Report on standardizing operating procedures in ethics assessment

Deliverable D7.1

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Content

Abstract

Introduction: The attention for and urgency of ethics assessment has increased. Public discussions on the ethical desirability of several research projects or innovations, e.g. GMO, nanotechnology, big data & privacy, drones.

Objectives: To assess the feasibility of developing a standard for ethics assessment of research and innovation.

Methodology: SATORI analysis of good practices in ethics assessment resulted in a framework for ethics assessment, including ethical impact assessment. Simultaneously, the project's workshops exchanged early findings with stakeholders to assess expectations and needs to standardize ethics assessment methodologies and practices. The standard procedure of the Comité Européen de Normalisation (CEN) Workshop Agreement was used to develop European consensus on the framework. The feasibility of standardizing ethics assessment was assessed by starting the standardization procedure, trying to reach consensus on the content. 75 experts from 15 European countries and 10 European organisations contributed.

Results: The SATORI framework for ethics assessment has been developed into a CEN Workshop Agreement (CWA). This (pre-)standard has 2 parts. Part 1 provides information on the role and functioning of an ethics committee, including procedures, quality assurance and an approach to ethical principles. This is useful for setting up an ethics committee or reviewing the functioning of an ethics committee. Part 2 on ethical impact assessment describes procedures and methodologies that individual researchers and assessors will find useful to assess the ethical impact of a research proposal or innovation. The standard is less aspirational and less comprehensive compared to the SATORI framework and therefore it is expected to be more practical to use and less expensive to implement.

Conclusions: SATORI succeeded in developing a pre-standard on ethics assessment for research and innovation. The CWA may, in the future and based on its use, be further developed into a European standard if such authority is required by the stakeholders.

Executive Summary

The attention for and urgency of ethics assessment has increased. In recent years there were public discussions on the ethical desirability of several research projects or innovations, e.g. GMO, nanotechnology, big data & privacy, drones.

Ethics assessment and ethical impact assessment help researchers, policy-makers and relevant stakeholders to deal with the ethics impacts of research and innovation. The need for methods for ethics assessment and ethics impact assessment arises out of the increasing focus on responsible research and innovation in policy contexts and in collaborative efforts of researchers, as well as from new legal regulations at the European level.

The SATORI (Stakeholders Acting Together On the ethical impact assessment of Research and Innovation, www.satoriproject.eu) research project, funded by the European Commission, developed a framework for common basic ethical principles and joint approaches and practices with the objective to harmonize and improve ethics assessment practices of research and innovation.

This D7.1 of Work Package (WP) 7 consists of 2 parts. Part l is a general study into standards and standardization efforts on assessment procedures, ethics and social responsibility. The study resulted in recommendations and inspiration for content and process for a European pre-standard in SATORI. Part 2 assesses the feasibility of standardizing ethics assessment of research and innovation. Part 2 further developed the WP4 reports into a CEN Workshop Agreement (CWA) on ethics assessment for research and innovation.

The CWA consists of two parts. Part 1 sets requirements and recommendations for the composition, role, functioning and procedures of an ethics committee. Organisations can use part 1 to strengthen and or improve the ethics assessment of their research and innovation projects. Ethics committees include, but are not limited to, research ethics committees, institutional review boards, ethical review committees, ethics boards, and units consisting of one or more ethics officers. Part 1 of the CWA is applicable to all ethics committees, regardless of their size scope or research and innovation area.

Part 2 provides researchers with guidance on ethical impact assessment. Ethical impact assessment is the process of judging the ethical impacts of research and innovation activities, outcomes and technologies that incorporates both means for a contextual identification and evaluation of these ethical impacts and translating to a set of guidelines or recommendations for remedial actions aiming at mitigating ethical risks and enhancing ethical benefits, typically in consultation with stakeholders. Ethics assessors and ethics committees will find this information useful as it describes ethics impact assessment in different stages of the ethics assessment. Part 2 is applicable to all researchers, innovators and ethics committees, regardless of the context they are working in.

1. Introduction

1.1 Objectives

Standardization has a significant role in the process of bringing innovation to the market, across all technical fields. In the context of ethics assessment, there might be limits to standardization (what can be standardized, why and why not) as well as to moving ethical issues from research into standardization (when standardization is used as a tool for knowledge transfer).

SATORI D7.1 reports on the work of task 7.1 and task 7.3[1].

- Task 7.1 analyses the existing standardization work. This includes looking into to what extent assessment procedures, ethics and social responsibility have become subjected to standardization. Task 7.1 is preparation for task 7.3. It sets out to:
  - explore standards/standardization in relation to assessment procedures, ethics and social responsibility;
  - identify possible limitations to standardizing ethics assessment;
  - find inspiration for a European (pre-)standard (e.g. CWA) in SATORI.
- Task 7.3 explores whether it is possible to standardize ethics assessment for research and innovation. Task 7.3:
  - used the recommendations from task 7.1 and the results from SATORI WP4 (the SATORI ethics assessment framework);
  - started the development of a pre-standard (CEN Workshop Agreement) to see whether it is possible to reach consensus on the content of an ethics assessment framework;
  - explained the challenges encountered and the solutions arrived at during the standardization effort;
  - will publish the result of the standardization effort.

Part I of D7.1 reports of the outcomes of task 7.1. Part II of D7.1 reports of the outcomes of task 7.3.

[1] Based on the SATORI Description of Work (DoW).

Part I - General study of standardizing operating procedures

2 Context and methodology

2.1 Standard

Standards are a way of communicating – a kind of common language – (often) in form of a technical specification. They are a means of communicating across languages to avoid misunderstandings. Standards define a product and agree on methods to test them.

Many standards exist in a wide range of fields. Some standards reflect common practice and are taken over from one generation to another; other standards are developed by consortia or by formal standardization organisations.

The standards developed by formal standardization organisations such as CEN and ISO (International Standards Organisation) are often referred to as 'formal standards' and are characterised by three basic features. CEN and ISO define a standard as: "Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. "[2] They are:

- **voluntary and market driven** – which means that a formal standard is developed and defined through a process of sharing knowledge and building consensus among technical experts nominated by interested parties and other stakeholders; including businesses, consumers, researchers, and NGO's, among others. The decision to develop new standards is driven by market needs/stakeholder requests.
- **consensus based** – which means that a formal standard is not written by one expert, but reflects the input and knowledge of all parties concerned.
- **developed and approved by a recognised body** – which means that a recognised body like CEN, ISO or a national standards body (e.g. NEN (Netherlands Standardization Institute) in the Netherlands and DS (Danish Standards) in Denmark) has approved the document and that the document has gone through the necessary procedures, public consultation, etc.[3]

Annex 5 provides the structure of a formal standard.

2.2 Standardization

The shortest way of describing standardization is the process where standards are made. In general, standardization is split into two categories: de facto and formal. Formal standardization is the process in which the formal standards are made. There are some very specific requirements for this process and it must be handled by a formal standardization organisation such as CEN and ISO. Due to the nature of formal standards, all interested parties can join the standardization work through their national standards body and thereby give their input to the upcoming standards.

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[2] EN 45020 – Standardization and related activities – General vocabulary ISO/IEC Guide 2 – Standardization and related activities – General vocabulary

[3] *A World Built on Standards*. 2015. 1st edition. Published by: Danish Standards Foundation.

De facto standardization is the process of making all types and kinds of standards that are not formal standards. These are standards developed by a company, organizations, a task force, an alliance or a non-formal standards development organisation etc. In some cases, the de facto standardization process is very similar to the formal standardization process – but not always – and there is no guarantee that any specific requirement is met during the development process. The company/organisation developing the standards sets their own rules.

Looking at the number of standards in the world, there are a large majority of de facto standards, but the use of formal standards is more widespread due to their role in regulation and the fact that they are developed in a consensus process by a recognised body. There are advantages with both – the important thing is to be aware of the difference.

2.3 CEN Workshop Agreement

Whereas European standards require a voting procedure before the start of the work, whereby 71% of the European countries vote positive on the need for the proposed standard, the development of a CEN Workshop Agreement (CWA) does not require this vote. The CWA is a 'light' version of a European standard. The CEN Workshop Agreements[4] have no legal status and their implementation is not mandatory. They represent expert opinion consensus in areas where scientific evidence is scarce and therewith are important first steps to agenda setting, raising awareness and starting public debate on evolving topics of potential societal impact. This makes the CWA the relevant choice for the form of European standard for the SATORI standardization effort.

The CEN Workshop Agreement (CWA) is developed and approved using the standardized methodology of a CEN Workshop. Participation is open to anyone with an interest in the development of the agreement. The development of a CWA is fast and flexible, on average between 10-12 months. A CWA does not have the status of a European Standard. It involves no obligation at national level. A CWA may not conflict with a European Standard; if a conflicting European Standard (EN) is subsequently published, the CWA shall be withdrawn.

2.4 Methodology

Objectives

The objective of the study is to:

- explore standards/standardization in relation to assessment procedures, ethics and social responsibility;
- identify ways in which ethics has been standardized;
- find inspiration for a European (pre-)standard (e.g. CWA) in SATORI.

To achieve these objectives and give inspiration and recommendations for the standardization work in SATORI, D7.1. used a combination of methodologies: literature searches for both formal and non-formal standards, a call for source documents, expert consultation and interviews.

[4] https://www.cen.eu/work/products/cwa/pages/default.aspx

Relevant standards were identified and used to generate recommendations regarding the making of a CWA for ethics assessment.

Literature searches

Two searches for relevant standards were carried out by professionals from the Danish Standards' Information Centre.[5]

- Search 1 was carried out using Google, Google Scholar, library databases and databases with research articles.
- Search 2 was carried out using miscellaneous standards databases as well as instructions and guides from the formal standardization work in CEN and CENELEC.

Key search words include: "standard* AND" + engagement, user involvement, stakeholder engagement, societal involvement, ethics, ethical assessment, ethical assessment framework, moral, civil inclusion/involvement, human involvement, ethical impact assessment, impact assessment, research ethics.

Call for source documents

In addition to the searches, stakeholder experts, interviewees and SATORI partners from the previous and ongoing WPs,[6] were requested to submit source documents for consideration. Identified documents were included in the study and the results are included in the lists of formal and non formal standards and documents.

Expert consultation

Due to the specific mention of ISO/IEC JTC1 (Joint Technical Committee, working group 1) in the SATORI DoW a meeting was held with Danish national expert and member of ISO/IEC JTC1 Niels Madelung, chief consultant at Danish Standards. This was done to determine the relevance of standards developed in JTC1 and to clarify if these could be used as inspiration for the SATORI CWA.

Interviews

To get input from experienced standardizers[7] regarding relevant standards to look into and get advice on how to approach the CWA on ethics, a number of interviews with standardization experts in Danish Standards were conducted.

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[5] Danish Standards' Information Centre consists of experts working with searches on standards, guidance on CE-marking and handle the Danish WTO Enquiry Point. http://www.ds.dk/da/standardisering/standarder-og-haandboeger/standarder/hjaelp-og-vejledning-om-standarder

[6] In particular WP1, WP2 and WP4, where standards may have come up during the development of deliverables such as *D1.1: Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and Selected Other Countries* (http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf).

[7] In this study standardizers (persons who develops standards on a professional basis) who have been working in the field of standardization between 2-40 years were interviewed.

A total of 15 interviews was conducted. The following four questions formed part of the interview questionnaire.[8] Each interview started with a brief introduction to the SATORI project.

1. Do you know of standards within your area of expertise that integrate ethics?
2. We are going to develop a CWA for an ethics assessment framework as part of a European research project. Do you think that any of these standards (from Q1) can be used as inspiration or input for the CWA?
3. Do you know of any standards from other areas that might be useful?
4. How would you approach the task of making a CWA for an ethics assessment framework? Any advice or ideas?

Interviews were conducted in two stages. First, 10 experts in relevant standardization areas, such as sustainability and environment, were interviewed. In the second stage 5 persons were interviewed; these persons were chosen to make sure that several standardization areas and not the ones that at first seemed obvious were covered.

The longlist of standards with content on ethics guided the selection of the CEN of ISO Technical Committees (CEN/TC or ISO/TC) by which the standards were developed. The experts selected were the Danish Standards standardization experts that held the secretariat of the respective Technical Committees. In some cases the persons in the second stage had been recommended as relevant interviewees by the persons who were interviewed in stage one.

Standardization areas covered were: quality management systems, sustainability, health, IT security, anti-bribery, foodstuff, medical devices, contraceptive devices, sports equipment, steel production, cigarettes, workplace expositor, energy management, (corporate) social responsibility, electronic devices, cloud computing, smart cities, tourism, aluminum, indoor climate, innovation management, and animal welfare.

[8] The questions were devised by an expert (Katrine Bergh Skriver, consultant) in Danish Standard in order to pinpoint standards that may have relevance for the SATORI project.

3. Exploring standards and standardization

3.1 Searches for standards

As a part of the preliminary work for the development of a CWA in the SATORI project, the DoW outlines that "the partners will study to what extent assessment procedures in general (i.e. also beyond research) have become subject to standardising operating procedures, and explore standards related to ethics or social responsibility".[9] The purpose of this search is to make a non-exhaustive but representative list of documents in order to get a picture of the standards landscape focusing on standards developed outside the formal standardization system (Search 1) and in the formal standardization system (Search 2). In Search 1, focus was put mainly on non-formal standards for ethics in research/innovation and impact assessment.[10] In search 2, the limited number of formal standards allowed for a broader focus including social responsibility, ethics and assessment procedures in general.

The standards found in each search were screened in order to build two representative lists of standards. The part of the search carried out in electronic databases revealed some standards that did include sections on ethics but were not considered relevant for the further work in WP7, mostly because they would mention ethics but were too field/service specific. These were deselected and not included in the lists (e.g. EN ISO 22716:2007 Cosmetics – Good Manufacturing Practices).

The lists of standards were created to provide inspiration for the CWA. Throughout the CWA process[11], it would be beneficial to continuously check the lists to draw on the knowledge in existing standards and to ensure that there is no overlap with the SATORI CWA. Annex 1 presents the full list of non-formal standards and Annex 2 presents the longlist of formal standards.

The two lists of standards were analyzed and the findings are presented below.

3.2 Search 1: non-formal standards

3.2.1 General findings on non-formal standards

Several attempts have been made to set up non-formal standards for ethical research/innovation. The vast majority of the non-formal standards are sector specific;[12] however, some have been created with the purpose of developing a regional standard for Europe or the world spanning all areas of research for example *the Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations,*[13] *the Singapore Statement on Research Integrity*[14] and *The European Code of Conduct for Research Integrity*.[15]

[9] Description of Work – SATORI project page 28
[10] As there are a great number of non-formal standards it was deemed necessary to reduce the search by using more specific keywords. Findings in previous work packages, in particular WP4 "Roadmap for a common EU ethics assessment framework" guided the selection of keywords.
[11] The SATORI CWA development process is described in detail in Part II, chapter 6.2 of this deliverable.
[12] E.g. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Council of Europe. 1997 or Ethical aspects of information and communication technologies. The European Group on Ethics in Science and New Technologies (EGE). November 2011.
[13] http://www.researchintegrity.org/Statements/Montreal%20Statement%20English.pdf

One common trait in the European or world-wide non-formal standards is that they are short (the majority being less than 25 pages), listing only the main principles/responsibilities and leaving it up to the reader/user to fill in the details. Compared to the sector-specific standards, there seems to be a tendency that the broader and more wide spread the standard is (i.e. crossing national, institutional, disciplinary and sector boundaries), the shorter it will be (in number of pages of text).

Variety in national standards

The country specific non-formal standards differ quite a bit going from broad frameworks specifying general principles of ethics to checklists that a researcher or assessor can use to evaluate if research/innovation is ethical. However, due to the fact that many of these are drafted in national languages, only Danish and Dutch national standards have been included in this analysis.[16]

Sector or scientific field specific standards

The sector or area specific non-formal standards are national, regional, European or international. These range from fields such as biomedicine to nanotechnology and ICT. As seen in the country specific non-formal standards, the standards differ in content. The standards may have a similar structure; starting with general principles followed by more sector specific guidance and tools. Whereas the general principles might apply to several fields of research/innovation (e.g. maintaining integrity and protection of intellectual property rights), there are some very specific elements integrated into the tools and guidelines that are not necessarily transferable to other fields of work e.g. respect for persons when using human tissues samples would not be relevant when assessing ethics in ICT.

European Commission standards

Commissioners, project officers, research proposal developers etc. are important stakeholders as potential users of the SATORI CWA. Therefore, taking a look at their structure and language would be a benefit. The documents developed by the European Commission are more descriptive and therefore a bit longer in size than the European or world-wide non-formal standards for ethics and ethical assessment found in this search. They are also more concrete in defining certain areas of importance such as human participants and the use of animals in research. Some of the documents identified in this study stem from the European Commission, e.g. *the Impact Assessment Guidelines,*[17] *Horizon 2020 – How to complete your ethics Self-Assessment*[18] and *the Guidelines on Impact Assessment toolbox-*[19] These documents are often targeted at European Commission staff preparing and carrying out assessments, research proposal developers, project officers etc. These documents can be seen as guidelines that provide assessors with tools and "how to's" for impact and ethics assessment on areas such as "how to set up an impact assessment steering group" and "how to fill in ethics issues checklists".

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[14] http://www.singaporestatement.org/downloads/singpore%20statement_A4size.pdf
[15] http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
[16] For more information on country specific practices to ethics assessment please see work package 3.
[17] http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf
[18] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf
[19] http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

Lack of focus on ethical impact assessment

Search 1 results showed that in non-formal standards there is a more prominent focus on evaluating and conducting ethical research/innovation than on assessing the ethical impacts/implications of research/innovation. The majority of the documents in Search 1[20] focus either on ethical research/innovation or impact assessment procedures in general (not focusing specifically on ethics). There seems to be a gap when it comes to non-formal standards that combine ethics and impact assessment into ethical impact assessment. Combining the two in a CWA on ethical impact assessment could be a great addition to the existing world of standards.

Importance of the ethics committee

Search 1 also showed the creation of an ethics committee is widely promoted in the non-formal standards (regardless if they are national, sector specific, European or international). An ethics committee evaluates if research/innovation is being performed ethically. This should be considered when developing the SATORI CWA.

3.2.2 Recommendations for the CWA

The SATORI CWA can draw on the experience/results of previous work done in the field of ethics assessment. The non-formal standards can be used as an inspiration. Based on the findings above it is recommended that the SATORI CWA:

- focuses on general principles and responsibilities of ethics committees;
- covers all sectors, scientific fields and areas of research/innovation;
- focusses more elaborately on ethical impact assessment;
- keeps the text short and to the point and adds any elaborations or examples in an Annex;
- leaves room for the user/reader to define the details and level of importance of each principle/responsibility;
- takes the ethics committee into consideration as its composition and tasks are key.

The documents developed by the European Commission described above are also important to keep in mind when drafting a CWA aimed at the European research community, as:

- researchers drafting a proposal for Horizon 2020 are asked to consider the ethical issues defined by the Commission before being able to send in an application and receive funding;
- cooperation with European ethics assessors[21] will strengthen the use of the CWA in European research, making it important to consider the language and principles/responsibilities they are used to.

[20] Annex 1 provides the full list of the non-formal standards used in this analysis.

[21] In SATORI deliverable 1.1. ethics assessors are defined as "agents (organisations or individuals) that engage in ethics assessment, usually on a professional basis. Sometimes, this term is used more broadly, to include agents that engage in any type of ethics assessment, guidance, awareness raising or advisement. This definition does not imply that an ethics assessor has ethics assessment as its primary mission, or even that it recognizes itself to be doing ethics assessment. It merely means that the agent repeatedly and systematically engages in activities that can be analyzed as involving ethics assessment." (*Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and Selected Other Countries*, op. cit., p. 6.)

The content of the non-formal standards and documents from the European Commission are also useful for creating the main body of text in the SATORI CWA. E.g. *the Impact Assessment Guidelines* offer a step by step approach to impact assessment that may be useful when drafting the CWA.

3.3 Search 2: formal standards

3.3.1 Database search

Search 2 focused on standards within the formal standardization system.[22] The database search resulted in a longlist of over 100 standards. The text of these standards was screened for elements that could provide usable input for the SATORI project (e.g. sections on ethics, research, accountability assessment, etc.). First review of the longlist resulted in a first shortlist of 35 standards that could provide input for the SATORI CEN Workshop Agreement. The shortlist of standards can be used as reference work during the CWA process. Annex 2 provides the longlist of standards.

3.3.2 Standards proposed by SATORI partners

SATORI partners were requested to provide input to task 7.1. considering their own individual knowledge of standards and work performed in other work packages. 11 standards in the were suggested by these partners. The standards were:

- CEN/TS 16937 Nanotechnologies — Guidance for the responsible development of nanotechnologies;
- ISO 14001 Environmental Management Systems;
- ISO 14006 Environmental management systems — Guidelines for incorporating eco-design;
- ISO/TS 14441 Health informatics - Security and privacy requirements of EHR systems for use in conformity assessment;
- ISO 22000 Food safety management systems — Requirements for any organization in the food chain;
- ISO/TR 22221 Health informatics — Good principles and practices for a clinical data warehouse;
- ISO 22222 Personal financial planning — Requirements for personal financial planners;
- ISO 22307 Financial services — Privacy impact assessment;
- ISO CD2 37001 Anti-corruption;
- ISO/IEC DIS 29134 Information technology — Security techniques — Privacy impact assessment — Guidelines;
- ISO/IEC 29187-1 Information technology -Identification of privacy protection requirements pertaining to learning, education and training (LET).

Most of the standards suggested by the SATORI consortium partners were already in the longlist of standards as they were also found in the database search described above, the missing ones were added to the longlist in Part 1 – Annex 2.

[22] E.g. CEN and ISO.

3.3.3 Standards in JTC1 Information Technology

In the SATORI Description of Work (DoW) the hypothesis is made that the privacy impact assessment standards are the closest analogue for standardization of ethics assessment (or ethics impact assessment).

A talk with the Danish national expert and member of ISO/IEC JTC1[23] was set up in order to evaluate whether the standards in JTC1 could be used in the SATORI project or not. Two JTC1 standards were highlighted by the expert as relevant for the project. These were ISO/IEC 29100 'Information technology – Security techniques – Privacy framework' and ISO/IEC 29101 'Information technology - Security techniques - Privacy architecture framework'. These standards were included in the longlist of standards in Annex 2. The standards were then further evaluated by SATORI WP7.1 consortium standardization experts to see if they could be relevant for the development of the SATORI CWA.

3.3.4 Findings

The search and review resulted in a final shortlist of 40 formal standards (the 35 from the first shortlist plus additional suggestions from the SATORI partners and JTC1) that are of interest to the SATORI project. After studying the standards in the shortlist, seven were selected for further analysis. The two national standardization organizations in SATORI, DS and NEN selected the most relevant standards based on standardization expert knowledge and the experiences gained in the work on the other SATORI work packages.[24] The standards were chosen based on their relevance and similarity to the SATORI research topic and/or the likelihood that the standards could serve as a backbone and provide inspiration when developing the SATORI CWA.

The seven selected standards are:

- DS 49001 Social responsibility management system – Requirements;
- ISO 9001 Quality Management;
- ISO 22222 Personal financial planning – Requirements for personal financial planners;
- ISO CD 20400 Sustainable Procurement;
- ISO 26000 Guidance on social responsibility;
- ISO 31000 Risk management – Principles and guidance;
- ISO/IEC 29100 Information technology – Security techniques – Privacy framework.

Annex 3 provides further details on the abovementioned standards in the *Resume of formal standards*. These resumes were used in the SATORI standardization potential workshop.

After carefully analyzing the seven standards listed above, four were selected to use as inspiration for the first basis for SATORI CWA. In the choice the more abstract standards were selected rather than the more field specific interpretations of the same abstract standards as these would allow easier 'tweaking' into ethics assessment. The abstract standards use the same ideas of quality- and risk management as for instance the information technology standards. The core elements of these standards and why they were selected is summarized in table 3.1.

[23] http://www.iso.org/iso/jtc1_home.html
[24] In particular WP1, WP2 and WP4 of SATORI.

The SATORI standardization potential workshop, on 16 September 2015 in Brussels, gave the resumes as preparation homework to the SATORI partners. DS and NEN, the standardization experts, presented the four selected standards. Together with the SATORI partners, more experts in ethics and ethics assessment useful ideas in components of the standards were discussed, selected and prioritized.

Table 3.1 Argumentation for use of selected formal standards as inspiration for SATORI CWA

Selected standard	Possible contribution to SATORI
ISO 26000 Guidance on social responsibility	ISO 26000 could provide important input for the structure of the SATORI CWA; methodologically it can prove to be applicable for a CWA describing an Ethical Impact Assessment Framework. One of the key features of this standard is that it lists several core subjects, but encourages an organization to define and analyze its priorities in regard to social responsibilities. Therefore, the standard is written in the tone of "should" (for recommendations) instead of "shall" (for requirements), hereby leaving room for tailor fitting the standard to fit the organization and situation in which it is to be used. In addition, the standard focuses on social responsibility, a topic that is highly relevant when discussing ethics. Therefore elements from the core of the standard might also be interesting to consider in this CWA.
DS 49001 Social responsibility management system – Requirements	DS 49001, is the Danish version of ISO 26000. Unlike ISO 26000 DS 49001 is (unlike ISO 26000) certifiable and organizations interested in ensuring conformity with the requirements of the standard have the option to get a third party verification (by an independent, external stakeholder) and declaration of conformity on the basis of an external audit.
NPR 9036	NPR 9036 is the Dutch version of the guidance document to ISO 26000. The Dutch opted for a compliance system based on self-assessment.
ISO 9001 Quality Management	ISO 9001 is the most used management system standard. Methodologically, it can prove to be highly applicable for a CWA describing an Ethics Assessment Framework. One of the key features of this standard is customer satisfaction. Identification of the customers and their demands is part of the process and guides the organization to define their priorities, objectives and policy. The standard focuses on the process of management, it does not specifically focus on impact assessment.

Selected standard	Possible contribution to SATORI
	ISO 9001 is designed to be 'generic and is intended to be applicable to all organizations, regardless of type, size and product and service provided'. As a result, the level of abstraction is high, leaving responsibility to the organisation to design its own operationalization of the management system. ISO 9001 has already been adapted for different other uses such as risk management, compliance management, Corporate Social Responsibility (CSR), food safety and different sectors such as health care, medical devices, oil and gas production.
ISO 22222 Personal financial planning – Requirements for personal financial planners	Standards for assessment services specify how an assessment procedure should be carried out and defines the role of the assessor. The ethics assessor has a key role to play in ensuring the success of any type of assessment Framework; therefore, including aspects on assessment services could be beneficial for the SATORI CWA. Standards for assessment services are of interest for the SATORI project if it is decided that (part of) the CWA should specify which abilities and skills the assessors of ethics in research and innovation should have. To provide inspiration for how this could be done, one may look to relevant standards on assessment services that already exist in the formal standardization system.

The follow-up SATORI Ethics assessment framework workshop in Delft in February 2016 presented different possible standard structures, and discussed the implications of accepting the structure of a standard from a different field. The scientists and ethicists liked the ideas in the standards, but considered the structure and the language of the standards unfamiliar and therefore not suitable. Participants decided that the language and structure of the SATORI ethics assessment framework, as developed in Work Package 4, was more desirable for the structure and language of the proposed CWA, compared to the structure and language of the formal standards.

NOTE: In this selection ISO 31000 was dropped. In a later stage, when commenting on the first draft (internal review) of the CWA, risk management was again considered a relevant methodology for risk based thinking in ethics management. The CWA internal review requested a focus on risk management and decided to include excerpts of the ISO 31000 standard in the CWA part 1 on the ethics committee.

3.3.5 Recommendations for the CWA

Search 2 resulted in a shortlist with 40 standards. This list can be used throughout the CWA process[25] to locate existing standards which may have useful input for the different elements in the CWA and to ensure that there is no overlap between existing standards and the SATORI CWA.

The four selected standards each have different elements/aspects that may be used as inspiration in the SATORI CWA. The Brussels standardization potential workshop approved of the choice of the selected standards and prioritized the following arguments for the use of the standards:

- DS 49001 Social responsibility management system – Requirements
  - can provide valuable input as it is a certifiable standard. It can show how a standard can be written in a way that enables certification in a related field (social responsibility). This is of interest if it is determined in task 7.4 (Development of a framework for certification for ethics assessment) that the SATORI CWA should be written in a way so that it may later be turned into a certifiable standard;
  - combines elements from three different relevant standards: ISO 9001[26], ISO 14001[27] and ISO 26000[28], thereby creating a management system (PDCA principles) which takes quality, environment and social responsibility into account.
- ISO 9001 Quality Management
  - is the most widely used management system standard in the world. Its methodology is well-known and accepted, so basing the SATORI CWA on this standard may ease acceptance in society as the methodology will be familiar to many;
  - is a generic standard that aims to fit all types and sizes of organizations as is the aim of the SATORI CWA.
- ISO 22222 Personal financial planning – Requirements for personal financial planners
  - focuses on the steps in an assessment process and the abilities and competences of an assessor (in this case a financial planner). The content of this standard is useful to take into account when considering the ethics committee in the SATORI CWA.
- ISO 26000 Guidance on social responsibility
  - is applicable to all organizations (like ISO 9001);
  - gives the international view on how to become a socially responsible organization. As the CWA in SATORI is European, this can give input to how a standard that spans borders in a highly related topic can look.

Even though the standards above are in many ways applicable during the development of the SATORI CWA, none of the standards are a perfect fit. This supports the hypothesis that there is a lack of formal standards in the field of ethics assessment and ethic impact assessment. Therefore, the SATORI CWA might use the standards as inspiration, but the detailed content will have to be developed by the SATORI consortium. Much of content can be based on the work carried in other work packages, especially WP4, but it is recommended that the methodologies, such as quality assurance and risk based thinking, and structure of the above mentioned standards are taken into account when developing and structuring the CWA.

[25] Chapter 6.2, of this Deliverable 7.1, provides detailed information about the CWA development process and additional consultation efforts.
[26] Standard for Quality management
[27] Standard for a Environmental management system
[28] Standard for Guidance on social responsibility

3.4 Interviews with standardization experts

3.4.1 Main conclusion from interviews

In addition to the searches, 15 interviews with standardization experts from Danish Standards were carried out covering a wide variety of standardization topics such as sustainability, IT security and anti-bribery. The purpose of the interviews was to learn from their experience regarding standards covering ethical topics/aspects and to get advice on how to approach a CWA process for ethics assessment. See the Methodology section for an overview of the method used to select the interviewees and the questions asked in the interviews.

Annex 4 presents the notes of the interviews with standardization experts.

A great amount of standards are implicitly ethical in one way or the other because a great amount of standards are made to ensure safety, help the environment, etc. These are all topics that may be subject to a certain kind of ethics assessment, e.g. how safe should a product be vs. the cost of ensuring safety.

In general, the 15 interviews resulted in recommendations that were quite similar despite the experts being in very different standardization fields. The most mentioned standards in the interviews were the ones for social responsibility (ISO 26000 and DS 49001).

The recommendations from the interviews on how to approach the CWA process for SATORI have been split under two headings; *Facilitation of the CWA process* and *Input for the structure of the CWA.*

3.4.2 Facilitation of the CWA process

The recommendations made by the interviewees were:

- to make it clear for the participants in the CWA workshop what to expect during the development of the CWA;
- to define the main characteristics of a CWA for the participants;
- to describe the process of a CWA including who is responsible for what, who is writing what etc.;
- to clearly define the division of responsibility etc. in the CWA itself (e.g. what are the roles of the researcher/the coordinator/research institute/standardization institutes etc.);
- to have a strict management of both the form/process/discipline and content – keeping deadlines etc. to enhance the chance of making a CWA in the quite narrow time span.

Additional advice was to divide people into smaller groups during the development of the CWA and appoint a convener for each group to make the work of the CWA process smoother.

3.4.3 Input for the structure of the CWA

The advice from the interviewees regarding the structure of the CWA document was in general to design the CWA as an intermediate between a management standard and a checklist – and maybe

include some of the characteristics from a CEN guide.[29] A number of examples for inspiration were mentioned – e.g. ISO 26000 Guidance on social responsibility, DS 49001 Social responsibility management system, CEN-CENELEC Guide 17 Guidance for writing standards[30] taking into account micro, small and medium-sized enterprises (SMEs) needs, and CEN Environmental Helpdesk[31] (especially the guide and the checklist).

The interviewees recommended using the CEN template for drafting a standard from the beginning.[32] Additional advice was to:

- include a section in the CWA with terms and definitions (but very brief definitions of the terms – max. 4-5 lines per term);
- keep the target audience in mind when drafting the CWA;
- keep it short and precise;
- write in a simple language, easy to understand for everybody;
- make it operational with a logic/clear structure;
- use examples to explain and support the content;
- think of the costs of implementing the CWA;
- consider the need for a manual for implementation.

[29] A guide is a document format used in the standardization world made to guide the readers through a certain standard or standardization related topic. The official definition of a guide is:
The CEN Guide is an informative document made available by CEN in at least one of the official languages, established and approved by a corporate body of CEN by simple majority vote.
A CEN Guide gives information about standardization principles and policies and guidance to standards writers.
A CEN Guide may be established with a view to serving for instance the purpose of:
- providing technical or administrative orientation to the work of CEN;
- giving advice on how to deal with matters of standardization;
- collecting decisions of a CEN corporate body on specific general questions related to standardization for future equal treatment of such questions.

Source: http://boss.cen.eu/ - Guidance documents
[30] http://www.cencenelec.eu/sme/smenews/Pages/guide17.aspx
[31] https://www.cen.eu/about/helpdesks/environmental/Pages/default.aspx
[32] All formal standards are structured in the same way. This makes it easier to get an overview of a new standard and to read standards. See Annex 5 – *Structure of a formal standard* for an outline of the structure of formal standards.

4. Moving ethical issues from research into standardization

4.1 Possible limitations to standardizing ethics assessment

Several non-formal standards for ethics-related subjects have already been developed (as presented in Annex 1). Additionally, several standards on similar topics and standards that include ethics in part exist in the formal standardization system (Annex 2). Keeping this in mind, it can be assumed that it is technically possible to create a standard for ethics (impact) assessment in research/innovation.

WP 1 reported that interviewees expressed doubts that ethics could be standardized at a European level. In standardization 'consensus'[33] is the principle of general agreement on the content of a standard. To assess the feasibility of standardizing ethics assessment, the formal standardization development process follows a 'let's start and see how far we get' approach. The consensus methodology includes presenting draft documents; inviting comments and alternative text proposals in the internal and external reviews and discussing and resolving the comments and text proposals in plenary meetings with stakeholders. The consensus methodology allows to accept, reject or amend comments and text proposals. This consensus methodology results in a document that includes those texts that the experts agree on and reject those texts that the experts do not agree on; controversial issues are not included. Part II of this deliverable describes the process, challenges and outcomes to standardize ethics assessment.

During the interviews in task 7.1 with the standardizers, the attitude was, that it is in fact possible to standardize ethics (impact) assessment in research/innovation, but that there are some things to pay special attention to, such as using examples to explain and support the content. Section 5 lists the recommendations.

Developing a standard always has a number of potential challenges; this is an unavoidable part of the standardization process due to the way it is structured. The strengths of the standardization system can at the same time be its weakness. Standardization is an open process involving stakeholders where consensus is one of the most important cornerstones – this gives the final standardization documents their weight and approval. At the same time, it is a potential challenge in any given standardization process that the stakeholders need to be engaged – stakeholders write the standards, so if they do not participate, the standard will not be written, or if they participate half-heartedly, this also adversely might affect the quality of the standard. If for some reason it is impossible to reach consensus the standard can also be adversely affected. Having the relevant and a broad representation of stakeholders is also always a challenge that needs to be addressed – the lack of a broad representation of relevant stakeholders in the standardization process will influence the impact of the finished standard document.

It is important to keep the possible obstacles mentioned above in mind to ensure that the quality of the SATORI CWA is sufficiently high.

[33] Consensus: general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments
NOTE Consensus need not imply unanimity. Source: ISO/IEC guide 2:2004
http://isotc.iso.org/livelink/livelink/fetch/2000/2122/4230450/8389141/ISO_IEC_Guide_2_2004_%28Multilingual%29_-_Standardization_and_related_activities_--_General_vocabulary.pdf?nodeid=8387841&vernum=-2

5. Conclusions Part 1 - Recommendations for SATORI CWA

Overall the main-conclusion is that some formal and non-formal standards as well as certain policy documents can provide inspiration for the SATORI CWA. The standards and standard documents described in this study can be used as source documents when refining and co-creating the main body of text in the SATORI CWA. For main ideas and source documents, however, the CWA will rely on the reports on the SATORI Work Package 4, especially on the SATORI ethics assessment framework.

This analysis also shows that it is important to follow some basic guidelines regarding the creation of standards. The recommendations from Part I in this report are split into three sections; recommendations for writing the CWA, recommendations for the CWA process and recommendations for the CWA content.

5.1 Recommendations for writing the CWA

The analysis provides the following recommendations for writing the CWA:

- keep the text short and to the point (add any elaborations or examples in an Annex);
- leave room for the user/reader to define the details and level of importance of each principle/responsibility;
- write in a simple language, easy to understand for everybody;
- structure the CWA as an intermediate between a management standard and a checklist – and maybe include some of the characteristics from a standard-making guide;
- to include a section in the CWA with terms and definitions (but very brief definitions of the terms – max. 4-5 lines per term);
- keep the target audience in mind when drafting the CWA;
- make it operational with a logic/clear structure;
- whenever possible use the language the target group is used to in order to ease implementation.

5.2 Recommendations for the CWA process

The analysis provides the following recommendations for the CWA process:

- make it clear for the participants in the CWA workshop what to expect;
- define the main characteristics of a CWA for the participants;
- describe the process of a CWA, distribute responsibilities and writing assignments among participants;
- have a strict management of the form, process, discipline and content – keeping deadlines etc., to enhance the chance of making a CWA in a quite short time span;
- make smaller groups and appoint a convener for each group to make the work go smoother;
- consider the need for a manual for implementation;

- cooperation with European ethics assessors and other key stakeholders will strengthen quality of the CWA and potentially facilitate implementation;
- use the four selected standards (DS 49000, ISO 9001, ISO 22222 and ISO 26000) as inspiration for the structure, etc., of the SATORI CWA and use the lists of standards (Annex 1 and Annex 2) continuously when inspiration or an example is needed.

The standardizers and persons drafting the SATORI CWA should strive to continuously use these recommendations throughout the CWA development process to ensure that it is well-written and that it thereby creates as much value as possible for the ethics (impact) assessment community and other stakeholders.

5.3 Recommendations for the CWA content

The analysis provides the following recommendations for the CWA content:

- many existing ethics assessment documents focus on ethics assessment in the medical scientific field. The SATORI CWA could get inspiration from good practices from the medical scientific field; however, the role of the model of the medical sciences should not be exaggerated as the ethical challenges in the medical field are different from ethical challenges in other scientific fields. The CWA should focus on general principles and responsibilities for all scientific fields and areas of research and innovation.
- for the CWA to have an added value, it should address more issues than a list of principles and procedures, as already many existing national and European documents focus on ethical principles and procedures;
- the role of the ethics committee is considered very important. The CWA could get inspiration from the role of the medical ethics committees to define the possible role for the ethics committees in other scientific fields. As before, the CWA should focus on general principles and responsibilities for all scientific fields and areas of research and innovation.
- whereas the selected standards contain good and relevant ideas, the structure and language of formal standards might not be familiar to ethicists and scientists. Therefore, the CWA should rather build on the structure and language from the ethics assessment framework as presented in SATORI WP4. The ideas form the standards, like quality management, social responsibility and risk based thinking can be included.
- take the ethics committee into consideration as its composition and tasks are key.
- whereas the medical scientific field provides good practices and guidance on ethics assessment, there is lack of guidance on ethical impact assessment. The latter should be prominently emphasized in the CWA. With regard to this, SATORI could get inspiration from technology assessment experiences.
- think of the costs of implementing the CWA.
- use examples to explain and support the content.

Part 2 – Standardizing ethics assessment for research and innovation

6. Objectives and methodology

6.1 Objectives

The SATORI project aims to assesses the feasibility of getting European consensus on ethics assessment for research and innovation. The standard procedure of the Comité Européen de Normalisation (CEN) Workshop Agreement (CWA) was used to develop European consensus.

The CWA sets requirements and provides guidelines for ethics assessment of research and innovation. It aims to improve the quality of ethics assessment and harmonize ethics assessment practices. The CWA has two parts:

— part 1 - Ethics committee: provides recommendations for the ethics committee on practices and procedures;

— part 2 - Ethical impact assessment framework: provides a practical, policy-oriented guide for researchers and ethics assessors on the different stages of the ethical impact assessment (EIA) process.

Both parts of the CWA are of interest to organisations or agents involved in performing, commissioning or funding research and innovation, and therefore have a responsibility to address ethical issues.

The focus of the CWA is on ethics assessment, not on ethical guidance.

6.2 Methodology

At the start of the standardization effort SATORI partners proposed the Workshop project plan (Annex 6) with the scope (objectives) of the CEN Workshop Agreement and the programme to reach European consensus.

The programme to reach the CEN Workshop Agreement is based on the CEN standard methodology for this deliverable. The 7 steps were performed within the planned timeframe.

