15, 23].
[379] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity. https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf [Article 17]; Espoo Convention on Environmental Impact Assessment in a Transboundary Context. http://www.unece.org/fileadmin/DAM/env/eia/documents/legaltexts/Espoo_Convention_authentic_ENG.pdf [Article 7]; Kyoto Protocol to the United Nations Framework Convention on Climate Change. http://unfccc.int/resource/docs/convkp/kpeng.pdf [Article 10].

properly implemented and monitored.[380] The regulations also advocate for policy discussions to include all relevant stakeholders, including local actors, private industry, NGOs and diverse community members (racially and by gender).[381]

As with SATORI, several international regulations create specific bodies to organise this conversation between the public, private and government. SATORI similarly proposes the creation of official, diverse and multidisciplinary committees that ensure that ethics standards remain relevant and uniform.

Much like international regulations, international guidelines differ in subject matter from SATORI but show a shared approach. The proposal for an organisational structure incorporating an EAU and implementing an EIA can be seen as in line with most major international guidelines.

9.2 Developing Countries

With the SATORI approach, national priorities may produce ethics assessment priority conflicts, such as the drive to grow economies in line with historical precedents for industrialization that may not account for current ethical considerations. Some developing countries argue that the necessity for growing the economy and opportunity outweigh the ethics principles and issues that govern sustainable environmental policy and that more developed countries benefited from a laxer environmental focus, so fairness dictates a right to develop using the same methods. Where this issue arises, the ethical deliberation principles advocated by the SATORI framework can be applied to provide a conduit for addressing the underlying issues and principles.

9.3 United States

The SATORI framework is compatible with the US approach to ethics assessment. This is due to the fact that many of the principles adopted by the SATORI framework are implicitly based in the ethical assessment framework of the US, such as the Belmont Report.

The places where the SATORI framework differs from that in the US arise from US specific factors including the decentralised R&I system. They do not, however, suggest conflicts of the core values of the system. The core divergence between the US and SATORI ethical assessment approaches regarding issues and principles occurs because the US does not have and does not appear to prioritise creating a centralised ethical assessment approach, which is one of SATORI's primary goals.

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[380] See, for example, UN Convention to Combat Desertification. http://www.unccd.int/Lists/SiteDocumentLibrary/conventionText/conv-eng.pdf [Article 10]; Convention on Biological Diversity, https://www.cbd.int/doc/legal/cbd-en.pdf [Article 5].

[381] See, for example, UN Convention to Combat Desertification. http://www.unccd.int/Lists/SiteDocumentLibrary/conventionText/conv-eng.pdf [Article 4 (e–f)]; Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters. http://www.unece.org/fileadmin/DAM/env/pp/documents/cep43e.pdf [Article 3].

The decentralised US approach means that there are gaps in the US system that do not align with SATORI principles. For example, many of the ethical issues focused on in the US are driven by domestic politics. In contrast, SATORI focuses on a non-politicised, independent and autonomous approach to ethics review that would not be controlled by domestic politics in this same way. At the same time it is important to highlight that there is no conflict between the ethical principles that *do* exist in the U.S. and those proposed by SATORI.

Conflict with the SATORI framework arises in the broader ethical assessment field in the US IRBs (Institutional Review Boards) only review federally funded research involving human subjects. Companies and higher education institutions that receive state funding or no government funding at all are not required to submit research to ethical reviews by IRBs. US research does not always face the level of ethics assessment desired by the SATORI framework, which has specific outlines for organising research ethics committees and conducting uniform, transparent ethics assessments.[382] The US system, though, reflects a lower ethical standard than SATORI, not a conflicting one.

9.4 China

China currently does not have a strongly developed infrastructure for ethics assessment, but it is rapidly developing one.

The major differences between the SATORI framework and Chinese approach to ethics assessment primarily arise from the China-specific factors including the political system.

Chinese and the SATORI frameworks align to some extent, particularly concerning the key issues and principles underlying ethics assessments for research aimed at technological innovations, research involving human subjects and research involving possible environmental risks.

Ethical review in relation to biomedical research involving human subjects in China is well covered by various national guidelines that adhere to international standards.[383] However, the ethical review is limited to biomedical research.[384] Moreover, there is also a question as to what extent the international rules are implemented.[385]

The conflicts between the SATORI approach and the Chinese approach may arise regarding stakeholders engagement, particularly engagement of CSOs, which is very limited in China.

[382] See chapter 4.
[383] Brey, Philip, Wessel Reijers, Sudeep Rangi, Dino Toljan, Johanna Romare, Göran Collste, Zuzanna Warso and Marcin Sczaniecki, *SATORI Deliverable D3.2 International Differences in Ethical Standards and in the Interpretation of Legal Frameworks*, September 2015. http://satoriproject.eu/media/D3.2-Int-differences-in-ethical-standards.pdf [p. 127].
[384] Ibid.
[385] Ibid.