In order to enhance the understanding of the standardization objectives and process with the SATORI partners as well as ethicists additional workshops were organized and experts were invited to share ideas, experiences, and understanding of the potential role of standardization for ethics assessment. The table presents the CWA methodology in the left column and the additional dialogue and mutual learning workshops in the right column.

Table 6.1 Stepwise methodology for the CWA development and additional communication, networking and mutual learning activities

CWA development steps	Communication and networking activities to support the CWA
Objectives and planning	
1. Organisation of the kick-off meeting The Project Plan and the invitation for the kick-off meeting was posted on the CEN Website for a period of 30 days. Participation in the development of a CEN Workshop Agreement is open to anyone, and the opportunity to participate was widely advertised in advance by CEN to its member bodies.	The opportunity to participate was widely advertised in advance by the SATORI network to its stakeholders
2. The **kick-off meeting on 17 September 2015,** in Brussels: • approved the Workshop Project Plan by agreement of the participants; • appointed the Workshop Chair and designated the secretariat; • solicited for source materials from the different participating stakeholders/countries.	On 16 September 2015 the **SATORI standardization potential workshop** highlighted and prioritized the for SATORI useful ideas in existing formal standards
First draft and internal review	
3. The NEN Standardization experts in the SATORI project reviewed source materials and compared these with the results of the different work packages in the SATORI project. On the basis of the SATORI reports and the workshopped first ideas, the standardization experts prepared the first draft for workshop consideration. The draft CWA document was sent for comments to SATORI partners in the **internal review**.	The NEN standardization experts discussed the first ideas and challenges for the CWA with the SATORI partners and external experts during the **SATORI Ethics assessment framework workshop,** on 17-18 February 2016 in Delft, the Netherlands.
4. On 1 June 2016 the first **Workshop plenary meeting** with SATORI partners and external experts resolved the comments from the **internal review** in Copenhagen. Annex 7 presents the comments and their resolution. All agreed comments were incorporated in the CWA documents. The second draft was approved in writing by all participants.	The first Workshop plenary meeting was organized in combination with the **SATORI cost effectiveness workshop** on 31 May in Copenhagen. Interested stakeholders contributed to the discussion on the first draft.

Second draft and external review	
5. A 60-day **Public commenting phase** was organized. The second draft was published for public comments on the CEN, DS and NEN websites. All stakeholders were invited to comment. The public enquiry resulted in over 500 comments on the CWAs, showing great interest in and commitment to improve de SATORI CWAs.	Originally a 60 day public enquiry was planned. The period was extended to 90 days to allow incorporating the comments from the participants in the **SATORI dialogue event** on 12 and 13 October 2016 in Milan, **Ethics assessment workshop** on 14 October in Milan and **SATORI mutual learning workshops** in November 2016 in London, Utrecht and Warsaw that used the CWAs in exercises and case studies.
6. 1 February 2017 a second **plenary Workshop meeting** resolved the comments from the public enquiry. A writers group of SATORI partners proposed text suggestions to facilitate the approval of 500 comments in a one day meeting. The meeting approved, disapproved or amended all comments. The comments were too many to be included in this Deliverable. All approved comments were incorporated in the CWA documents. By correspondence all SATORI partners and external experts that participated approved the final draft of part 1. As the workshop did not finalize all comments and text suggestions on part 2 an additional meeting was organized in May in Brussels. This meeting resolved the last outstanding issues and approved the publication of part 2.	Experts invited to the SATORI Heritage workshop also participated in the plenary Workshop meetings in Ljubljana and Brussels.
Publication	
7. SATORI partners approved the publication of SATORI CWAs part 1 and part 2. This means that consensus had been reached on ethics assessment for research and innovation. The Workshop secretariat has submitted both CWA documents to the CEN-CENELEC Management Centre for **publication**. The CWA documents will be available as reports on the SATORI website. The publication versions are annexed to this Deliverable report, in Annex 9 and 10. The CWA documents are also available at normal cost from CEN and all national standardization institutes.	

7. Standardization benefits and challenges

7.1 ISO standards as inspiration

During the early stages of the process much effort was made to familiarize the SATORI consortium partners with standardization. Apart from the standard organisations, most SATORI partners had never been involved in the making of a standard. The underlying values, objectives and procedures were explained. This allowed the research to benefit from the standardization, as will be explained below. The results from task 7.1 with respect to the facilitation were taken at heart.

Part 1 of this deliverable presents a list of standards that have assessment procedures, ethics assessment and social responsibility in their scope. The ISO standards on quality management and corporate responsibility and risk management were considered relevant to be used as inspiration for the CWA.

However, the structure of the standards and chapter headings were considered uninspiring by SATORI partners. The language and use of concepts was considered unfamiliar to scientists and ethicists. The participants in the ethics assessment framework workshop and first CWA plenary meeting suggested to use the division of chapters as presented in the SATORI framework as suitable for the CWA. However, the information on quality management, one of the most well known subjects within standardization, was extensively used and recognised as a good practice in the research results of WP4 and incorporated in the SATORI framework.

The ideas in the ISO standards on quality management, risk assessment and social responsibility were considered interesting, useful and challenging for the CWA on ethics assessment.

7.2 Existing ethics assessment documents as inspiration

Many existing ethics assessment documents focus on ethics assessment in the medical scientific field. The authors of the SATORI ethics assessment framework analyzed these documents for good practices.[34] The role model of the medical sciences should not be exaggerated as the ethical challenges in the medical field is different from the ones in other scientific fields. The CWA focuses on general principles and responsibilities for all scientific fields and areas of research and innovation.

7.3 SATORI ethics assessment framework as inspiration

The writing of the ethics assessment framework in WP4 had not been finished yet at the time when it was necessary to develop the first draft of the CWA. As a result, early drafts of the WP4 reports were used as a source.

This parallel work on two deliverables has resulted in improvements in both. The authors of the WP4 deliverables are predominantly academic researchers. The authors of the CWAs are predominantly standardization experts. Both have different competences and different ways of

[34] SATORI WP4 deliverables on www.satoriproject.eu.

working. The result of the parallel work has allowed co-creation and refinement of both the deliverables in WP4 and WP7. The standardization experts asked for clarifications to be able to include the conclusions in the standard. The academic deliberations on advantages and disadvantages of different options did not always lead to clear conclusions. Earlier drafts of the framework stated that the plan had to be assessed. The standardization experts highlighted the need to determine who is responsible for doing that specific task and requested further elaborations. Expressions that needed clarifications were for example 'small size' and 'near future'.

The parallel work also affected the outcome as extra time was needed to achieve consensus. During the internal review meeting the text of the CWA was not yet very mature. The discussion between SATORI partners mostly focused the role and procedures of the ethics committee. The comments on the chapters on ethics impact assessment in the CWA were not discussed at length as a major revision of the text in the section was still envisaged. The internal review meeting resulted in the decision to separate the CWA in two parts; part 1 on the role and procedures of the ethics committee and part 2 on the ethical impact assessment framework.

The public enquiry resulted in substantial comments on part 2. The substantial changes to the texts in part 2 required an additional review before the final texts could be approved. The resulting final drafts of the CWAs were approved by SATORI partners and participating experts.

7.4 Concepts and definitions

The CWA chapter on concepts and definitions received many comments in the reviews of the drafts. Several European organisations have presented lists of concepts and definitions and, especially those with a medical background, highlighted the importance to follow the already existing concepts and definitions and put the SATORI project under pressure not to come up with a new set. Though agreeing with the need to use widely accepted terms and definitions, SATORI has merged the ethical discussions from different scientific fields and has elaborated on impact assessment. Therefore, the final set of concepts and definitions does not exactly copy any previously existing set. Rather, the final set of definitions is a combination of previously established definitions. SATORI added new terms and definitions where existing definitions were not considered adequate. The terms and definitions chapter in the CWAs refers to the sources of definitions.

After publication of CWA part 1 the definition of human participants was contested. After approval by SATORI partners and external experts a revised version of CWA part 1 was published in July 2017 with a correction notice.

7.5 Aspirational versus practical

SATORI WP4 presents a framework for ethics assessment of research and innovation. The framework’s section on ethical impact assessment was used as the basis for the CWA part 2. Right from the start discussions in the SATORI project focused on whether the ethical impact assessment framework was practical enough to be developed into a standard and questions were raised whether the framework would not be too ambitious, too elaborate and costing too much time to perform, adding substantially to the cost of research or innovation.

The dilemma between the aspirational and the practical is a known challenge in the development of standards. For those who want to improve their practices, it is important that a standard is aspirational and presents clear and challenging requirements with sufficient guidance on how to

meet them. However, when such an aspirational standard seems too far removed from the existing practices, the proposed standard could be interpreted as a hindrance to innovation, unpractical and unrealistic to achieve. Some standards would therefore rather advocate for minimum requirements.

The dilemma between the aspirational and the practical has extensively been discussed in the making of the CWAs on ethics assessment. The first drafts of the CWA part 2 were ore comprehensive and elaborate than the later ones. The public enquiry and especially the SATORI dialogue and SATORI mutual learning workshops resulted in comments to reduce the procedures and requirements for the ethical impact assessment framework in CWA part 2 as it would be impossible for small and medium enterprises to comply. It took the project an additional meeting to approve the reduced version of the framework. An important argument in not further reducing the framework is that it is not possible to present a 'one size fits all' approach and a certain level of scaling is required.

7.6 The role of researchers in ethical impact assessment

The ethics assessment procedures in the SATORI framework mainly focusses on the roles, competences, procedures and practices of the ethics committees. The researchers, however, have a large responsibility in the ethical impact assessment of their own research work. As the target audiences are different for the different chapters of the framework; ethics committees for ethics assessment and individual researchers and ethics assessors for ethical impact assessment, the CWA Internal review meeting decided to spit the framework into two documents. The result is a CWA with two parts: part 1 on the ethics committee and part 2 on the ethical impact assessment framework.

7.7 Communication, dissemination and support

In order to assure that interested parties outside the SATORI project consortium would share their experiences and participate in the project's activities, much effort was put in communicating and disseminating the CWA development. Co-operation from external experts and stakeholders was considered op utpost importance to create buy-in from stakeholders outside the project, learn from their input and further improving the final product, the CWA.

Throughout the standardization process, the SATORI project activities and the standardization activities reinforced each other in bringing attention to and discussing the dynamics around ethics (impact) assessment, including exchanging opinions between the SATORI partners and stakeholders, especially in the SATORI dialogue and mutual learning workshops that were organized in combination with the CWA meetings[35]. This exchange had substantial impact on the content of the CWA and the SATORI project results. SATORI project partners hope that participation in the workshops and in the standardization process has inspired external experts and stakeholders, creating buy-in with the SATORI results. This would entail that the CWA will be put into practice and remain relevant after the project finishes.

A communication plan for the public enquiry was drafted so that the interested parties would be informed about the progress during the different stages of the development of the CWA, in collaboration with the consortium partners of SATORI WP 10. Several press releases were sent out, public presentations were given and articles published. Annex 8 presents the public enquiry

[35] Table 6.1 presents the SATORI CWA meetings and SATORI workshops.

communication plan and some of the articles. The communication has contributed to active participation from interested parties during the SATORI workshops, the CWA meetings and most notably during the public enquiry phase and the mutual learning workshops..

The standardization effort on ethics assessment of research and innovation highlighted the need to raise awareness on the importance of ethics (impact) assessment in general. Most organisations and individuals may have heard of ethical issues regarding research and innovation and may have read articles on current discussions on privacy, big data, nanotechnology, embryo research, and similar topics, but they might not be aware that ethical issues are relevant to their own research and innovation practices and that addressing ethical issues might improve the outcomes of research, acceptance of innovations and the benefits to society.

In total 75 experts from 15 European countries and 10 European institutes participated in the development of the CWA. The number does not include the experts, innovators and researchers that participated in the SATORI mutual learning workshops; the SATORI partners submitted the comments on their behalf during the public enquiry.

8. Conclusions

The publication of the SATORI CWA: 2017 Ethics assessment of research and innovation – Part 1 Ethics committee and – Part 2 Ethical impact assessment framework[36] prove it has been possible to standardize ethics assessment for research and innovation, and to what extent.

Part 1 of the CWA on ethics committees includes chapters on ethics committee (roles, responsibilities, competencies, appointment and composition), ethical issues and principles, procedures for ethics assessment and quality assurance in ethics assessment. The annexes provide additional information on basic and scientific field specific ethical principles, risk based thinking and guidelines for the use of plan-do-check-act for quality assurance in ethics assessment.

Part 2 of the CWA on ethical impact assessment framework includes chapters on the ethical impact assessment framework and its components: ethical impact assessment threshold analysis and plan, ethical impact anticipation and evaluation, remedial actions, review and audit. The annexes include information on ethical issues for the threshold analysis, technology scale ethics assessment, methods for ethical impact anticipation, determination and evaluation.

In total 75 experts from 15 European countries and 10 European institutes participated in the development of the CWA.

The CWAs can provide ethics assessors, researchers and innovators with motivation and guidance to improve ethics assessment practices and perform the research and innovation that will contribute to desirable outcomes for society.

[36] The final publications are available from the SATORI website.

Annex 1 – Search 1: full list of non-formal standards

- A Framework for Science Advice on Health: Principles and Guidelines. European Science Advisory Network for Health. October 2011.
- A framework for the ethical impact assessment of information technology. Wright, David. Springer Science+Business Media. July 2010.
- A Framework of Policies and Procedures for University Research Ethics Committees. The Association of Research Ethics Committees, 2013.
- AA1000 Stakeholder Engagement Standard 2011, AccountAbility, 2008.
- ASSESSING THE COSTS AND BENEFITS OF REGULATION – Study for the European Commission, Secretariat General. December 2013.
- *Basel Declaration – A call for more trust, transparency and communication on animal research.* Adopted on the occasion of the first Basel conference »Research at a Crossroads. November 2010.
- *Better Regulation Guidelines.* European Commission, May 2015.
- Code of Ethics and Conduct – Guidance published by the Ethics Committee of the British Psychological Society. Ethics Committee of the British Psychological Society. August 2009.
- Code of ethics in science and research Good scientific practice. Ljiljana Vučković-Dekić et AL, Stom Glas S, vol. 54, 2007
- Code of Practice for Research – promoting good practice and preventing misconduct. UK Research Integrity Office, September 2009
- *CODEX – Rules and Guidelines for Research*. http://www.codex.vr.se/en/regler.shtml
- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Council of Europe. 1997.
- *Danish Code of Conduct for Research Integrity.* Danish Ministry of Higher Education and Science, November 2014
- 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. Official Journal of the European Union
- ESRC Framework for Research Ethics (FRE) 2010 Updated September 2012. ESRC, 2012.
- Ethical and Regulatory Challenges to Science and Research Policy at the Global Level. Directorate- General for Research and Innovation. EU, 2012.
- *Ethical aspects of information and communication technologies*. The European Group on Ethics in Science and New Technologies (EGE). November 2011.
- Ethical Perspective on Science, Technology and Society: A Contribution to the post-2015 agenda. UNESCO & COMEST, 31 July 2015.
- Ethical Principles for Climate Change: Adaptation and Mitigation. UNESCO & COMEST, 1 October 2015
- *Ethical questions in the area of age appropriate assisting systems.* A. Manzeschke, K. Weber, E. Rother, H. Fangerau, commissioned by VDI/VDE Innovation & Technik GmbH, March 2015.
- *Ethics Matters – managing ethical ethics in higher education,* The Council for Industry and Higher Education & The Institute of Business Ethics
- *European Textbook on Ethics in Research.* European Commission Directorate-General for Research, Publications Office of the European Union, 2010

- Forskning i sundhedsdata og biologisk materiale i Danmark – Udtalelse. Det Etiske Råd. 2015.
- *Global Health Ethics Unit – Newsletter*. World Health Organization, September 2015.
- *Governance arrangements for research ethics committees - A harmonised edition.* DH Research and Development Directorate, National Institute for Social Care and Health Research, Chief Scientist Office & R&D Division, Public Health Agency, 1st September 2011.
- Guide for Research Ethics Committee Members - Steering Committee on Bioethics. Council of Europe, April 2012
- *Guidelines on Impact Assessment*. EC. http://ec.europa.eu/smart-regulation/guidelines/ug_chap3_en.htm & toolbox http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm
- Guidelines on the practice of ethics committees in medical research with human participants. 4th Edition, The Royal College of Physicians of London, September 2007
- Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework. Special Representative of the Secretary-General. UN. June 2011.
- Horizon 2020 – How to complete your ethics Self-Assessment. Version 1.1, European Commission, December 2014
- *HTA Core Model for screening technologies*. Work Package 4 Core HTA, EUnetHTA Joint Action 2010 – 2012. September 2011.
- IMPACT ASSESSMENT GUIDELINES. EC. January 2009.
- International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organizations of Medical Sciences. 2002.
- Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations. Developed as part of the 3rd World Conference on Research Integrity, May 2013
- *National Statement on Ethical Conduct in Research Involving Humans.* Commonwealth of Australia 1999, Issued by the National Health and Medical Research Council (NHMRC) in accordance with the NHMRC Act, 1992 (Cth).
- *Online Ethics Centre for Engineering and Research.* http://www.onlineethics.org/Resources/ethcodes/EnglishCodes.aspx
- Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (The Vancouver Regulation), ICMJE, 2013
- Recommended checklist for researchers. UK Research Integrity Office
- REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. Official Journal of the European Union, May 2014.
- Report of the IBC on the Principle of the Sharing of Benefits. UNESCO & IBC, October 2015.
- Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights. UNESCO & IBC, October 2015.
- Research ethics committees – Basic concepts for capacity-building. World Health Organization. 2009.
- Research ethics committees Basic concepts for capacity-building. World Health Organization, 2009.
- RESPECT Code of Practice for Socio-Economic Research. RESPECT project. 2004.

- Responsible Conduct in the Global Research Enterprise. InterAcademy Council, September 2012.
- *Responsible Research and Innovation in Industry - The Case for Corporate Responsibility Tools.* Konstantinos Iatridis & Doris Schroeder, SpringerBriefs in Research and Innovation Governance, 2016.
- Rulebook on the Contents of the Application, and/or Documentation on the Approval of Clinical Trials for Medicines and Medical Devices, as well as the Method of Implementation for Clinical Trials of Medicines and Medical Devices. Official Gazette of the RS", nr. 64/2011 of 31 August 2011.
- *RULES OF PROCEDURE of the Scientific Committees.* European Commission DG for health & consumers, December 2009.
- *Singapore Statement on Research Integrity*, developed as part of the 2nd World Conference on Research Integrity, July 2010
- Standardising Responsibility? The Significance of Interstitial Spaces. Fern Wickson & Ellen-Marie Forsberg, Sci Eng Ethics, October 2014
- Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market. DG Enterprise and Industry. 2nd draft. June 2014
- *The assessment of ethics*. Hughes, Clair. The University of Queensland, Australia. 4th Asia Pacific Conference on Educational Integrity (4APCEI) 28–30 September 2009, University of Wollongong NSW Australia
- *The European Code of Conduct for Research Integrity.* The European Science Foundation & All European Academies, March 2011
- The protection of individuals with regard to the processing of personal data and on the free movement of such data. DIRECTIVE 95/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 October 1995
- *UN Global Compact*. UN. https://www.unglobalcompact.org/
- *Universal Declaration on Bioethics and Human Rights*. UNESCO's General Conference. http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/. 19 October 2005.
- University Research Ethics Committees: Their role, remit and conduct. Tinker, Anthea. King's College London. September 2004.
- WMA Declaration of Helsinki – Ethical Principles for medical Research involving Human Subjects. The World Medical Association (WMA). October 2013.
- *World Medical Association – medical ethics manual*, The World Medical Association, 2nd edition 2009

Annex 2 – Search 2: longlist of formal standards and formal standard documents

Organisation - Number - Title	Why
CEN Guide 17 Guidance for writing standards taking into account micro, small and medium-sized enterprises (SMEs) needs (also as ISO/IEC guide)	Inspiration on how to write the CWA. A well-written guide, concrete and operational. Well arranged.
CEN TS 16555-1 Innovation Management - Part 1: Innovation Management System	This Technical Specification provides guidance on assessing the innovation management system and its performance. It describes how organizations can create transparency internally on strengths and weaknesses in their innovation management system. This transparency can be used as a basis to develop effective actions to improve the innovation management capabilities and performance. This standard is interesting for the SATRORI project due to its focus on innovation and assessment; however there is no focus on ethics or social responsibility in the Technical Specification.
CEN/TS 16937 Nanotechnologies — Guidance for the responsible development of nanotechnologies.	This Technical Specification provides a guidance for the responsible development of nanotechnologies taking into account: — Board Accountability; — Stakeholder Involvement; — Worker Health and Safety; — Benefits to and Risks for Public Health, Safety and the Environment; — Wider Social and Ethical Implications and Impacts; — Engagement with Business Partners; — Transparency and Disclosure.
DS 49001	Ethical aspects of social responsibility – relevant for

Social responsibility management system – Requirements	SATORI. Also relevant in relation to certification and structure of the CWA.
NPR 9036 Due diligence	NPR 9036 provides guidance on the integration of due diligence based on the UN Guiding Principles on Business and Human Rights (UNGP) in existing (risk) management systems that companies already apply (formally or informally) to identify and evaluate specific and/or generic risks and to take the necessary actions to address these as part of their business operations. There are several advantages to integrating due diligence in existing (risk) management systems. This avoids duplication, ensures building on existing experience and knowledge, application of proven techniques and promotes that due diligence becomes part of the 'normal' operations of a company, both in its own operations and those of its business partners in the value chain.
EN 1176-series Playground equipment and surfacing	Ethical considerations regarding safety. Making risk assessments on how to balance the risks, for instance of falling, with the benefits, for instance of exposure and learning.
EN 13757-series Communication systems for meters	Ethics is not explicitly mentioned in the standard, but has been discussed a lot in the development process and afterwards. The ethical aspect of the storage of the data form the meters – they can be misused.
EN 16224 Healthcare provision by chiropractors	Treatment of customers – ethical aspects.
FPrCEN/TS 16937 Nanotechnologies - Guidance for the responsible development of nanotechnologies	This Technical Specification provides a guidance for the responsible development of nanotechnologies. This Technical Specification intendeds to cover nanotechnology activities involving manufactured nanomaterials.
prEN 16708 Beauty Salon Services - Requirements and recommendations for the provision of service	Treatment of customers – ethical aspects.
EN 16775 Expertise activities - General	The quality of an expertise service depends on professional competence, impartiality, objectivity,

requirements for expertise services	independence and integrity of the experts involved. This standard is aimed at pointing out the minimum requirements of the criteria influencing every expertise service (e.g. ethical assessment service).
prEN 50637 Hospital beds for children	Ethical considerations in the development process of the standard. How should the bed be "designed" in order to be safe, but not "a prison".
IEC/TR 61508-0 Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 0: Functional safety and IEC 61508	There are four levels of safety in the standards. The user of the standard is to pick the level himself based on factors such as economy.
ISO 9001 Quality Management	A management system that may provide inspiration for the backbone of the CWA.
ISO 10001 Quality management - Customer satisfaction - Guidelines for codes of conduct for organizations	There is a section in the standard defining different types of companies – might be relevant to do something similar in the CWA on research institutions and other stakeholders.
ISO 10667-1 and 2 Assessment service delivery - Procedures and methods to assess people in work and organizational settings - Part 1: Requirements for the client, and Part 2 Requirements for service providers	Ethical aspects related to the psychological dimension of the standard.
ISO 10990-series Animal (mammal) traps	Might contain ethical aspects due the killing of animals.
ISO 14001 Environmental Management Systems (under review, final updated version is expected by October 2015)	This is an internationally agreed standard that supports the management of environmental responsibilities. It enables an organisation to provide assurances that its environmental impact is being measured and improved. The Standard has more than 300,000 certifications in 171 countries. It requires that an organisation considers all environmental issues relevant to its operations, such as air pollution, water and sewage issues, waste management, soil contamination, climate change mitigation and adaptation, and resource use and efficiency. It also includes the need for continuous improvement of an organization's systems and approach to environmental concerns (this resonates well with the

	need to continually monitor ethical issues in research and innovation).
ISO 14006 Environmental management systems - Guidelines for incorporating eco-design	Contains guidelines to assist organizations in establishing a systematic and structured approach to the incorporation and implementation of an ecodesign process within an environmental management system. For ethics assessment, it might provide a good way of showing how to integrate ethical aspects into research design and innovation development, and help reduce ethical impacts throughout its lifecycle.
ISO/TS 14441 Health informatics -- Security and privacy requirements of EHR systems for use in conformity assessment	Includes a cross-mapping of 82 security and privacy requirements against the Common Criteria categories in ISO/IEC 15408. This TS also includes discussion of the theoretical foundations underpinning the requirements; guidance on best practice for establishing and maintaining conformity assessment programs; description of the conformity assessment process, including the key concepts and processes.
ISO 19381-series Sustainable and traceable cocoa	Many ethically relevant topics, dilemmas and discussions in relation to the development of the standards for cocoa. Might also be inspirational to the CWA on how to handle ethical aspects in standardization. Similar standards are being developed for timber – but the work in those areas is still very new.
ISO 20121 Event sustainability management systems - Requirements with guidance for use	General ethical relevance due to the sustainability aspect.
ISO CD 20400 Sustainable Procurement	General ethical relevance due to the sustainability aspect.
ISO 22000 Food safety management systems - Requirements for any organization in the food chain	Ethical aspects regarding human resources, but only in relation to food safety.
ISO/TR 22221 Health informatics - Good principles and practices for a clinical data warehouse	The goal of the standard is to define principles and practices in the creation, use, maintenance and protection of a CDW, including meeting ethical and data protection requirements and recommendations for information governance and security policies.

ISO 22222 Personal financial planning - Requirements for personal financial planners	Defines the personal financial planning process and specifies ethical behaviour, competences and experience requirements for personal financial planners.
ISO 22307 Financial services -- Privacy impact assessment	This standard is relevant due to its descriptions of privacy impact assessment activity in general. It defines the common and required components of a privacy impact assessment, regardless of business systems affecting financial institutions, and provides informative guidance to educate the reader on privacy impact assessments.
ISO 26000 Guidance on social responsibility	Includes ethical aspects of social responsibility. Also relevant as inspiration on how to structure the CWA.
ISO 31000 Risk management – Principles and guidance	Risk-based thinking enables a research and innovation project to determine the factors that could cause its activities to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise. The methodology for risk management: risk assessment and risk treatment could be very similar to ethical impact assessment and ethical impact treatment
WD ISO 34700 Animal welfare management –General Requirements and Guidance for Organizations in the Food Supply Chain	Ethical relevance in the standard being developed on animal welfare.
ISO 37120 Sustainable development of communities - Indicators for city services and quality of life	General ethical relevance due to the sustainability aspect.
ISO CD2 37001 Anti-corruption (TC/SC: ISO/PC 278)	Ethical aspects explicitly mentioned.
ISO Guide 82 Guidelines for addressing sustainability in standards	General ethical relevance due to the sustainability aspect.
ISO/IEC 29100 Information technology - Security	Information security involves ethical aspects. The standard also offers assessment methods.

techniques - Privacy framework	
ISO/IEC 29101 Information technology - Security techniques - Privacy architecture framework	Information security involves ethical aspects. The standard also offers assessment methods.
ISO/IEC 29187-1 Information technology -Identification of privacy protection requirements pertaining to learning, education and training (LET)	The standard is relevant because it was developed to support the modelling of generic international requirements for identifying and providing privacy protection of personal information throughout any kind of ICT-based learning transaction where the individual has the role of an individual learner. It provides users and designers with a methodology and tools addressing privacy protection and related requirements imposed by applicable jurisdictional domains. This might have some important lessons for modelling EU ethics assessment which also faces scientific field specific and national challenges.
ISO/IEC DIS 29134 Information technology -- Security techniques – Privacy impact assessment – Guidelines	A pre-standard that offers a privacy impact assessment (PIA) tool. It is an instrument for assessing the potential privacy impacts of a process, an information system, a programme, a software module, a device, etc.
OHSAS 18001 Occupational health and safety management systems – Specification	General ethical aspects of occupational health and safety management.
OHSAS 18002 Occupational health and safety management systems - Guidelines for the implementation of OHSAS 18001:2007	General ethical aspects of occupational health and safety management.

Other relevant formal standard documents	Why
Standards for risk assessment	There are many standards for risk assessment within different areas. They might be able to provide aspects of the benefit vs. consequence-aspect, which is also relevant in many ethical assessments.
Bio banks	A standard is being developed for bio banks. The ethical aspects are being discussed and are likely to be directly included in the standard.
Standard for child welfare service's interviews (e.g. in connection with the parents' divorce)	This is a standard under development. It discusses many relevant ethical aspects of interviewing children – especially in difficult situations.
Sustainable tourism	A standard is being developed for sustainable tourism. This standard might be relevant due to the sustainability aspect.
CEN/TC 350 and CEN/TC 351	Two Technical Committees working with sustainable buildings – might be relevant due to the sustainability aspect.
CEN Environmental Helpdesk[37]	The CEN Environmental Helpdesk has been recommended by several standardization experts for inspiration. Especially the guide and the checklist for creating standards.
ISO CASCO **ISO committee for conformity assessment**[38]	ISO CASCO develops policy and publishes standards related to conformity assessment.
Management standard type b	A suggestion to structure the CWA as a management standard (MSS) type b. Unlike MSS type a, MSS type be provides guidelines rather than requirements.

[37] https://www.cen.eu/about/helpdesks/environmental/Pages/default.aspx
[38] http://www.iso.org/iso/Casco

Annex 3 – Resume of 7 selected formal standards

DS 49001 Social responsibility management system – Requirements

This standard provides organisations with elements of an efficient social responsibility management system, which can be integrated with other management requirements and which help organisations meet their social responsibility objectives.

This standard specifies requirements for a social responsibility management system so that organisations are able to develop and implement a policy and objectives, which are based on respect for international norms of behaviour. At the same time, Danish legal requirements have been taken into account, and guidance is given for how organisations can go beyond the fulfilment of legal requirements.

Structure

This standard is structured similarly to ISO 9001 for quality management and ISO 14001 for environmental management based on the elements which the management system is to include. Requirements and content of the individual elements are based on the international ISO 26000, Guidance on social responsibility, meaning that this Danish standard can also be used as a reference document in relation to requirement standards and guides of other countries which also refer to ISO 26000.

The structure of the standard is illustrated in figure A3.7.

This standard is based on the methodology known as "Plan-Do-Check-Act" (PDCA)

Principles of social responsibility

This standard for social responsibility provides ten basic principles. The organisation shall ensure that its behaviour is based on respect for these principles, and that the principles are leading for the organisation in its work to define and review strategies, policies, procedures and implementation processes.

The ten principles are the following:

1. Accountability
2. Transparency
3. Ethical behaviour
4. Respect for stakeholder interests
5. Respect for the rule of law
6. Respect for international norms of behaviour with national law.
7. Respect for human rights
8. Significance
9. Holistic approach
10. Continual improvement

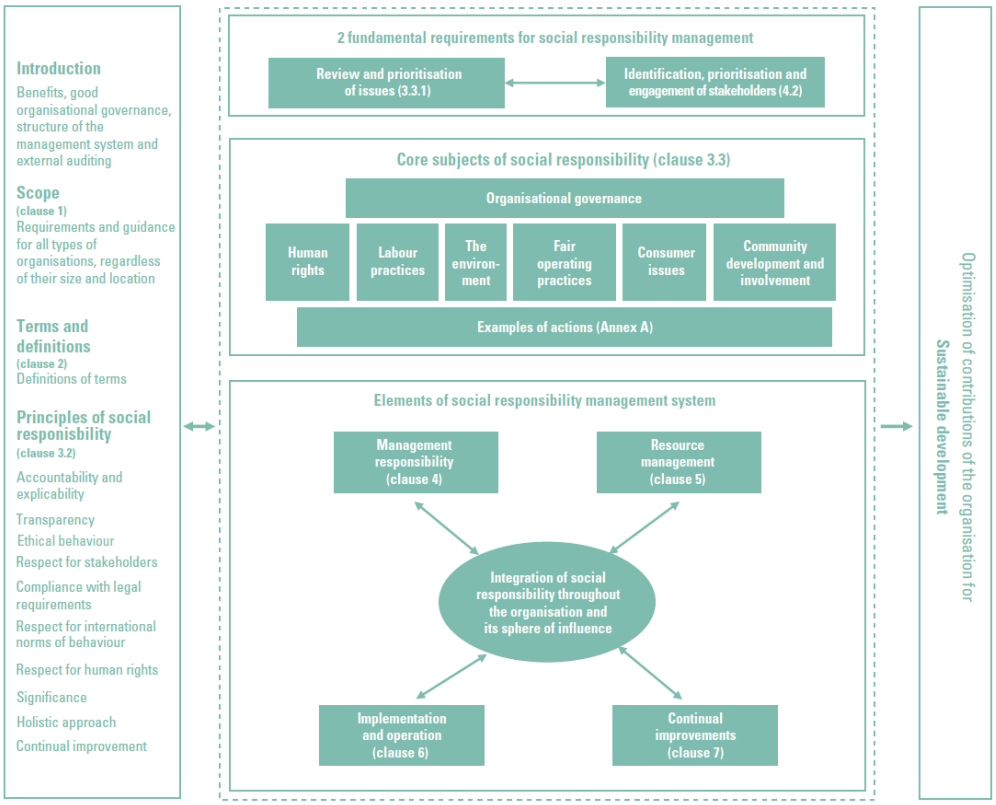

Figure A3.7 - Structure of ISO 26000

Core subjects and issues within social responsibility

The seven core subjects describing different elements of social responsibility of organisations are:

a) Organisational governance

b) Human rights

c) Labour practices

d) The environment

e) Fair operating practices

f) Consumer issues

g) Community involvement and development

Each of these seven core subjects contains a number of issues describing what each core subject specifically deals with.

All core subjects – but not necessarily all issues – are relevant for all organisations. Significant stakeholders shall be involved in the identification of relevant issues in order to improve the basis for decisions and broaden the perspective on the issues.

Implementation and operation

In order to fulfil its targets, the organisation shall establish, implement, maintain and document short-, medium- and long-term action plans. The action plans shall specify descriptions of tasks necessary to fulfil each target and associated:

a) deadlines;

b) responsibilities and tasks;

c) identification of the necessary means.

Continual improvements

The organisation shall plan and implement monitoring, measuring, analysis and improvement processes necessary to:

a) demonstrate conformity with own requirements, legal requirements and other requirements that form part of the organisation's work with social responsibility;

b) ensure that the management system complies with requirements of social responsibility in this standard;

c) continually improve effectiveness of the social responsibility management system;

d) continually improve performance within social responsibility core subjects and issues.

Management review

Top management shall review the organisation's social responsibility management system at planned intervals to ensure continuous suitability, adequacy and effectiveness. This review is to include an assessment of opportunities for improvement and the need for changes to the management system, including the core subjects and issues that the organisation addresses as well as the social responsibility policy and targets. Records of management reviews shall be maintained.

External auditing and certification

Organisations interested in ensuring conformity with the requirements of the standard may have this verified by an independent, external stakeholder in form of a third party verification and declaration (typically from a certification body) on the basis of an external audit. If the organisation wants to communicate externally that it meets the requirements of the standard, this shall be documented through an independent, external audit. The external auditor shall be able to document the necessary qualifications regarding DS 49001, achieved through participation in relevant, qualifying courses or similar training.

As part of the management system the organisation shall carry out an internal audit, and the results from this will form part of the basis for an external audit. Other management system standards also provide the possibility of self-declaration of conformity with the requirements of the standard, but this is not recommended in this standard.

ISO 9001 Quality Management

Why ISO 9001 could be used as input or inspiration for the ethics assessment framework

ISO 9001 can provide important input for developing the structure of the CWA in the SATORI project; methodologically it can prove to be highly applicable for a CWA describing an Ethics Assessment Framework. ISO 9001 is the most used management system in the world.

One of the key features of this standard is customer satisfaction. Identification of the customers and their demands is part of the process and guides the organization to define priorities, objectives and policies. The standard focuses on the process of management, it does not specifically focus on impact assessment.

ISO 9001 is designed to be 'generic and is intended to be applicable to all organizations, regardless of type, size and product and service provided'. As a result, the level of abstraction is high, leaving responsibility to the organisation to design its own operationalization of the management system.

ISO 9001 has already been adapted for different other uses such as risk management, compliance management, Corporate Social Responsibility (CSR), food safety and different sectors such as health care, medical devices, oil and gas production.

Introduction to ISO 9001- quality management systems - Requirements[39]

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

[39] The text is copied 'cut and paste' from ISO 9001:2015(FDIS version). The text is not complete!.

Scope

This International Standard specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide product or service that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product and service provided.

Quality management process

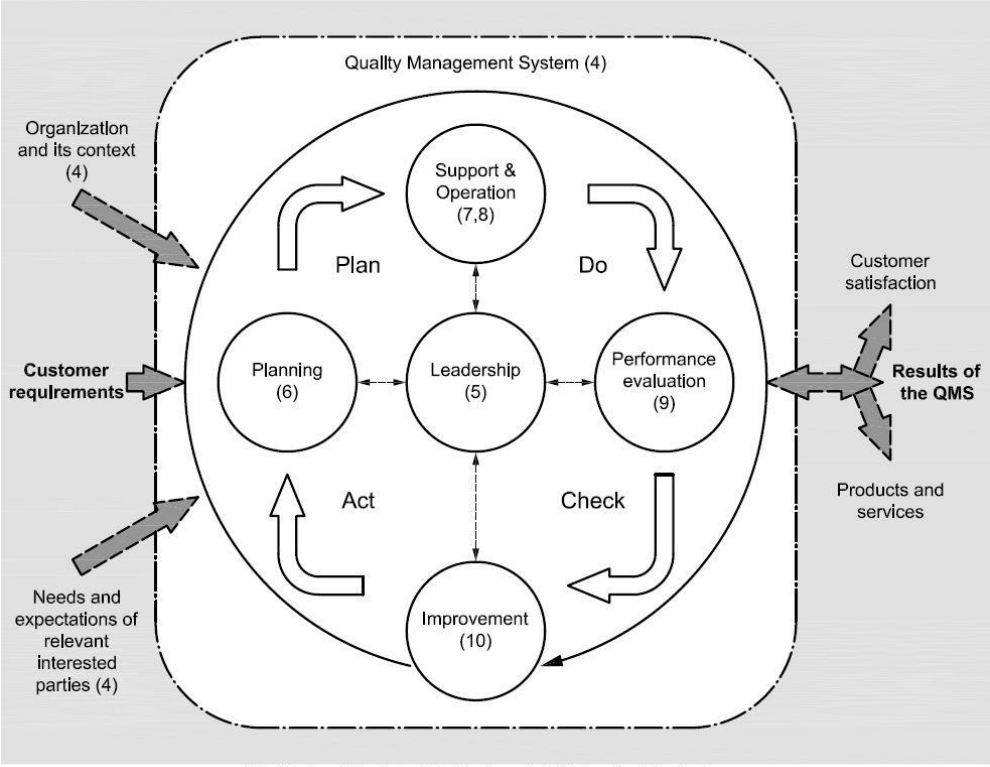

Figure A3.8 — Representation of the structure of ISO 9001 in the PDCA cycle

ISO 9001 promotes the adoption of a process approach and risk based thinking when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Figure A3.8 provides the structure.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Risk-based thinking is essential for achieving an effective quality management system. The concept of risk-based thinking includes, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

The chapters and subchapters in ISO 9001 set requirements to each of the elements of the structure.

1-3	Scope, definitions and references
4	**Context of the organization**
4.1	Understanding the organization and its context
4.2	Understanding the needs and expectations of interested parties
4.3	Determining the scope of the quality management system
4.4	Quality management system and its processes
5	**Leadership**
5.1	Leadership and commitment
5.2	Policy
5.3	Organizational roles, responsibilities and authorities
6	**Planning**
6.1	Actions to address risks and opportunities
6.2	Quality objectives and planning to achieve them
6.3	Planning of changes
7	**Support**
7.1	Resources
7.2	Competence
7.3	Awareness
7.4	Communication
7.5	Documented information
8	**Operation**
8.1	Operational planning and control

8.2 Requirements for products and services
8.3 Design and development of products and services
8.4 Control of externally provided processes, products and services
8.5 Production and service provision
8.6 Release of products and services
8.7 Control of nonconforming outputs
9 Performance evaluation
9.1 Monitoring, measurement, analysis and evaluation
9.2 Internal audit
9.3 Management review
10 Improvement
10.1 General
10.2 Nonconformity and corrective action
10.3 Continual improvement

ISO 9001 – level of abstraction

All requirements of ISO 9001 are generic and are intended to be applicable to all organizations, regardless of type, size and product and service provided. The following text on requirements for 'people' and 'competence' highlight the implication:

- **People**
  The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.
- **Competence**
  The organization shall:

  a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

  b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

  c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

  d) retain appropriate documented information as evidence of competence.

  NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

ISO 22222 Personal financial planning -Requirements for personal financial planners

Why standards for assessment services can be used as input or inspiration for the CWA

Standards for assessment services specify how an assessment procedure should be carried out and defines the role of the assessor.

In Deliverable 1.1., the SATORI analysis of ethics assessors organisations revealed that: "All categories of ethics assessor organisations face the problem of lack of resources (financial, human, time, knowledge). The two other significant problems highlighted are: heterogeneity in ethics assessment approaches & guideline implementation within the organisational categories themselves and across countries; and a lack of awareness of ethics issues within the *organisations, and a lack of structured approaches*."[40] The ethics assessor has a key role to play in ensuring the success of the SATORI Ethical Impact Assessment Framework; therefore, including aspects on assessment services could be beneficial for the SATORI CWA.[41]

Standards for assessment services would be of interest for the SATORI project if it will be decided that (part of) the CWA should specify which abilities and skills the assessors of ethics in research and innovation should have. To provide inspiration for how this could be done, one may turn to relevant standards on assessment services that already exist in the formal standardization system.

This section describes how existing formal standards can be used when drafting the SATORI CWA. It is based primarily on ISO 22222[42]; an international standard for professionals providing the service of financial planning. "*Consumers need to have confidence in their personal financial planner*".[43] This standard specifies both the assessment service (in this case financial planning) and how conformity assessment can be carried out. Where deemed relevant, aspects from another international standard, ISO 10667-2[44], are integrated into this document. ISO 10667-2 is an international standard for assessment delivery services developed in order to assess people in work and organizational settings.

They provide examples of how a standard for assessment services can be developed and how conformity to the standard can be declared (demonstration that the specified requirements relation to the person(s) are fulfilled).

Potential content of the CWA in SATORI

Part of the SATORI CWA can be based on the content of ISO 22222 and draw on aspects of the ISO 10667-series.

The bullets below suggest elements selected from the standards that may be considered as possible content when drafting the SATORI CWA:

- Steps in the assessment procedure

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[40] *Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and Selected Other Countries*, op. cit., p. 78.
[41] CEN Workshop Agreement. For more information see http://www.cen.eu/work/products/CWA/Pages/default.aspx
[42] ISO 22222 Personal financial planning – Requirements for personal financial planners.
[43] ISO 22222 p. v.
[44] ISO 10667-2 Assessment service delivery – Procedures and methods to assess people in work and organizational settings – Part 2: Requirements for service providers.

- Ethical principles for assessors
- Competence of the assessor
- Experience of the assessor
- Assessment and certification
- Continuous update of competences

Steps in the assessment procedure

In ISO 22222, there are six steps (that can be repeated) in the personal financial planning process:

- Establishing and defining the client and personal financial planner relationship
- Gathering client data and determining goals and expectations
- Analysing and evaluating the client's financial status
- Developing and presenting the financial plan
- Implementing the financial planning recommendations
- Monitoring the financial plan and the financial planning relationship[45]

Likewise in ISO 10667-2, each assessment stage is described.[46]

- a) Agreement procedures describes mutual responsibilities and obligations of the client and the service provider, as well as the format of their agreement and a description of what must be covered in the agreement.
- b) Pre-assessment procedures covers:
    - 1) identifying what needs to be assessed and how, together with choosing the criteria for evaluating success and having a clear expectation of the utility of the process;
    - 2) determining whether there are conflicting interests that need to be balanced;
    - 3) providing a clear rationale for the assessment; documenting the agreement between the client and the service provider through a written statement of work, or contract, as appropriate.
- c) Assessment delivery covers all phases of preparing for and carrying out the assessments.
- d) Post-assessment review) covers reviewing the assessment process to determine whether the outcomes, consequences and utility of the assessment are consistent with the assessment needs, whether the goals are met, and what changes in the assessment process should be adopted for future use by the client.[47]

These procedures can be used as inspiration for the CWA in regard to assessment steps/stages in ethics assessment.

The elements above can be combined, restructured and rewritten to better fit SATORI. E.g.:

Steps/stages in ethics assessment

- Agreement procedures
- Pre-assessment procedures
- Assessment delivery
    - Establishing and defining the relevant ethical aspects

[45] ISO 22222 p. 3-6.
[46] The procedure for each assessment stage is described in further detail in ISO 10667-2 p. 5- 14.
[47] ISO 10667-2 p. viii.

  - Gathering data and determining goals and expectations
  - Analysing and evaluating the research and innovation project's current status
  - Developing and presenting an ethics impact plan
  - Implementing the ethics impact recommendations
  - Monitoring ethics impact throughout the project
- Post-assessment review

Ethical principles for assessors

Part of ISO 22222 is dedicated to specifying how ethics plays a role in personal financial planning. These ethical principles are also relevant for a person assessing ethics in research and innovation. The standard states: "*A personal financial planner shall strive for conduct that reflects honourably upon the profession of personal financial planning*."[48] In addition to this: "*Ethical behaviour presumes and goes beyond compliance with applicable rules and regulations*."[49]

ISO 22222 defines 10 important ethical principles that a personal financial planner should be able to handle. In order to demonstrate how these could be relevant for SATORI, "ethics assessors" has been put in brackets throughout the document where this may improve the understanding of the possible application.

- 5.2.1 Integrity
  Personal financial planners [Ethics assessors] shall be open, honest, responsive, accountable and committed to acting
  competently, responsibly, reliably, fairly and with respect in all professional relationships.
- 5.2.2 Priority of client's interests
  Personal financial planners [Ethics assessors] shall make the legitimate interests of the client paramount.
- 5.2.3 Due care and diligence
  Personal financial planners [Ethics assessors] shall conduct their professional activities with due skill, care, diligence and competence.
- 5.2.4 Compliance and professionalism
  Personal financial planners [Ethics assessors] shall comply with relevant rules and regulations and observe standards of professional good practice.
- 5.2.5 Conflicts of interests
  Personal financial planners [Ethics assessors] shall disclose and fairly manage all conflicts of interest.
- 5.2.6 Communication
  Personal financial planners [Ethics assessors] shall convey information and recommendations in an understandable, effective and constructive manner.
- 5.2.7 Objectivity
  Personal financial planners [Ethics assessors] shall act objectively and recommend solutions that fit the client's situation.
- 5.2.8 Confidentiality
  Personal financial planners [Ethics assessors] shall safeguard client confidentiality unless subject to regulatory and or legal obligations.

[48] ISO 22222 p. 6.
[49] ISO 22222 p. 6.

- 5.2.9 Disclosure
  Personal financial planners [Ethics assessors] shall provide accurate and relevant information, including statements of
  qualifications, credentials and type of conformity assessment with this International Standard.
- 5.2.10 Competence
  Personal financial planners [Ethics assessors] shall not accept or perform work which they are not competent to undertake unless they obtain such advice and assistance as should enable them to carry out the work competently.[50]

Competence of the assessor

Competence is key for an assessor, which is further elaborated in ISO 22222. This can be used as an inspiration for the considerations concerning assessors' competences in the SATORI CWA.:

"Personal financial planners [ethics assessors] shall have knowledge specific to the jurisdictions in respect of which they are performing a service of personal financial planning.

Personal financial planners [ethics assessors] shall have a broad general knowledge of the rules and regulations that apply to personal financial planning [ethics assessment].

Personal financial planners [ethics assessors] shall abide by the applicable rules and regulations to which they are subject, including those of any professional bodies or regulators.

Personal financial planners [ethics assessors] shall understand what services should be rendered based on the scope of an engagement."[51]

A table is set up, specifying which competences a personal financial planner is expected to have. Figure A3.9 presents an example.

[50] ISO 22222 p. 6-7.
[51] ISO 22222 p. 7.

	H	Personal financial planners shall be able to integrate the various financial plan components, explain the resulting comprehensive financial plan and obtain the properly informed commitment of the client to proceed.	
		a) Knowledge/understanding — Shall understand the comprehensive nature of financial planning. — Shall understand how the various areas of a client's financial life interact.	b) Skills — Shall be able to compile the various components into a logical and appropriate financial plan for a client. — Shall be sure the recommendations answer the questions of who, what, when, where, why and how. — Shall be able to evaluate alternative strategies and determine how they could affect the overall financial plan. — Shall be able to evaluate a comprehensive financial plan to determine if it meets the needs and stated objectives of a client. — Shall be able to explain the plan.

Figure A3.9 - Example from table in ISO 22222[52]

The standard presents an additional table with the necessary characteristics outcomes for minimum assessment level. Examples of these characteristics are:

- Knowledge and understanding
  - An outline knowledge and understanding of research and equivalent scholarly/academic processes.
- Communication, information technology and numeracy skills
  - Convey complex information to a range of audiences and for a range of purposes.
- Autonomy, accountability and working with others
  - Deal with ethical and professional issues in accordance with current professional and/or ethical codes or practices under guidance.[53]

Experience of the assessor

Should an ethics assessor have a certain level of experience? "Experience helps ensure that the quality of advice delivered by the personal financial planner [ethics assessors] will benefit the consumer and preserve the integrity of the profession. Experience involves a general understanding, working knowledge and practical application of financial *planning* [ethics assessment]."[54]

The standard defines how many years of experience the assessor shall have is defined in the standard. E.g.: "*two years of teaching or training in the personal financial planning process*".[55]

[52] ISO 22222 p. 8-15.
[53] ISO 22222 p. 16.
[54] ISO 22222 p. 18.
[55] ISO 22222 p. 19.

Assessment and certification

A CWA is not certifiable, but as future needs might show that there is a need for a certifiable standard on ethics assessment based on the SATORI CWA, the SATORI project should be on the forefront and consider different assessment methods that could be used.

ISO 22222 defines different assessment methods regarding compliance with the standard, as presented in figure A3.10.

The following assessment methods should be considered in demonstrating initial competence:

a) written examination;

b) multiple-choice examination;

c) portfolio of evidence, which may include some or all of:

1) individual performance measurements such as:

— spread of business: to ensure that the planner is not concentrating on the sale of a particular product instead of giving the client an overall financial plan;

— persistency: to measure the extent to which clients maintain their personal financial planner's implemented strategies;

— implementation: measures how often a client says they will take the advice of the planner and then does not take up the recommendations;

— repeat business: to measure how well planners take care of their existing clients;

— complaints: timeliness and accuracy of response;

— compliance: to measure compliance with local laws and regulations;

— administration and record keeping: quality and precision of written work and records;

— adherence to codes of practice of relevant industry bodies;

2) random examination of complete files of current clients;

3) case studies;

4) oral assessment;

5) client satisfaction survey;

6) work-based assessment;

7) scripted-answer examinations.

Figure A3.10 - Excerpt from ISO 22222 with different assessment methods in relation with compliance to the standard[56]

[56] ISO 22222 p. 17.

In the standard 3rd party certification is strongly recommended, but if this is for legitimate reasons not possible, compliance to the standard is possible through self-assessment. Compliance with the entire International Standard is required.

Continuous update of competences

For an ethics assessor it is important to have updated competences as the competences needed might change over time. "*Personal financial planners* [Ethic assessors] *shall be able to demonstrate continuing competence based upon the requirements set forth in this International Standard after obtaining initial certification or declaration of conformity*."[57]

The personal financial planner is required to demonstrate the most current competence requirements through continuing education, as clarified in figure A3.11.

6.4.3 Content of continuing education

Continuing education should include one or more of the following activities in areas related to personal financial planning:

a) attending courses, conferences, seminars or workshops;

b) actively participating in discussion meetings or similar events;

c) giving presentations in classes, symposiums or similar events;

d) teaching areas of financial planning;

e) writing books or publishing professional articles;

f) attending group studies, listening to audiotape programmes, viewing video programmes, using relevant media, technical reading and learning with computer-based training programs;

g) earning professional licenses or designations related to personal financial planning upon the successful completion of the examinations;

h) passing continuing education tests provided that the tests cover required topics and aim at maintaining professional competences.

Figure A3.11 - Excerpt from ISO 22222 on continuing education[58]

[57] ISO 22222 p 17.
[58] ISO 22222 p. 18

ISO CD 20400 Sustainable Procurement

This summary highlights excerpts from the standard that could be relevant for the SATORI ethics impact assessment framework.

Introduction

"This International Standard assists organisations to meet their sustainability responsibilities by providing an understanding of:

- what sustainable procurement is;
- what the sustainability impacts and considerations are across the different aspects of procurement activity: policy, strategy, organisation, process; and
- how to implement sustainable procurement practically.[59]

This International Standard is applicable to any organisation, either public or private, regardless of its size and location, and aims to be understood by any stakeholder involved in or impacted by procurement decisions and processes." .[60]

"As a general principle, when taking steps to encourage sustainable procurement, public and private sector procurement professionals need always consider the legislative, policy and ethical framework that regulate their procurement activities. The legislative, policy and ethical framework includes legislation, international obligations, and local regulations, and also the specific procurement, ethics and sustainability policies that apply to the organisation." [61]

Schematic overview of ISO 20400 gives the most important information, as presented in figure A3.11.

"Clause 4 provides an overview of sustainable procurement and is applicable to all. It describes the scope and principles of sustainable procurement and examines why organisations should undertake sustainable procurement. Important considerations include prioritization, exercising due diligence, exercising influence and avoiding complicity.

Clause 5 provides guidance about how sustainability considerations should be integrated at a strategic level within the procurement function of an organisation to ensure that the intention, direction and key sustainability priorities of the organisation are documented and understood by all parties involved in sustainable procurement. This clause is applicable to all but help top management define sustainable procurement policy and strategy.

[59] Pr ISO CD4/DIS 20400, p vii
[60] Pr ISO CD4/DIS 20400, p vii
[61] Pr ISO CD4/DIS 20400, p vii

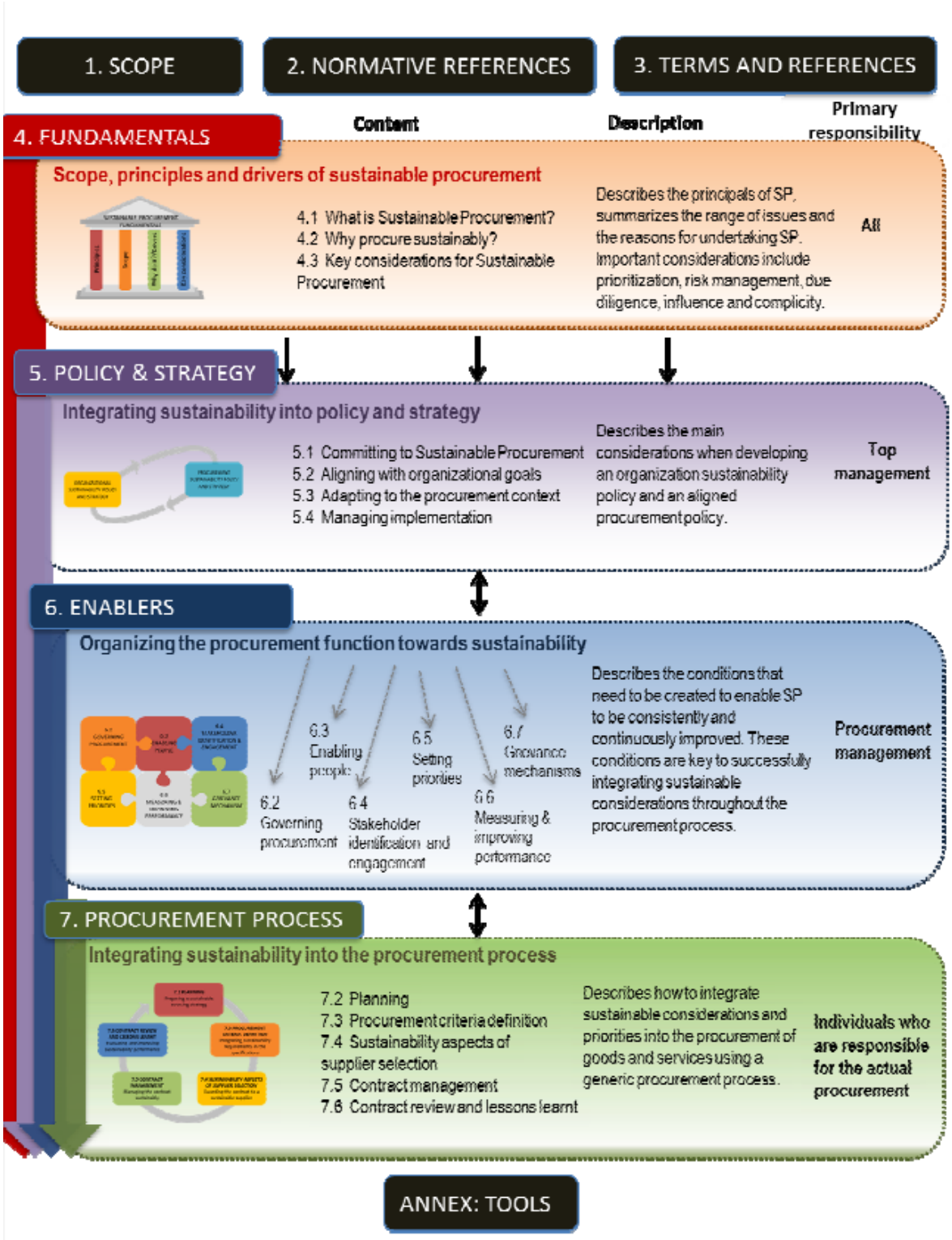

Figure A3.12 - Schematic overview of ISO 20400[62]

[62] Pr ISO CD4/DIS 20400, p viii

Clause 6 describes the organizational conditions and management techniques needed in order to successfully implement and continually improve sustainable procurement. Procurement management should ensure such conditions and practices are in place in order to help individuals with responsibility for procurement of goods and services integrate sustainability considerations into the procurement and management of contracts.

Clause 7 addresses the procurement process and is intended for individuals who are responsible for the actual procurement carried out within their organisation. This clause may also be of interest to those in associated functions. It describes how sustainability considerations should be integrated into existing procurement processes and the creation of a parallel process should be avoided."[63]

Table 1 — Examples of considerations when setting priorities of sustainability issues

Relevance = The sustainability issue or the aspect applies to the organisation. If Not: Specify why not (comply or explain) Relevance is determined by factors such as: - (Potential) impact on social, environmental and economic aspects and stakeholders; - Connection with activities (processes, goods and services) of the organisation - Linkage to legislation and regulations; - Activities of other organisations in the value and supply chain and within the organisation's sphere of influence; - (Potential) impact of other organisations or persons on the organisation. - Sector organisations codes of conduct - Specific circumstances such as emergency or evacuation situations	**Significance** = The extent of the impact of activities and decisions by the organisation on sustainable development (people, society, environment and economy). Criteria include: - Extent of the impact on sustainable development and stakeholders; - Potential effect of taking action or failing to take action; - Concerns of stakeholders regarding the issue - Societal expectations of responsible behaviour concerning the impacts.	**Priority** = The priority for attention and action. Issues/aspects that are relevant and significant deserve attention and action. Considerations include: - What has to be done (effort) to achieve the required result and level of ambition for sustainability; - Performance with regard to legal compliance, international standards, international norms of Behaviour, state-of-the-art and best practices; - Contribution to important organisational objectives; - Costs, revenues and value creation; - Ease or difficulty of realization; - Time required for reaching the required results.

Figure A3.13 - Excerpt from Clause 4, p 10.

[63] Pr ISO CD4/DIS 20400, p ix

ISO 26000 Guidance on social responsibility

This summary highlights excerpts from the standard that could be relevant for the SATORI ethics impact assessment framework.

Scope

"This International Standard provides guidance to all types of organizations, regardless of their size or location."[64]

"This International Standard is intended to assist organizations in contributing to sustainable development. It is intended to encourage them to go beyond legal compliance, recognizing that compliance with law is a fundamental duty of any organization and an essential part of their social responsibility. It is intended to promote common understanding in the field of social responsibility, and to complement other instruments and initiatives for social responsibility, not to replace them.

This International Standard is not intended to prevent the development of national standards that are more specific, more demanding, or of a different type."[65]

The schematic overview of ISO 26000, in figure A3.14 gives the most important information of ISO 26000:

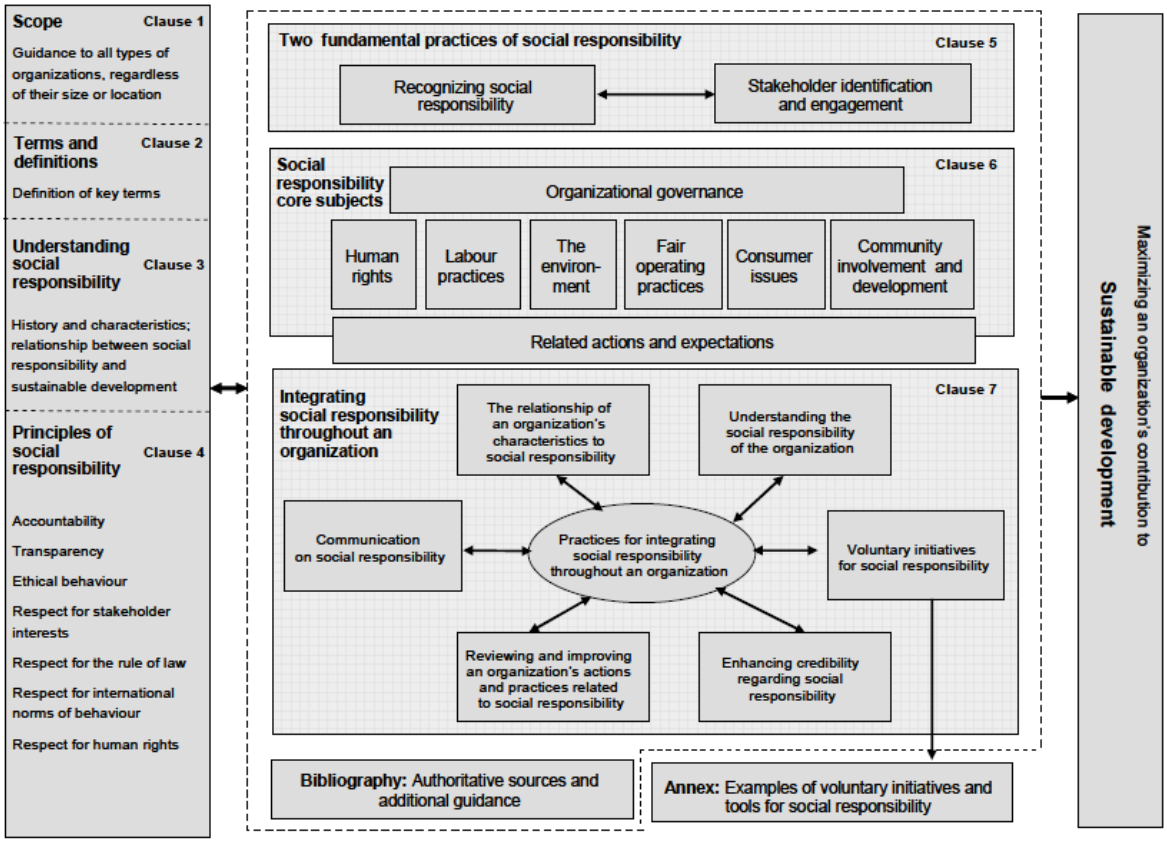

Figure A3.14 – Schematic overview of ISO 26000[66]

[64] ISO 26000, p 1
[65] ISO 26000, p 1
[66] ISO 26000:2010, p. ix.

The standard gives 7 principles of social responsibility on which behavior of organisations should be based. Principles include among others: accountability, transparency, respecting human rights, and taking into account the interests of stakeholders.

Seven core topics are defined that can, but not necessarily are, of relevance for an organization. Through engaging with stakeholders, organizations identify their most important CSR issues and what related action they will undertake. They report about what choices they have made in identifying the most important issues and related actions so that stakeholders are informed and can pose questions.

The 7 principles and 7 core topics are not exhaustive. Others may be included.

Both top management and staff of an organization are involved in CSR. Management defines the policy and integrates it in different aspect of the organization. Staff implements this and is one of the stakeholders in identifying CSR issues.

Relevance, significance and priority of issues

All the core subjects, but not all issues, have relevance for every organization. An organization should review all core subjects to identify which issues are relevant.

To start the identification process, an organization should, where appropriate:

- list the full range of its activities;
- identify stakeholders;
- identify the activities of the organization itself and of the organizations within its sphere of influence. The decisions and activities of suppliers and contractors can have an impact on the social responsibility of the organization;
- determine which core subjects and issues might arise when the organization and others within the sphere of influence and/or the value chain carry out these activities, taking into account all applicable legislation;
- examine the range of ways in which the organization's decisions and activities can cause impacts on stakeholders and on sustainable development;
- examine the ways in which stakeholders and social responsibility issues can impact the decisions,
- activities and plans of the organization; and. identify all issues of social responsibility that relate to day-to-day activities as well as those that arise only occasionally under very specific circumstances.[67]

“Once an organization has identified the broad range of issues relevant to its decisions and activities, it should look carefully at the issues identified and develop a set of criteria for deciding which issues have the greatest significance and are most important to the organization. Possible criteria include the:

- extent of the impact of the issue on stakeholders and sustainable development;
- potential effect of taking action or failing to take action on the issue;
- level of stakeholder concern about the issue; and

[67] ISO 26000, 2010, p 71

- identification of the societal expectations of responsible behaviour concerning these impacts.

Issues that are generally considered to be significant are non-compliance with the law; inconsistency with international norms of behaviour; potential violations of human rights; practices that could endanger life or health; and practices that could seriously affect the environment."[68]

"An organization should determine and commit to its priorities for integrating social responsibility throughout the organization and its daily practices. Priorities should be established from among the issues considered significant and relevant. Stakeholders should be involved in the identification of priorities. Priorities are likely to vary over time.

Organizations should consider the following to determine whether an action to address an issue is a high priority or not:

- the current performance of the organization with regard to legal compliance, international standards, international norms of behaviour, the state-of-the-art and best practice;
- whether the issue can significantly affect the ability of the organization to meet important objectives;
- the potential effect of the related action compared to the resources required for implementation;
- the length of time to achieve the desired results;
- whether there can be significant cost implications if not addressed quickly; and
- the ease and speed of implementation, which may have a bearing on increasing awareness of and motivation for action on social responsibility within the organization.

The order of priorities will vary among organizations."[69]

Other relevant elements in ISO 26000

Chapter 3 – Understanding Social Responsibility gives a brief overview of the history and recent trends. It provides information on the main characteristics.

In the introduction, ISO 26000 gives reasons of why organizations should work on their social responsibility. An organization engages its stakeholders to identify and understand its most important social responsibility issues and communicate about them:

- "Identification of and engagement with stakeholders are fundamental to social responsibility. An organization should determine who has an interest in its decisions and activities, so that it can understand its impacts and how to address them. Although stakeholders can help an organization identify the relevance of particular matters to its decisions and activities, stakeholders do not replace broader society in determining norms and expectations of behaviour. A matter may be relevant to the social responsibility of an organization even if not specifically identified by the stakeholders it consults." [70]
- Creating a culture of social responsibility and building competencies for implementing social responsibility;

[68] ISO 26000, p 72
[69] ISO 26000: 2010: p 73
[70] ISO 26000: 2010, p 7

- Communicating about social responsibility through different means, like meetings, reports;
- Transparency and verifiable data are important here;
- With respect to the development of the standard: "This International Standard was developed using a multi-stakeholder approach involving experts from more than 90 countries and 40 international or broadly-based regional organizations involved in different aspects of social responsibility. These experts were from six different stakeholder groups: consumers; government; industry; labour; non-governmental organizations (NGOs); and service, support, research, academics and others. In addition, specific provision was made to achieve a balance between developing and developed countries as well as a gender balance in drafting groups. Although efforts were made to ensure balanced participation of all the stakeholder groups, a full and equitable balance of stakeholders was constrained by various factors, including the availability of resources and the need for English language skills."[71]

[71] ISO 26000: 2010, p v

ISO 31000 Risk management – Principles and guidance

This summary highlights excerpts from the standard that could be relevant for the SATORI ethics impact assessment framework. Like the SATORI impact assessment framework, this summary focuses on assessment without defining the measures to take to reduce risks.[72]

Introduction to ISO 31000

All activities of an organization involve risk. Organizations manage risk by identifying it, analyzing it and then evaluating whether the risk should be modified by risk treatment in order to satisfy their risk criteria.

Throughout this process, they communicate and consult with stakeholders and monitor and review the risk and the controls that are modifying the risk in order to ensure that no further risk treatment is required. This International Standard describes this systematic and logical process in detail.

This International Standard establishes a number of principles that need to be satisfied to make risk management effective. The Standard recommends that organizations develop, implement and continuously improve a framework whose purpose is to integrate the process for managing risk into the organization's overall governance, strategy and planning, management, reporting processes, policies, values and culture.

Risk management can be applied to an entire organization, at its many areas and levels, at any time, as well as to specific functions, projects and activities.

The adoption of consistent processes within a comprehensive framework can help to ensure that risk is managed effectively, efficiently and coherently across an organization. The generic approach described in this International Standard provides the principles and guidelines for managing any form of risk in a systematic, transparent and credible manner and within any scope and context.

Elements in ISO 31000 that can be used as input or inspiration for the CWA SATORI

For the SATORI ethics impact assessment CWA, the most relevant part of this standard is the methodology for risk assessment, which could be incorporated as a component of ethics impact assessment.

It would be interesting to replace 'risk management' with 'ethics management' and 'organization' with 'research/innovation' in the document and see how relevant the results would be to the SATORI CWA.

ISO 31000 (also) includes the methodology to set up a framework. This summary did not include the methodology to set up a framework.

Risk management process

Figure A3.15 describes the risk management process according to ISO 31000.

[72] The following text is copied 'cut and paste' from ISO 31000. The text is not complete.

ISO 31000:2009(E)

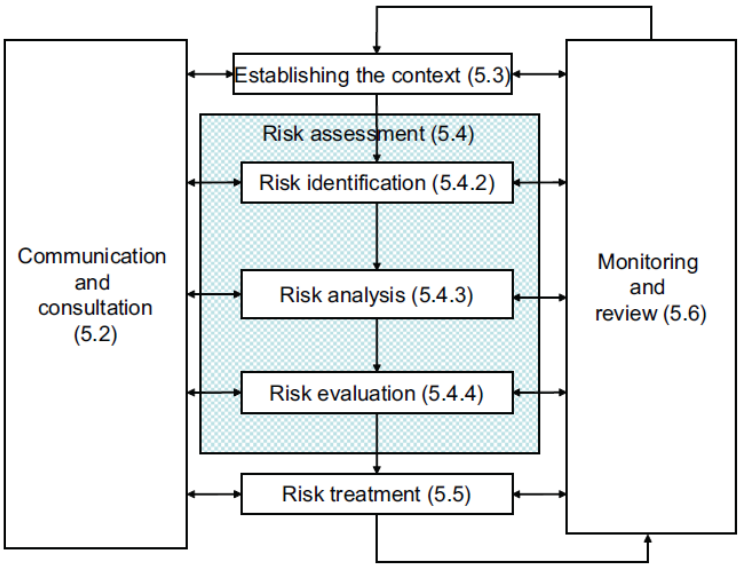

Figure 3 — Risk management process

Figure A3.15 – Risk management process in ISO 31000

Communication and consultation

Communication and consultation with external and internal stakeholders should take place during all stages of the risk management process.

Therefore, plans for communication and consultation should be developed at an early stage. These should address issues relating to the risk itself, its causes, its consequences (if known), and the measures being taken to treat it. Effective external and internal communication and consultation should take place to ensure that those accountable for implementing the risk management process and stakeholders understand the basis on which decisions are made, and the reasons why particular actions are required.

A consultative team approach may:

– help establish the context appropriately;

– ensure that the interests of stakeholders are understood and considered;

– help ensure that risks are adequately identified;

– bring different areas of expertise together for analyzing risks;

– ensure that different views are appropriately considered when defining risk criteria and in evaluating risks;

– secure endorsement and support for a treatment plan;

– enhance appropriate change management during the risk management process; and

– develop an appropriate external and internal communication and consultation plan.

Communication and consultation with stakeholders is important as they make judgements about risk based on their perceptions of risk. These perceptions can vary due to differences in values,

needs, assumptions, concepts and concerns of stakeholders. As their views can have a significant impact on the decisions made, the stakeholders' perceptions should be identified, recorded, and taken into account in the decision making process.

Communication and consultation should facilitate truthful, relevant, accurate and understandable exchanges of information, taking into account confidential and personal integrity aspects.

Establishing the context

By establishing the context, the organization articulates its objectives, defines the external and internal parameters to be taken into account when managing risk, and sets the scope and risk criteria for the remaining process.

The **external context** is the external environment in which the organization seeks to achieve its objectives. Understanding the external context is important in order to ensure that the objectives and concerns of external stakeholders are considered when developing risk criteria. It is based on the organization-wide context, but with specific details of legal and regulatory requirements, stakeholder perceptions and other aspects of risks specific to the scope of the risk management process.

The external context can include, but is not limited to:

– the social and cultural, political, legal, regulatory, financial, technological, economic, natural and competitive environment, whether international, national, regional or local;

– key drivers and trends having impact on the objectives of the organization; and

– relationships with, perceptions and values of external stakeholders.

The **internal context** is the internal environment in which the organization seeks to achieve its objectives. The risk management process should be aligned with the organization's culture, processes, structure and strategy. Internal context is anything within the organization that can influence the way in which an organization will manage risk. It should be established because:

a) risk management takes place in the context of the objectives of the organization;

b) objectives and criteria of a particular project, process or activity should be considered in the light of objectives of the organization as a whole; and

c) some organizations fail to recognize opportunities to achieve their strategic, project or business objectives, and this affects ongoing organizational commitment, credibility, trust and value.

It is necessary to understand the internal context. This can include, but is not limited to:

– governance, organizational structure, roles and accountabilities;

– policies, objectives, and the strategies that are in place to achieve them;

– capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies);

– the relationships with and perceptions and values of internal stakeholders;

– the organization's culture;

– information systems, information flows and decision making processes (both formal and informal);

– standards, guidelines and models adopted by the organization; and

– form and extent of contractual relationships.

Establishing the context of the risk management process

The objectives, strategies, scope and parameters of the activities of the organization should be established. The management of risk should be undertaken with full consideration of the need to justify the resources used in carrying out risk management. The resources required, responsibilities and authorities, and the records to be kept should also be specified.

The context of the risk management process will vary according to the needs of an organization. It can involve, but is not limited to:

– defining the goals and objectives of the risk management activities;

– defining responsibilities for and within the risk management process;

– defining the scope, as well as the depth and breadth of the risk management activities to be carried out, including specific inclusions and exclusions;

– defining the activity, process, function, project, product, service or asset in terms of time and location;

– defining the relationships between a particular project, process or activity and other projects, processes or activities of the organization;

– defining the risk assessment methodologies;

– defining the way performance and effectiveness is evaluated in the management of risk;

– identifying and specifying the decisions that have to be made; and

– identifying, scoping or framing studies needed, their extent and objectives, and the resources required for such studies.

Defining risk criteria

The organization should define criteria to be used to evaluate the significance of risk. The criteria should reflect the organization's values, objectives and resources. Some criteria can be imposed by, or derived from, legal and regulatory requirements and other requirements to which the organization subscribes.

When defining risk criteria, factors to be considered should include the following:

– the nature and types of causes and consequences that can occur and how they will be measured;

– how likelihood will be defined;

– the timeframe(s) of the likelihood and/or consequence(s);

– how the level of risk is to be determined;

– the views of stakeholders;

– the level at which risk becomes acceptable or tolerable; and

– whether combinations of multiple risks should be taken into account and, if so, how and which combinations should be considered.

Risk assessment

Risk assessment is the overall process of risk identification, risk analysis and risk evaluation.

NOTE ISO/IEC 31010 provides guidance on risk assessment techniques.

Risk identification

The organization should identify sources of risk, areas of impacts, events (including changes in circumstances) and their causes and their potential consequences. The aim of this step is to generate a comprehensive list of risks based on those events that might create, enhance, prevent, degrade, accelerate or delay the achievement of objectives. It is important to identify the risks associated with not pursuing an opportunity. Comprehensive identification is critical, because a risk that is not identified at this stage will not be included in further analysis.

Identification should include risks whether or not their source is under the control of the organization, even though the risk source or cause may not be evident. Risk identification should include examination of the knock-on effects of particular consequences, including cascade and cumulative effects. It should also consider a wide range of consequences even if the risk source or cause may not be evident. As well as identifying what might happen, it is necessary to consider possible causes and scenarios that show what consequences can occur. All significant causes and consequences should be considered.

The organization should apply risk identification tools and techniques that are suited to its objectives and capabilities, and to the risks faced. Relevant and up-to-date information is important in identifying risks. This should include appropriate background information where possible. People with appropriate knowledge should be involved in identifying risks.

Risk analysis

Risk analysis involves developing an understanding of the risk. Risk analysis provides an input to risk evaluation and to decisions on whether risks need to be treated, and on the most appropriate risk treatment strategies and methods. Risk analysis can also provide an input into making decisions where choices must be made and the options involve different types and levels of risk.

Risk analysis involves consideration of the causes and sources of risk, their positive and negative consequences, and the likelihood that those consequences can occur. Factors that affect consequences and likelihood should be identified. Risk is analyzed by determining consequences and their likelihood, and other attributes of the risk. An event can have multiple consequences and can affect multiple objectives. Existing controls and their effectiveness and efficiency should also be taken into account.

The way in which consequences and likelihood are expressed and the way in which they are combined to determine a level of risk should reflect the type of risk, the information available and the purpose for which the risk assessment output is to be used. These should all be consistent with the risk criteria. It is also important to consider the interdependence of different risks and their sources.

The confidence in determination of the level of risk and its sensitivity to preconditions and assumptions should be considered in the analysis, and communicated effectively to decision makers and, as appropriate, other stakeholders. Factors such as divergence of opinion among experts, uncertainty, availability, quality, quantity and ongoing relevance of information, or limitations on modelling should be stated and can be highlighted.

Risk analysis can be undertaken with varying degrees of detail, depending on the risk, the purpose of the analysis, and the information, data and resources available. Analysis can be qualitative, semi-quantitative or quantitative, or a combination of these, depending on the circumstances.

Consequences and their likelihood can be determined by modelling the outcomes of an event or set of events, or by extrapolation from experimental studies or from available data. Consequences can be expressed in terms of tangible and intangible impacts. In some cases, more than one numerical value or descriptor is required to specify consequences and their likelihood for different times, places, groups or situations.

Risk evaluation

The purpose of risk evaluation is to assist in making decisions, based on the outcomes of risk analysis, about which risks need treatment and the priority for treatment implementation.

Risk evaluation involves comparing the level of risk found during the analysis process with risk criteria established when the context was considered. Based on this comparison, the need for treatment can be considered.

Decisions should take account of the wider context of the risk and include consideration of the tolerance of the risks borne by parties other than the organization that benefits from the risk. Decisions should be made in accordance with legal, regulatory and other requirements.

In some circumstances, the risk evaluation can lead to a decision to undertake further analysis. The risk evaluation can also lead to a decision not to treat the risk in any way other than maintaining existing controls. This decision will be influenced by the organization's risk attitude and the risk criteria that have been established.

ISO/IEC 29100 Information technology - Security techniques - Privacy framework

ISO/IEC 29100 gives a framework for the protection of personally identifiable information within information and communication technology systems. It is general in nature and places organizational, technical, and procedural aspects in an overall privacy framework.

The standard aims to support an organization in:

- specifying a common privacy terminology;
- defining the actors and their roles in processing personally identifiable information;
- describing privacy safeguarding requirements;
- referencing known privacy principles.

The standard provides definitions for terms such as anonymity, consent, privacy risk assessment, etc.

In addition to this, focus of the standard is on stakeholders, knowledge flow, anonymity, documentation, control, policy (top management involvement), openness, accountability, etc.

The standard defines 11 principles for privacy, as presented in figure A3.16:

Table 3 – The privacy principles of ISO/IEC 29100

1.	Consent and choice
2.	Purpose legitimacy and specification
3.	Collection limitation
4.	Data minimization
5.	Use, retention and disclosure limitation
6.	Accuracy and quality
7.	Openness, transparency and notice
8.	Individual participation and access
9.	Accountability
10.	Information security
11.	Privacy compliance

Figure A3.16 – Privacy principles according to ISO 29100

The standard also touches upon assessment: “One deliverable can be a privacy impact assessment, which is the component of risk management that focuses on ensuring compliance with privacy and data protection legislation requirements and assessing the privacy implications of new or substantially modified programs or activities. Privacy impact assessments should be framed within an organization's broader risk management framework.” (page 10)

Elements in ISO/IEC 29100 that can be used as input or inspiration for the CWA on Ethical Impact Assessment of research an innovation in SATORI are the following.

Methodically, ISO/IEC 29100 is built on “situational management” meaning that the organization[73] should specify how to implement the standard based on their own situation. In the standard, it is

[73] Or in the case of a CWA on an Ethical Impact Assessment: research project.

recommended that all principles should preferably be followed; however, if a principle is not relevant for the particular situation then it can be left out.

The standard provides examples for many of the topics in the standard, which can provide inspiration for implementation and easy reading of the standard.

The standard should be seen as complimentary to legal requirements, which should also be the case in the SATORI CWA.

ISO/IEC 29100 could be used as a reference in the CWA if a framework for protection of personally identifiable information proves to be a valuable aspect of the CWA.

Annex 4 - Interviews with standardization experts

This annex contains notes from the interviews with standardization experts in Danish Standards. The notes express what the interviewee said during the interviews and are only recited as notes - not full sentences, and without editorial comments. This might make it hard to understand the context sometimes, but the main conclusions and advice given can be found in the report above (section 4).

The numbers refer to the question answered. NOTE: Not all interviewees had comments for all questions.