10 SUMMARY OF RECOMMENDATIONS

This report has presented the results of our efforts to create an ethics assessment framework for research and innovation in the European Union member states. At the core of our efforts has been the development of proposals for good practices for ethics assessment, including the development of ethics assessment units and the protocols of these units. We have developed a general toolkit for such assessment, as well as specialized tools and toolkits for specific types of organisations and scientific fields. In addition, we have developed recommendations for the general institutional structure of ethics assessment in the EU and its member states.

In the report, we first presented the results of our analysis of stakeholders' expectations about a shared European framework for ethics assessment of research and innovation. The analysis was based on 153 interviews with different kinds of stakeholders, both ethics assessors and non-assessors, who were asked to share their opinions on the desirability and possibility of such a framework. Of all interview respondents, 51.6 percent thought it would be desirable to have a shared European framework, and 30 percent were conditionally positive on the desirability of the framework. Many interviewees cited as potential benefits the unification, harmonisation and convergence of EA principles and procedures. They also highlighted two major challenges for the development of a common framework. The first is to achieve harmonisation of ethical principles and procedures, while at the same time allowing for differences between countries and scientific fields. The second is for the framework to function at a general level to account for differences between countries, cultures, ethical values, philosophies, and scientific fields, while at the same time providing useful tools for solving concrete ethical dilemmas.

We subsequently proposed a framework of ethical issues and principles that is applicable to a broad range of R&I activities. This framework firstly lists eight key ethical principles that apply to all types of research, each of which is operationalized through a set of guidelines. These eight principles are: research integrity, social responsibility, avoidance of and openness about potential conflicts of interest, protection of and respect for human research participants, protection of and respect for animals used in research, protection and management of data, protection of researchers and the research environment, dissemination of research results. Second, the framework specifies additional issues and principles that apply to specific fields of research and innovation, including the natural sciences, the engineering sciences, the medical sciences, the life sciences, the computer and information sciences, and the social sciences and humanities. It was noted that because ethical issues are frequently triggered by special conditions that often arise across multiple fields, it becomes important to identify applicable ethical principles on a case-by-case basis for each research and innovation project, while taking account of special provisions, conventions and regulation that may apply to specific fields.

Next, we outlined recommendations for best practices in Ethics Assessment Units (EAUs). These recommendations are structured around a series of parameters common to all EAUs that review R&I activity: composition and expertise; appointment and training; procedures prior to assessment; procedures during assessment; procedures after assessment; supervision; quality assurance; efficiency considerations; organisational and cultural factors. For example, we recommended that the membership of an EAU be arranged so that it encourages rigorous discussion and evaluation of R&I activity – which could best be achieved by including members who are competent (technically, ethically, and administratively), independent of the researchers

and the institutions involved, diverse in backgrounds and expertise, and representative of the communities affected by their decisions. Another recommendation holds that the assessment procedure be designed to ensure that the conducted R&I activity (1) protects stakeholders from undue risk and harm, (2) ensures that participation in research, trials and similar activities related to the R&I activity is voluntary, (3) determines if the research or innovation methods are appropriate, and (4) aims to increase the awareness of the ethical impact of R&I. Finally, to highlight one last recommendation, we have proposed that EAUs consider using a modified version of the *Plan-Do-Check-Act* (PDCA) process for quality assurance of ethics assessment.

We then presented an overview of SATORI's Common Framework for Ethical Impact Assessment. This framework can be used by governance bodies to set up new regulations in relation to ethical impact assessment in R&I; by research funding organisations to set up new procedures for conducting EIAs in the projects they fund; and by local research organisations and companies in order to set up internal procedures for conducting an EIA in their R&I projects. Our framework presents the EIA process as a series of five stages: the *EIA threshold analysis stage*, the *ethical impact anticipation and determination stage*, the *ethical impact evaluation stage*, the *remedial actions stage*, and the *review and audit stage*. The threshold analysis stage of an EIA is aimed at determining the kind of EIA procedure that could be implemented in an R&I project (small-scale, mid-range, or full-scale EIA). In the EI anticipation and determination stage, the persons involved in the EIA try to map the ethical impacts that might occur in the context of the R&I project and put them on a timeline (short-term, medium-term, and long-term impacts). The EI evaluation stage is aimed at evaluating the relative severity of the potential impacts, the likelihood of their occurrence, and any potential value conflicts that may arise. In the remedial actions stage, remedial actions may be designed and performed in response to the negative impacts found and analysed during EI anticipation & determination and EI evaluation stages. The review and audit stage of an EIA, finally, is aimed at ensuring independent evaluation of the EIA process and, if necessary, independent corrective intervention in it.