Questions:

1. Do you know of standards within your area of expertise that integrate ethics? E.g. the standard for cocoa or IT safety.
2. We are going to develop a CWA for an ethics assessment framework as part of a European research project. Do you think that any of these standards (from Q1) can be used as inspiration or input for the CWA?
3. Do you know of any standards from other areas that might be useful?
4. How would you approach the task of making a CWA for an ethics assessment framework? Any advice or ideas?

Helene Jackson, consultant for standardization, Danish Standards

1. Chiropractor services.
4. Keep the division of responsibility within the different areas of the standard in mind (e.g. the researcher, the coordinator).

Peter Engel, chief consultant, Danish Standards

1. The standards for environment (ISO 14001) and for occupational health and safety (OHSAS 18001) on an overall level. It is an ethical way of working when you consider/work with these things in a goal oriented and systematic way. The standards for CSR are probably the most spot on (DS 49001 and ISO 26000).
2. DS 49001 and ISO 26000.
4. As a management standard - find/define the relevant topics and elaborate with sub-topics.

Lars Brogaard, senior consultant for standardization, Danish Standards

1. Cocoa - in these standards ethical aspects are explicitly mentioned e.g. labour rights, animal welfare, environment etc. ISO is also in the progress of making a similar standard for wood.

   Implicitly all standards that handle safety - toys, medical equipment etc.
2. ISO 26000 – the highest bar within ethics in standardization. The cocoa standards are more detailed/specific.
3. ISO/TC 34 – standards for animal welfare.

4. As a management system – possibly divided into different parts, one management standard and one standard with the system requirements.

Josefin Hörnqvist, consultant for standardization, Danish Standards

1. Biotechnology – a fast growing area, therefore the regulation is lagging behind. The committee is looking for gaps – one of them is ethics.

   Standard for biobanks are under development, but the work is not that far yet.

   Standards for anticorruption – CD2 (37001) – something very fluffy being standardized. Corruption is wrong. Economic aspects also included. Ethics is also part of the focus in the standard.

2. Maybe something in the standard for biotechnology. Otherwise anticorruption.

Maibritt Agger, head of department – standardization, Danish Standards

1. CSR: ISO 26000, DS 49001. And the other areas we have discussed (see the previous interviews). Maybe also sustainable procurement will be worth to look at.
2. The ISO 26000 structure – good advice instead of requirements, one way of insuring that you get round all relevant topics.
4. See Q2 + make sure that the relevant partners participate in the CWA process.

Jesper Jerlang, vice president standardization, Danish Standards

1. CSR/ISO 26000, animal welfare, animal traps (for hunting), environmental management, occupational health and safety management.

   Distinguish between standards about ethics (CSR) and standards that have ethics as part of their fundamentals (e.g. IT safety).

2. Two types of inspiration: ISO 26000 for the methodology – make sure that it is considered which ethical aspects that are relevant. When this is established, how do we then handle the issues we have identified.

   Standards for privacy etc. can be a help to protect e.g. data in the best way – or a method to deal with data protection issues.

3. No.
4. The CWA group should - before getting started – be very clear about which type of standard they want to develop + the distinction between the ethical aspects/issues and how to handle these. Therefore, it may be a good idea to make a group of standards rather than one standard. The method/approach used in ISO 26000 – making a guide being methodical in its approach – will be a good way of doing it.

Remember guidance on division of responsibilities within the different areas/ethical aspects.

Pernille Tebina, consultant for standardization, Danish Standards

1. Not really. Working with electronic equipment we do a lot to ensure the safety of children, elderly etc. Also to help elderly, disabled etc. to live/stay in their own home.

   SME's are also taken into account when we develop standards.

2. Management standards – something checklist-like.
3. Maybe on cosmetics?

Mette Juul Sandager, consultant for standardization, Danish Standards

1. Ethical guidance in the treatment of customers e.g. cosmetologist/beauticians.

   Safety at playgrounds – here are some ethical considerations regarding safety. No children must die, but maybe in rare cases a broken leg is okay if many children have learned to play, developed their motor function and make "risk assessments".

2. Risk assessment – benefit vs consequence.

   Do it as a management system type b.

Karsten Toelloese, senior consultant, Danish Standards

1. In the establishment of a safety-level for buildings – this is implicit part of the standards. We must build cheap/cost efficient, but the buildings must continue to stay up – and no one must die.

   Renovation of existing buildings: if it is expensive to achieve the safety-level of today, then a lower safety-level is used.

   Ethics is often in the background documents within the field of building standards.

2. Mainly quality management, environmental management etc.

   DS/EN for technical prevention of crime – what comes closest to handling ethical issues, but still very technical.

Lene Alsbaek, senior consultant, Danish Standards

1. Standards for interviewing children (public authorities etc. e.g. when parents are divorced) – ethical because of the psychological aspects. There have not really been made any standards with the psychological field. There might be some inspiration in ISO 10667-1 and -2 (assessment of service delivery).
2. A mix of CSR (ISO 26000/DS 49001) and some of our guides in order to make it (the CWA) more specific and concrete – e.g. guide 17 a well-written guide with specific and useful guidance + a good set-up.

Carina Dalager, senior consultant, Danish Standards

1. Animal welfare (still under development in ISO), food safety standards have some aspects regarding human resources, but only in connection to food safety not for the sake of the humans.
3. Management standards in general – the principles behind the management standards. Keep it short and precise!
4. A management system; you define your own level and keep increasing over time.

Regnar Schultz, senior consultant, Danish Standards

1. Remote reading of electricity meter – this puts data in a shared database. The sensitivity of the data – what if others gain access to the database? Are they then able to read/see if people are at home or not? This have been discussed quite a lot in the committee and a conference have been arranged, but nothing has been included in the standard. This problem is also related to smart-grid.

   Hospital beds for children. Is it for instance necessary to put a "lid" on a bed for the safety of the child? How can these hospital beds for children be designed not to be too prison-like? But still have great focus on safety issues! This is work in progress in CENELEC.
2. Not the standard for electricity meter – too technical. Better to use the other one on hospital beds as an example.
3. Functional Safety – an evaluation of when it is okay for someone to get hurt and how often. This is in the standard as four levels of functional safety. You have to choose a level based on e.g. economy. See IEC 61508-0.

   Also standards for environmental safety and safety in production.
4. As a management standard/risk assessment – do a checklist. + a guide: what to remember.

Niels Madelung, chief consultant, Danish Standards

1. A: Privacy ISO/IEC 29100 and other

   B: CSR ISO 26000

   C: Sustainable events

   D: Sustainable tourism

   E: More technical standards can also contain ethical elements.
2. ISO/IEC 29100 and ISO/IEC 29101 + see list above.
3. No. But see this article on ethics in information security: http://link.springer.com/article/10.1007%2Fs10676-010-9242-6.
4. A: Define our own (broad) understanding of ethics

   B: Use this to pick out some standards + use our committee members to get examples of standards, contact to TCs and SCs to screen for ongoing work with ethics and moral

   C: Maybe try to google for more de facto standards

D: Use the result to formulate a definition of ethics. Use this as input for the group. This sequence will enhance our role and the role of standards in the project.

Joergen Hagelund, senior consultant, Danish Standards

1. Look/search for standards with ethics in the title.
4. A checklist is probably better than a management standard, which is just an "empty shell"; it does not describe what is inside. Take environmental appraisal as an example: does x have an effect on the water environment? On the air? Etc. "CEN Environmental Helpdesk" – a tool for standardizers to evaluate the environmental impact of the product they are standardising. https://www.cen.eu/about/helpdesks/environmental/Pages/default.aspx

   Create consensus on the overall frame for the standard/CWA. Make a checklist or something similar.

   Remember legislation e.g. for test animals. There can be national legislation – therefore also remember questions like: "Are there national legislation for x?"

   Remember section with definitions in the CWA.

Charlotte Vincentz Fischer, consultant for standardization, Danish Standards

1. CSR: ISO 26000, DS 49001. Sustainable procurement (labour rights/conditions), sustainable societies (the management standard for sustainable societies – linked to ISO 26000. How do we measure if a society is sustainable? Also more concrete elements e.g. indicators for unemployment, number of women in the city council, air pollution etc.) also a minor link to smart cities (look at ISO 37120 and 37xxx).
2. Look at ISO 37120 and 37xxx – sustainable societies. ISO 26000 + DS 49001.
3. Sustainable construction (buildings), environmental tools/environmental product declarations CEN/TC 350 and CEN/TC 351.

   Costumer satisfaction in ISO 10001 – a section defining different kinds of companies (types). Might be transformable for some kinds of research projects etc.
4. Strict management/administration of both form and content. Matching of expectations in relation to who are going to write the standard + the length.

   I agree in finding inspiration in CEN Environmental Helpdesk and that you should make it checklist-like.

Annex 5 – The structure of a formal standard

Type of element	Arrangement of elements[a] in document
Preliminary informative	*Title page*
	Table of contents
	Foreword
	Introduction
General normative	**Title**
	Scope
	Normative references
Technical normative	Terms and definitions Symbols and abbreviated terms ... Normative annex
Supplementary informative	*Informative annex*
Technical normative	Normative annex
Supplementary informative	*Bibliography*
	Indexes

[a] Bold type = mandatory element; upright type = normative element; italic type = informative element.

Annex 6 - Workshop project plan

Project Plan for the CEN Workshop on Ethics Assessment of research and innovation; CEN/WS SATORI

2015-10-01

1. Status of the Project

The Project Plan was approved during the Kick-off meeting on 2015-09-17 in Brussels. The Project Plan follows the requirements in CEN-CENELEC Guide 29.[74]

2. Background to the Workshop: European research policy and responsible research and innovation

Background

The Workshop builds on and will further develop the challenges for ethics assessment as presented by the European Strategic Forum on Research Infrastructures (ESFRI) (2006), the recent report on Ethical and Regulatory Challenges to Science and Research at the Global Level,[75] the existing European framework for ethics review,[76] recent publications on ethics of research and innovation at the European level,[77] and the notion of Responsible Research and Innovation (RRI).[78]

Responsible Research and Innovation has been defined as a "transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)".[79] Responsible Research and Innovation is concerned with giving shape to responsible practices of research and innovation which involve both innovators and stakeholders. A significant part of the concern is the identification and assessment of ethical issues that may emerge in research and innovation.

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[74] ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Guides/29_CENCLCGuide29.pdf

[75] Directorate-General for Research and Innovation, European Commission (2012), *Ethical and Regulatory Challenges to Science and Research at the Global Level.* Office for Official Publications of the European Communities, Luxembourg.

[76] Pauwels, E. (2007). *Ethics for Researchers: Facilitating Research Excellence in FP7.* Office for Official Publications of the European Communities, Luxembourg.

[77] E.g., Dench, S., Iphofen, R., Huws, U. (2004), *A EU Code of Ethics for Socio-Economic Research.* IES Report 412, IES, Brighton, UK; Hughes, J. (ed.) (2010), *European Textbook on Ethics in Research*. European Commission, Directorate-General for Research and Innovation, Science, Economy and Society, Luxembourg: Publications Office of the European Union, 2010; opinions of the European Group on Ethics in Science and New Technologies.

[78] Owen, R., MacNaghten, P. and Stilgoe, J. (2012), Responsible research and innovation: From science in society to science for society, with society, *Science and Public Policy* 39(6): 751-760.

[79] Von Schomberg, R. (2011): "Introduction", in Von Schomberg, R. (ed.) (2011), *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields*, Luxembourg: Publications Office of the European Union, pp. 7-16 [p. 9].

Research ethics and innovation ethics

Whereas science is concerned with understanding phenomena and finding truth, innovation is concerned with creating goods or services that have value and meet needs. Innovation results in the creation of products, processes, methods or ideas that have use value and that can serve markets, governments or society at large. Due to the conceptually different aims of scientific research and innovation, the ethics of innovation has evolved largely separately from research ethics. Where in research ethics, the driving field has been medicine, in the ethics of innovation, it has been engineering.

In research ethics, a major focus exists on ethical issues within the professional activity of doing research, technology ethics is less concerned with ethical issues in the activity of developing technology, and is more concerned with ethical issues that arise from the resulting impact on society. This concern for outcomes and impacts on society and is what distinguishes the ethics of innovation, more generally, from research ethics.

Technology ethics is increasingly concerned with new and emerging technologies which are still in the research and development stage, and which have resulted in few concrete products and resulting social impacts. For this reason, technology ethics increasingly relies on technology assessment, as well as on futures studies. [80] Both futures studies and technology assessments are of use for forecasting the development and impacts of emerging technologies. Another development which is more salient for technology than it is for scientific research is the focus on public participation and the engagement of stakeholders. The recent approach of Responsible Research and Innovation builds on all of the above developments and attempts to incorporate them into one approach.

Ethics assessment

The emerging notion of Responsible Research and Innovation requires more systematic focus on scientific responsibility, which goes beyond what scientists do to consider the consequences of their actions. This ethical approach proposed considers science and technology jointly, and has a major focus on the ethics assessment of potential and actual social impacts.[81] The focus within the ethics of technology on societal consequences or impacts may well be transferable to the ethics of scientific research. These approaches constitute a potential improvement over traditional research ethics, which has always only had a limited consideration of the potential utilization of research results and the resulting impact on society.

Ethics assessment of research and innovation typically considers potential societal harms and risks and implications for fundamental rights, justice, well-being of citizens and the common good. Such assessments may require a consideration of potential impacts on health, the environment, work, leisure, social relations, politics, values and so on. To achieve this, ethics assessment often combines ethical analysis with social impact analysis, futures studies, scenario analysis and technology assessment. Engagement with stakeholders and public dialogue are other natural actions within ethics assessment, as stakeholders can help anticipate utilizations and impacts, and can voice their concerns and interests as part of the process of ethics assessment.

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[80] Bell, W. (1997). *Foundations of Futures Studies, Vol. 1: Human Science for a New Era: History, Purposes, Knowledge.* New Brunswick and London: Transaction Publishers.

[81] Brey, P. (2012), Ethics for Emerging Technologies, *Nanoethics* 6(1), 1-13; Swierstra, T., and Rip, A. (2007). Nano-ethics as NEST-ethics: Patterns of Moral Argumentation About New and Emerging Science and Technology, *Nanoethics* 1(1): 3-20.

The SATORI Workshop will assess the feasibility of the development of an European level consensus document on ethics assessment of research and innovation.

3. Workshop proposers and Workshop participants

Proposers

The proposer of the workshop is University of Twente, the Netherlands, in its role as coordinator of the SATORI project.

Associated SATORI partners include: Montfort University, Trilateral Research & Consulting, Danish Board of Technology, Center for the Promotion of Science, European Union of Science Journalists' Association, Helsinki Foundation for Human Rights, VTT Technical Research Centre of Finland, Italian Association for Industrial Research (Associazione Italiana Per La Ricerca Industriale), Research Ehtics Committee 'Instituto de Salud Carlos III', Scientific Research Centre of the Slovenian Academy of Sciences and Arts, United Nations Educational, Scientific and Cultural Organization, National Bioethics Committee, Ericsson Telecomunicazioni SpA, the Secretariat of the Austrian Bioethics Commission, Danish Standards (DS) and Nederlands Normalisatie-Instituut (NEN).

Participants

Participation in the Workshop is open to anyone, and the opportunity to participate is widely advertised in advance by its proposers and by CEN and its member bodies.

The SATORI project circulated the invitation to the kick-off meeting to identified stakeholders. Simultaneously CEN published the CWA Project Plan "Ethics assessment of research and innovation" and invitation through the CEN channel.

Participants can join the Workshop at any time during the process, while accepting the decisions earlier in the process. Prospective participants can express their interest to the secretariat.

4. Workshop scope and objectives

This CEN Workshop Agreement sets requirements and provides guidelines for ethics assessment of research and innovation.

The CWA aims to improve the quality of ethics assessment and harmonize ethics assessment practices.

The CWA applies to organizations or agents involved in performing, commissioning, funding or assessing research and innovation, and therefore have a responsibility to address ethical issues.

5. Workshop programme

The working language during the Workshop is English. The CWA will be drafted and published in English.

The programme to reach the CEN Workshop Agreement entails the following steps:

1. Organisation of the kick-off meeting

The CEN Management Centre (CCMC) posted the Project Plan, the invitation and the agenda for the kick-off meeting on the CEN Website for a period of 30 days. The interested parties registered on the NEN website. In parallel, the invitation was forwarded to the SATORI stakeholders.

Participation in the development of the CEN Workshop Agreement is open to anyone, and the opportunity to participate will be widely advertised in advance by its proposers, the SATORI network and by CEN and its member bodies.

2. The CCMC has organized the **kick-off meeting on 17 September 2015,** at the CEN-CENELEC Management Centre in Brussels, to plan the CEN Workshop Agreement. The kick-off meeting:
    - approved the Workshop Project Plan by agreement of the participants;
    - selected the project team, appoint the Workshop Chair and designate the secretariat;
    - solicits for source materials from the different participating countries.
3. The Workshop secretariat, on behalf of the project team, solicits relevant source materials from the respective countries/organizations.
4. In the **preparatory meeting**, **the project team** will review source materials, compare these with the results of the different work packages in the SATORI project and prepare the first draft for workshop consideration.
5. The Workshop secretariat will organize the first **CEN Workshop plenary meeting** for all registered participants.
6. An internal reviewing period will be carried out to allow for inclusion of final comments from Workshop participants to ensure consensus is reached on the content.
7. A 60-day Public commenting phase will be carried out.
8. A second **plenary meeting** for registered Workshop participants will be organized for the resolution of the comments received during the 60-day public comment phase.
9. The chairman will check by correspondence that a consensus has been reached on the final draft of the CWA.
10. When the consensus is met, the Workshop secretariat will submit the approved CWA CEN-CENELEC Management Centre for publication.

Work progress

	Assessing the feasibility of European consensus on Ethics assessment of research and innovation	**Deadline/date**
0	Preliminary activities before the launch of the Workshop Business Plan	
1	Invitation to the kick-off meeting	10 Jul 2015
2	**Workshop Kick off meeting** CWA open to any interested party	17 Sep 2015 Brussels
3	Survey planned on availability of relevant source documents for the Workshop	Oct 2015
4	**Project team preparatory meeting,** reporting on the applicability	17-18 Feb 2016 Delft

	of relevant source documents	
	Report results of survey by the project team	Mar 2016
5	**CEN Workshop plenary meeting** for registered participants	May 2016 Copenhagen
6	Draft Report on Ethical impact assessment framework and internal reviewing period	Jul 2016
7	Public comment phase on Draft CWA Ethics assessment of research and innovation	Sep-Oct 2016
8	**CEN Workshop plenary meeting** for registered participants for resolution of comments	Jan 2017 Llubljana
10	Publication of CEN Workshop Agreement on Ethics assessment of research and innovation	

6. Workshop structure

The working language during the Workshop is English. The SATORI CWA will be drafted and published in English.

According to the requirements of the EC the draft documents and final CWA publication will be available through the SATORI website free of charge. The documents on the SATORI website will be identical to the documents available from CEN and, as such, will carry the CEN logo.

The CWA will be published by CEN and made publicly available through CEN and the different Standardization Institutes in the member states at normal costs in line with the guidelines in CEN Guide 10:2015.[82]

7. Resource requirements

All costs related to the participation of interested parties in the Workshop's activities have to be borne by themselves.

The SATORI project (funded under the European Union Seventh Framework Programme (FP7/2007-2013), grant agreement n° 612231) includes the NEN participation in the Workshop secretariat.

8. Further information

Further information on the SATORI project is available from http://satoriproject.eu/

Further information on CEN and the CEN Workshop Agreement is available from http://boss.cen.eu/developingdeliverables/CWA/Pages/default.aspx

[82] ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Guides/10_CENCLCGuide10.pdf

9. Contact points

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Annex A Template for the self-assessment

Title of the proposed CWA: Ethics assessment of research and innovation

1. Does the proposed CWA conflict with an EN or an HD for CENELEC?

☒ NO

☐ YES **WARNING**: Work on the proposed CWA shall not be initiated.

2. Does the proposed CWA intend to define requirements related to safety aspects?

☒ NO

☐ YES -> Is the proposed CWA within the scope of

☐ CEN? The CWA proposal shall be submitted to CEN/BT for decision.

☐ CENELEC? **WARNING**: Work on the proposed CWA shall not be initiated.

3. Is the scope of the proposed CWA within the scope of an existing CEN/CENELEC technical body?

☐ NO

☒ YES -> The CEN/TC 389 is consulted on the CWA proposal:

- CEN/TC 389 responded positively (N 203) and sees no harm in the CWA being developed.
- The CWA will manage the information/consultation flows in line with Guide 29.

4. Does the proposed CWA intend to define requirements related to management system aspects?

☒ NO

☐ YES -> The CWA proposal shall be submitted to the CEN/CENELEC BT(s) for decision.

5. Does the proposed CWA intend to define requirements related to conformity assessment aspects?

☒ NO

☐ YES -> CEN/CENELEC Internal Regulations - Part 3, 6.7 applies.

Annex 7 – Internal review meeting comments table

(starts next page)

		Whole document		ge	It would be better to use the term "research integrity" and not the term "scientific integrity" (there were long discussions among native speakers about this issue...), at least you should use only one of them in the entire paper.	With respect to the definition (page 12), we recommend to have a look at the ORI or NSF websites or at the European Code of Conduct (ESF/ALLEA),... to use an appropriate definition!	
1		Introduction		ge	We realize the introduction is still incoherent. So far it only includes issues that have been mentioned to be put in the introduction.	Text suggestions from SATORI partners are welcome!	
2		Introduction		ge	1. What do you mean by Helsinki Declaration (1962 and on)? 2. Change title to: Brief historical background, recent trends, objective of this CWA 3. Where does the following quote end: "transparent, interactive process by which societal actors and innovators become mutually responsive to each other with view on the acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)? 4. Replace "The overarching aim of ethics assessment has been to prevent harm" for "The overarching aim of ethics assessment has been to prevent the harm it may cause". 5. Why not use the RRI in the Rome Declaration on Responsible Research and Innovation in Europe 2014: Responsible Research and Innovation (RRI) is the on-going process of aligning research and innovation to the values, needs and expectations of society, https://ec.europa.eu/research/swafs/pdf/rome_declaration_RRI_final_21		Philip and NEN to write

					_November.pdf 6. Change 'kick off' to 'kick-off'. 7. Replace "The development of this CWA was part of the research project SATORI" with "The development of this CWA was part of the SATORI research project" 8. Replace "How does ethical impact assessment fits in the picture" with " How does ethical impact assessment fits in the picture" 9. It is not clear how the bullet points fit into the text.		
3		2		ge	This section is too long.		Check for terms that are not used in the document And suggest which terms not to include.
4		2.1		Ed	numbers of definitions to change, this one to 2.1, throughout.		Done Splitting the document solves part of the problem. NEN does some cleaning
5		2.2		Te	There is a definition in ISO 10667 that might be used as inspiration	**Assessor** person or organization responsible for evaluating and interpreting an assessment participant's performance on the assessment tasks and providing appropriate reporting and feedback to assessment participants and the client NOTE Assessors are competent to make decisions about the use and interpretation of assessment procedures. In relation to psychological testing, in some countries they are referred to as "test users" to distinguish them from "test proctors", "test administrators" or "monitors". Assessors can be employees of the service provider or the client, or third parties contracted for the purposes of the	Remove Redundant definitions

						assessment.	
6		2.2		Te	**Assessor** A person or entity making an assessment or judgment	**Assessor** A person or entity making an assessment or judgment	Remove Redundant definition
7		2.5		te	1. It might be worth noting that the ethics assessment itself is not responsible for or capable of preventing dual use, only raising awareness of the potential 2. Is there a comma missing here between 'technologies and minimising'? 3. please close the space between the punctuation and the preceding words in this Note. Add, Add note to entry 2	**avoidance of dual use** principle for awareness of potential malicious uses for new technologies, minimising the malicious uses of new technologies while maintaining their beneficial applications Note to entry 1 More specifically, dual use is often about possible non-civilian use (e.g. military). Note to entry 2 Ethics assessment raises awareness of the potential of dual use. Ethics assessment is not responsible for or capable of preventing dual use.	Amend **dual use** research or innovation that is developed for benefit but can be misapplied to do harm, for example in a military or malicious context Adapted from WHO http://www.who.int/csr/durc/en/
8		2.7		te	Perhaps mention that this principle should be applied in conjunction with the principles of beneficence and non-maleficence. Add at the end: with a main goal of reducing unnecessary suffering. What do you mean by 'participants' - is this clear ? Research subjects?	**avoidance of harm to human subjects** principle for minimizing the potential harms to ~~participants~~ research subjects as much as possible if the risk of harm is unavoidable with a main goal of reducing unnecessary suffering	accept
9		2.8		te	Is it intentional to give two definitions for beneficence?	Which one is preferable? **2.8** **beneficence** principle for acting with the best interest of the other in mind [SOURCE: Beauchamp and Childress, Principles of Biomedical Ethics, 2001] **OR**	Accept and amend second definition Because of a broader application Amend: Remove 'involved' Include: principle for acting to the benefit of society;

						2.8 **beneficence** principle for guaranteeing that any risk ~~involved~~ for people involved in or impacted by research is proportional to the expected benefits or the research; meaning that expected benefits always outweigh the risk i~~nvolved~~	Include reference of the second
10		2.9		te	Field of ethical enquiry or field of applied ethics	**2.9** **bioethics** field of ~~ethical enquiry~~ applied ethics that examines ethical issues and dilemmas arising from health, health care and research involving humans.	Withdrawn Not used in the doc
11		2.10		te	Add to the end of the sentence: with the main goal of reducing unnecessary suffering.	**2.10** **care for animal research subjects** principle for humane and considerate treatment, proper care and housing of animal subjects with the main goal of reducing unnecessary suffering [SOURCE: adapted from Shamoo and Resnik, 2003.]	Accepted, combined with the other definition on animals 2.6 and 2.52 **care for animal research subjects** principle for humane and considerate treatment, proper care and housing of animal subjects and reducing the use of animals in experimental settings with the main goal of reducing unnecessary suffering [SOURCE: adapted from Shamoo and Resnik, 2003.]
12		2.10		te	"Animal welfare" is a value of the Union that is enshrined in Article 13 of the Treaty on the Functioning of the		Accepted Add: Note to entry

					European Union (TFEU). Why not quote from: 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?		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 provides requirements.
13		2.11		te	What type of participant - research participant? participant in innovation activity?	**2.11** **competence** mental capacity of a potential or in research or innovation activity enrolled participant to provide informed consent	Rejected Remove the term
14		2.12		te	**Please strike out "easily understandable" - not every consent form is "easily understandable".** **Suggest the following alternative definition:** A form signed by a research subject (i.e. participant) prior to their engagement in a research activity (e.g. trial, interview, research study) to confirm that she or he is agrees to participate in the activity and is aware of the risks involved and their rights. The primary purpose of the form is to provide evidence of such agreement. Please modify the language in the Notes to read... The form should....	**2.12** **consent form** ~~easily understandable~~ written document that documents a potential participant's consent to be involved in research and describes the rights of an enrolled research participant + 2 notes Or **2.12** **consent form** form signed by a research subject, i.e. participant, prior to their engagement in a research activity, e.g. trial, interview, research study, to confirm that he or she understands the risks involved, their rights, and that she or he agrees to voluntarily participate in the activity. Note to entry The primary purpose of the consent form is to provide evidence of such agreement.	Accepted Second definition is preferred with modifications Remove brackets Change sequence: form agreed to by a research subject, i.e. participant, prior to their engagement in a research activity' e.g. trial, interview, research study, to confirm that she or he: - understands the main issues of the research; - is aware of the risks involved; - knows her of his rights; - and agrees to participate

							in the activity voluntarily. Note to entry The primary purpose of the consent form is to provide evidence of such agreement.
15		2.14		te	Per SATORI D1.1, p 27: ethical impacts are impacts that concern or affect human rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good.	**2.14** **ethical impact** impact that concerns or affects human rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good	Accepted Edit: add 2x s
16		2.15		te	Add "In consultation with stakeholders" at the start of the definition. From D1.1 add: It is a means of actioning social responsibility in research and innovation.	**2.15** **ethical impact assessment (EIA)** ~~in consultation with stakeholders non-prescriptive~~ process of judging the ethical impacts of research and innovation activities, outcomes and technologies that incorporates both means for a contextual identification and evaluation of these ethical impacts to translating ethical risks to. guidance taking remedial action generally in consultation with stakeholders. and a translation ~~to a policy level~~, a providing guidance for setting up remedial actions or recommendations. It is a means of actioning social responsibility in research and innovation. [SOURCE: Wright, D. A framework for the ethical impact assessment of information technology. Ethics and Information Technology, 13, 2011. 199–226. http://doi.org/10.1007/s10676-010-9242-6]	Accepted with modification: Remove non-presciptive Add: typically in consultation with stakeholders in the end. process of judging the ethical impacts of research and innovation activities, outcomes and technologies that incorporates both means for a contextual identification and evaluation of these ethical impacts and translation to a set of guidelines or recommendations for remedial actions aiming at mitigating ethical risks and enhancing ethical benefits, typically in consultation with stakeholders. It is a means of actioning social responsibility in research and innovation.

17		2.16		te	Should we define also ETHICAL RESEARCH: The application of fundamental ethical principles and legislation to scientific research in all possible domains of research – for example biomedical research, nature sciences, social sciences and humanities. (European Commission: https://ec.europa.eu/programmes/horizon2020/en/h2020-section/ethics)	**2.xx** **ethical research** application of fundamental ethical principles and legislation to scientific research in all possible domains of research – for example biomedical research, nature sciences, social sciences and humanities [SOURCE: European Commission: https://ec.europa.eu/programmes/horizon2020/en/h2020-section/ethics]	Rejected The term is not used in the text of the document
18		2.16		te	Note that, "The EC perceives 'ethics' as including questions of legal and regulatory compliance as well as a branch of philosophy". http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf	**2.16** **ethics** about what is morally the right thing to do Note to entry The EC perceives 'ethics' as including questions of legal and regulatory compliance as well as a branch of philosophy". http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf	18+19 Not discussed Definition changed and note accepted
19		2.16		te	Simplistically, per Oxford English Dictionary: Moral principles that govern a person's behaviour or the conducting of an activity; The branch of knowledge that deals with moral principles	**or** **2.16** **ethics** ~~about what is morally the right thing to do~~ moral principles that govern a person's behaviour or the conducting of an activity; The branch of knowledge that deals with moral principles [SOURCE: Oxford English Dictionary]	Not discussed Accepted
20		2.17		ed	Replace with: any institutionalized assessment, evaluation,	**2.17** **ethics assessment** any institutionalized ~~kind of~~ assessment,	Accepted

					review, appraisal or valuation of plans, practices, products and uses of research and innovation that makes use of ethical principles or criteria	evaluation, review, appraisal or valuation of plans, practices, products and uses of research and innovation that makes use of ~~primarily~~ ethical principles or criteria [SOURCE: SATORI D1.1, 2015]	
21		2.18		ed	replace 'this' with 'ethics'	**2.18** **ethics assessment unit** institution~~s~~ that performs ~~this~~ ethics assessment Note to entry Ethics assessment units may assess research or innovation goals, new directions, projects, practices, products, protocols, new fields, etc. and their work may be performed before, during, and after the implementation of the projects they assess. [SOURCE: adapted from SATORI D 1.1, 2015]	accepted
22		2.19		te	Issues that may be relevant for evaluating the ethical implications of maxims, principles, or particular courses of action.	**2.19** **ethical issues** issues that may be relevant for evaluating the ethical implications of maxims, principles, or particular courses of action	Not discussed Accepted as no other definition was provided
23		2.20		te	Any general principles that may be relevant for making ethical evaluations. Such principles include beneficence, non-maleficence, autonomy, justice, and dignity.	**2.20** **ethical principles** any general principles that may be relevant for making ethical evaluations. Such principles include beneficence, non-maleficence, autonomy, justice, and dignity	Not discussed Accepted as no other definition was provided
24		2.21		Ed	Revise 'raise' to 'raised'.	**2.21** **ethics protocols** use of approved protocols for commonly occurring situations such as research with normally developing children in schools. These	Accepted

						can expedite ethics review as Principal Investigators can confirm in a 'light touch' review to their REC that there is an approved protocol that appropriately covers the ethics issues raised by their research. It will be the responsibility of the local REC to approve the suggested protocol for the work [SOURCE: ESRC 2012, Framework for research ethics]	
25		2.26		Ed	Revise to: process of reviewing and analysing current literature, web sites, and other media to identify and describe noteworthy trends and their possible development and future	**2.26** **horizon scanning** initial and continuing process of reviewing and analysing current literature, web sites, and other media to identify and describe noteworthy trends and their possible development and future [SOURCE: Jackson, M. (2013) Practical Foresight Guide. Chapter 11 – Foresight Glossary. Shaping Tomorrow. <http://www.shapingtomorrow.com/media-centre/pf-ch11.pdf> accessed on February 2016] or **2.26** **horizon scanning** process of reviewing and analysing current literature, web sites, and other media to identify and describe noteworthy trends and their possible development and future	Accepted
26		2.28		te	proposed replacement:The influence or effects (e.g. societal, ethical, legal, political, economic, environmental etc) of research and innovation.	**2.28** **impact of research and innovation** dimension in ethics assessment concerning the future impacts of the research	Not discussed Accepted

						or **2.28** **impact of research and innovation** influence or effects (e.g. societal, ethical, legal, political, economic, environmental) of research and innovation	
27a		2.29		ge	This definition needs to be re-written - please see below. "Informed Consent is the decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation." Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use is adopted. The principle of "informed and free decision" remains valid for any other kind of research.	**2.29** **informed consent** decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation." Note to entry Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use is adopted. The principle of "informed and free decision" remains valid for any other kind of research.	Not discussed Accepted
27b		2.30			2 definitions of 'innovation'. Which one do we choose?	**2.30** **innovation** development - based on new ideas or inventions - of new products, services, processes and methods believed to create added value for society.	Still to be discussed. CEN/TS 16555 is from CEN/TC 389 innovation management

						[SOURCE: SATORI, D 1.1, p 17] **2.30** **innovation** implementation of a new or significantly improved product (good or service), or process, new marketing method, or new organisational method in business practices, workplace organization or external relations [SOURCE: CEN/TS 16555-1:2013]	
28		2.35		ed	Replace with: long-term process of transformation with a broad scope and a dramatic impact. Megatrends are considered to be powerful factors that shape future markets.	**2.35** **megatrend** long-term process of transformation with a broad scope and a dramatic impact. Megatrends are considered to be powerful factors~~, which~~ that shape future markets.	Accepted
29		2.36		Te	Research on healthy subjects may apply this principle by evaluating whether the research poses any risk greater than the subjects might encounter in their everyday lives.	**2.36** **non-maleficence** principle for, "above all, not doing harm", as stated in the Hippocratic Oath Note to entry Research on healthy subjects may apply this principle by evaluating whether the research poses any risk greater than the subjects might encounter in their everyday lives.	Not discussed Accepted
30		2.38		te	Please use the definition from the **General Data Protection Regulation,** Article 4 (1): personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic,	**2.38** **personal data** data which relates to a living individual who can be identified a) from those data or, b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the	Not discussed Accepted

					mental, economic, cultural or social identity of that natural person;	individual [Data Protection Act 1998] **or** **2.38** **personal data** information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person [SOURCE: General Data Protection Regulation]	
31		2.40		te	**<u>Please revise; this is a definition of data protection, not privacy.</u>** Privacy has many definitions - this one is more restrictive and personal data orientated. Finn, Wright & Privacy has many definitions - this one is more restrictive and personal data orientated. Finn, Wright & Wadhwa 2013 identified seven different types of privacy - privacy of the person, privacy of behaviour and action, privacy of data and image, privacy of communication, privacy of thoughts and feelings, privacy of location and space, and privacy of association (including group privacy).	**2.40** **privacy** principle for guaranteeing to render anonymous identifiable information about research participants and to protect collected data from unauthorised access and store participant data securely **2.40** **privacy** dkljf;lasdj;fl Note to entry Privacy has many definitions - Finn, Wright & Wadhwa 2013 identified seven different types of privacy - privacy of the person, privacy of behaviour and action, privacy of data and image, privacy of communication, privacy of thoughts and feelings, privacy of location and space, and privacy of association (including group	Not discussed Accepted as no other definition was provided

						privacy).	
32		2.41		te	Should we add: giving proper credit for research conducted?	**2.41** **professionalism/respect for colleagues** principle for respecting fellow researchers and treating them fairly, rejecting discrimination, assisting to educate and mentor junior researchers and upholding the standards of the profession giving proper credit for research conducted	Not discussed Accepted
33		2.42		te	**The definition does not fit the title. Revise to:** Agreed and established norms of behaviour, set of rules and responsibilities of, or proper practices applicable to an individual, group or organization.	**2.42** **professional principles or code of conduct:** dimension in ethics assessment concerning the working context of the researcher; e.g. the way (s)he treats his or her colleagues **or** **2.42** **professional principles or code of conduct** agreed and established norms of behaviour, set of rules and responsibilities of, or proper practices applicable to an individual, group or organization	Not discussed Accepted
34		2.47		te	Do RECs always deal only with research involving human participants? Propose revision: A group of people formally appointed to review research proposals or initiatives to assess if the research is ethical.	**2.47** **research ethics committee, REC** multidisciplinary, independent body charged with reviewing research involving human participants to ensure that their dignity, rights and welfare are protected. Note to entry The independence of a REC is founded on its membership, on strict rules regarding conflict of interests, and on regular monitoring of and accountability for its decisions. Or **2.47** **research ethics committee, REC** group of people formally appointed to review	Not discussed

						research proposals or initiatives to assess if the research is ethical	
35		2.49		Te	Would recommend deleting this definition. It is too problematic.	~~**2.49**~~ ~~**respect**~~ ~~principle for treating with respect of subjects partaking in or directly impacted by research; treating them never as merely means, taking into account their value systems~~	Not discussed Accepted
36		2.52		ed	Revise to: principle for reducing as much as possible the use of animals in experimental settings, reducing the suffering of animals by applying less invasive techniques, guaranteeing better living conditions and adhering to ethical experimental procedures.	**2.52** **respectful treatment of animals in experiments** principle for reducing as much as possible the use of animals in experimental settings, reducing the suffering of animals by applying less invasive techniques, guaranteeing better living conditions and adhering to ~~to~~ experimental procedures	Withdrawn Combined with definition 2.6 and 2.10
37		2.53		te	RRI is the focus in the pages that follow; isn't that then a more relevant definition to have (given its wider acceptability too)? Suggest removing RCR. Responsible Research & Innovation (RRI): transparent, interactive process by which societal actors and innovators become mutually responsive to each other with view on the acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society).	**2.53** **responsible conduct of research (RCR)** principle for disclosing information about research aspects which can have harmful side effects, the uncertainty/unforeseen consequences and potential short and long-term effects and preventing violations involving the use of radioactive, biologic, or chemical materials add? **2.xx** **responsible research and innovation (RRI)** transparent, interactive process by which societal actors and innovators become mutually responsive to each other with view on the acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of	Withdrawn Because of comment from and decision to remove research integrity from the CWA. Not discussed Added

						scientific and technological advances in our society).	
37a		2.53		te	RCR is a common used term in the "RI-world", you should be very careful about the definition (page 11).	We recommend to have a look at the ORI or NSF websites or at the European Code of Conduct (ESF/ALLEA),... to use an appropriate definition! The same goes for "scientific/research integrity" (page 12)	Not discussed Noted
38		2.55		te	A plan that matches short-term and long-term goals with specific solutions to help meet those goals. It is a plan that applies to a new product or process, or to an emerging technology.	**2.55** **roadmapping** graphic representation showing key components of how the future might evolve, usually applied to a new product or process, or to an emerging technology matching short and long term goals with specific solutions Note to entry Strategic roadmapping is emerging Or? **2.55** **roadmapping** vision tool to align service, solution and technology development with market developments and wider societal drivers [SOURCE: Presentation Raija] **Or?** **2.55** **roadmapping** plan that matches short-term and long-term goals with specific solutions to help meet those goals. It is a plan that applies to a new product or process, or to an emerging technology	Not discussed Combined
39		2.56		te	Ethical principle for avoiding injury or other	**2.56** **safety**	Not discussed

					harm.	ethical principle for avoiding injury or other harm	Accepted as no alternative proposed
39a		2.60		te	See general comment "0"	We recommend to have a look at the ORI or NSF websites or at the European Code of Conduct (ESF/ALLEA),... to use an appropriate definition for "scientific/research integrity" (page 12)	Not discussed Noted
40		2.61		te	Social responsibility is greater than just environmental effects...	**2.61** **social responsibility** principle for accountability to the potential environmental effects of research, the protection of the environment, biosphere, and biodiversity, serving the public interest with regards to their environment, awareness of the societal interest in environmental values and engagement with the societal concerns regarding the environment ?????	Alternative suggested
41		2.63		Ed + te	**Replace with:** principle for responsibility for care and use of natural resources, restoration of the ecology when damaged and responsibility for waste management	**2.63** **sustainability** principle for responsibility for care and use of natural resources, ~~restauration~~restoration of the ecology when damaged ~~in research~~ and responsibility for waste management	Not discussed accepted
42		2.64		te	Proposed revision: A systematic evaluation of properties, effects, and/or impacts of technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. *Adapted from the EC definition of HTA.*	**2.64** **technology assessment (TA)** exploring consequences of new technology (and science) in advance to help create better technologies (and societies) or **2.64** **technology assessment (TA)** systematic evaluation of properties, effects, and/or impacts of technology. It may address the	Not discussed New proposal accepted

						direct, intended consequences of technologies as well as their indirect, unintended consequences. [SOURCE: Adapted from the EC definition of HTA]	
43		2.65		te	remove 'in research ethics'. this is obvious	**2.65** **transparency ~~in research ethics~~** full, accurate, and open disclosure of relevant information	Not discussed Accepted
44		3		ge	The stuff on the ethics assessment unit is too detailed and seems to imply this EAU would be in a big organisation with lots of resources whereas much smaller organisations might still need, at least, one ethics assessor and maybe could not afford more than one assessor		Noted and withdrawn
45		3.1		te	The ethics assessment unit should monitor and review the scope of its operation in consultation with its stakeholders. This requirement is not in WP for, it originates from ISO 9001. Do we want to include it.	The ethics assessment unit should monitor and review the scope of its operation in consultation with its stakeholders.	Accepted and amended ..considering the stakeholder interest and opinions.
46		3.1	Last par	ge	Delete last sentence as it is repeated in section on **Appointment of the EAU and its members**	~~Legal requirements must take precedence over other considerations in the organisation and operation of an EAU.~~	Accepted
47		3.1	3 par	te	1. Should we add the text in bold at the end of the following sentence: The ethics assessment unit should monitor and review the scope of its operation in consultation with its stakeholders and their relevant requirements**, while being mindful of available resources.**	The ethics assessment unit should monitor and review the scope of its operation in consultation with its stakeholders and their relevant requirements**,** while being mindful of available resources**.**	Rejected, already resolved in 45

48		3.1		ed	1. In the EXAMPLE, make 'object' plural as follows: The objects for assessment can be, but are not limited to, research proposals or policies, guidelines, tools and principles for ethics assessment of R&I, innovation goals, new directions, projects, practices, products, protocols, new fields. 2. In the following sentence, replace 'their' with 'its': In any case, the EAU should be independent in ~~their~~ decision-making; independent of the researchers and of the institutions involved. Its work should be fair and unbiased.	In par 2 2nd- Example The objects for assessment can be, but are not limited to, research proposals or policies, guidelines, tools and principles for ethics assessment of R&I, innovation goals, new directions, projects, practices, products, protocols, new fields. The assessment may be performed before, during, and after the implementation of the projects and practices they assess. In par 4 An EAU might be part of a larger organization or independent. If the EAU is part of a larger organisation, it should recognise the goals of this organisation. In any case, the EAU should be independent in ~~their~~ decision-making; independent of the researchers and of the institutions involved. Its work should be fair and unbiased.	Accepted
49		3.3		te	This seems highly relevant. But WP 4 provides little requirements. Maybe COE 2007 5A3 REC appointment and renewal process can serve as inspiration.	Who can provide input The processes by which EAU members are appointed and membership is renewed should be transparent and fair. The process should be free of partisanship that might hamper the independence of the committee. The term of office of EAU members, including the option of membership renewal, shall be clearly prescribed, bearing in mind the need to maintain an appropriate balance between continuity of accumulated expertise and appointment of new members. The issue of maintaining independence with respect to ethics review and follow-up of reviewed research and innovation highlights the	Amend REC-> EAU Adapted from COE Research project -> research and innovations Secretariat and Sudeep to condense the third paragraph, check for overlap with 3.2: Managing possible conflicts of interests to preserve the independence of the ethics review process is necessary. As such, any potential EAU

						management of possible conflicts of interest. Consequently, when people are appointed to be EAU members, they should declare any actual or potential conflicts of interest with respect to the work of the EAU and agree to declare any conflicts that may arise subsequently. Such declarations should be documented and kept up to date. People appointed EAU members should be given a document of appointment. It may be useful for them to receive written specifications of their responsibilities established by that appointment. [Source COE 2007 5A3]	members should declare any actual or perceived conflicts of interest that exist or may arise as a result of participating in the activities of the EAU. Such declarations should be documented, considered, and periodically updated. Subsequently, appointed EAU members should be given a document of appointment, and, where useful, documented specifications of the responsibilites established by their appointment.
50		3.3		te	Is "appointment" not different from "organisation and operation"...please consult drafter and revise section 3.3.		Already resolved Merge 3.3 with 3.4 as it is only one sentence. Add the sentence to 3.4 Legal requirements must take precedence over other considerations in the organisation and operation of an EAU.
51		3.4	3	te	second bullet point: • expertise not relevant to the research being reviewed. This does not make sense, Perhaps contrasting	expertise contrasting to the research being reviewed	Accepted with modifications. The objective is diversity. How broadly do we want to define this?

					expertise could be more relevant.		Join 1st and 2nd bullet Expertise in the field of research and innovation and outside of it. Amend third bullet Lay person, end user, or representative of the end user organization, for example patient or elderly. Remove brackets. Check doc for consistent use of lay person/lay member (use: lay person)
52		3.4	6	te	6th paragraph ....interest in the proposal. I take it that you mean personal interest or gain. replace 'interest' with 'personal interest or gain	Apparent and potential conflicts of personal interests or gain should be declared and avoided among EAU members. EAU members with an apparent conflict of interest should not participate in discussions or decisions where that interest may affect their judgement.	Accepted
53		3.4	8	te	8th paragraph, second bullet: • good communication skills, both written and interpersonal I would consider deleting the last bit. This may rule out non academics.	• good communication skills ~~both written and interpersonal~~	Accepted
54		3.4	8	te	8th paragraph, 6th bullet • experience of serving in committees Is this really necessary.	Replace with: • ability to cooperate in a group	Accepted
55		3.4	1	ge	1st par This means that ther's a strong split between EAU and the people doing ethical impact assessment (because those often are part of project teams). This probably needs to be made explicit.		Already resolved by the decision to split the document in EAU and EIA.

56a		3.4	1, 3, 4	Te	**1st Par: Please revise text:** The membership of an EAU should be arranged in a way that it encourages rigorous discussion and evaluation of research proposals. This is best achieved by a membership that is independent of the researchers and the institutions involved, diverse in backgrounds and expertise, and representative of the communities that will be affected by its decisions, and also includes scientific expertise relevant for particular areas of inquiry.	1 par, add last sentence: The membership of an EAU should be arranged in a way that it encourages rigorous discussion and evaluation of research proposals. This is best achieved by a membership that is independent of the researchers and the institutions involved, diverse in backgrounds and expertise, and representative of the communities that will be affected by its decisions, and also includes scientific expertise relevant for particular areas of inquiry.	Accepted
56b		3.4	3	Te	**3rd Par: The following sentence does not make any sense:** Lay persons should only be permitted to serve as an EAU member for a limited time so that such members continue to provide an 'outside' perspective on research	3 par, 3rd bullet: Lay persons should ~~only~~ be permitted to serve as an EAU member for a limited time so that such members continue to provide an 'outside' perspective on research	Already discussed
56e		5			**Additional comment** Include a non-disclosure agreement		A non-disclosure agreement protects the member of the EAU. There is a need to balance transparency and non-disclosure; you do not have to say who said something in a committee Jeroen submitted a text suggestion: - An addition regarding confidentiality, this could either be added to section 3.1 or 5, wherever you think it fits best: (Added to chapter 5) The discussions within an

							ethics assessment unit should be kept confidential. At a minimum it is recommended to apply the Chatham house rule[1], or to have a non-disclosure agreement. Results from an ethics assessment should be communicated clearly on behalf of the ethics assessment unit to the relevant parties only. [1]: https://www.chathamhouse.org/about/chatham-house-rule
56c		3.4	4	Te	**4th par: Strike out the following separate bullet and merge it in bullets before it:** Other expertise may be included: Ethical expertise from both secular moral traditions and the most important religion(s) of the region where the research takes place.	4 par: ~~Other expertise may be included:~~ • ~~Ethical expertise from both secular moral traditions and the most important religion(s) of the region where the research takes place.~~	Accepted with modification. Keep the bullet but Remove 'the most important' Ethical expertise about secular and religious moral traditions, especially those traditions represented in communities affected by the research. Important to add something whether the person acts in his personal or professional capacity. Sudeep provided a text proposal on this issue for

							3.2: Ethical expertise about both secular and religious moral traditions especially those traditions represented in communities involved or affected by the research
56d		3.4		Ed	**Please eliminate spelling errors and insert appropriate punctuation on this page.**		Accepted
57		3.4	8	te	**Add 'declared and'in:** "Apparent and potential conflicts of interests should be avoided among EAU members" with "".	Apparent and potential conflicts of interests should be declared and avoided by EAU members	Already accepted in 52.
58		3.4	8	ed	Each EAU member 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 being assessed; • Personal commitment to the goals of ethics assessment; • No apparent and potential conflicts of interests; • Awareness of the cultural factors that may influence the community perception of the research under consideration	Each EAU member 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 being assessed; • An ability to engage in reasoned debate and discussion to reach and accept a balanced view of the research projects being assessed; • Personal commitment to the goals of ethics assessment; • No apparent and potential conflicts of interests; • Awareness of the cultural factors that may influence the community perception of the research under consideration.	Accepted

59		3.4	8	te	**Proposed a deletion of:** Experience of serving in committees; as this would disqualify a lot of people from serving on EAUs	• ~~Experience of serving in committees~~	Already discussed in 54
60		4		Te	The document should give some examples of ethical principles, e.g., relating to fairness, power, equity, inclusion, solidarity, etc.		Discuss with authors of the framework where to put these principles. Check with text in 4.3 deliverables.
60a		4		ge	The context in which RI and RCR is mentioned is a bit confusing for us (page 15/16)		Research integrity is not responsibility of the EAU and removed from this chapter
60b		4		Ge	We appreciate the promotion of RCR within the process but doubt if it is possible to assess RI or possible research misconduct in assessment processes, especially in the beginning of a project (then it could only be plagiarism..)..		Research integrity is not responsibility of the EAU and removed from this chapter
60c		4		Te	It is not clear who would be responsible to investigate such allegations, maybe you could also have a few sentences on this issue.		Research integrity is not responsibility of the EAU and removed from this chapter
60d		4			Regarding the promotion of RI: It would be good to mention that researchers have to adhere to local or national guidelines, CoC and/or international guidelines such as the Singapore Statement or the European Code of Conduct (e.g. if there are no national guidelines).		Research integrity is not responsibility of the EAU and removed from this chapter
						Add text to the bullet: Ethical dimension typically include the following dimension The prof…..	The secretariat consults the authors of 4.2 and 4.3 to rephrase this section • Now mainly principles, include the

						This dimension is normally assessed by the scientific board and not by the ethics assessment unit. [Put this as the third in the sequence of the 3 bullets]	ethical issues. • An option is to provide more explanation/ framework in an annex with a summary in the main text. • Need to include examples to illucidate • Let the annex be coherent with the text in the deliverable
61		4	1, 2nd-	Te	1st par, 2nd - wo comments only 'research integrity' or research integrity and societal responsibility Only 'research' or research and innovation?	....with the mandate to promote research integrity and societal responsibility in general and in a scientific field of research and innovation;	Rejected Preference for 'social responsibility'. This is broadly defined and includes environmental responsibility. Check definition; it should include the environment.
62		4	1, 3rd -	Te	1st par, 3rd - add societal responsibility	.... best practices on research integrity and societal responsibility	Not discussed
63		4	1	ge	1st par I don't understand the purpose of this section. Why not remove all ethical principles from the terms and definitions and just provide a short and consise summary of the main principles to be taken into account (only the shared ones or also per scientific field)		Not discussed
64		4	2, 1st -	Te	2nd par — the professional and code of conduct	For discussion, which ones to include in the professional code of conduct dimension?	Not discussed

					dimension typically include the principles: honesty, accountability, professionalism/respect for colleagues, stewardship, scientific freedom, scientific integrity and openness; (From SATORI 4.1.2) SATORI deliverable 4.2.2 provides a larger list for the professional code of conduct dimension: Scientific integrity, honesty, accountability, reliability, objectivity, fairness, transparance, openness and accessiblity, verifiability, duty of care, independence, impartiality, scepticism, scrupulousness, responsibility. Which ones to include?	Based on D 4.1.2. Do we want the whole of 4.2.1 ch 1.10 in an informative annex for guidance???	
65		4	2, 2nd -	Te	— the research practice dimension typically includes the principles: respect, justice and beneficence; (From satori 4.1.2) 2nd par, 2nd - In SATORI D 4.2.2 also information security and accessiblity are included in the research practice dimension. Which ones to include?	For discussion: to include information security and accessibility	Not discussed
66		4	2, 3rd -	Te	— the impact dimension typically includes the principle social responsibility. Social responsibility seems a bit unambitious. Which ones to include in the impact dimension In SATORI D 4.2.6 impact dimension also includes:	Which ones to add?	Not discussed

					public health protection, preserving, protecting and improving the quality of the environment, protecting the health, safety and exonomic interests of consumers and workers, protection of health and life of humans, animals or plants, protecting human rights.		
67a		4	1, 1st -	ge	What do you mean by "global discussion"?		Not discussed
67b		4	1, 2nd -	ge	How is the determination of ethical issues and principles advocated and developed by.....? Please review the following statement: — advocated and developed by national and international organisations with the mandate to promote research integrity in general and in a specific field of research;		Not discussed
67c		4	2, 1st -	te	Delete 'and' 1st - the professional and code of conduct dimension typically include**s** principles of honesty, accountability, professionalism/ respect for colleagues, stewardship, scientific freedom, scientific integrity and openness	1st - the professional ~~and~~ code of conduct dimension typically include**s** principles of honesty, accountability, professionalism/ respect for colleagues, stewardship, scientific freedom, scientific integrity and openness	Not discussed
67d		4	2	ed	**Add "of" in between "principle" and social responsibility in the following sentence**: the impact dimension typically includes the principle social responsibility.	- the impact dimension typically includes the principle of social responsibility. Or - the impact dimension typically includes the principle: social responsibility.	Accepted
68		4	3, 1st -	te	technological innovations typically include the	technological innovations typically include the following field specific ethical	Not discussed

					following field specific ethical principles: avoidance of dual use, precaution and justice; ; - **replace with avoidance with awareness:**.	principles: ~~avoidance~~ awareness of dual use, precaution and justice	Accepted
69		4	3, 6th -	Ed	**Please delete the following and add RCR to the first bullet that talks about environmental risks to eliminate the duplication:** research involving potential environmental risks typically includes the following field specific ethical principle: responsible conduct of research (RCR)	Add principle to the 2nd bullet — research involving potential environmental risks typically includes the following field specific ethical principle: safety, social responsibility, sustainability and responsible conduct of research (RCR)	Not in line with the decision to remove RCR from the standard as this is not the responsibility of the EAU
70		4	3, 7th -	Te	Please add to the research in ICT bullet: typically includes the following field specific principles: autonomy, privacy, data protection, security of information, non-discrimination, informed consent, confidentiality.	- research in ICT: typically includes the following field specific principles: autonomy, privacy, data protection, security of information, non-discrimination, informed consent and confidentiality.	Accepted and amended Added beneficence, avoidance of harm, What about data analysis and big data. Jeroen provides a text suggestion:. - research involving data analysis, ICT and Internet research typically includes the following field specific ethical principles: beneficence, privacy, data protection/security of information, informed consent, avoidance of harm to human subjects, avoidance of bias and protection of the vulnerable, social responsibility
71		4	4	te	**replace reassure with ensure**		Not discussed

					The ethics assessment unit should reassure that the institutions, that submit proposals under scrutiny, acknowledge the responsibility for ethical professional behaviour	The ethics assessment unit should ensure that the institutions, that submit proposals under scrutiny, acknowledge the responsibility for ethical professional behaviour.	
72		4	7, 4th -	te	To **unambiguous definitions of various kinds of misconduct**, add: improper credits of authorship.	— unambiguous definitions of various kinds of misconduct. Misconduct typically includes FFP (Fabrication, Falsification and Plagiarism), improper credits of authorship, conflict of Interest/misrepresentation of interests, breach of confidentiality, lack of informed consent, abuse of research subjects or material, improper dealing with infringements, minor misdemeanours;	Not discussed
73		4		ge	The document should give some examples of ethical principles, e.g., relating to fairness, power, equity, inclusion, solidarity, etc.		
74		5		ge	I think this section will need to be more extensive in the eventual CWA	Who adds suggestions?	The current text refers current operating procedures. The new texts of 4.3 includes new recommendations for ethics assessment procedures. Participants provide comments on the text in 4.3.1.1. and inform the secretariat.
75		5	2, 1st -	Te	promote ethical reflection of the applicant. What does this mean?	- to promote ethical reflection in research and innovation practices	Accepted with modifications You like to stimulate the scientists to refect rather

							then to comply to a check list. Amend - Enhance the ethical awareness concerning the research and its consequences of applicants rather than promote mere rule following.
76		5		Te	Consider defining 'standard operating procedures' in the terms and definitions list	standard operating procedures	The term ‘standard operating procedures’ is a typical lab expression. There is a demand for standardization of operation procedures. Often ‘good practices’ is used as the preferred ‘operating procedures. Avoid the term ‘standard operating procedures’ The CWA provides a general framework for operating procedures Rephrase the paragraph. Keep the examples. Text with in the CWA doc
77		5	2, 3rd-	te	The wording “ensure that participation in research is voluntary” may put too much strain on the ethics assessment. I.e. ethics assessors cannot ensure this without being present when subjects are recruited.	Maybe use, "Require that the researchers follow the procedures for recruiting voluntary subjects”	Accepted with modifications Remains defining the limitations of ‘voluntary’ What about the situation that is it not possible to ask the subjects, like in big

							data research. Decide to skip the bullet point.
78		6		Ge	The CWA should recognise the similarities between an EIA and a PIA and the desirability of subsuming or at least undertaking in parallel a PIA with an EIA		Not discussed
79		6		ge	I think we should first explain what this is and under what circumstances it should be part of ethics assessment. This is as of yet a controversial practice, and perhaps should therefore be in a separate chapter. Moth ethics committees (a) do not consider impacts of research, and (b) if they do, do not do so using an EIA but do so more informally, focusing on one or two types of impacts and addressing them in a simplistic way.	for discussion	Not discussed
80		6		ge	This is not the task of the EAU. Rather this can be done by the R&I project team itself (ethicists working in the team) and it can be determined by e.g. funding bodies.	What is the role of the EAU in ethical impact assessment? THe CWA sets requirements for the EAU. For discussion	Not discussed
81		6		ge	I think we need to be more clear about the difference between ethics assessment and ethical impact assessment; the first focusing on research ethics and the latter focussing on ethical impacts of R&I.	Or is ethical impact assessment an essential element of ethics assessment in RRI? of course when the threshold analysis indicates this.	Not discussed
82		6		ge	EIA is not only under the remit of EAUs. It might also be done by researchers and third parties (sometimes private companies) hired for that purpose.		Not discussed

83		6		ge	The document should recognise the similarities between an EIA and a PIA and the desirability of subsuming or at least undertaking in parallel a PIA with an EIA		Not discussed
84		6		ge	The document should say something about risk assessment. In some strong measure, an EIA is a risk assessment process. An organisation undertakes an EIA to avoid ethical risks. How should those risks be assessed and managed (avoided, minimised, transferred, shared).		Not discussed
85		6		ge	There was one further comment that I wanted to make, which relates to the foresight studies referenced in the draft standard. While I think scenarios are very useful in an EIA, I'm less convinced that horizon scanning and some other foresight tools are necessary. In an EIA, an organisation will be assessing a particular service or technology or programme or even legislation, so developing scenarios that can show the ethical consequences of taking (or not taking) some actions to address the ethical issues is appropriate, but in such a case there is no need (in my view) to engage in horizon scanning. HS is appropriate when you are looking for some new issues or some new development, but in an EIA, the assessor already knows what he or she is dealing with. In drafting the standard, we have to exercise our judgement about what will be realistically do-able by government agencies and, especially, the private sector. If the EIA process is too long or		Not discussed

					too complicated, they won't both with it.		
86		6.1	Figure 1	te	Explain what the full/mid/small scale is and what the criteria are		Not discussed
87		6.1	4	te	Where are the impact related questions; what about environmental and societal consequences, How does the research/innovation contribute to sustainability, equity reduction, societal desirability?	Valid question. A new list of questions will be send in due time	Not discussed
88		6.1	4	te	We should say explicitly for whom the questionnaire is designed, e.g., researchers, the organisation, project managers, etc.		Not discussed
89		6.1	4	te	Please replace "Typically the threshold analysis ~~includes~~ a questionnaire with the following questions"	with: Typically, the threshold analysis might include the following questions:	Not discussed
90		6.1		Ed	Please delete the ??? after pt. 11		Agreed
91		6.2	2	Te	bullet points What is near future, what is small?	Will be revised	Not discussed
92		6.2	1	Te	Who is the assessor? From the EAU or from the research project. The CWA sets requirements to the EAU, what is its role in EIA?	Not from the EAU	Not discussed
93		6.2		Ge	Please edit this page in line with PDF emailed to NEN on 25/5.		Not discussed
93a		6.2	5	ed	**Please delete 'fairly wide'**	Those involved in conducting the foresight exercise have a ~~fairly wide~~ discretion in the selection of appropriate foresight methods and depend on the scale of the EIA; full scale, medium or small scale	Accepted

93b		6.2		ed	Font sizes differ on this page. Please revise.		Accepted
93c		6.2	7	te	" medium scale EIA foresight is less expensive, less time consuming and less accurate". **Please delete this. On what basis is this assumption being made? Has it been tested? Highly inadvisable to make this statement.**	" ~~medium scale EIA foresight is less expensive, less time consuming and less accurate~~	Not discussed Removed
93d		6.2	1		Replace "comprehensive descriptions" with "scenarios"	During the foresight stage the assessor produces scenarios ~~comprehensive descriptions~~ of alternative futures of a technology, application, service, process, as well as their potential societal and environmental consequences.	Not discussed
94		6.2		ge	Re the foresight studies referenced in the draft standard: While scenarios are very useful in an EIA, we are less convinced that horizon scanning (HS) and some other foresight tools are necessary. In an EIA, an organisation will be assessing a particular service or technology or programme or even legislation, so developing scenarios that can show the ethical consequences of taking (or not taking) some actions to address the ethical issues is appropriate, but in such a case there is no need (in our view) to engage in horizon scanning. HS is appropriate when you are looking for some new issues or some new development, but in an EIA, the assessor already knows what he or she is dealing with.		Not discussed
95		6.3.1		ge	Who is the assessor? From the EAU or from the research project? The CWA sets requirements to the EAU. What is its role in EIA?	The researcher in the R&I project is the assessor.	Not discussed
96		6.3.1		ge	Replace "After the determination, at the recommendation stage, the assessor should recommend the	**with:** During the recommendation stage, the assessor should make recommendations to stakeholders	Not discussed

					involved stakeholders in the project or program on how to proceed in addressing ethical issues that were previously identified and evaluated"	involved in the project or program about how to proceed in addressing the identified and evaluated ethical issues.	
97		6.3.2	1	Ed	Please delete 'that are'	In the identification stage the ethical issues are identified. The assessor should investigate if the alternative futures ~~that are~~ identified in the foresight are likely to impact ethical issues.	Agreed
97a		6.3.2	1, 1st -	Ed	Please delete 'that were' text that has been struck through:	Ethical checklist approach: the assessor crosschecks a list of ethical issues with the technological options ~~that were~~ identified at the foresight stage.	Agreed
98		6.3.3		Ed	This table is out of place where it is now located.	Move it to just after the sentence where it mentions the table. i.e. before the sentence "Ethical impact assessment often is an iterative process".	Not discussed
98a		6.3.3		Ed	Replace "typically consist" with "typically consists" - see second sentence, para beginning with *Based on...*		Agreed
98b		6.3.3		Ed	Replace "stakeholders which" with "stakeholders who". para 3 second sentence.		agreed
99		6.4		Ge	The CWA should say something about risk assessment. In some strong measure, an EIA is a risk assessment process. An organisation undertakes an EIA to avoid ethical risks. How should those risks be assessed and managed (avoided, minimised, transferred, shared).		Not discussed
100		6.4	Title	Ed	Please re-title this section to plural: **Recommendations and remedial actions**	Recommendations and remedial actions	Agreed
100a		6.4	1	Te	**Re first line:** At the *recommendation stage*, the assessor should recommend the involved stakeholders in the research or innovation on how to proceed in	**Please replace with:** At the recommendation stage, the assessor should make recommendations on how to address the identified ethical issues.	Not discussed

					addressing ethical issues that were previously identified and evaluated.		
100b		6.4		Ed	In "The recommendation stage includes follow up on": **change "follow up" to "follow-up"**		Agreed
101		6.5		Ge	The EIA should give more prominence to consulting with stakeholders. Currently, it describes an EIA as a four-step process, but I've suggested in the text to make it (at least) a five-step process by including another step regarding consultation with stakeholders.	Make EAI a five-step-process and add a step regarding stakeholders	Not discussed
102		7	8	Te	Last sentence comes from COE 2007. Do we want to include it?	The information, in their entirety or in the form of an executive summary, should also be made publicly available.	Accepted
103		7	2	Ed	**In para 2, make the following correction in sentence 2:**	The evaluation should include ~~gauge~~ views of relevant stakeholders	Agreed
103a		7	4	Ge	**Change** "The ethics assessment unit ~~shall~~ consider the results of analysis and evaluation, from internal and external review, to determine if there are needs or opportunities that ~~shall~~ be addressed as part of continuous improvement"	**to**: The ethics assessment unit <u>should</u> consider the results of analysis and evaluation, from internal and external review, to determine if there are needs or opportunities that <u>should</u> be addressed as part of continuous improvement.	Agreed
103b		7	5	Ge	**Change "shall" in the following sentence to "should"**: The ethics assessment unit shall……	The ethics assessment unit <u>should</u> continuously improve the suitability, adequacy and effectiveness of the ethics assessment system.	Agreed
103c		7	6	Ed	**Edit the following sentence**: A recommended approach to quality assurance ~~uses~~ the Plan-Do-Check-Act (PDCA) approach. **Replace 'is' for 'uses'.**	A recommended approach to quality assurance <u>is</u> the Plan-Do-Check-Act (PDCA) approach.	Agreed
103d		7	6	Ed	**Edit the following sentence**: Using this approach could help ethics assessors to plan their ethics assessment processes and interactions better, ensure ~~its~~ quality by enabling	Using this approach could help ethics assessors to plan their ethics assessment processes and interactions better, ensure ~~its~~ quality by enabling them to ensure "processes are adequately	Agreed

					them to ensure “processes are adequately resourced and managed, and that opportunities for improvement are identified and acted on. **Delete the 'its' and remove the quotation marks.**	resourced and managed, and that opportunities for improvement are identified and acted on.	
103e		7	8	Ed	In the following sentence – The EAU should regularly provide sufficient information about their work – ethics review, research follow up, and other activities – to their appointing institution or authority. **Change "follow up" to "follow-up".**	The EAU should regularly provide sufficient information about their work – ethics review, research follow-up, and other activities – to their appointing institution or authority.	Accepted
104a		Annex B	PLAN	Te	**In the PLAN part, change ‘shall’to ‘should’** - the methods/techniques to be used and how performance shall be measured"	the methods and techniques to be used and how performance should be measured".	Accepted with modification: Is measured
104b		Annex B	DO, 1st -	Ed	**delete the word "also**	- 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...	Accepted
104c		Annex B	DO, 7th -	Ed	add "the" before the word purpose:	Retaining appropriate documented information as evidence of fitness for the purpose of the ethics assessment process	Accepted
105a		Annex B	CHECK, 1, 1st-	Ed	**change "were" to "are":**	What is the origin of the ethics assessment policy, practice or procedure and what are its objectives?	Accepted
105 b		Annex B	CHECK, 2, last -	Te	**Replace the '/' with "and":**	Did evaluation or review policies and procedures allow for the addressing of things affecting the achievement of the objectives of the ethics assessment policy, practice or procedure?	Accepted

		ANNEX B	CHECK, 3 3rd -	Ed	**Replace the '/' in the following sentence with "or". Replace 'which' with 'that':**	To what extent are the costs involved justified, given the changes or effects that have been achieved?	Accepted
		ANNEX B	CHECK, 3, 4th-	Ed	replace "was" with "have been":	What factors influenced the efficiency with which the achievements observed have been attained?	Accepted
		ANNEX B	CHECK 4, 4th -	Te	**replace** "(~~N.B. Could include issues related to the specify policy here~~)"	Issues related to the specific policy could be included here.	Accepted
		ANNEX B	CHECK 5, 1st -	Ed	**In the following sentence, replace "which" with "that":**	To what extent is ethics assessment policy, practice or procedure coherent with other ethics assessment policy, practice or procedures that have similar objectives?	Accepted
		ANNEX B	ACT 1st par	Ed	rt, in "" replace "this includes" with "These include".	These include following type of activities	Accepted
106		Bibliography		Ed	Please cite all relevant deliverables from WP4 as well, once published, particularly 4.1		Accepted

Annex 8 – Communication plan for the CWA public enquiry

A8.1 Marketing communication plan public enquiry CEN/CWA Ethics Assessment for Research and Innovation

Introduction

The objective of this CWA is to improve and harmonize ethics assessment of research and innovation. The CWA consists of two parts. Part one describes the composition, role and functioning, and procedures of an ethics committee. Part two provides practical guidance for researchers and ethics assessors on ethical impact assessment.

A CWA is a pre-standard. This type of document is often developed when a relatively new area for standardization is explored.

The CWA can be used by all types of organization (profit, non-profit) and research areas.

Context

The attention for and urgency of ethics assessment has increased. In recent years there were public discussions on the ethical desirability of several research projects or innovations (e.g. GMO, nanotechnology, big data & privacy, drones).

The notion of ethical impact assessment is relatively new and a guidance document provides a practical tool. This CWA aims to improve and harmonize ethics assessment. Ethical assessment of research and innovation has been a fairly longstanding practice, most notably within medical sciences. In other scientific fields it is less established. All scientific fields can benefit from the CWA.

However, ethical impact assessment is a relatively new concept that is gaining attention. As this is an unknown field, the CWA provides researchers and ethics assessors with a practical tool.

Part 1 describes the composition, role and procedures of an ethics committee. This will help organisations to implement ethics assessment of their research and innovation projects.

Part 2 of the CWA describes how an ethical impact assessment of an individual research project can be conducted. This information is also useful for ethical committees as it gives them an understanding of the different steps of the EIA process and their role in it.

The CWA is developed as part of the European project SATORI. Within CEN the CWA is embedded in the CEN/TC Innovation Management.

What is the objective of this plan?

SATORI aims to gather as much (relevant) input on the draft CWAs as possible, during the public enquiry phase. This way relevant knowledge will be included in the documents. The support from relevant stakeholders for the documents will be higher and the information in the document will go beyond theoretical knowledge.

During the public enquiry phase the document will be disseminated through normontwerpen.nen.nl for comments. Period: mid September - mid November.

Core message

Ethics assessment of research and innovation is becoming increasingly important. The CWA provides organisations and individuals with a practical tool to start with ethical (impact) assessment or enhance the quality of their existing practices.

What are the target groups?

The CWA part one on EAUs is intended for all types of organisations (profit, non-profit, government; small, medium, large) and fields of research and sectors.

Part two is relevant for researchers and ethics assessors. EAUs will also benefit from the information.

The target group can be split into two parts: primary and secondary. The primary group consists of direct users. The secondary group consists of influencers that can communicate the standard to the primary target group. The stakeholder categories of the SATORI project are included.

The following categories are defined for each of the CWA's:

Primary	**Secondary**
CWA part 1 Ethics Committee	
Quality management	University associations
Sustainability managers	Researchers
Innovation managers	NGOs (animal welfare, human rights, religious organisations)
Universities (excluding ethics committees) and research institutes, and departments	European Commission
Academies of science	European Parliament
	National Parliaments
	Professional and scientific associations and societies
	Technology assessment organisations and programmes
Industries	
Ethics committees	Ethics committees
Research funding bodies	
CWA part 2 Ethical Impact Assessment	
Researchers universities	University associations
Ethics assessors	Researchers
Ethical impact assessors	Researchers
Universities (excluding ethics committees) and research institutes, and departments	NGOs (animal welfare, human rights, religious organisations)

	European Commission
	European Parliament
	National Parliaments
	Quality management
	Sustainability managers
	Innovation managers
	Academies of science
	Professional and scientific associations and societies
	Technology assessment organisations and programmes
Research funding bodies	
Industries	
Ethics committees	Ethics committees

Importance of communication for the participants of the CWA committee

- increase the visibility of the CWA;
- increase the visibility of the stakeholders that participated in the development of the CWA;
- eventually: improve acceptance (support) and application of the CWA resulting in improved ethics assessment.

Communication channels

For each of the communication channels relevant activities were performed:

PR	Press release at the start of the public enquiry
Website NEN and website SATORI	Back ground information on the project
Twitter	Online article shared through the SATORI account and by the participating organisations (people) in the CWA
LinkedIn:	Online articles can also be shared through the personal accounts of the participants of the CWA
Facebook	Online article shared in SATORI group
Communication tools of the participating organisations in the CWA	Website, social media, newsletters
Presentation at relevant events	Presentation at events to reach different target groups
Direct targeting of key stakeholders	Either through a personal email or conversation

Paper	Digital	Personal
Kwaliteit in Bedrijf, SIGMA, TGTHR (through NEN)	Twitter, facebook	Secretaries NEN shadow committee innovation management, big data, medical labs, environmental labs (milieukwaliteit), nucleair, statistical applications. Nanotechnology
KAM nieuwsbrief NEN	Linkedin	NEN: CEN/TC Innovation Management
University magazines	Unesco.nl	Email list with contacts that have shown an interest
Magazines of target groups (above)	Newsletters & websites SATORI partners	NEN: NWO, KNAW, IT sector European Parliament, European Commission List of stakeholders WP2

Planning of actions

What	Who	When
Webpage at NEN website https://www.nen.nl/Standardization/SATORI-harmonising-ethical-impact-assessment-of-research-and-innovation.htm	NEN	early 2015
Webpage at CEN https://www.cen.eu/work/areas/InnoMgmt/Pages/WS-SATORI.aspx	NEN	Early 2015
Press release at start of CWA https://www.nen.nl/NEN-Shop/Nieuwsberichten-Milieu/Start-ontwikkeling-Europabrede-afspraken-over-ethische-toetsing-van-onderzoek-en-innovatie.htm	NEN	Aug 2015
General email invitation for first meeting	NEN, all partners	Aug 2015
Longer article in KAM Nieuwsbrief NEN start public enquiry	NEN	Sept 2016
General press release for dissemination public enquiry	NEN, All	Sept 2016

	partners	
Article on website SATORI (press release)	WP 10, all partners	Sept 2016
Press release will be shared through social media	All partners	Sept 2016
General email that can be sent to relevant stakeholders	All partners	Sept 2016
Personal conversations with relevant stakeholders	All partners	Sept/Oct 2016
Presentation to the CEN/TC innovation management	NEN	Sept 2016
Participation in SATORI workshops	NEN, all partners	Nov / dec 2016
Presentation to conference Open.IT (Netherlands)	NEN, UT	March 2017
Presentation to the 3rd European Technology Assessment Conference	NEN & SATORI partners	May 2017
Presentation to hackers conference	NEN	Summer 2017

A8.2 Press release for the public enquiry on the CWA

PRESS RELEASE

FOR IMMEDIATE RELEASE

Brussels, 15 September 2016

Have your say on ethics assessment in Europe

SATORI project invites you to give your feedback on the first version of the CEN Workshop Agreement

Having confidence in science is immensely important. Its far-reaching consequences call for a broad stakeholder involvement to increase legitimacy. However, many sensitive topics in this field give us ethical dilemmas. How do we keep our privacy in the drone era? Should we edit genes at embryo level in humans? Is there any unwanted usage of personal data for medical purposes? Well-established agreements on different issues will create safer outcome and improved procedures of projects and ethics assessment units.

EU FP7 SATORI project aims at reaching a harmonized approach towards ethics assessment of research and innovation (R&I), while exploring differences in values, principles and research practices between different countries, organisations and scientific fields.

This have resulted in CEN (Comité Européen de Normalisation) Workshop Agreement (CWA) which sets requirements and provides guidelines for ethics assessment undertaken by research ethics committees and other units and individuals that have a responsibility to evaluate the ethical aspects of R&I.

Given the immense societal impact of the research and innovations, SATORI project invites you to provide your feedback on the first version of the CWA document.

The CWA consists of two parts. The first part provides organizations and individual researchers a practical tool to help them establish and run an ethical assessment unit, which will in turn strengthen and improve the ethics assessment of their research practices.

The second part of the agreement provides researchers and ethics assessors a "how to" for ethical impact assessment, a practical, policy-oriented guide aimed at the different stages of the ethical impact assessment process.

"The objective of the CWA is to come to widely supported agreements on ethical assessment for all scientific disciplines", said Marlou Bijlsma from the Netherlands Standardization Institute (NEN), a SATORI partner in charge of creating the CWA and for facilitating the process of achieving agreements on the document.

Netherlands Standardization Institute (NEN), SATORI partner, is in charge of creating the CWA and for facilitating the process of achieving agreements on the document.

The CWA process takes about a year and is typically used for new subjects within standardization. The document is again reviewed after three years, while a full standard can only be developed after five years. A CWA is also called a pre-standard. Part of the development of a CWA is a public inquiry phase.

Public inquiry opened until mid-November

From mid-September to mid-November stakeholders are invited to review the first version of the document through normontwerpen.nen.nl website. The document is available in English and comments will be only accepted in English. Stakeholders are all organizations or individuals involved in the process

of research and innovation: researches, universities, ethics committees and assessors, research organizations, industry, funding agencies etc.

Give us your feedback at: normontwerpen.nen.nl

For more information, please contact:

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A8.3 Example of an article to announce the public enquiry of the CWA

Hoe ethische toetsing drones, disruptors en nanotech verder helpt

Big data, drones, gen- en nanotechnologie, embryo-onderzoek, synthetische biologie, nucleaire energie. Het zijn innovaties die tot stevige publieke debatten leiden. Maar hoe kan dit debat bijdragen aan de acceptatie van nieuwe ontwikkelingen?

Disruptieve deelplatformen als Uber en AirBnB stellen wetgeving op de proef. Drones bieden een nieuw perspectief op de wereld, maar verstoren tegelijkertijd het vliegverkeer en roepen vragen op over privacy. Dat laatste geldt ook voor internet-of-things-toepassingen.

Het maatschappelijke debat over de negatieve en positieve kanten van innovaties vindt volop plaats. Dit debat speelt een belangrijke rol in het inventariseren van de mogelijke kansen en belemmeringen voor de succesvolle acceptatie van innovaties, zeker wanneer onderwerpen als privacy en veiligheid onderwerp van de discussie zijn. Ethische toetsing van onderzoeksprojecten en innovaties wordt daarom belangrijker. Normalisatie-instelling NEN faciliteert het proces om tot afspraken te komen over die toetsing.

Door voor, tijdens en na het onderzoek na te denken over ethische vraagstukken, en oplossingen, kan worden voorkomen dat investeringen in innovaties op een flop uitdraaien. Bij aanvragen voor onderzoeksprojecten wordt bovendien vaak gevraagd om een ethische verantwoording.

Goede afspraken, met name over de methodiek van het betrekken van stakeholders in de discussie over de wenselijkheid, vergroten het vertrouwen in innovaties. Maar hoewel onderzoek zich tegenwoordig vooral afspeelt op internationaal niveau, zijn er nog weinig internationale raamwerken waarbinnen ethische afwegingen worden gemaakt.

NEN is partner van het SATORI-project (Stakeholders Acting Together On the ethical impact assessment of Research and Innovation). Dit door de Europese Commissie gefinancierde project onderzoekt de principes en ‘good practices’ van ethische beoordeling van onderzoek en innovatie, en ontwikkelt Europese afspraken voor ethische toetsing.

De afspraken bestaan uit twee delen. Het eerste deel geeft aanbevelingen voor een reilen en zeilen van een 'ethische assessment unit', die onderzoeks- en innovatieprojecten beoordeelt. Het tweede deel van de afspraken biedt een “how to” voor ethische impact assessment.

16 Europese partijen , waaronder Universiteit Twente, Ericsson en Unesco doen mee aan dit project. NEN is projectleider van het deelproject dat tot afspraken over een raamwerk voor ethische assessment moet komen, en tegelijkertijd onderzoekt of en welke vorm van conformiteitsbeoordeling geschikt zou zijn.

Van half september tot half november kunnen belanghebbenden commentaar geven op de eerste versie van het document via www.normontwerpen.nen.nl. Alle organisaties, bedrijven en personen die betrokken zijn in het uitvoeren van, opdracht geven tot of financieren van onderzoeks- of innovatieprojecten zijn van harte welkom om mee te denken.

Annex 9 – SATORI CWA Part 1 Ethics committee[83]

[83] CWA 17145-1 is available on the SATORI website.

CEN

WORKSHOP

AGREEMENT

CWA 17145-1

May 2017

ICS 03.100.02; 03.100.40

English version

Ethics assessment for research and innovation - Part 1: Ethics committee

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodies.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Contents

Page

European foreword

CWA 17145-1:2017 was developed in accordance with CEN-CENELEC Guide 29 “CEN/CENELEC Workshop Agreements – The way to rapid agreement” and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was agreed on 2017-03-27 in a Workshop by representatives of interested parties, approved and supported by CEN following a public call for participation made on 2017-08-01. It does not necessarily reflect the views of all stakeholders that might have an interest in its subject matter.