Next, we presented recommendations for specialized forms of ethics assessment and guidance. Specifically, we outlined standards, tools and best practices for (1) policy-oriented assessment and guidance of new developments and practices in R&I; (2) guiding, assessing and supporting ethical professional behaviour by scientists and innovators; and (3) the ethics assessment of innovation and technology development plans. With regard to policy-oriented assessment and guidance, we recommended, for example, that governmental organisations directly involve CSOs and non-ethicists or lay persons in the ethics assessment and guidance processes, and that they take into account the value of democracy in the composition of ethics guidance and assessment bodies. In relation to guiding, assessing and supporting ethical professional behaviour by scientists and innovators, we recommended, for example, that researchers abide by ethical standards that include principles such as objectivity and impartiality, truthfulness and transparency, honesty and openness, respect and fairness, conformity to regulation, guidelines and good practices, integrity in international cooperation, and social responsibility. Finally, with regard to ethics assessment of innovation and technology development plans, we proposed, among other things, increased stakeholder participation in the EIA process for building projects in urban areas (given their large potential impacts on communities), and an EIA that is more principle-driven for (consumer) product development.

We subsequently discussed ethics assessment and guidance in the context of four specific types of organisations: universities, CSOs, industry and RFOs. We recommended that universities develop generalised codes of ethics (not focused on any specific discipline) which explicitly address researcher conduct in R&I, that these codes be implemented in their curricula and institutional strategies, and that research integrity boards investigate alleged breaches of the codes of ethics in an independent, fair and credible way. For CSOs, we recommended increased involvement in RECs as representatives for specific vulnerable groups or interests, and the creation of ethics-assessment-related CSO networks for the exchange of best practices. For industry, we outlined as number of good practices, which include defining responsibility for ethics assessment along all levels of the organisation, setting a company-wide strategy for ethics assessment based on a structured, step-by-step procedure (e.g., the *Plan, Do, Check, Act* cycle), and ensuring transparency and responsibility in the ethics assessment process. Finally, we recommended that RFOs establish procedures for *in-house* ethics assessment going beyond what is required by law, and focus their evaluations on issues and principles specific to the field of research to which the proposal under consideration belongs, among other things.

We then outlined proposals for the institutional structure of ethics assessment in eight types of ethics-assessment-performing organisations in the EU member states: universities, national science academies, RFOs, RECs, NECs, academic and professional organisations, CSOs, and companies. In addition, we presented recommendations for the institutionalisation of ethics assessment for selected European countries. We recommended, for example, that university associations and national academies of sciences should, with the help of professional organisations, establish and commit to a joint framework that would set general standards at a national level regarding RECs in the higher education system. In addition, we recommended that NECs broaden their focus to encompass all other scientific fields besides the medical and life sciences, thus instituting special sub-committees for different disciplines. We further recommended that academic and professional organisations create forums for the consolidation of developments in ethics assessment. Lastly, with regard to national institutional structures, we recommended, for example, that in countries where a NEC is missing, governments establish a NEC to coordinate RECs, develop EA and guidance procedures, and provide a platform for discussion and cooperation on ethics assessment.

Finally, we argued for the compatibility of existing ethics assessment frameworks with the SATORI framework. Our framework does not seem to have any clear areas of conflict with international regulations or guidelines. General human rights guidelines helped guide the inauguration of formal ethics assessment, and SATORI draws heavily on the notion of human rights issues and principles as a basis for ethics assessment and guidance. Therefore, there is an obvious synergy between them. And even though international regulations may operate in different fields, the procedures they offer for their own implementation affirm the type of approach that SATORI suggests. As with SATORI, the regulations advocate for policy discussions to include all relevant stakeholders, including local actors, private industry, NGOs and diverse community members (racially and by gender). Even so, national priorities may produce priority conflicts with the SATORI approach, such as the drive to grow economies in line with historical precedents for industrialization that may not account for current ethical considerations. Where this issue arises, the ethical deliberation principles advocated by the SATORI framework can be applied to provide a conduit for addressing the underlying issues and principles.

11 ANNEXES

The annexes consist of stand-alone downloadable reports with proposals for improving ethics assessment and ethical guidance in relation to specific topics. All of them are summarized in the main document (this document). They are downloadable at:

http://satoriproject.eu/work_packages/a-report-on-the-legal-frameworks-that-guide-or-constrain-ethical-procedures-within-research-in-the-eu/

1. **A Reasoned Proposal for Ethical Impact Assessment**

2. **Standards, Tools and Best Practices for Policy-Oriented Assessment and Guidance of New Developments and Practices in Research and Innovation**

3. **Standards, Tools and Best Practices for Guiding, Assessing and Supporting Ethical Professional Behaviour by Scientists and Innovators**

4. **Standards, Tools and Best Practices for the Ethics Assessment of Innovation and Technology**

5. **Models for Ethics Assessment and Guidance in Higher Education**

6. **Models for Ethics Assessment and Guidance at CSOs**

7. **Models for Ethics Assessment and Guidance in Industry**

8. **Models for Ethics Assessment at Research Funding Organisations**

9. **Proposals for the Institutional Structure of Ethics Assessment in the EU and its Constituent Countries**

10. **Compatibility of Existing Ethics Assessment Frameworks with the SATORI Framework**