The final text of CWA 17145-1:2017 was submitted to CEN for publication on 2017-04-03.

A list of the individuals and organisations that supported the technical consensus represented by the CEN Workshop Agreement is available from the CEN-CENELEC Management Centre. These organisations were drawn from the following economic sectors industry, universities, civil society organisations, technology boards, European organisations.

It is possible that some elements of CWA 17145-1:2017 may be subject to patent rights. The CEN-CENELEC policy on patent rights is set out in CEN-CENELEC Guide 8 “Guidelines for Implementation of the Common IPR Policy on Patents (and other statutory intellectual property rights based on inventions)”. CEN shall not be held responsible for identifying any or all such patent rights.

The Workshop participants have made every effort to ensure the reliability and accuracy of the technical and non-technical content of CWA 17145-1:2017, but this does not guarantee, either explicitly or implicitly, its correctness. Users of CWA 17145-1:2017 should be aware that neither the Workshop participants, nor CEN can be held liable for damages or losses of any kind whatsoever which may arise from its application. Users of CWA 17145-1:2017 do so on their own responsibility and at their own risk.

Introduction

The increasing pace of technological developments such as genetic technologies, geo-engineering, ICT and synthetic biology has been stimulating questions and discussion on the desirability and governance of their societal impacts. Ethics assessment and ethical impact assessment help ethicists to investigate ethical challenges. Ethics assessment and ethical impact assessment help researchers, policy makers and relevant stakeholders to deal with the ethical impacts of research and innovation.

The need for agreed methods for ethics assessment and ethical impact assessment arises out of the increasing focus on responsible research and innovation in policy contexts and in collaborative efforts by researchers, as well as from new legal regulations for research and innovation at the European level. The European Commission, has been a driving force behind the development of ethics assessment and impact assessment practices, by incorporating the need for responsible research and innovation in its framework programmes.

The SATORI (Stakeholders Acting Together On the ethical impact assessment of Research and Innovation, www.satoriproject.eu) research project, funded by the European Commission, developed a framework for common basic ethical principles and joint approaches and practices with the objective of harmonizing and improving ethics assessment practices of research and innovation.

The SATORI project developed a framework based on research into existing practices. These research findings are the basis of this CWA. This CWA consists of two parts.

Part 1, outlined here, makes recommendations for the composition, role, functioning and procedures of ethics committee. Organisations can use part 1 to strengthen and/or improve the ethics assessment of their research and innovation projects. Ethics committees include, but are not limited to, research ethics committees, institutional review boards, ethical review committees, ethics boards, and units consisting of one or more ethics officers. Part 1 of the CWA is applicable to all ethics committees, regardless of their size, scope or research and innovation area.

Part 2 provides researchers and organisations with guidance on ethical impact assessment; a comprehensive approach for ethically assessing the actual and potential mid- and long-term impacts of research and innovation on society. Researchers and ethics committees will find this information useful as it describes ethical impact assessment at different stages of the ethical assessment. Part 2 is applicable to all researchers and innovators, regardless of the context they are working in or their research and innovation area.

1 Scope

This document, (CWA 17145-1:2017) sets requirements and provides guidelines for ethics assessment in research and innovation (R&I).

The CWA aims to improve the quality of ethics assessment and to harmonize ethics assessment practices.

The CWA has two parts:

— part 1: Ethics committee. This part provides recommendations for ethics committees on practices and procedures;

— part 2: Ethical impact assessment framework. Part 2 provides a practical, policy-oriented guide for researchers and ethics committees on the different stages of the ethical impact assessment (EIA) process.

Both parts of the CWA are of interest to organisations or agents who are involved in performing, commissioning or funding research and innovation, and therefore have a responsibility to address ethical issues.

The focus of the CWA is on ethics assessment, not on ethical guidance.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
avoidance of bias
principle of avoiding partial data or participants selection, conclusions or presentation of findings due to prejudice, conflict of interest, etc

2.2
avoidance of harm to human subjects and participants
principle of minimising the potential harms to research subjects and participants as much as possible, if the risk of harm is unavoidable, with a primary goal of reducing unnecessary suffering

Note 1 to entry: This principle is applied in conjunction with the principles of beneficence and non-maleficence.

2.3
beneficence
principle of acting to the benefit of the participants and society; guaranteeing that any risk to people involved in or impacted by research is proportional to the expected benefits of the research, meaning that expected benefits always outweigh the risk involved

[SOURCE: adapted from Brey et al., 2016, and Beauchamp et al., 2001]

2.4
care for animals used for scientific purposes
principle of humane and considerate treatment, proper care and housing of animal subjects and avoiding unnecessary suffering by following the three Rs: replacing, reducing and refining the use of animals in experimental settings

2.5
conflict of interest
set of conditions in which professional judgement concerning a primary interest (e.g., a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (e.g., financial gain)

[SOURCE: Thompson, 1993]

2.6
dual use
research or innovation that is developed for benefit but can be misapplied to do harm, for example for a military or malicious purpose

[SOURCE: adapted from WHO, http://www.who.int/csr/durc/en/]

Note 1 to entry: Ethics assessment raises awareness of the potential for dual use.

Note 2 to entry: Although research is usually carried out with benign intentions, it has the potential to harm humans, animals, or the environment. Examples of research that has potential for misuse include: research involving information on, or the use of, biological, chemical, radiological and nuclear security-sensitive materials and explosives (CBRNE); research with a potential impact on human rights e.g. relating primarily to surveillance technologies, new data-gathering and data-merging technologies (e.g. in the context of big data) or social or genetic research that could lead to discrimination or stigmatization; research that has other potential misuses e.g. providing terrorists or criminals with information or technologies that would have substantial direct impacts on the security of individuals, groups, or states.

[Source: H2020 How to complete your ethics Self-Assessment, 2016]

2.7
ethical impact
impact that concerns or affects human rights and responsibilities, human dignity and fundamental freedoms, benefits and harms, justice and fairness, well-being or the social good

2.8
ethical impact assessment
EIA
process of judging the ethical impacts of research and innovation activities, outcomes and technologies that incorporates both the means for a contextual identification and evaluation of these ethical impacts and the development of a set of guidelines or recommendations for remedial actions aimed at mitigating ethical risks and enhancing ethical benefits, typically in consultation with stakeholders

Note 1 to entry: Ethical impact assessment is the overall process of ethical impact anticipation, -determination and -evaluation.

Note 2 to entry: Ethical impact assessment is a means of actioning social responsibility in research and innovation.

[SOURCE: adapted from Wright, 2011]

2.9
ethical issues
issues that may be relevant for evaluating the ethical implications of maxims, principles, or particular courses of action

2.10
ethical principles
general principles that may be relevant for making ethical evaluations

Note 1 to entry: Such principles include beneficence, non-maleficence, autonomy, justice, and dignity. Annex A provides an overview of ethical principles.

2.11
ethics
moral principles that govern a person's behaviour or the conducting of an activity; the branch of knowledge that deals with moral principles

Note 1 to entry: The EC perceives 'ethics' as including questions of legal and regulatory compliance as well as being a branch of philosophy, in European Commission: Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects.

[SOURCE: Oxford English Dictionary]

2.12
ethics assessment
institutionalised assessment, evaluation, review, appraisal or valuation of plans, practices, products and uses of research and innovation that makes use of ethical principles or criteria

[SOURCE: SA TORI D1.1, 2015]

2.13
ethics committee
institution, committee, board or officer that performs ethics assessment

Note 1 to entry: Ethics committees may assess research or innovation goals, new directions, projects, practices, products, protocols, new fields, etc. and their work may be performed before, during, and after the implementation of the projects they assess.

Note 2 to entry: Ethics committee may also be called Ethics Review Board, Ethics Assessment Unit, Ethics Board or other terms.

[SOURCE: adapted from SATORI D 1.1, 2015]

2.14
human participants
living human beings about whom a researcher obtains data through intervention or (indirect) interaction with the individual or from individually identifiable information. Persons may also become a human participant through the use of their tissue

Note 1 to entry: Diseased persons may not qualify as human participant in the full sense but special consideration may be needed, e.g. informed consent by next of kin.

Note 2 to entry: Some are of the opinion that embryos and fetuses have an independent status. However, in any case informed consent from the legal representative(s) is needed.

2.15
impact of research and innovation
influence or effects, e.g., societal, ethical, legal, political, economic or environmental, of research and innovation

EXAMPLE: Environmental consequences of technological innovations resulting from research in the chemical sciences

2.16
informed consent
decision, written, dated and signed, to be a research participant, taken freely after being duly informed of its nature, significance, implications and risks of the research. Informed consent must be appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative

Note 1 to entry: The above definition is in line with that in Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. The principle of 'informed and free decision' remains valid for any other kind of research.

Note 2 to entry: If the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.

2.17
innovation
development, based on new ideas or inventions, of new products, services, processes and methods

[SOURCE: adapted from Shelley-Egan et al., 2015. SATORI D 1.1]

2.18
justice
principle of equal rights of all persons, both participants and researchers, involved in or impacted by research

Note 1 to entry: Any inequality arising from research practices is designed to bring about the greatest benefit for the least advantaged.

[SOURCE: adapted from Rawls, 1971]

2.19
lay person
person without relevant professional expertise to better reflect the social and cultural diversity of society

Note 1 to entry: This term is used in reference to a member of an ethics committee.

2.20
non-maleficence
principle of, 'above all, do no harm', as stated in the Hippocratic Oath

Note 1 to entry: Research on healthy subjects may apply this principle by evaluating whether the research poses any risk greater than the subjects could encounter in their everyday lives.

[SOURCE: Beauchamp et al., 2011]

2.21
openness
principle of willingness to consider new ideas in the research field and of sharing data, resources and procedures

2.22
personal data
information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person

[SOURCE: art. 4(1) 679/2016 General Data Protection Regulation]

2.23
precaution
principle of methodologically considering the likelihood of benefits and harms from new technologies and for revising their development if the risk of damage is significant

2.24
professional conduct
principle of respecting fellow researchers and treating them fairly, rejecting discrimination, assisting in educating and mentoring junior researchers, giving proper credit for conducted research and upholding the standards of conducted research, upholding the standards of the profession and following the guidelines of professional conduct

2.25
professional principles or code of conduct
agreed and established norms of behaviour; set of rules and responsibilities of, or proper practices applicable to, an individual, group or organisation

2.26
protection and preservation of communities
ethical principle of ensuring that research being conducted is responding to the needs of specific communities and is of value and in the interest of those affected and involved; of making provisions for the needs of vulnerable cultures, including those who cannot consent on their own behalf, and of recognising the practices and knowledge of traditional communities and avoiding their exploitation and stigmatisation

Note 1 to entry: In cases where people in a position of power or criminal groups are being researched in the social sciences, research findings may be critical of the practices in which these people or groups are involved. In such cases, special care should be given to the protection of the researchers.

2.27
protection of the vulnerable
principle of taking additional care to prevent vulnerable populations from exploitation or stigmatisation

Note 1 to entry: Alternatives to informed consent are sought and obtained if the participants are unable to give such consent themselves.

2.28
research
form of systematic inquiry that aims to contribute to a body of knowledge or theory

2.29
research ethics
moral principles guiding research from its inception through to completion and publication of results and beyond

2.30
research ethics committee
REC
group of people formally appointed to review research proposals or initiatives to assess if the research is ethical

Note 1 to entry: The independence of a REC is founded on its membership, on strict rules regarding conflict of interest, and on regular monitoring of and accountability for its decisions.

2.31
research practice
practices of systematic, methodical creation of new knowledge or the use of existing knowledge in a new and creative way so as to generate new concepts, methods or understandings

2.32
respect for biodiversity and cultural diversity
principle of recognising the value of cultural diversity and biodiversity and the means for preserving them when conducting research

2.33
respect for human participants
principle of obtaining informed consent from human participants, minimising harm, ensuring that the potential benefits outweigh the harms caused to research participants, fairly distributing the benefits and burdens of research, and taking additional steps to protect participants from vulnerable groups

2.34
responsible research and innovation
RRI
transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the acceptability, sustainability and societal desirability of the innovation process and its marketable products, in order to allow a proper embedding of scientific and technological advances in society

2.35
responsible treatment of cultural heritage
principle of protecting and promoting ”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” and recognizing the shared aspects within human diversity and culture

[SOURCE: adapted from UNESCO, Cultural heritage]

2.36
ensuring safety
ethical and legal principle of undertaking actions to avoid injury or other harm to research participants and researchers

2.37
scientific freedom
principle of freedom of thought and research, not subject to political or institutional interference

2.38
scientific integrity
principle of carrying out research practices in an honest, objective, impartial, independent, responsible, and fair way

2.39
social responsibility
responsibility to consider the societal impacts of research and innovation and for taking steps to minimise anticipated harm and maximise benefits

Note 1 to entry: These impacts include among other things socio-economic impacts, environmental impacts, impacts on health, safety, human rights, civil liberties, etc.

2.40
stewardship
principle of wisely using resources, whether they are human, technological, or natural and the care-taking of research sites, artefacts and collected samples

2.41
sustainability
principle of responsible care and use of economic, social, institutional and environmental resources so that they are preserved for future generations

Note 1 to entry: Environmental sustainability concerns more specifically the preservation of environmental resources and biodiversity.

2.42
transparency
full, accurate, and open disclosure of relevant information

Note 1 to entry: This is important where the research involves new and innovative methodologies.

3 Ethics committee

3.1 Role and responsibilities

The objective of an ethics committee is to assess, evaluate, review, appraise or valuate practices, products and uses of research and innovation. In order to achieve this objective, the ethics committee makes use of primarily ethical principles or criteria.

The ethics committee should determine its scope of operation. The scope of operation includes:

— objects of assessment;

EXAMPLE: The objects for assessment can be, but are not limited to, research proposals or policies, guidelines, tools and principles for ethics assessment of R&I, innovation goals, new directions, projects, practices, products, protocols, and new fields. The assessment may be performed before, during, and after the implementation of the projects and practices they assess;

— scientific fields;

— goals and expectations. The goals and expectations typically include that the work is fair and unbiased and compliant with legislation, ethics standards, polices and declarations.

The ethics committee should determine whether it is part of its 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, wastes resources and provides possibly false 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 ethics committee, and that an assessment of scientific adequacy may require extra effort and expertise.

The ethics committee should monitor and review its scope and mode of operation by considering stakeholders' interests and opinions.

The ethics committee may either be part of a larger organization or independent. If the ethics committee is part of a larger organization, it should recognize the goals of this organization. In both cases, the ethics committee should be independent in its decision-making, and independent of the researchers and institutions involved. Its work should be fair and unbiased.

Ethics committees associated with industry should take into account the corporate social responsibility goals of the industry and the research's potential impact on the business goals of the company. This consideration should not compromise the ethics committee's judgement or influence it to approve research that it would otherwise reject as unethical.

Cultural factors should only be used to justify stricter requirements than those imposed by national or international laws, or by accepted international guidelines on research ethics. Having members on the ethics committee who have training and experience in applied ethics can assist in identifying and addressing cultural factors that could affect how the general community perceives the research.

Ethics committees should secure adequate resources which could include compensation in time, working space and secretarial support.

Independent ethics committees could secure funding from government and partially from fees paid by organisations requesting ethics assessments.

Ethics committees that are part of a larger organization could secure funding from this organization. They could also ask for fees for ethics assessments performed for outside organisations (e.g. commercial companies).

3.2 Competencies

The ethics committee should determine and maintain the necessary competencies of its membership. Members should be *professional* (technically, ethically, and administratively), *independent* of the researchers and the institutions involved, *diverse* in their backgrounds and expertise, and *representative* of the communities affected by the committee's decisions.

The ethics committee should evaluate whether the necessary competencies are present within the ethics committee. The ethics committee should ensure that the members are competent on the basis of appropriate education, training and experience. The ethics committee should retain appropriate documented information as evidence of competence.

The ethics committee should, where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken. Ethics training could be made 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 [6].

The ethics committee chairperson should possess administrative competence. This includes interpersonal skills for managing group decisions and communication skills to convey the ethics committee's decisions to researchers and supervisors.

3.3 Appointment of the ethics committee and its members

The ethics committee should determine, monitor and maintain procedures for the appointment of the ethics committee 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 ethics committee.

Legal requirements shall take precedence over other considerations in the organization and operation of an ethics committee.

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

— the chairperson should be elected by the members;

— the organization should appoint qualified experts;

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

— lay persons should not be exclusively selected by scientific experts;

— the chief executive of the organization should not be a member of the ethics committee;

— in cases where a newly elected member of the ethics committee 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, knowledge is transferred and training may take place.

Ad hoc members may be appointed to the ethics committee and either be treated as advisors who present their informed opinion of the activity under review, or as ad hoc members who participate in the ethics committee's full decision-making process. The term of office of ethics committee 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 ethics committee should rotate, over a fixed time period and through a democratic process, among members of the ethics committee who possess strong administrative competence.

It is necessary to manage possible conflicts of interest to preserve the independence of the ethics review process. For this reason, any potential ethics committee members should declare any actual or perceived conflicts of interest that exist or may arise as a result of participating in the activities of the ethics committee. Such declarations should be documented, considered, and periodically updated. Subsequently, appointed ethics committee members should be given a document of appointment and, where useful, documented specifications of the responsibilities established by their appointment.

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

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

3.4 Composition

Members of an ethics committee should be able to recognize the ethical concerns raised by R&I activity during its planning, development and application. The committee's composition should encourage rigorous discussion and evaluation of research proposals. This is best achieved by a membership that is independent of the researchers and the institutions involved, diverse in background and expertise, and

representative of the communities that will be affected by its decisions. It should also include scientific expertise relevant for particular areas of inquiry.

NOTE While appointing members belonging to the same organization may reduce perceived independence, this can be countered by appointing sufficient non-affiliated members, such as lay persons and outside experts, to provide balance.

The number of members in an ethics committee may depend on relevant legislative requirements, the available resources, and the need to include a diversity of perspectives on the research while maintaining a manageable size to allow for fruitful discussion and deliberation.

The ethics committee should include at least one representative of each of the following areas of expertise and or background:

— scientific or technical expertise, preferably both related to the field being reviewed and outside that field;

— lay persons: lay persons should only be permitted to serve as ethics committee members for a limited time so that they continue to provide an 'outside' perspective on the research;

— end-user, or representative of the end-user group or organization, for example, patients or senior citizens;

— ethical expertise;

— legal expertise.

Additional expertise may be included:

— ethical expertise about both secular and religious moral traditions, especially those traditions represented in communities involved in or affected by the research;

— the ethics committee may consult ad hoc experts when necessary.

All members are equally important. Expert and non-expert members should be open-minded and impartial in considering research proposals, and be willing to discuss their views and consider alternative perspectives in making their decisions.

Apparent or potential conflicts of interest (personal or financial) should be declared and avoided among ethics committee members. Ethics committee members with an apparent conflict of interest should not participate in discussions or decisions where that interest may affect their judgement.

The composition of the ethics committee should provide well-balanced representation of each of the categories above. There should be enough lay persons to ensure that their views are not ignored by members with directly relevant expertise.

Each ethics committee member should possess the following characteristics:

— relevant expertise (professional members) or an informed interest (non-professional members or lay persons, experts from other fields) in the research under assessment;

— ability to evaluate the benefits, risks, and burdens of the specific research projects being assessed;

— personal commitment to the goals of ethics assessment;

— communication skills;

— ability to cooperate in a group;

— no apparent and or potential conflicts of interest;

— ability to engage in reasoned debate and discussion in order to reach and accept a balanced view of the research projects assessed;

— awareness of the cultural factors that may influence the community perception of the research under consideration.

3.5 Conflicts of interest of the ethics committee

The ethics committee should establish, monitor and maintain a conflict of interest policy to assess and manage the conflicts of interest of members of the ethics committee. 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 (for instance, 2.5);

— 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);

  - 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 ethics committee's home institution or an institution with which an individual ethics committee member is affiliated);

— 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: ethics committee 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 ethics committee about their actual, possible or perceived conflicts of interest;

  - regular conflict of interest disclosure rounds at ethics committee meetings;

- submission, by the chairperson of the ethics committee, of the conflict of interest reports to an audit subcommittee or other appropriate oversight authority for review;

— procedure on how to identify and deal with conflicts of interest whose value exceeds a minimum threshold. The procedure should state that it is the conflict of interest audit body that identifies actionable conflicts of interest. The audit body should decide whether a particular ethics committee member may serve as a reviewer, participate in discussions at specific meetings, or vote on the relevant ethics assessment decision; or whether he or she should completely divest of any conflicting interests;

— outline of possible consequences and penalties for non-compliance with the policy (e.g. removal from the ethics committee).

The risk of conflicts of interest may relate to the institutional structure of ethics committees. A good solution to achieve independent operation is that ethics committees are not embedded in research institutions. If the ethics committee is embedded in the research institution, the personal and professional affiliations between members of the committee and the work they review should be carefully considered to avoid conflicts of interest. Members of the same department should not assess each other's proposals. In addition, the ethics committee should operate independently from the executive(s) of its host organization.

The ethics committee should determine and maintain a procedure of appeal to allow resubmission of proposals for assessment to another ethics committee.

4 Ethical issues and principles

4.1 General

The ethics committee should determine and maintain the ethical issues and principles that are to be considered in the ethics assessments within its mandate. It should consider ethical issues and principles that generally apply to all fields of research and innovation, and ethical issues and principles specific to the field(s) of research and innovation that fall under the scope of its ethics assessments.

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** are ethical principles that specifically concern the behaviour and practices of individual researchers and innovators and the way they treat others. Assessment of behaviour is not normally the responsibility of ethics committees. Instead, it is the responsibility of research integrity boards, research integrity offices, professional ethics boards or disciplinary committees, or may be considered as part of ordinary job performance evaluations. Principles of research integrity belong in this category;

— **ethical guidelines for institutional responsibility and integrity** 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** are ethical principles for the assessment of plans and practices in research and innovation. They are central to the work of ethics committees.

Ethical issues relating to research integrity typically do not fall within the remit of ethics committees.

NOTE **Research integrity**, or scientific integrity, is about possessing and firmly 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 and research institutions (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. Research integrity can, however, 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 (if there is no other unit that does this), and to observe and identify flaws in research plans and activities that could provide evidence of scientific misconduct.

The determination of ethical issues and principles is typically:

— based on an international discussion among a variety of stakeholders, with reference to shared values;

— often prompted by critical incidents and specific cases and guided by moral intuitions;

— advocated and developed by national and international organisations with the mandate to promote ethical issues in general and in a specific field of research;

— revised according to new technological challenges, best practice experience, and new research findings.

Note that ethical principles and protocols are sometimes stated as voluntary guidelines, but may also be encoded in of 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 ethics committee should resolve conflicts between ethical principles by means of arguments referring to more basic ethical views such as maximizing utility (utilitarianism) and respecting individual rights (deontological ethics). Annex B provides information on moral decision-making and resolving conflicts between ethical principles.

4.2 General and field-specific ethical principles

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.

NOTE The ethical principles that specifically concern the behaviour of the researcher, of which most can be defined in terms of research integrity, such as avoidance of plagiarism, are normally considered by research integrity boards, although ethics committees may address them in their work.

Among its ethical principles, the ethics committee should include general ethical principles that potentially apply to every major field of research and innovation. Annex A, section A.2, offers detailed operationalisations of the following general ethical principles (in addition to that of research integrity):

— social responsibility;

— protection and management of data;

— dissemination of research results;

— protection of researchers and the research environment;

— avoidance of, and openness about, potential conflicts of interest.

The following two principles do not apply to all research, but could play a role in all fields (some more so than others) and for this reason have been included in the list of general ethical principles for research ethics committees in Annex A:

— protection of and respect for human research participants;

— protection of and respect for animals used in research.

In addition to these general ethical principles, the ethics committee should 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 utilization 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.

In different scientific fields, different special conditions may arise, and with differing frequency. In addition, fields may include field-specific methods, approaches, practices and conventions that also necessitate field-specific principles and protocols.

NOTE Annex A, sections A.3 through A.8, offers detailed statements on field-specific principles in six key scientific fields: natural sciences, engineering sciences, medical sciences, life sciences, computer and information sciences and social sciences and humanities.

Figure 1 provides an overview of both general and field-specific ethical principles.

Because ethical principles are primarily triggered by special conditions that often obtain across multiple fields, it is not strictly necessary to organize ethical principles for ethics assessment by field. It is possible to identify on a case-by-case basis for each research and innovation project what special conditions obtain and then to apply the relevant ethical principles and protocols, while taking into account special provisions, conventions and regulations that may apply to specific fields.

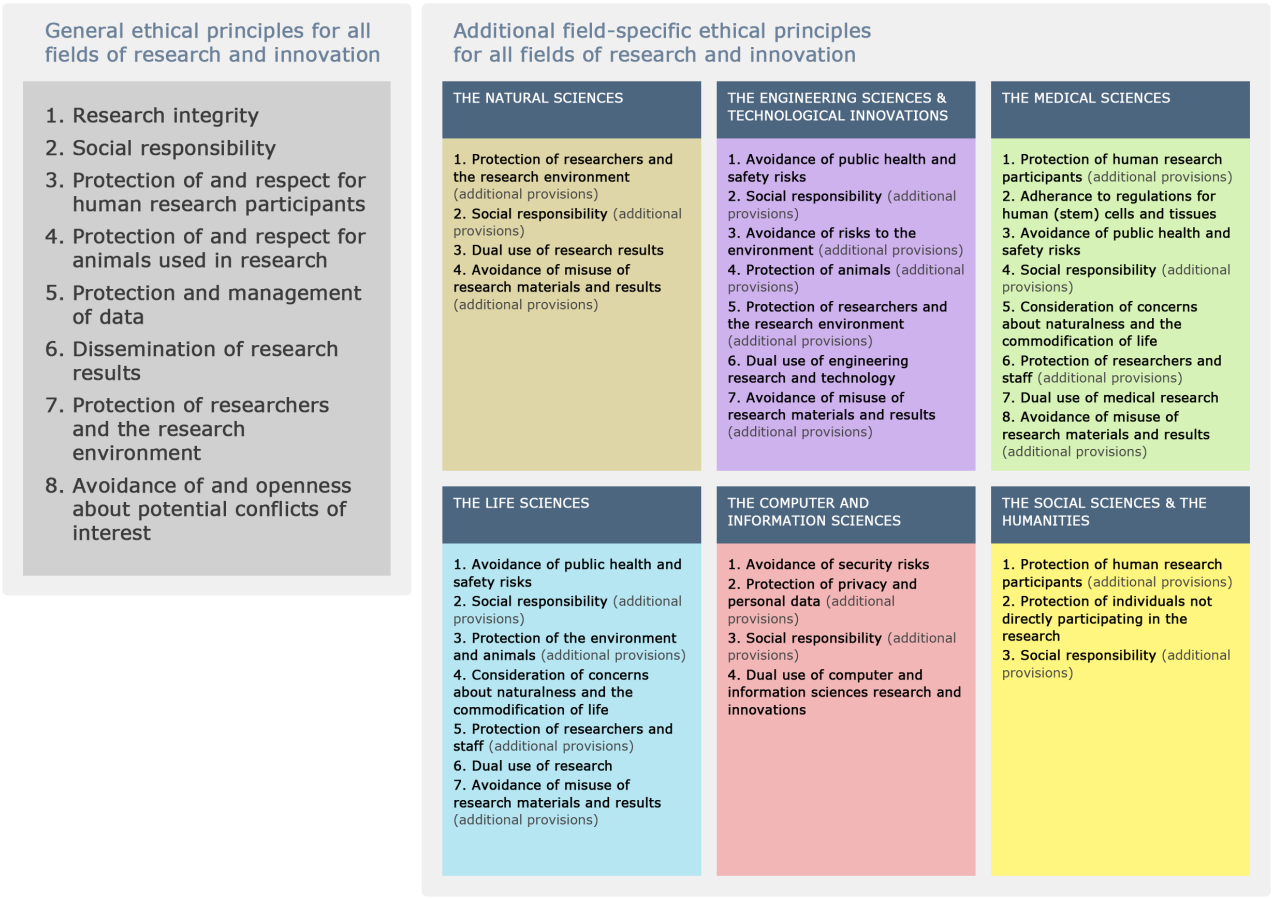

Figure 1 — Framework of ethical principles and issues in research

4.3 Conflicts of interest of the researcher(s) proposing research

Ethics committees should evaluate research proposals for possible conflicts of interest on the part of the researcher(s) and institution(s) involved. Participating researchers should disclose such potential conflicts of interest on standard application forms prior to ethics assessment. In particular, possible conflicts of interest of the following kinds should be disclosed:

— financial interests of participating researcher(s) that could affect or reasonably appear to affect the ethical conduct, review or oversight of the proposed research;

— non-financial interests of the participating researcher(s) that could cause conflicts of interest, including conflicts of commitment (situations in which persons have obligations to others that may interfere with the ethical conduct, review or oversight, such as research collaboration or supervision) and conflicts of conscience (situations in which the personal beliefs of persons, such as religious, political or ideological beliefs, could interfere with the ethical conduct, review or oversight).

5 Procedures for ethics assessment

5.1 General

The ethics committee should determine, implement and maintain operating procedures for ethics assessment. The operating procedures should support the goals and expectations of ethics assessment. In addition to political and legal issues the ethics committee should have the mandate to select topics

and issues the ethics committee itself finds pressing. The ethics committee should make its ethical principles transparent.

The ethics assessment procedures should as a minimum:

— enhance the ethical awareness of the applicants concerning the research and its consequences rather than promote mere rule-following;

— protect stakeholders (e.g. individuals participating in the research) from undue risk and harm or violation of their rights;

— determine if the research or innovation methods are appropriate;

— increase awareness of the ethical impact of research and innovation;

— avoid unjustified duplication of ethics assessment.

In shaping their procedures, the ethics committee should consider available good practice, operating procedures and voluntary harmonization procedures at national and international levels. Operating procedures include both general and field-specific procedures.

Ethics committees should meet in person, if possible, to engage in joint ethics assessments. Discussions could also take place by means of teleconference meetings. Exchanges through e-mail and other textual media are acceptable for routine issues, but should be avoided for issues that require extensive deliberation.

EXAMPLE Several European institutes have published examples of good practice in ethics assessment procedures. Examples are: Economic and Social Research Council (ESRC), *Framework for research ethics 2015*; Association for Research Ethics Committees (AREC), *Framework of policies and procedures for university research ethics committees, 2013*; Council of Europe, *Guide for research ethics committee members, 2012*; European Commission, *ERC Rules for Submission and Evaluation, requirement of an ethics-ready proposal 2014*.

The procedures typically include:

— procedures prior to assessment. These typically include a self- assessment by the researcher or applicant;

— procedures during assessment;

— procedures after assessment. These typically include procedures for dissemination, appeal and follow-up for on-going research;

— procedures for appeal. Researchers may appeal and submit a proposal for second review.

The ethics committee should determine, implement and maintain the criteria and conditions for cases where iterative ethics assessment procedures are required.

The procedures for ethics assessment should be clearly stated so that researchers have clear expectations about the time needed to perform assessment. The ethics committee should keep the applicants informed about the progress of the assessment.

5.2 Procedures prior to assessment

Recommendations for procedures prior to assessment are the following:

— **use of a standard application form** including the following topics:

  - person responsible for conducting the project;

- description of the R&I activity including the scientific questions, and the overall aim and purpose of the research and or experiment;
- methodology;
- procedures for obtaining informed consent;
- significance of the R&I activity and expected benefits;
- social impact and context of the R&I activity;
- documentation and data protection and or how biological material is to be stored;
- identified stakeholders.

— **use of self-assessment**: The research proposal should include the researchers' description and assessment of the ethical considerations;

NOTE A benefit of self-assessment is that the researchers reflect on the ethical issues of the project. Making researchers aware of the ethical impact of their research is one aim of ethics review.

— **use of pre-assessment**: Pre-assessment, or screening, deals with the question of whether the ethical issues of the project have already been addressed. One or two persons from the ethics committee could perform the pre-assessment of proposals. Pre-assessment includes:

- summary of the case;
- reflection on the ethical issues that the researcher has identified and resolved;
- identification of ethical issues that the researcher has not addressed;
- suggestions, with supporting arguments, for a decision on the case.

NOTE The use of pre-assessments allows the ethics committee to reduce time spent on ethically non-sensitive proposals thereby allowing the ethics committee to focus on ethically sensitive proposals.

5.3 Procedures during assessment

Recommendations for procedures during assessment are the following:

— the ethics committee unit should determine, implement and maintain decision procedures. The decision procedures should be documented and made public;

— the ethics committee should determine, implement and maintain a methodology for weighing the benefits of the research against its risks and harms, to individuals, animals, society or the environment;

NOTE Annex C provides information on risk-based thinking for ethics assessment, based on the principles and guidelines of ISO 31000 Risk management.

— the discussions within an ethics committee should be kept confidential. At a minimum, the ethics committee should apply the Chatham House rule, or have a non-disclosure agreement.

NOTE Information on the Chatham House rule, which ensures that neither the identity nor affiliation of speakers at an event may be revealed in later discussion, is at https://www.chathamhouse.org/about/chatham-house-rule. The full protocol should be available to all members.

— the ethics committee should establish mechanisms for communicating their decisions to the researchers;

— the ethics committee should provide ample explanation of their decisions;

— the ethics committee should establish procedures for dealing with conflicts of interest within the unit;

— researchers should be obliged to state any potential conflicts of interest;

— the ethics committee may use check boxes and lists in order to check the presence of ethical issues. It should always be possible to add ethical issues to the list. The use of check boxes and lists should not replace an open discussion.

5.4 Procedures after assessment

Recommendations for procedures after assessment include the following:

— the decisions of the ethics committee should be recorded for internal access, and for external reference if this required by legislation or for audit;

— the ethics committee should provide the applicant with a written assessment that explains the ethics committee's decision. If the decision by the ethics committee is not unanimous, this should be noted in the written assessment. The decision could take a number of forms:

  - In cases of obligatory assessment, the ethics committee could:
    - o approve the R&I activity;
    - o ask for amendments: there should be a dialogue between the ethics committee and the submitter regarding the ethical issues and how to deal with them;
    - o reject the proposal and halt the R&I activity.
  - In cases of non-obligatory assessment, the ethics committee could recommend that the R&I activity should either proceed, be revised or be halted;

— the ethics committee should provide an opportunity to appeal against the ethics committee's decision. The right to appeal is necessary in order to correct mistakes and to uphold the integrity of the research ethics system;

— the ethics committee should determine, implement, and maintain procedures for monitoring the compliance of assessed R&I activities. In cases of non-compliance, the ethics committee should:

  - report cases of non-compliance to the funding agency;
  - report cases of non-compliance to the relevant authority.

NOTE Non-compliance can seriously affect the reputation of the organization.

— each decision made by the ethics committee should have a written justification. Minority voices or opinions should be included;

— the ethics committee should oblige researchers to provide annual reports, end-of-study reports, and reports on adverse events.

6 Quality assurance in ethics assessment

Quality assurance in ethics assessment can help determine and ensure that the ethics assessment is meeting its goals and expectations. Quality assurance can help correct any misinterpretations or misapplications of ethics policies and procedures. Quality assurance activities help foster communication between different agents involved in the ethics assessment process – i.e. those making the policy and those implementing it. Quality assurance can also help develop and strengthen best practice and tailor ethical policies and procedures to meet different requirements, e.g. in relation to different scientific fields.

The ethics committee should self-evaluate the suitability, adequacy and effectiveness of their ethics assessment policies and procedures on a defined, regular basis. This evaluation should include the views of relevant stakeholders. Third-party evaluations are recommended to demonstrate the quality of the ethics committee's work.

The ethics committee should be supervised by a senior administrative or managerial level of the organization within which they operate. The supervision of ethics committees should not compromise their ability to be independent in their decision-making.

The ethics committee should consider the results of analysis and evaluation, from internal and external review, to determine if there are needs or opportunities that should be addressed as part of continuous improvement.

The ethics committee should continuously improve the suitability, adequacy, and effectiveness of their ethics assessment system.

A recommended approach to quality assurance is the Plan-Do-Check-Act (PDCA) approach. This approach is particularly relevant as it is a continuous improvement model. Using this approach could help ethics assessors plan their ethics assessment processes and interactions better, and ensure quality by enabling them to check that processes are adequately resourced and managed, and that opportunities for improvement are identified and acted on.

NOTE The PDCA approach is used in the ISO 9001 Quality management systems — Requirements.

The PDCA approach for ethics assessment has the following elements:

— **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 organization's policies;

— **Do:** implement what was planned;

— **Check**: monitor and (where applicable) measure ethics assessment processes and their results against policies, objectives and requirements, and report the results;

— **Act:** take actions to improve performance, as necessary.

Annex D provides guidelines for the use of the PDCA approach for ethics assessment.

The ethics committee should regularly provide sufficient information about its work – ethics review, research follow-up, and other activities – to its appointing institution or authority. This information should not reveal confidential details about the research or its participants. The information, in its entirety or in the form of an executive summary, should be made publicly available.

Annex A
(informative)

General and field-specific ethical principles

A.1 General

This annex lists and operationalises ethical principles for ethics assessment for all of the major fields of scientific research and (technological) innovation. The lists are comprehensive, but may not be complete. Ethics committees and organisations that provide guidance for ethics committees are encouraged to further adapt and develop the principles for the particular fields that they cover, and to make adaptations to account for national legislation and regulations and for the particular institutional, social and cultural settings in which research and innovation activities are carried out. Ethics committees may develop specific protocols for the application of ethical principles. Further development of field-specific principles may include the introduction of principles, protocols or considerations for specific issues, methods and approaches in these fields and for specific subfields.

EXAMPLE For the social sciences and humanities, special principles and protocols could be developed for specific data collection methods, specific types of research involving human research participants and specific fields, e.g. psychology, anthropology or visual arts., internet research

Section A.2 lists general ethical principles that apply to every major field of scientific research and innovation. These principles should be incorporated in the ethics protocols for all fields, although an exception can sometimes be made for the principles concerning human research participants and research involving animals since there are fields in which such research activities are rare.

Sections A.3 through A.8 list ethical principles that apply only to specific fields of research and innovation – the natural sciences (A.3), the engineering sciences (A.4), the medical sciences (A.5), the life sciences (A.6), the computer and information sciences (A.7), and the social sciences and the humanities (A.8). These lists constitute field-specific additions to the general ethical principles in section A.2. For "hybrid" fields that combine elements of two or more of these fields (e.g. biomedical engineering, geo-information sciences), the ethical principles of all of the "parent" fields should be used. Multidisciplinary research should use the combined ethical principles of the participating fields.

The principles are intended to be used as guiding principles for research ethics committees and for the development of self-assessment forms and questionnaires for researchers who are preparing a request for assessment. The complexity of self-assessment forms should be proportional to the nature and size of the research and innovation projects that are being assessed. For example, for basic research and for smaller and more routine applied projects, the inclusion of only one or a few questions about social responsibility may be sufficient.

NOTE Examples of self-assessment forms will be posted on the SATORI project website, http://satoriproject.eu.

A.2 Ethical principles and issues applicable to all fields of research and innovation

— **Research Integrity**

- Employ and apply appropriate research methods and take responsibility for the trustworthiness of results;
- Avoid unintentional bias in the selection of research methods and analysis of research data;

- Avoid the manipulation of research instrumentation, materials or processes and the omission or distortion of research data;
- Avoid the inclusion of data, observations or characterisations that did not occur in the gathering of data or running of experiments;
- Ensure autonomy of research and freedom of critical thinking from ideological bias and political pressures;
- Avoid conflicts of interest, and disclose financial and other conflicts of interest that could compromise the trustworthiness of one's work in research proposals, publications, public communications or review activities;
- Avoid representing the work of others as one's own, and cite all sources used;
- Avoid misrepresenting one's qualifications, experience or research accomplishments;
- Respond to and report irresponsible research practices by others.

NOTE 1 Research integrity, or scientific integrity, is not normally a principle of ethics assessment conducted by ethics committees. It concerns the behaviour and conduct of researchers, and is normally considered by scientific integrity boards that investigate cases of scientific misconduct. It is, nevertheless, in the interest of research ethics that ethics committee members, researchers and innovators are aware of the core principles of research integrity. It is also in the interest of research ethics that members of ethics committees are aware of field-specific codes of ethics for researchers and know how these relate to the ethics assessment that they perform for these fields.

NOTE 2 Relevant international guidance and regulations exist for scientific integrity, such as the *Singapore Statement on Research Integrity* (2010), the *European Code of Conduct for Research Integrity* (2017) and the *Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations* (2013). In addition, national guidelines exist in many countries.

— **Social responsibility**

The social responsibility principle applies to the assessment of research and innovation plans and practices, rather than the conduct of individual researchers or innovators:

- Anticipate and consider the potential consequences of the research and innovation project for society, including plausible future uses and applications of the results of project, and take appropriate remedial action to address any (potentially) negative societal and environmental impacts if such action seems justified;
- Consider whether and how the research or innovation activity could positively or negatively contribute to the interests, rights and well-being of individuals and groups, the common good or a just and peaceful world society;
- Consider whether the research or innovation promotes or is compatible with sustainable development, and how it could promote environmental sustainability;
- Acknowledge the economic and cultural value of local knowledge, pursue dialogue with local knowledge bearers, involve them in the research and let them share in the benefits. This

applies to research and innovation that directly builds on other types of knowledge, specifically local or traditional knowledge, and the skills and practices found in individuals and local communities;

- Avoid the misuse of research materials and results by considering whether the materials, methods, technologies, and knowledge involved in or generated during the research or innovation could serve, or be modified or enhanced to serve, alternative (unethical or ethically questionable) purposes that could harm individuals, animals, society and or the environment;

- Take into account the concerns of stakeholders when planning and conducting the research, and communicate important research results and (potential) societal consequences to relevant stakeholders and to the general public to ensure their proper interpretation, while explaining the degree of uncertainty involved. This applies specifically to research and innovation projects with significant potential consequences for society.

Special provisions for research involving low income or lower-middle income countries:

- Be responsive to the particular (research) needs of the country or community where the research is carried out;

- Share the benefits of research involving local research participants or resources with local stakeholders, including local research participants and local communities;

- Involve local researchers in the research – preferably as equal partners – to help build local research capacity;

- Minimize the diversion of local (human) resources towards the research if this could have detrimental effects on the local community;

- Show respect for local cultural traditions and value systems.

NOTE 1 Social responsibility is both a quality of individual researchers and of the research itself. When applied to researchers and innovators, it is part of their professional responsibility and is usually included in ethics codes for professional conduct. It includes anticipation of and taking responsibility for the effects on society and the environment of one's research and innovation activities, taking proper precautions to avoid negative effects, communicating one's activities and their consequences effectively to stakeholders and the public, and addressing concerns to superiors and acting as a whistle-blower, if necessary. Ethics committees do not normally consider the behaviour of individual researchers, but may consider whether a research design of activity includes proper precautions and actions to address issues of social responsibility.

NOTE 2 Local resources can include, among other things, animal or human tissue samples, genetic material, live animals, human remains, materials of historical or cultural value, endangered fauna or flora samples, and fossils. Most countries have regulations on these resources.

NOTE 3 Benefits of research for local stakeholders can include, among other things, development of research infrastructure, distribution of research results, publications, access to data, intellectual property, proper compensation for use of resources and services, and technology transfer.

NOTE 4 Relevant guidelines for human rights include the *Universal Declaration of Human Rights* (1948) and the *Charter of Fundamental Rights of the European Union* (2000). Relevant guidelines for benefit sharing and research involving low-income countries include the *Nagoya Protocol*, the *United Nations Declaration on*

the Rights of Indigenous Peoples, the *Ethical and Regulatory Challenges to Science and Research Policy at the Global Level* of the European Commission (2012) and the SATORI project deliverables D3.1 to D3.4

— **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);
- 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.

NOTE 1 The term 'research participant' refers to any or all of the following: *research subjects* (e.g. experiments), *research respondents* (e.g. surveys), *research informants* (e.g. anthropological studies) and *research participants* (e.g. interviews).

NOTE 2 The principle of protection of and respect for human research participants is relevant to most fields, but can be downgraded or removed in protocols for fields in which research involving human research participants is rare or non-existent, such as in the natural sciences.

NOTE 3 There is a debate on whether informed consent always requires explicit written and signed notification of consent. Many experts in research ethics now hold that for anonymous surveys and surveys that provide minimal risk to participants, a signed consent form is not necessary and a simple consent paragraph in the survey is sufficient. Some also hold that it is sufficient that the participant has been informed of risks, benefits and procedures in the study and has expressed consent in some way that can be verified, such as by text, on video or by returning a survey that contains a consent paragraph.

NOTE 4 Regarding the bullet point on the representativeness of one's pool of human research participants, it can be argued that the representativeness is part of proper research methodology rather than of research ethics. It need not be included in ethics assessment when a separate scientific evaluation takes place that can be expected to include the representativeness.

Special provisions for the protection of children, mentally disabled persons and other vulnerable groups:

- Only carry out research with children or other persons unable to give consent if there are no acceptable alternatives, if the risks and burdens to participants are minimal, and if substantial benefits will accrue to the participants or the group represented by the participants;

- If the participant is a child, obtain informed consent from the parent(s) or legally authorized representative(s), and obtain assent from the child if possible;

- If the participant is an adult who is judged as lacking the mental capacity to give consent, obtain informed consent from the legally authorized representative(s), and obtain assent from the participant if possible;

- Ensure that inducements, rewards or compensation for participating in the research do not threaten or challenge the ability of participants to provide genuine informed consent;

- Take special care in all aspects of the research where vulnerable individuals or groups are involved.

NOTE 5 Vulnerable people include, among others, children, persons unable to give informed consent, people with mental or physical disabilities, pregnant women, senior citizens, residents of retirement and assisted living facilities, patients with incurable diseases, people with addictions and problematic substance use, poor persons (including the homeless and people receiving welfare or social assistance), the unemployed, prisoners, first-generation immigrants, members of groups that face discrimination, persecution and exclusion, and persons in low or lower-middle income countries.

NOTE 6 No international regulations or frameworks for the protection of human research participants currently exist that cover all scientific fields. There are, however, frameworks that are specifically directed at the medical sciences and/or social and behavioural sciences.

— **Protection of and respect for animals used in research**

Respect for life (three Rs – replacement, reduction, refinement):

- Consider all possibilities for replacing animal experiments with research methods that are less harmful to animals;

- Make an effort to minimize the number of animals involved in the experiment;

- Minimize the suffering of animals during the experiment and in the context of animal keeping and breeding.

NOTE 7 This principle can be downgraded or removed in protocols for fields in which research involving animals is rare or non-existent. Research involving animals occurs most frequently in medical and life sciences, may also occur in behavioural sciences and engineering sciences, but is rarer in social and economic sciences, humanities, computer and information sciences and natural sciences.

NOTE 8 Potential causes of suffering or harm to animals include invasive procedures, disease and deprivation of basic physiological needs. Other sources of harm for many animals include social deprivation and loss of the ability to fulfil natural behaviours.

Respect for the welfare of animals:

- Ensure that the potential benefits of the animal experiment outweigh the (potential) harm caused to the animals involved;
- Provide reasonable accommodation for the species-specific characteristics, needs and behaviours of animals involved in experiments;
- Only use animals bred to have genetic diseases and defects or behavioural disorders if their use is deemed essential following careful ethical balancing.

Special provisions for the protection of non-human primates and wild animals and species:

- Avoid the use of non-human primates in animal experimentation;
- Only use animals captured in the wild or animals from species that live in the wild if their use is deemed necessary following careful ethical balancing.

Special provisions for the protection of animals in low or lower-middle income countries:

- Help in building local capacity for the humane conduct of animal experimentation;
- Only use endangered species if the experiment contributes to the conservation of the species in question.

NOTE 9 Relevant regulations for the protection of animals in research are the *Directive 2010/63/EU on the protection of animals used for scientific purposes* and the *United Nations Convention on Biological Diversity* (1992).

— **Protection and management of data and dissemination of research results**

Management of data and open data:

- 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 the research data produced will be locatable by and accessible to other researchers, interoperable with other data and tools, and reusable in future research.

NOTE 10 Source of points 1–3 is the *FAIR Guiding Principles for scientific data management and stewardship*, 2016.

NOTE 11 General guidelines on open data are provided by the European Commission, *Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020*, 2016.

Protection of personal data:

- 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 any personal data collected are not used for other research (secondary use) without the consent of the participants involved or proper justification if consent cannot be obtained;
- 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).

Protection of personal data and ethics in Internet research:

- 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;
- Take special precautions to guarantee proper consent in cases where such consent is required. Specifically, special precautions should be taken to ensure that persons are not recruited who should not be participating in the study, such as children in studies targeted at adults. It is also important to ensure that subjects adequately and correctly understand the information provided concerning the research and why consent is requested if the information is communicated in writing only, and over the Internet;
- Inform participants in open online forums about systematic registration or reporting of information when possible;
- Take precautions to ensure anonymity when using information from Internet sources (since such information may be searchable);
- 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.

NOTE 12 A relevant regulation for data protection is the European Union *General Data Protection Regulation (GDPR) EU 2016/679.*

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.

NOTE 13 General guidelines on open access are provided by the European Commission, *Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020*, 2016.

— **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 low income or lower-middle income countries;

- Avoid harm to the local community as a result of any field work or experiments;

- Minimize 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.

— **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.

NOTE 14 A relevant national guideline for conflicts of interest in research is chapter 7 of the *Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (2014).

A.3 Additional ethical principles and issues in the natural sciences

NOTE 1 For applied work in the natural sciences, see also A.4 on engineering sciences.

— **Protection of researchers and the research environment**

- 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 minimize 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.

NOTE 2 For applied work in the natural sciences, see also A.4 on engineering sciences.

— **Social responsibility**

(additional provisions specific to the natural sciences)

- Anticipate and consider the technological applications of the research and their potential positive and negative impacts on society and the environment;
- Take special care to communicate and ensure proper interpretation among stakeholders and the public of research and research results that have, or are could be perceived as having, potentially significant consequences or implications for society and/or the environment, such as research in climatology, astronomy and or astrobiology, experimental particle physics.

— **Dual use of research results**

- Consider whether the results of the research could have military applications;
- Consider whether the results of the research could contribute to the proliferation of weapons of mass destruction;
- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if the research has significant military applications or if it contributes to the proliferation of weapons of mass destruction.

— **Avoidance of misuse of research materials and results**

(additional provisions specific to the natural sciences)

- 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, classification, training for staff).

A.4 Additional ethical principles and issues in the engineering sciences and in technological innovation

— **Avoidance of public health and safety risks**

- Ensure that the technology that is developed, in terms both of the production and the societal use of any goods based on it, does not pose inherent direct or long-term risks of harm to public health and safety.

— **Social responsibility**

(additional provisions specific to the engineering sciences)

Respect for individual rights and liberties:

- Ensure the technology does not pose inherent risks to individual freedom, autonomy, authenticity or identity; or to individual privacy, human dignity, or human bodily integrity.

Protection and promotion of well-being and the common good:

- Consider how the technology could potentially harm or benefit the well-being and interests of individuals and groups in society;

- Consider how the technology could help to protect and promote important social institutions and structures, democracy, and important aspects of culture and cultural diversity.

Protection and promotion of justice and equality:

- Consider how the technology could harbour biases or negative effects that disproportionally impact people in terms of age, gender, sexual orientation, social class, race, ethnicity, religion, culture or disability;

- Consider how the technology could contribute to the reduction of unjust biases, stigmatization or discrimination in society in terms of age, gender, sexual orientation, social class, race, ethnicity, religion, culture or disability;

- Consider how the technology could widen or help narrow social inequalities in terms of the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks or hazards;

- Consider how the technology could harm or benefit vulnerable, disadvantaged, or underrepresented individuals, groups, and communities in society or individuals, groups and communities in low-income and lower-middle income countries;

- Consider how the technology could harm or benefit future generations.

— **Avoidance of risks of harm to the environment**

(additional provisions specific to the engineering sciences)

Protection of the environment:

- Anticipate and assess potential risks of harm to the (urbanised or natural) environment as a result of the applications or uses of the technology, and take appropriate measures to address them during the innovation process;

- Consider the possibility of unforeseen or long-term environmental effects of the technology;
- Take special precautions to prevent environmental harms caused by the use of biological, chemical, radiological, nuclear, or explosive materials;
- Promote a clear understanding of the actions required to restore the environment once it has been disturbed as a result of the technology.

Promotion of environmental sustainability:

- Optimize the technology for effective and cost-efficient resource recovery (recycling);
- Take responsibility to search for technological solutions that lower the potential consumption of raw materials and energy;
- Take responsibility to search for technological solutions that lower the production of environmentally harmful wastes and lessen environmental pollution;
- Be conscious of the interdependence between eco-systems and the importance of bio-diversity.

Social environmental responsibility:

- Be conscious of, and engaged with, any (local) societal concerns and interests regarding the ways in which the technology could affect the environment.

— **Protection of animals (if the technology is intended for use around animals)**

- Ensure that the technology does not pose any unnecessary risks of harm to animals;
- Respect the characteristics, needs and behaviours of the animal species involved.

— **Protection of researchers and the research environment**

(additional provisions specific to the engineering 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.

— **Dual use of engineering research and technology**

- Consider whether the technology could have military applications;
- Consider whether the technology could contribute to the proliferation of weapons of mass destruction;
- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if the technology has significant military applications or if it contributes significantly to the proliferation of weapons of mass destruction.

— **Avoidance of misuse of research materials and results**

(additional provisions specific to the engineering sciences)

- 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, classification, training for staff).

NOTE 3 A relevant national guideline for the engineering sciences is the *Guidelines for Research Ethics in Science and Technology* by The Norwegian National Committee for Research Ethics in Science and Technology (2016).

A.5 Additional ethical principles and issues in the medical sciences

— **Protection of human research participants**

(additional provisions specific to the medical sciences)

- Take special precautions to ensure the participant has a full understanding of all the risks, including potential unforeseen risks, associated with participating in the research;

- Take special precautions to ensure respect for the participant's bodily integrity;

- Take special precautions to ensure the participant's long-term quality of life (including its physical, functional, psychological/emotional, and social/occupational aspects) is not negatively affected as a result of their participation in the research.

NOTE 1 Relevant frameworks and regulations for the protection of human research participants in the medical sciences are the following: the *Declaration of Helsinki* (1964, last amended 2013), WHO *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants* (2011), the *Oviedo Convention*, the UNESCO *Declaration of Bioethics and Human Rights,* CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2016), the *Nuremberg Code* and the *Belmont Report*.

— **Adherence to regulations for research involving human embryonic stem cells**

NOTE 2 Relevant regulations and guidelines for research involving human embryonic stem cells are: Declaration C 373/12 of the European Commission, the Council of Europe's *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings* and the International Society for Stem Cell Research *Guidelines for Stem Cell Research and Clinical Translation (*2016).

— **Adherence to regulations for research involving human cells and tissues**

NOTE 3 Relevant regulations for research involving human cells and tissues are: Directive 2004/23/EC of the European Parliament and of the Council of Europe's *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin* and the Council of Europe's *Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin*.

— **Avoidance of public health and safety risks**

- Ensure that the medical research, regardless of its potential applications, does not pose any direct or long-term risks of harm to public health and safety (e.g. take adequate preventative measures against accidental release of hazardous biological agents);
- Anticipate, assess, and communicate any potential direct or long-term public health and safety risks caused by the medical innovation.

— **Social responsibility**

(additional provisions specific to the medical sciences)

- Ensure that the medical research or innovation has an appropriate cost-benefit ratio;
- Avoid raising unrealistic expectations about the medical innovation in society;
- Ensure that applied medical research or innovation is a response to actuals health needs and priorities.

Respect for individual rights and liberties:

- Ensure that medical innovation does not pose inherent risks to human dignity, individual freedom, autonomy, authenticity, identity (and sense of self) or individual privacy.

Protection and promotion of the well-being of individuals and groups in society:

- Consider how the medical innovation could harm or promote the well-being of individuals and groups in society;

Protection and promotion of justice and equality:

- Consider how the medical research or innovation could exacerbate or help reduce social inequalities in terms of the distribution of primary goods, capabilities, risks or hazards;
- Consider how the medical research or innovation could harm or serve the interests of vulnerable, disadvantaged or underrepresented individuals, groups and communities in society;
- Consider how the medical research or innovation could harm or serve the interests of individuals, groups and communities in low-income and lower-middle income countries;
- Consider how the medical innovation could affect future generations.

— **Consideration of concerns about naturalness and the commodification of life**

- Have consideration for concerns about naturalness, *i.e.* authentic generation by nature without human interference, in relation to (aspects of) human genetics research, human enhancement research, and other subfields of the medical sciences;
- Have consideration for concerns about the commodification of life in relation to (aspects of) human genetics research and human reproductive technologies.

— **Protection of researchers and staff**

(additional provisions specific to the medical 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, or radiological materials.

— **Dual use of medical research**

- Consider whether the research or innovation could have military applications;
- Consider whether the research or innovation could contribute to the proliferation of biological weapons of mass destruction;
- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if the research or innovation has significant military applications or if it contributes significantly to the proliferation of biological weapons of mass destruction. Even if publication is allowed, find a proper balance between security and freedom of publication.

— **Avoidance of misuse of research materials and results**

(additional provisions specific to the medical sciences)

- Take special precautions to prevent or counter the effects of the potential misuse of security-sensitive biological, chemical or radiological materials and knowledge (e.g. the appointment of a security advisor, limiting dissemination, classification, training for staff).

NOTE 4 The precautions in this bullet point are in conformity with the Declaration of Helsinki, the Nuremberg Code and the Belmont Report with regard to the requirement for ensuring the balance of risk and benefit in conducting medical sciences research on human subjects. They are in line with the UNESCO Declaration and the CIOMS Guidelines with regard to the responsibility for the protection of local and indigenous populations, especially in low-income and resource-poor countries. They draw from the CIOMS Guidelines and the Oviedo Convention, particularly with respect to concerns about the commodification of life, and special consideration of human tissue and embryonic cells. They also share concerns about future generation with the UNESCO Declaration of Bioethics and Human Rights. The emphasis on the priority of the interests of human beings (over the interests of science or society), the protection of human rights and dignity and the requirement for informed consent for medical science research and experimentation are universally shared across existing major international conventions and guidelines including the Nuremberg Code, the Declaration of Helsinki, the UNESCO Declaration, the CIOMS Guidelines and the Oviedo Convention. For medical research in European Union Member States, the above guidelines should be supplemented with the Oviedo Convention protocol, which is legally binding within the EU, as well as with other appropriate EU regulations and legislation.

NOTE 5 While International ethical guidelines for research in the medical sciences tend to have a focus on research involving human research participants (note at the beginning of section A.4), many also address some other ethical issues in medical research, such as benefit sharing, the use of human cells and tissues, and dual use. For many specific topics (e.g. genetics research, epidemiological research, stem cell research, medical devices, clinical drug trials, biobanking, research on transplantation, experiments on animals) separate guidelines and directives exist either at international (including EU) or national levels. The US International Compilation of Human Research Standards, 2017 edition contains an exhaustive overview of legislation, guidelines and directives across the world relating to different topics in medical research and innovation.

NOTE 6 Ethical guidelines for medical research in low- or low-middle income countries are provided in the Nuffield Council of Bioethics report *The ethics of research related to healthcare in developing countries* (2014).

A.6 Additional ethical principles and issues in the life sciences

— **Avoidance of public health and safety risks**

- 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. take adequate preventative measures against accidental release of hazardous biological agents);

- Anticipate, assess, and communicate any potential direct or long-term public health and safety risks caused by the intended applications of the research.

— **Social responsibility**

(additional provisions specific to the life sciences)

Protection and promotion of justice and equality:

- Anticipate, assess, and communicate how innovations based on the research could affect social inequalities in terms of the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks, and hazards;

- Anticipate, assess, and communicate how innovations based on the research could affect vulnerable, disadvantaged or underrepresented individuals, groups, and communities in society, and individuals, groups, and communities in low income and lower-middle income countries;

- Anticipate, assess, and communicate how innovations based on the research could affect future generations.

Protection and promotion of rights, well-being and the common good:

- Consider how the research could 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 could be directed to enhance rights, well-being and the common good.

— **Protection of the environment and animals**

(additional provisions specific to the life sciences)

Protection of the environment:

- Take special precautions to prevent environmental harms caused by the use of biological, chemical or radiological materials during the research;

- Anticipate, assess and communicate how innovations based on the research could harm biodiversity and the integrity of natural ecosystems.

Protection of animals:

- Anticipate, assess and communicate how innovations based on the research could harm (or contribute to) the welfare of animals.

Social responsibility:

- Be conscious of, and engaged with, any societal concerns and interests regarding the ways in which innovations based on the research could affect the environment.

— **Consideration of concerns about naturalness and the commodification of life**

- Consider concerns about naturalness in relation to research into animal and plant breeding, cloning, and the (genetic) modification of organisms;

- Consider concerns about the commodification of life in relation to genetic patenting and research into animal and plant breeding, cloning, and the (genetic) modification of organisms.

— **Protection of researchers and staff**

(additional provisions specific to the life sciences)

- Take 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, or radiological materials.

— **Dual use of research**

- Consider whether the research results could have military applications;

- Consider whether the research results could contribute to the proliferation of biological weapons of mass destruction;

- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if the research has significant military applications or if it contributes significantly to the proliferation of biological weapons of mass destruction. Even if publication is allowed, find a proper balance between security and freedom of publication.

— **Avoidance of misuse of research materials and results**

(additional provisions specific to the life sciences)

- Take special precautions to prevent or counter the effects of the potential misuse of security-sensitive biological, chemical, or radiological materials or knowledge (e.g. the appointment of a security advisor, limiting dissemination, classification, training for staff).

A.7 Additional ethical principles and issues in the computer and information sciences

— **Avoidance of security risks**

- Ensure that new research concepts and innovations offer reasonable protection against any potential unauthorised disclosure, manipulation or deletion of information and against

potential denial of service attacks, e.g. protection against hacking, cracking, cyber vandalism, software piracy, computer fraud, ransom attacks, disruption of service;

- Ensure that new research concepts and innovations, by themselves or through their use in a system, do not pose inherent direct or long-term risks of harm to public health and safety, e.g. ICT innovations used in healthcare, ICT innovations used in the monitoring and control of public infrastructure, ICT innovations that could lead to addiction;

- Do not engage in research that involves attempts to make unauthorised access to telephone systems, computer networks, databases or other forms of ICT; such research is illegal and unethical, regardless of motivation;

- Treat with extreme caution the dissemination of research involving the identification of undiscovered security weaknesses in existing systems;

- Avoid practical experiments with computer viruses or perform them in a controlled environment, and exercise extreme caution in the dissemination of the results of paper-based (theoretical) computer virus experiments;

- Carry out any experiments in breach security on designated, standalone (offline) computers or on designated isolated networks of computers.

— **Protection of privacy and personal data**

(additional provisions specific to the computer and information sciences)

- 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;

- If research concepts and innovations involve the combination of multiple data sources, carefully consider the effects on (informational) privacy;

- If research concepts and innovations involve the development of capabilities for, or the use of, data surveillance or human subject monitoring or surveillance, then invoke the requirement for informed consent, if appropriate. Strike an appropriate balance between the need to monitor and control personal information and the right of individuals to (informational) privacy and other human rights.

— **Social responsibility**

(additional provisions specific to the computer and information sciences)

Respect for freedom of expression:

- Ensure that new research concepts and innovations do not pose unjustified inherent risks to the freedom of individuals to express themselves through the publication and dissemination of information, or to their freedom of access to information;

- If research or innovation involves the use of censorship methods, strike an appropriate balance between the need for content control and the right of individuals to express themselves freely.

Respect for intellectual property:

- Ensure that new research concepts and innovations do not pose unjustified inherent risks to the intellectual property rights of individuals or organisations;

- Avoid research that could generate copyright issues, such as research involving peer-to-peer networking or file sharing and distribution.

Respect for other individual rights and liberties:

- Ensure that new research concepts and innovations do not pose inherent risks to autonomy, authenticity or identity. In particular, ensure that information systems do not unnecessarily or unjustifiably take away control from users by limiting their choices or making choices for them that they would prefer to make themselves;

- Ensure that decisions made by information systems that have significant social impact take into account the rights, values and interests of stakeholders, including users, and make efforts to ensure that the reasons for decisions made by information systems can be retrieved, so as to make the systems accountable;

- Take into account the issue of how responsibilities and liabilities are assigned between humans and machines when information systems are involved in decision-making.

Avoidance of harms to justice and equality:

- Consider how new research concepts and innovations could widen or narrow social inequalities in terms of the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks or hazards;

- Consider how new research concepts and innovations could harbour or counter unjust bias in terms of age, gender, sexual orientation, social class, race, ethnicity, religion or disability;

- Consider how new research concepts and innovations could harm or promote the interests of vulnerable, disadvantaged, or underrepresented groups and communities in society, including those in low income and lower-middle income countries.

Promotion of well-being and the common good:

- Consider how the research or innovation activity could 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);

- Consider how the research or innovation activity could harm or promote the social skills and behaviour of individuals, and how it could harm or promote the learning or exercising of important virtues, such as patience and empathy;

- Consider whether and how the research or innovation activity could harm or promote important social institutions and structures, democracy, and important aspects of culture and cultural diversity.

Promotion of environmental sustainability:

- Optimize technologies for effective and cost-efficient resource use (including raw materials and energy), for resource recovery (recycling), and for lowering the production of environmentally harmful wastes and environmental pollution.

— **Dual use of computer and information sciences research and innovations**

- Consider whether new research concepts and innovations could have military applications;
- Consider whether new research concepts and innovations could contribute to the proliferation of weapons of mass destruction;
- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if a technology has significant military applications or if it contributes significantly to the proliferation of weapons of mass destruction. Even if publication is allowed, find a proper balance between security and freedom of publication.

NOTE An example of ethics guidelines for computer and information sciences is the 2013 publication *Applying Ethical Principles to Information and Communication Technology Research* by the US department of Homeland Security.

A.8 Additional ethical principles and issues in the social sciences and the humanities

— **Protection of human research participants**

(additional provisions specific to 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;
- Only consider exceptions to the requirement for informed consent in cases where the research cannot be effective if the participants are formally notified in advance of the topic of the research;
- Do not ascribe irrational or unworthy motives to participants without providing convincing documentation and justification. Show respect for the values and views of research participants, including those that deviate from those generally accepted by society.

— **Protection of individuals not directly participating in the research**

- 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;
- When conducting research on public individuals, communities, and organisations who are not directly participating in the research, strike an appropriate balance between consideration of the effects of the research on their reputations and privacy on the one hand and the societal benefit of such research on the other hand;
- Act with due consideration of the effects of the research on their posthumous reputations, when conducting research on deceased persons.

— **Social responsibility**

(additional provisions specific to the social sciences and the humanities)

- Acquire knowledge of local traditions, traditional knowledge and social matters and enter, as far as possible, into a dialogue with local inhabitants, representatives of the culture and local authorities when conducting research on other cultures, either in other countries or in minority cultures;
- Avoid using classifications or designations that allow for unreasonable generalisations when conducting research on other cultures.

Respect for individual rights and liberties:

- Consider how the research could contribute to a better understanding of, and better protections for, basic human rights, such as freedom, autonomy, human dignity, and privacy;
- Strike an appropriate balance between the recognition of cultural differences and the recognition of basic human rights.

Protection and promotion of justice and equality:

- 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;
- Consider how the research could contribute to the reduction of unjust biases, stigmatization, and discrimination in society in terms of age, gender, sexual orientation, social class, race, ethnicity, religion, culture, and disability;
- Consider how the research could contribute to the reduction of social inequalities in terms of the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks or hazards;
- Consider how the research could help to protect and promote the interests of vulnerable, disadvantaged, or underrepresented groups and communities in society, including those in low income and lower-middle income countries.

Protection and promotion of well-being and the common good:

- Consider how the research could help to protect and promote the general well-being of individuals and groups in society;
- Consider how the research could help to protect and promote important social institutions and structures, democracy, and cultural diversity;
- Protect and promote the responsible treatment of the physical artefacts and intangible attributes of a group or society that constitute cultural heritage, including sites, monuments, artefacts, texts, archives, remains, and information about the past.

NOTE Several ethics guidelines and regulations for the social sciences and humanities exist, such as the EU *Code of Ethics for Socio-Economic Research* (2012), the Norwegian *Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology* (2016), the USA *Federal Policy for the Protection of Human Subjects* (2015), the British *Code of Human Research Ethics* (2010) and the Canadian Tri-Council Policy Statement on *Ethical Conduct for Research Involving Humans* (2014).

Annex B
(informative)

Conflict between ethical principles

B.1 Ethical principles in moral decision-making

Moral decision-making involves considering both the relevant facts, such as the potential outcomes of different decisions and the likelihood of these outcomes, and the application of value judgements. Value judgements can be justified by appealing to ethical principles. These principles help to explain why particular aspects of research and innovation activity could be of ethical concern and assist in communicating and justifying these concerns to others. Examples of ethical principles are listed in Annex A.

Ethical principles guide moral decision-making by emphasizing particular moral aspects of the possible outcomes of the decision. For example, non-maleficence calls for avoiding harm. Applying this principle to an evaluation of research and innovation activity would involve examining how the various outcomes could cause harm, and to whom, and whether it is possible to reduce or avoid the potential harm from these outcomes.

B.2 Resolving conflicts between ethical principles

Ethical principles could provide conflicting guidance when applied to some issues. This requires a choice to be made about which principle should be given priority over another. Which principle should take precedence is a matter of judgement and will depend on the context in which the research and innovation activity takes place. For example, the principles of beneficence (promoting well-being in others) and non-maleficence (avoiding harm) could conflict in medicine, where a medical procedure that could cause temporary harm is necessary to improve a patient's long-term health. In this case, the likelihood of the procedure's success in promoting future well-being would need to be considered against the degree of harm and discomfort caused by the procedure.

There are a variety of methods for deciding how a conflict between ethical principles should be resolved. Four such methods are the *utilitarian calculus*, *libertarian side-constraints*, *prima facie principles* and *specification*. An ethics committee may use one or more of these methods to assist in its decision-making.

— Utilitarian calculus

  The utilitarian calculus uses the concept of utility to decide between possible actions. Utility is usually understood as desirable consequences for those affected by an action, including happiness, pleasure, and well-being. If the positive consequences of an action outweigh the undesirable consequences (such as harm or pain) then the action has positive utility and should be performed. The differences in the utility of various outcomes can be compared to decide which action has the greatest likelihood of producing positive utility.

— Libertarian side-constraints

  Libertarian side-constraints emphasize the rights of those affected by an action and the importance of protecting these rights against violation. The rights of individuals, such as the rights to life and liberty, serve as constraints on the permissible actions of others.

— *Prima facie* principles

The *prima facie* approach sees ethical principles as valid only if they do not conflict with each other. In other words, these principles create *prima facie* duties that may be overridden by the requirements of another principle. When principles conflict with each other, the moral intuitions and experience of the decision-makers can help direct them in deciding which of the conflicting principles should take precedence over the others.

— Specification

The method of specification seeks to resolve conflicts between ethical principles by recognizing that such principles are understood as being valid 'in general', and may be made more specific to handle particular cases and to recognize the priority of other principles. For example, a potential conflict between the principle of beneficence and the individual's right to liberty could be avoided by specifying the principle of beneficence as the duty to increase the health and well-being of others in accordance with their right to choose their actions for themselves.

Annex C
(informative)

Risk-based thinking in ethics assessment

C.1 Risk-based thinking

Risk-based thinking enables to determine the factors that could cause a project's activities to deviate from the planned results, to put in place preventive controls to minimize negative effects, and to make maximum use of opportunities. This annex briefly explains the following steps in risk management:

communication and consultation;

— establishing the context;

— risk assessment;

— risk treatment.

NOTE ISO 31000 provides requirements and recommendations for risk management.

C.2 Communication and consultation

Communication and consultation with external and internal stakeholders should take place during all stages of risk management. The R&I project members should identify, record and take stakeholder views into account in the decision-making process.

C.3 Establishing the context

To establish the context, the R&I project members should articulate the project's objectives, define the external and internal parameters to be taken into account when managing risk, and set the scope and risk criteria for the project.

The external context is the external environment in which the R&I project members seek to achieve project objectives and includes specific details of legal and regulatory requirements, stakeholder perceptions and other aspects of risk specific to the scope of the project.

The internal context is the internal environment in which the R&I project members seek to achieve project objectives and includes the project's culture, processes, structure and strategy. Internal context is anything within the project that influences risk management.

C.4 Risk assessment

Risk assessment is the overall process of risk identification, risk analysis and risk evaluation.

— **Risk identification:** Risk identification involves identifying sources of risk, areas of impact, events including changes in circumstances, and their causes and potential consequences. The aim of this step is to generate a comprehensive list of risks based on those events that could create, enhance, prevent, degrade, accelerate or delay the achievement of objectives. It is important to identify the risks associated with not pursuing an opportunity. Risk identification should include examination of consequences and cumulative effects;

— **Risk analysis:** Risk analysis involves developing an understanding of the risk. Risk analysis involves consideration of the causes and sources of risk, their positive and negative consequences, their likelihood, and the timeframe in which the consequences could occur. Factors that affect consequences and likelihood should be identified. The combination of consequences, likelihood and timeline determines the level of risk and sensitivity to preconditions. Factors such as divergence of opinion among experts; uncertainty; the availability, quality, quantity and relevance of information, or limitations on modelling should be stated and can be highlighted;

— **Risk evaluation:** Risk evaluation involves comparing the level of risk with the objectives and context. The purpose of risk evaluation is to assist in making decisions, based on the outcomes of risk analysis, about which risks need treatment and the priority for treatment implementation.

C.5 Risk treatment

Risk treatment involves selecting one or more options for modifying risks, and implementing those options. Risk treatment involves a cyclical process of:

— assessing a risk treatment;

— deciding whether residual risk levels are tolerable;

— if they are not tolerable, generating a new risk treatment;

— assessing the effectiveness of that treatment.

Risk treatment options are not necessarily mutually exclusive or appropriate in all circumstances. The options can include the following:

— avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk;

— taking or increasing the risk in order to pursue an opportunity;

— removing the risk source;

— changing the likelihood;

— changing the consequences;

— sharing the risk with another party or parties (including through contracts and risk financing);

— retaining the risk by informed decision.

Selecting the most appropriate risk treatment option involves balancing implementation costs against benefits, with regard to legal, regulatory and other requirements, such as social responsibility and protection of the environment. Some risks warrant risk treatment but this is not justifiable on economic grounds, e.g. severe (high negative consequence) but rare (low likelihood) risks.

Treatment options can be considered and applied either individually or in combination. The R&I project will normally benefit from the adoption of a combination of treatment options.

Annex D
(informative)

Guidelines for the use of the Plan-Do-Check-Act approach (PDCA) for ethics assessment

Table 1 — Guidelines for the use of PDCA for ethics assessment

PLAN The ethics committee should adequately plan for quality assurance (QA) in their ethics assessment. The ethics committee should develop a quality assurance plan that typically includes the following: — the objectives of QA; — the strategy and approach to QA; — the methods and or techniques to be used and how performance is to be measured; — who has the responsibility for QA.
DO DO envisages the implementation of the QA plan and ensuring that its arrangements are followed. The ethics committee should, for example: — Determine and provide 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 what needs to be obtained from external providers); — Determine and provide the *persons* necessary for the effective implementation, operation and control of its ethics assessment processes; — Determine, provide and maintain the *infrastructure*[1] necessary for the operation of processes to ensure the quality of ethics assessment; — Determine, provide and maintain the *environment* necessary for the operation of its ethics assessment processes; — Determine and provide the resources needed to ensure valid and reliable results in the ethics assessment process; — Ensure that the resources provided: • are suitable for the specific type of ethics assessment being undertaken; • are maintained to ensure their continuing fitness for purpose. — Retain appropriate documented information as evidence of the fitness for purpose of the ethics assessment process. — Determine the knowledge required for the operation of its ethics assessment processes. — Ensure: • the required level of competence of person(s) doing work under its control where this affects the performance and effectiveness of the ethics assessment process; • that these persons are competent on the basis of appropriate education, training, or experience;

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

- where applicable, taking actions to acquire the required level of competence, and evaluating the effectiveness of the actions taken;
- the retention of appropriate documented information as evidence of competence.

— Ensure that relevant persons working under the organization's control (e.g. ethics assessors, other staff) are aware of:
- the quality assurance policy;
- relevant quality objectives;
- their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- the implications of not conforming with the ethics assessment process requirements.

— Determine the internal and external communications relevant to the ethics assessment process (what, when, with whom, how);

— Maintain the documented information that the organization has determined necessary for the effectiveness and quality of the ethics assessment process.

CHECK

To facilitate the CHECK stage, the ethics committee should assess the quality of ethics assessment policy, practice and procedure:

Typical example questions include:

— What is the current situation?
- What is the origin of the ethics assessment policy, practice, or procedure and what are 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).

— How effective has the ethics assessment policy, practice, or procedure been?
- 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?
- What factors influenced the achievements observed?
- To what extent did different factors influence the achievements observed?
- Did evaluation or review policies and procedures enable researchers to address things affecting achievement of the objectives of the ethics assessment policy, practice, or procedure?

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

— How relevant is the ethics assessment policy, practice or procedure?
  - To what extent is the ethics assessment policy, practice or procedure still relevant?
  - To what extent have the (original) objectives proved 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? Issues related to the specific policy could be included here.
  - How relevant is the ethics assessment policy, practice or procedure to individuals or citizens?
— How coherent is the ethics assessment policy, practice, or procedure internally and with other external actions?
  - To what extent is the ethics assessment policy, practice or procedure coherent with other ethics assessment policies, practices 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?
— What is the EU added value of the ethics assessment policy, practice,or procedure?
  - 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?

ACT

The ACT part envisages review and continuous monitoring and improvement to improve the performance, adequacy and effectiveness of the ethics assessment process. The ethics committee should take actions to improve the ethics assessment policy, practice and procedures and correct undesirable effects (e.g. the passing of a highly unethical project with detrimental effects on society). These 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).

NOTE The key questions in the CHECK section are based upon and adapted from the EC Better Regulation Guidelines on Evaluation and Fitness Checks. http://ec.europa.eu/smart-regulation/guidelines/ug_chap6_en.htm.

Bibliography

AMERICAN PSYCHOLOGICAL ASSOCIATION (APA). *Guidelines for Ethical Conduct in the Care and Use of Nonhuman Animals in Research*. http://www.apa.org/science/leadership/care/guidelines.aspx

Association of research ethics committees (AREC). *A Framework of policies and procedures for university research ethics committees*. 2013

BAILEY M., DITTRICH D., KENNEALLY E. *Applying Ethical Principles to Information and Communication Technology Research*. Department of Homeland Security, USA, 2013. (http://mdbailey.ece.illinois.edu/publications/menlo_report_companion_actual_formatted.pdf)

BEAUCHAMP T.L., CHILDRESS J.F. *Principles of Biomedical Ethics*. Oxford University Press, New York, Fifth Edition, 2001

REPORT B. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/

Brey, Philip, Wessel Reijers, Philip Jansen, Rowena Rodrigues, David Wright, Raija Koivisto, Anu Tuominen, Lise Bitsch, SATORI WP4 report *A reasoned proposal for Ethical Impact Assessment*, 2016

BRITISH PSYCHOLOGICAL SOCIETY. (2010). *Code of Human Research Ethics*. (http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf

CANADIAN TRI-COUNCIL POLICY STATEMENT ON ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS. (2014) (http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/

COUNCIL FOR INTERNATIONAL ORGANISATIONS OF MEDICAL SCIENCES (CIOMS). *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2002. (http://www.cioms.ch/publications/layout_guide2002.pdf)

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

COUNCIL OF EUROPE. *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings*, reference: ETS No.168 (http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/168)

Council of Europe. *Guide for research ethics committee members, steering committee bioethics*. 2012

Council of Europe. *Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin.* 2016

DENCH S., IPHOFEN R., HUWS U. *An EU Code of Ethics for Socio-Economic Research*. Institute for Employment Studies report 412. 2012. http://www.respectproject.org/ethics/412ethics.pdf

ECONOMIC AND SOCIAL RESEARCH COUNCIL (ESRC). *ESCR Framework for research ethics*. 2015. http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/

EUROPEAN COMMISSION. *Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects*. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf

EUROPEAN COMMISSION. *Better Regulation. Guidelines on evaluation and fitness checks*. http://ec.europa.eu/smart-regulation/guidelines/ug_chap6_en.htm

European Commission. *Declaration C 373/12* (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF)

EUROPEAN COMMISSION. *Ethical and Regulatory Challenges to Science and Research Policy at the Global Level*. Directorate-General for Research and Innovation, 2012. http://ec.europa.eu/research/science-society/document_library/pdf_06/ethical-and-regulatory-challenges-042012_en.pdf

EUROPEAN COMMISSION. *ERC Rules for Submission and Evaluation*. H2020, 2014. http://ec.europa.eu/research/participants/data/ref/h2020/sgl/erc/h2020-erc-se-rules-1617_en.pdf

EUROPEAN COMMISSION. *Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020*. DG Research and Innovation, 2016http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf

EUROPEAN PARLIAMENT AND THE COUNCIL. *Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes*. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF

EUROPEAN PARLIAMENT AND THE COUNCIL. *Charter of Fundamental Rights of the European Union*, OJ C 326, 26.10.2012. http://www.europarl.europa.eu/charter/pdf/text_en.pdf

EUROPEAN PARLIAMENT AND THE COUNCIL. *Directive 2010/63/EU 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

European Science Foundation (ESF) and All European Academics (ALLEA). The European Code of Conduct for Research Integrity, Revised edition, 2017

H2020. *How to complete your ethics Self-Assessment*, Version 5.2 12 July 2016. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH. *Guidelines for Stem Cell Research and Clinical Translation*, 2016. (http://www.isscr.org/docs/default-source/guidelines/isscr-guidelines-for-stem-cell-research-and-clinical-translation.pdf?sfvrsn=2)

Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations, 2013. http://www.icsu.org/icsu-asia/news-centre/news/MontrealStatementonResearchIntegrityJune21_2013.pdf

Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

NORWEGIAN NATIONAL RESEARCH ETHICS COMMITTEES. *Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology*, 2016. https://www.etikkom.no/globalassets/documents/english-publications/60127_fek_guidelines_nesh_digital_corr.pdf

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

Nuffield Council of Bioethics. *The ethics of research related to healthcare in developing countries* (2014)

Nuremberg Code (http://www.cirp.org/library/ethics/nuremberg/)

Oviedo Convention. Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. (http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164)

RAWLS J. *A Theory of Justice*. Harvard University Press, 1971

SATORI project deliverables. http://satoriproject.eu/media/D3.3_legal_aspects_globalisation.pdf and http://satoriproject.eu/media/3.4.Responsible-and-Ethical-Governance-of-Research-and-Innovation-in-the-Context-of-Globalization.pdf

Shamoo, Adil E., and David B. Resnik, Responsible Conduct of Research. Oxford University Press, Oxford, 2003

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*, 2015

SINGAPORE STATEMENT ON RESEARCH INTEGRITY. 2010. http://www.singaporestatement.org/statement.html

THOMPSON D.F. Understanding financial conflicts of interest in *New England. J. Med.* 1993, **329** pp. 573–573

UNESCO. *Cultural Heritage*. http://www.unesco.org/new/en/cairo/culture/tangible-cultural-heritage/

UNESCO. *Declaration of Bioethics and Human Rights*. http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/

UNITED NATIONS CONVENTION ON BIOLOGICAL DIVERSITY. 1992. (https://www.cbd.int/doc/legal/cbd-en.pdf)

UNITED NATIONS DECLARATION ON THE RIGHTS OF INDIGENOUS PEOPLES. http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf

UNITED NATIONS. *The Universal Declaration of Human Rights*, 1984. http://www.un.org/en/universal-declaration-human-rights/

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. *International Compilation of Human Research Standards*, 2017. https://www.hhs.gov/ohrp/sites/default/files/international-compilation-of-human-research-standards-2017.pdf

U.S. DEPARTMENT OF HOMELAND SECURITY ET AL. *Federal Policy for the Protection of Human Subjects* (draft updated version), Federal Register vo. 80, no. 173 (USA), 2015. (https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf

WILKINSON M.D. et al. The FAIR guiding principles for scientific data management and stewardshipIn. *Sci. Data*. 2016, ••• p. 3

WORLD HEALTH ORGANIZATION. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants,* 2011. http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf?ua=1&ua=1

WORLD MEDICAL ASSOCIATION. *The Declaration of Helsinki*. (Adopted 1964, last amended 2013) http://www.wma.net/en/30publications/10policies/b3/index.html

WRIGHT D. A framework for the ethical impact assessment of information technology in *Ethics and Information Technology*, 13, 2011. 199–226. http://doi.org/10.1007/s10676-010-9242-6

Correction Notice

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Brussels, 2017-07-26

Please include the following minor editorial correction(s) in the document related to:

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- ☒ English
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- ☐ PQ/UQ
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- ☐ 2nd Parallel Formal Vote
- ☐ UAP
- ☐ TC Approval
- ☐ 2nd TC Approval
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- ☐ Parallel Publication

It has been brought to our attention that this document, issued on 2017-05-10, requires modification.

The definition 2.14 has been reworded.

Please find enclosed the updated English version.

We apologise for any inconvenience this may cause.

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Annex 10 – SATORI CWA Part 2 Ethical impact assessment framework[84]

[84] CWA 17145-2 is available on the SATORI website.

CEN

WORKSHOP

AGREEMENT

CWA 17145-2

June 2017

ICS 03.100.02; 03.100.40

English version

Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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Contents

Page

European foreword

CWA 17145-2:2017 was developed in accordance with CEN-CENELEC Guide 29 "CEN/CENELEC Workshop Agreements – The way to rapid agreement" and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was agreed on 2017-05-22 in a Workshop by representatives of interested parties, approved and supported by CEN following a public call for participation made on 2015-08-01. It does not necessarily reflect the views of all stakeholders that might have an interest in its subject matter.

The final text of CWA 17145-2:2017 was submitted to CEN for publication on 2017-05-24.

A list of the individuals and organisations that supported the technical consensus represented by the CEN Workshop Agreement is available from the CEN-CENELEC Management Centre. These organisations were drawn from the following economic sectors industry, universities, civil society organisations, technology boards, European organisations.

Among the organisations and representatives who developed and approved CWA 17145-2:2017 are the following:

— Associazione Italiana per la Ricerca Industriale (AIRI), Italy	Andrea Porcari
— Austrian Agency for Research Integrity (OeAWI)/European Network of Research Integrity Offices (ENRIO), Austria	Nicole Foeger
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It is possible that some elements of CWA 17145-2:2017 may be subject to patent rights. The CEN-CENELEC policy on patent rights is set out in CEN-CENELEC Guide 8 “Guidelines for Implementation of the Common IPR Policy on Patents (and other statutory intellectual property rights based on inventions)”. CEN shall not be held responsible for identifying any or all such patent rights.

The Workshop participants have made every effort to ensure the reliability and accuracy of the technical and non-technical content of CWA XXX, but this does not guarantee, either explicitly or implicitly, its correctness. Users of CWA 17145-2:2017 should be aware that neither the Workshop participants, nor CEN can be held liable for damages or losses of any kind whatsoever which may arise from its application. Users of CWA 17145-2:2017 do so on their own responsibility and at their own risk.

Introduction

The increasing pace of technological developments such as genetic technologies, geo-engineering, ICT and synthetic biology has been stimulating questions and discussion on the desirability and governance of their societal impacts. Ethics assessment and ethical impact assessment help ethicists to investigate ethical challenges. Ethics assessment and ethical impact assessment help researchers, policy makers and relevant stakeholders to deal with the ethical impacts of research and innovation.

The need for agreed methods for ethics assessment and ethical impact assessment arises out of the increasing focus on responsible research and innovation in policy contexts and in collaborative efforts by researchers, as well as from new legal regulations for research and innovation at the European level. The European Commission, has been a driving force behind the development of ethics assessment and impact assessment practices, by incorporating the need for responsible research and innovation in its framework programmes.

The SATORI (Stakeholders Acting Together On the ethical impact assessment of Research and Innovation, www.satoriproject.eu) research project, funded by the European Commission, developed a framework for common basic ethical principles and joint approaches and practices with the objective of harmonizing and improving ethics assessment practices of research and innovation.

The SATORI project developed a framework based on research into existing practices. These research findings are the basis of this CWA. This CWA consists of two parts.

Part 1, outlined here, makes recommendations for the composition, role, functioning and procedures of ethics committee. Organisations can use part 1 to strengthen and/or improve the ethics assessment of their research and innovation projects. Ethics committees include, but are not limited to, research ethics committees, institutional review boards, ethical review committees, ethics boards, and units consisting of one or more ethics officers. Part 1 of the CWA is applicable to all ethics committees, regardless of their size, scope or research and innovation area.

Part 2 provides researchers and organisations with guidance on ethical impact assessment; a comprehensive approach for ethically assessing the actual and potential mid- and long-term impacts of research and innovation on society. Researchers and ethics committees will find this information useful as it describes ethical impact assessment at different stages of the ethical assessment. Part 2 is applicable to all researchers and innovators, regardless of the context they are working in or their research and innovation area.

1 Scope

This CEN Workshop Agreement (CWA) sets requirements and provides guidelines for ethics assessment of research and innovation.

The CWA aims to improve the quality of ethics assessment and harmonize ethics assessment practices.

The CWA consists of two parts:

— part 1 Ethics committee; Part 1 provides recommendations for the ethics committees on practices and procedures;

— part 2 Ethical impact assessment framework. This part provides a practical, policy-oriented guide for researchers and ethics assessors on the different stages of the ethical impact assessment (EIA) process.

Both parts of the CWA are of interest to organisations or agents involved in performing, commissioning or funding research and innovation, and therefore have a responsibility to address ethical issues.

The focus of the CWA is on ethics assessment, not on ethical guidance.

2 Terms and definitions

For the purposes of this document the following terms and definitions apply.

2.1
Delphi survey
method for estimating future measures by asking a group of experts to make estimates, recirculating the estimates back to the group, and repeating the process till the numbers/answers converge

[SOURCE: Global Foresight Glossary, 2013]

2.2
design intervention
deliberate action aimed at bringing about changes in the design of the R&I project and its outcomes in order to resolve identified ethical impacts

2.3
ethical impact
impact that concerns or affects human rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good

2.4
ethical impact identification
use of foresight methods to describe different future applications of research and innovation (R&I)

[SOURCE: adapted from SATORI deliverable 4.3.1.2]

2.5
ethical impact assessment
EIA
process of judging the ethical impacts of research and innovation activities, outcomes and technologies that incorporates both means for a contextual identification and evaluation of these ethical impacts and development of a set of guidelines or recommendations for remedial actions aiming at mitigating ethical risks and enhancing ethical benefits, typically in consultation with stakeholders

Note 1 to entry: Ethical impact assessment is the overall process of ethical impact identification, analysis and evaluation.

Note 2 to entry: Ethical impact assessment is a means of actioning social responsibility in research and innovation.

[SOURCE: adapted from Wright, 2015]

2.6
ethical impact analysis
description of the ethically relevant aspects of the possible applications of research and innovation

[SOURCE: adapted from SATORI deliverable 4.3.1.2]

2.7
ethical issues
issues that may be relevant for evaluating the ethical implications of maxims, principles or particular courses of action

2.8
ethical principles
general principles that may be relevant for making ethical evaluations

Note 1 to entry: Such principles include beneficence, non-maleficence, autonomy, justice and dignity

2.9
ethics
moral principles that govern a person's behaviour or the conduct of an activity; the branch of knowledge that deals with moral principles

Note 1 to entry: The European Commission (EC) perceives 'ethics' as including questions of legal and regulatory compliance as well as being a branch of philosophy, in European Commission: Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects, 2012.

[SOURCE: Oxford English Dictionary]

2.10
ethics assessment
institutionalized assessment, evaluation, review, appraisal or valuation of plans, practices, products and uses of research and innovation that makes use of ethical principles or criteria

[SOURCE: Shelley-Egan et al., SATORI D1.1, 2015]

211
ethics committee
institution or committee that performs ethics assessment

Note 1 to entry: Ethics committees may assess research or innovation goals, new directions, projects, practices, products, protocols, new fields, etc. and their work may be performed before, during and/or after the implementation of the projects they assess.

Note 2 to entry: An ethics committee may also be called an Ethics Review Board, Ethics Assessment Unit, Ethics Board or other terms.

[SOURCE: adapted from Shelley-Egan et al., SATORI Deliverable 1.1, 2015]

2.12
foresight
action-oriented, multidisciplinary and participatory strategic intelligence focused on alternative futures

Note 1 to entry Foresight methods aim to produce knowledge interactively between multiple stakeholders with specific interests and differing perspectives towards the topic under exploration and to facilitate interaction between the relevant stakeholders and catalyse the desired developments and strategies

[SOURCE: Eerola. and Jørgensen, Technology Foresight in the Nordic Countries, 2002]

2.13
futures
alternative future
idea that there is not a single future, but a range of possible futures, which are influenced by human choices today

[SOURCE: Adapted from Global foresight – glossary, 2016]

2.14
futures wheel
instrument for graphical visualization of direct and indirect future consequences of a particular change or development

[SOURCE: Jackson, Practical Foresight Guide, 2013]

2.15
horizon scanning
process of reviewing and analysing current literature, web sites, and other media to identify and describe noteworthy trends and their possible development and future

[SOURCE: adapted from Jackson, Practical Foresight Guide, 2013]

2.16
impact of research and innovation
influence or effects, e.g., societal, ethical, legal, political, economic, environmental, of research and innovation

EXAMPLE Environmental consequences of technological innovations resulting from research in the chemical sciences.

2.17
informed consent
decision, written, dated and signed, to be a research participant, taken freely after being duly informed of its nature, significance, implications and risks of the research. Informed consent must be appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative

[SOURCE: adapted from Widdows, Global Ethics: An Introduction, 2013]

Note 1 to entry: The above definition is in line with that in Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. The principle of 'informed and free decision' remains valid for any other kind of research.

Note 2 to entry: If the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.

2.18
innovation
development, based on new ideas or inventions, of new products, services, processes and methods

[SOURCE: adapted from Shelley-Egan et al., SATORI Deliverable 1.1, 2015]

2.19
personal data
information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person

[SOURCE: Art. 4(1) (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data]

2.20
remedial action
activity aimed at improving ethical impacts

Note 1 to entry: Remedial actions can be aimed at intervention into the design of the research and innovation project and at recommendations for future R&I efforts.

2.21
research
form of systematic inquiry that aims to contribute to a body of knowledge or theory

2.22
responsible research and innovation
RRI
transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the acceptability, sustainability and societal desirability of the innovation process and its marketable products, in order to allow a proper embedding of scientific and technological advances in society

[SOURCE: Von Schomberg, A vision of Responsible Research and Innovation, 2013]

2.23
roadmapping
vision-driven tool for presenting the path from the current state to the desired future state. It provides a graphical representation showing key components of how the future might evolve, usually applied to a new product or process, or to an emerging technology matching short and long term goals with specific solutions

Note 1 to entry The tool is often combined with vision-building and participatory methods

Note 2 to entry Strategic roadmapping is emerging

2.24
scenario
predicted sequence of events that might possibly occur in the future

[SOURCE: Jackson, Practical Foresight Guide, 2013]

2.25
scenario planning
strategic planning method that e.g. organisations use to make flexible long-term plans

[SOURCE: Jackson, Practical Foresight Guide, 2013]

2.26
social responsibility
principle for raising awareness of the societal impacts of research and innovation, including taking appropriate remedial actions if deemed necessary

2.27
technology assessment
TA
scientific, interactive and communicative process that aims to contribute to the formation of public and political opinion on societal aspects of science and technology

[SOURCE: Bütschi et al., The Practice of TA; Science, Interaction, and Communication, 2004]

Note 1 to entry: It may address the direct intended consequences of technologies as well as their indirect, unintended consequences.

2.28
technology readiness level
TRL
method of estimating technology maturity of critical technology elements of a program during the acquisition process

[Source: Adapted from Wikipedia. https://en.wikipedia.org/wiki/Technology_readiness_level]

Note1 to entry: TRLs are based on a scale from 1 to 9 with 9 being the most mature technology

Note2 to entry: The European Association of Research and Technology Organisations (EARTO) has published a comprehensive approach and discussion about TRLs

2.29
trend
tendency or direction evident from past events, it usually suggests a pattern

Note 1 to entry: A trend can be increasing or decreasing in strength of frequency of observation.

[SOURCE: adapted from Jackson, Practical Foresight Guide, 2013]

2.30
vision
carefully formulated and clearly articulated description of a desired future state of affairs as stated by an individual or a group. The ambition of the vision is to motivate, inspire and give direction to those who are committed to the vision

[SOURCE: van der Helm, The vision phenomenon: towards a theoretical underpinning of visions of the future and the process of envisioning, 2009]

2.31
weak signal
past or current development or issue with ambiguous interpretations of its origin, meaning and or implications. Weak signals are unclear observables warning us about the probability of future events

[SOURCE: Jackson, Practical Foresight Guide, Chapter 11 – Foresight Glossary, 2013]

2.32
wild card
unpredictable event or situation; event that has a low probability but a high impact

Note 1 to entry: Wild cards are often recognized and known, but discounted, even when the event is relatively certain over a period of years.

[SOURCE: Jackson, Practical Foresight Guide, 2013]

3 Ethical impact assessment framework

The framework presents a comprehensive methodology for conducting an ethical impact assessment (EIA) in research and innovation (R&I) projects. An EIA can be part of regular ethics assessment, as performed by ethics committees, or a separate procedure.

The EIA framework consists of the following steps:

— 1. conduct an EIA threshold analysis [Clause 4];

— 2. prepare an EIA plan if the threshold analysis concludes that ethical issues are involved [Clause 5];

— 3. identify ethical impacts, typically in consultation with stakeholders [Clause 6];

— 4. evaluate the ethical impacts, typically in consultation with stakeholders [Clause 7];

— 5. formulate and implement remedial actions [Clause 8];

— 6. review and audit the EIA [Clause 9].

NOTE The EU has adopted regulations concerning research and innovation. These regulations and the national legislation on their basis in the EU-Member States prevail all other provisions for the mentioned research. Examples in the field of healthcare are Regulation 2014/535 on clinical trials on medicinal products for human use and Regulation 2017/745 on medical devices. Another example is the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

Figure 1 provides a graphic presentation of the ethical impact assessment framework.

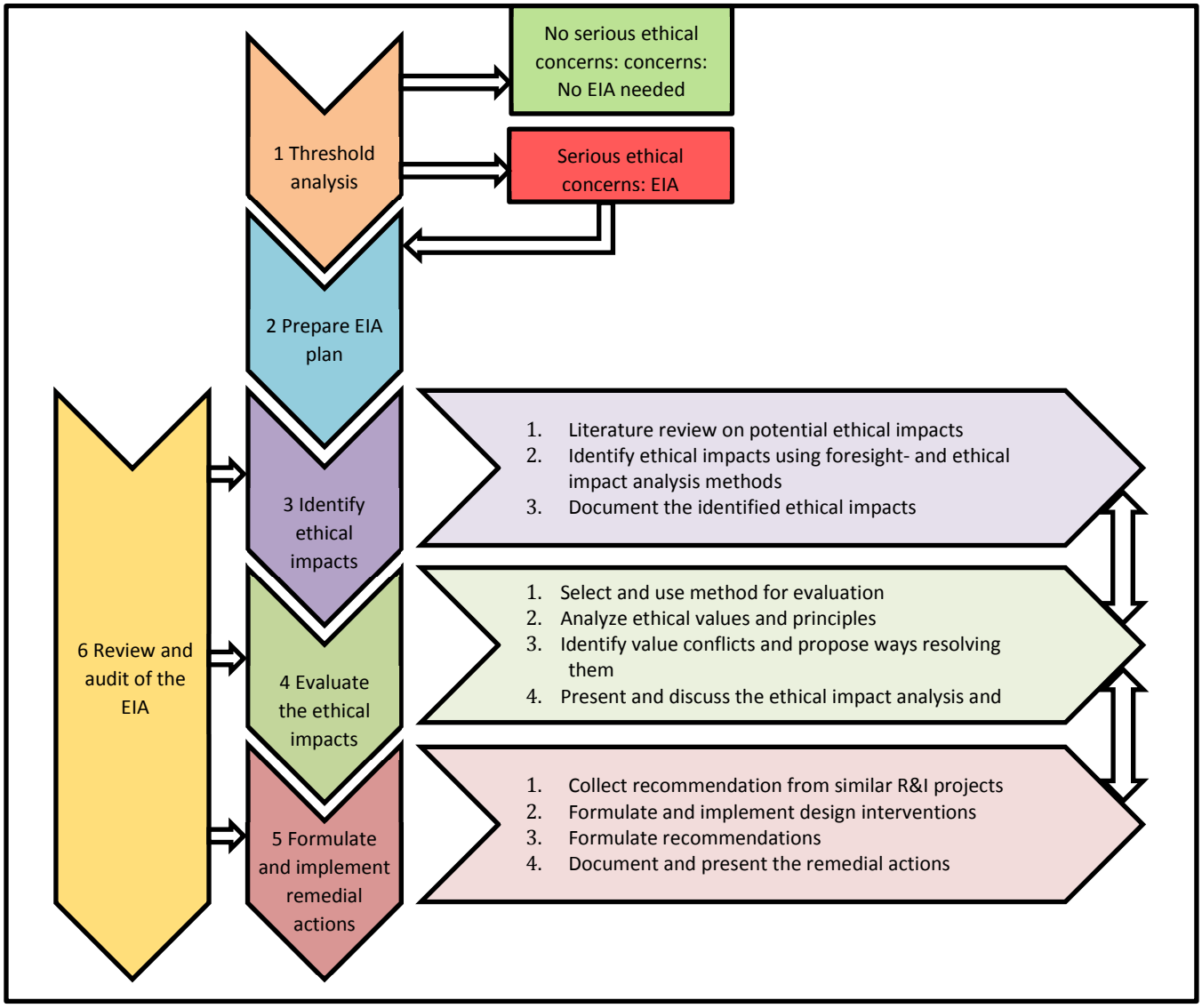

Figure 1 — Graphical presentation of the ethical impact assessment framework

4 Conduct an ethical impact assessment threshold analysis

4.1 Objective

The purpose of the EIA threshold analysis is to determine whether or not ethical issues are involved in an R&I project that demand an EIA.

4.2 Who performs the threshold analysis

The institutional context indicates who should conduct the EIA threshold analysis. The responsible person most likely is:

— **designated administrator at a public research institute or a company** for larger institutions or companies. For universities, this could be the person who is responsible for co-ordination of research funding proposals. For companies, this could be the corporate responsibility manager, R&D manager, project manager or a member of the R&I team;

— **researcher within the R&I project team** in case the institution or company, such as an SME, does not have a designated administrator who could perform the threshold analysis;

— **third party representative** an independent consultant could perform the threshold analysis in order to give an impartial view about whether the project should be initiated.

4.3 Design and complete the threshold analysis questionnaire

The threshold analysis typically consists of a questionnaire, which does not need be long or complex. In fact, the most important question for an organization to ask itself is: Does the project (or technology or service or application) raise any ethical issues? If it seems that it does, then an ethical impact assessment should be carried out. Annex A provides an overview of ethical impacts to which the organization could refer to for inspiration.

Table 1 provides a basic format for an ethical impact threshold analysis questionnaire. The questionnaire should be amended to include project- or scientific-field-specific ethical issues.

The threshold analysis should take place during the project proposal-writing stage of an R&I project. The EIA threshold analysis should be timely and done efficiently and should not unnecessarily hinder the planning of the R&I project.

Table 1 — Basic format for an ethical impact threshold analysis questionnaire

Please provide an answer between 1 (i.e. very unlikely and/or very low potential severity) and 5 (i.e. very likely and/or very high potential severity) to the following questions.						
Does the project include, or could its results easily be used for, the design or development of technologies, policies or protocols, that:	**1**	**2**	**3**	**4**	**5**	**Comment on your answer / specify briefly any potential ethical issues:**
1. are used in a health-care context, *or* could have a negative impact on public health or safety?						
2. involve the collection, processing, storing and/or transfer of personal data? *(Consider, in particular, whether sensitive personal data are collected relating to health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.)*						

Please provide an answer between 1 (i.e. very unlikely and/or very low potential severity) and 5 (i.e. very likely and/or very high potential severity) to the following questions.						
Does the project include, or could its results easily be used for, the design or development of technologies, policies or protocols, that:	**1**	**2**	**3**	**4**	**5**	**Comment on your answer / specify briefly any potential ethical issues:**
3. could have a negative impact on the rights and liberties of individuals and groups? *(Consider effects on freedom, autonomy, authenticity, identity, privacy, human dignity, human bodily integrity, intellectual property, among others.)*						
4. could have a negative impact in terms of social justice and equality? *(Consider effects on the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks and hazards, and have special consideration for effects on vulnerable, disadvantaged, and under-represented individuals, groups, or communities in society, including future generations and individuals, groups and communities in low income and lower-middle income countries.)*						
5. could have a negative impact on the well-being of individuals or groups, and/or on the common good, including cultural heritage? *(Consider effects on the well-being and interests of individuals and groups in society, including the quality of work, and effects on social institutions and structures, democracy and important aspects of culture and cultural diversity. Cultural heritage includes physical artefacts and intangible attributes of a group or society, such as sites, monuments, artefacts, texts, archives, remains and information about the past.)*						
6. could have a negative impact on the environment, animals and/or plants, including through the use of genetically modified organisms (GMOs)? *(Consider, amongst others, the direct and long-term effects on the environment, animals and plants of any biological, chemical, radiological, nuclear or explosive elements used, including GMOs, as well as any effects in terms of human encroachment on natural habitats and environmental policy.)*						

Please provide an answer between 1 (i.e. very unlikely and/or very low potential severity) and 5 (i.e. very likely and/or very high potential severity) to the following questions.						
Does the project include, or could its results easily be used for, the design or development of technologies, policies or protocols, that:	**1**	**2**	**3**	**4**	**5**	**Comment on your answer / specify briefly any potential ethical issues:**
7. could raise concerns in terms of sustainable development? *(Consider whether the R&I project is compatible with sustainable development in terms of the use of resources, the generation of harmful waste products, et cetera.)*						
8. could have significant military purposes (dual use)? *(Consider, amongst others, any effects in terms of the development of weapons of mass destruction, military surveillance systems and autonomous weapons systems.)*						
9. could become subject to misuse? *(Consider, amongst others, whether [information about] harmful biological, chemical, radiological, nuclear, or explosive materials, and/or the means of their delivery, can easily [or accidentally] be misused and whether it may easily fall into the hands of terrorists or criminals, and whether the R&I project may result in abuses by governmental and other institutional actors in non-military contexts.)*						

4.4 Review of the threshold analysis

If the threshold analysis has not identified ethical issues, an independent body should review the threshold analysis.

NOTE Review by an independent body does not absolve the organization of accountability.

5 Ethical impact assessment plan

5.1 Objective

If the threshold analysis [4] has identified ethical issues, the organization or project consortium should prepare an EIA plan. The EIA plan should include the following sections:

— **assessing the scale of the EIA;**

— **allocating the budget** in line with the scale of the EIA;

— **composing the EIA team** in line with the scale of the EIA;

— **formulating review criteria:** Certain criteria could be formulated for reviewing the EIA, such as milestones for EIA reports, quality insurance standards or publication targets for large-scale EIAs;

— **(optional) revisiting the threshold analysis:** For R&I project dealing with emerging technologies and/or changing risks for ethical impacts throughout the duration of the project, the funding body and the project team should agree on a periodic threshold analysis;

— **(optional) consulting with stakeholders:** In case the threshold analysis demands a medium-scale or large-scale EIA, the project team should consult with stakeholders at the start of the project. This consultation should aim to:

  - map the different relevant stakeholders;
  - raise awareness amongst stakeholders that the project will take place;
  - gather more details from stakeholders about possible ethical impacts.

5.2 Assess the scale of the EIA

The scale of the EIA has implications for the EIA team composition and budget:

— **Scale of EIA:**

  - **small-scale:** When a limited number (one or two) of the ethically significant uses of the activities and outcomes of the R&I project are identified and the risk of at least one of them is seen as only mildly severe (2 on the 5-point scale);
  - **medium-scale:** When a substantial number (three or four) of the ethically significant uses of the activities and outcomes of the R&I project are identified and the risk of at least one of them is deemed substantially severe (3 or 4 on the 5-point scale);
  - **large-scale:** When a large number (five or more) of the ethically significant uses of the activities and outcomes of the R&I project are identified, and the risk of at least on of them is deemed serious (4 or 5 on the 5-point scale).

— **EIA team composition**: The following minimum considerations apply to the different scales of EIA:

  - **small-scale** EIA mostly requires deskwork . The EIA team is led by a (research) assistant who is member of the R&I project team. This is a part-time position;
  - **medium-scale** EIA requires setting up consultative and participatory processes. The EIA team is led by a (research) member in the R&I project. This is a full-time position;
  - **large-scale** EIA requires the use of a variety of participatory efforts, involving multiple stakeholders. The EIA team is led by a senior member; in research institutes this could be a professor) in the R&I project or an independent, third-party consultant. This is a full-time position.

— **Budget composition**: An EIA should preferably require 1 %–10 % of the budget of an R&I project, with a maximum of 20 %. The following estimations may guide considerations for budget composition:

- **small-scale:** approximately 90 % direct personnel costs and 10 % other costs;
- **medium-scale:** approximately 80 % direct personnel costs and 20 % other costs;
- **large-scale:** approximately 70 % direct personnel costs and 30 % other costs.

NOTE 1 Budget and team composition are roughly based on the H2020 budget document of EU Research: EURESEARCH, Horizon 2020 – How to Budget My Project Costs, 2014.

NOTE 2 A technology-scale EIA might be considered in addition to an EIA at one of the scales above. Annex B provides additional information for the technology-scale EIA.

5.3 Review and approval of the EIA plan

5.3.1 Who reviews and approves the EIA plan

An independent body should review the EIA plan.

NOTE Research funding organisations may establish an independent body responsible for conducting the review and audit of EIA plans and EIAs.

5.3.2 Communication of the review

The reviewer should communicate his or her decisions to the EIA team. The decisions could be one of the following:

— **The reviewer accepts the EIA plan:**

- selection of review criteria, scale, budget and team composition are approved.

— **The reviewer asks for amendments to the EIA plan**, for example, including:

- additional ethical impacts that the project team did not include in their threshold analysis but that could reasonably have been expected;
- additional requirements for budget team composition and/or scale.

— **The reviewer rejects the EIA plan** in the following cases:

- when the threshold analysis calls for an EIA scale that does not fit the size of the project;
- when some ethical impacts are deemed too severe for the means available to the project team.

The outcome of the review of the EIA plan should be kept confidential and can only be accessed by the reviewing organization.

6 Ethical impact identification

6.1 Objective

Ethical impact identification aims to identify and describe the ethical impacts of the R&I project and places these impacts in a temporal perspective, anticipating short, medium and long-term impacts.

6.2 Procedure

The ethical impact identification stage has the following steps:

— 1. Identify potential (future) ethical impacts through literature reviews on the ethical impacts of similar projects;

— 2. Further specify and identify additional potential ethical impacts through the use of both foresight methods and ethical impact analysis methods.

— 3. Document the results of the ethical impact identification activities.

The ethical impact identification should start at the beginning of the project so that its potential ethical impacts can be evaluated and translated into remedial actions when they could influence the future course of the project.

6.3 Foresight for ethical impact identification

The EIA team should identify potential ethical impacts by selecting the ethical impact identification methodologies and performing the activities:

— review literature on existing ethical analyses of similar projects to collect the identified ethical issues. Policy analyses may also contain ethical observations;

— use foresight- and ethical impact analysis methods to corroborate and further specify the ethical issues and to identify additional ethical issues:

  Foresight methods are used to identify possible, probable, and preferable future states of affairs resulting from the R&I project, and can focus on a technology's future capabilities, applications, and societal context. Ethical impact analysis methods are used to systematically identify and describe the project's ethical impacts. Foresight methods are typically used before ethical impact analysis methods are used. However, this order is not strict, since both methods can inform one another.

EXAMPLE 1 Foresight methods may result in detailed descriptions of a particular technology's future capabilities, applications and societal context, which in turn may be subjected to ethical analysis; yet, ethical impact analysis methods may uncover hints of important potential ethical impacts that require further analysis using foresight methodology.

In the identification of ethical impacts, the EIA team maps the ethical principles, such as freedom, privacy or justice, against the potential impacts from the project, such as social, economic or environmental impacts. The EIA team identifies how these impacts may affect the ethical principles. The identification of potential ethical impacts should be done in significant detail.

EXAMPLE 2 Robots may replace many workers in the service sector in the next 20 years. Ethical impact identification correlates the potential economic impacts with ethical impacts, for instance, on well-being or justice.

The EIA team should balance the allocation of time and resources between foresight methods and ethical impact analysis methods. This balance can be determined by assessing the technology readiness level (TRL) of the project's expected outcomes. Technologies that are at an early stage of development have a low TRL and require greater relative emphasis on foresight methodology. Annex C offers additional information on how to determine the TRL for a project.

The foresight methods for ethical impact identification differ in their reliance on sources of knowledge: *evidence, expertise*, *interaction and creativity*. Methods can be classified based on their degree of reliance on expertise vs. interaction and on creativity vs. evidence. The EIA team should select a combination of methods that rely on different sources of knowledge in order to obtain the most accurate and widest range of analysis, thereby decreasing the chance that potential ethical impacts are missed.

The selection of foresight methods for ethical impact identification also depends on the scale of the EIA and are open to interpretation depending on the scientific discipline.

Table 2 provides and overview of different foresight ethical impact identification methods for the different EIA levels. Annex D provides additional information on foresight methods.

Table 2 — Overview of foresight methods for ethical impact identification, according to EIA scale

	Evidence	*Expertise*	*Interaction*	*Creativity*
Small-scale EIA	Horizon scanning	Expert consultation	Stakeholder consultation	
Medium-scale EIA	Horizon scanning; Trend analysis	Expert consultation	Stakeholder consultation; Brainstorming; Futures wheel	Roadmapping
Large-scale EIA	Horizon scanning; Trend analysis	Expert consultation; Delphi interviews	Stakeholder consultation; Brainstorming; Futures wheel; Citizen panels	Roadmapping; Scenario writing

NOTE The categories that refer to these methods may actually rely on more than one source of knowledge; the columns in the basis of table indicate the method predominant source of knowledge involved for each of the methods.

The ethical impact analysis methods analyse the identified potential ethical impacts. The EIA team should select methods and perform activities for ethical impact analysis.

This selection of methods and activities for ethical impact analysis depends on the scale of the EIA [5.2], type of analysis and the ethical issues of concern:

— ethical impact analysis methods can be differentiated by their focus on either conceptual analysis, which uses conceptual methods without external consultation, or by empirical analysis, for instance, by consulting experts;

— during ethical impact identification, the EIA team may identify two types of ethical issues:

  - explicit ethical issues, where the results of a project potentially violates a moral principle, value or norm;

  - intuitive ethical issues, where the results of a project have certain characteristics or implications that intuitively feel morally problematic or controversial, even though it is not immediately clear how and whether the option violates any ethical principle.

EXAMPLE The ethical impact identification may conclude that developments in robotics may result in violation of people's autonomy or privacy.

Table 3 provides an overview of ethical impact analysis methods, according to types of analysis and types of ethical issues. Annex E provides brief descriptions of these methods and specifies when they can be used.

Table 3 — Overview of ethical impact analysis methods

	Conceptual analysis	**Empirical analysis**
Explicit ethical issues	Ethical checklist approaches *(for small-scale EIAs);* Ethical theories *(for medium- and large-scale EIAs)*	Consultative approaches *(for all scales of EIAs)*
Intuitive ethical issues	Situational approaches *(for large-scale EIAs)*	Techno-ethical scenarios approach *(for large-scale EIAs)*

6.4 Document the identified ethical impacts

The EIA team should document the outcomes of ethical impact identification activities. The report typically has the following structure:

— Introduction;

— Description of methods used;

— Results of expert consultations and/or stakeholder engagement;

— Description of identified potential ethical impacts, short, medium and long term;

— Summary.

As the EIA progresses, the EIA team and stakeholders who participate may identify additional values and principles impacted by the proposed project or technology.

7 Ethical impact evaluation

7.1 Objective

In ethical impact evaluation, the EIA team should assess the relative importance, the likelihood of occurrence and the possible value conflicts of ethical impacts that have been determined in the ethical impact identification stage [6].

EXAMPLE In a proposed project on the Internet of Things (IoT), the ethical impact identification determined that behavioural profiling by IoT systems presents fairness and autonomy issues. In the evaluation, the assessor determines the threats, vulnerabilities and risks, advantages and disadvantages, the impacts on fairness and autonomy of these technologies, how privacy may conflict with other values in the use of IoT technologies, such as autonomy, security and well-being, and on what grounds such conflicts could and should be resolved.

7.2 Procedure

The ethical impact evaluation stage has the following steps:

— 1. Select the methods and perform the activities for ethical impact evaluation;

— 2. Assess whether and how ethical values and principles are threatened or benefitted;

— 3. Identify value conflicts and propose possible ways of resolving them;

— 4. Present and discuss the ethical impact evaluation with stakeholders.

7.3 Select methods and perform activities for ethical impact evaluation

The EIA team should select the methods and perform the activities for the ethical impact evaluation. The choice of these methods depends on the scale of the EIA. The methods can be distinguished in three types of inquiries:

— **Desk-research** forms the basis of all activities undertaken to conduct the ethical impact evaluation. These include literature reviews and reviews of existing evaluation of ethical impacts in related projects and the deployment of certain conceptual frameworks, for instance, when trying to resolve conflicts of values;

— **Expert consultation** calls for ethical expertise or expertise in other specific areas, such as field-specific expertise. Similar methods as those mentioned in the ethical impact identification stage can be selected, such as Delphi, interviews and workshops. The aim of the consultation is to help determine the relevant importance of identified ethical impacts and possibly to help balance them;

— **Participatory approaches** are preferred if the scale of the EIA and the available resources allow the selection. These focus on stakeholder engagement, for instance, in the form focus groups or citizen panels. The aim of the consultation is to help determine the relevant importance of identified ethical impacts and possibly to help balance them.

7.4 Assess whether and how ethical principles are threatened or benefitted

Using conceptual analysis and the application of ethical theories, the EIA team should clarify the ethical principles and values at stake in the identified ethical impacts and examine justifications for their significance and the manner and degree to which they should be respected.

EXAMPLE 1 Particular application in neuro-technology could seriously undermine the ethical principle of human autonomy. By arguing that autonomy is an essential value, we could conclude that this technology raises potentially significant ethical impacts.

To conduct this analysis, the EIA team could:

— review literature definitions of the respective ethical principle or value and ethical theories that introduce further distinctions and that provide moral justifications of the principle or value;

— apply ethical theories to the ethical impacts to further clarify the values and principles at issue, to provide justifications for their significance, and to recommend general courses of action for upholding them.

The EIA team should next assess the degree to which the ethical value or principle is likely to be violated or benefited in the expected ethical impact(s). This includes assessing the likelihood that the value or principle is violated or benefited in future scenarios, and the degree to which it is violated or benefited.

EXAMPLE 2 Authorized users could hack or access a centralized national registry of health data in unauthorized ways, which would violate people's medical privacy. An assessment can be done of the likelihood to which unauthorized access takes place, and the likely scope and scale of such unauthorized access and the potential risks to medical privacy that result.

7.5 Identify value conflicts and propose ways of resolving them

The EIA team should identify actual value conflicts. The EIA team should propose ways to resolve value conflicts that may occur when science and technology generate impacts. Based on the relative importance of the ethical impacts, the relationships between these ethical principles and values should be evaluated by identifying possible value conflicts and aiming to overcome them.

Rarely does a particular technological product or scientific application have impact on one value and is neutral to all the others. Normally, technological products and their use could support certain values or principles, while violating or harming others. An attempt to mitigate the violation of one principle may result in the violation of another principle. This creates a value conflict.

EXAMPLE 1 CCTV cameras are intended to provide security, but in doing so, they potentially violate privacy. Removing the cameras protects privacy, but runs the risk of compromising security.

Example: New technologies that allow parents to select the sex of their child give people more autonomy and choice, but could also threaten gender equality and support sex discrimination.

The EIA team can resort to rules of thumb that explicate the different types of procedures that can be used to identify and resolve value conflicts:

— **first rule of thumb:** fundamental values take precedence over non-fundamental values. Fundamental values are not reducible to other values and are important to uphold, considering public consensus;

EXAMPLE 2 In the West, fundamental values include the right to life, autonomy, freedom, dignity, justice, well-being, privacy, equality, security and bodily integrity.

- **procedure:** refer to fundamental values as they are discussed in ethical theories and/or are agreed upon in authoritative, widely accepted documents such as the law or declarations of human rights (e.g. the Charter of Fundamental Rights of the European Union);

— **second rule of thumb:** assess the degree of violation and choose the action that least compromises a fundamental value;

EXAMPLE 3 If the choice is between a mild violation of autonomy, in which informed consent is partially but not fully realized, and a large injustice, in which thousands of people are denied opportunities that others have, then based on the degree of violation, the fundamental value given priority is that which would be violated most. This kind of assessment requires an understanding of the circumstances in which the violations occur in order to assess the severity of violation.

- **procedure:** take into account the expected severity of the ethical impacts on the values at stake in this evaluation;

— **third rule of thumb**, project moral values into situations when two fundamental values seem to be equally violated to determine which value appears more important in the particular situation. State the reason(s) for giving priority;

EXAMPLE 4 In an airport, the value of security is generally thought to be more important than the value of privacy.

- **procedure:** construct an ethical argument, based on moral intuition, to favour one value over another;

— **fourth rule of thumb:** negotiate conflicts of moral values between different parties, who constitute or represent stakeholders in the situation;

- **procedure:** organize a stakeholder consultation and use stakeholder inputs for balancing the values at stake in a medium-scale or large-scale EIA;

— **fifth rule of thumb:** avoid the value conflict by reconfiguring the situation. It may be possible to avoid value conflicts by avoiding situations in which they occur;

- **procedure:** investigate to what extent alternative technological designs or research arrangements, or changes to the social, organisational and cultural context in which technology is used, can help avoid value conflicts.

EXAMPLE 5 CCTV cameras may violate privacy while providing enhanced security. However, a redesign of CCTV cameras may be possible in which personally identifiable information is automatically blocked from operators. Alternatively, strict regulations may be created for the storage and consultation of CCTV images that minimize privacy risks.

7.6 Present and discuss the ethical impact evaluation with stakeholders

The EIA team should document and communicate with stakeholders the outcomes of the impact evaluation activities, with a frequency agreed in the EIA plan. The EIA team should organize sessions in which the results are discussed with stakeholders and questions answered. Results of the ethical impact evaluation can optionally be published and presented to the public.

NOTE A knowledge repository with documents, either in full or in part, relevant for ethical impact evaluation, such as lists with ethical principles and human rights declarations and ethical impact evaluation reports, would be very useful for assessors in order to reduce the amount of time spend on activities such as desk review.

8 Remedial actions

8.1 Objective

Based on the results of the ethical impact evaluation [7], the EIA team formulates and makes recommendations to the project manager, which may include design interventions, to minimize or overcome the ethical impacts.

8.2 Procedure

The remedial action stage has the following steps:

— 1. Collect information about remedial actions proposed by other related R&I projects;

— 2. Formulate and implement design interventions;

— 3. Formulate recommendations at different levels;

— 4. Present the remedial actions.

8.3 Collect information about remedial actions

The EIA team should collect information on remedial actions proposed by related R&I projects. The list of ethical impacts in Table 4 guides the selection of the type of remedial actions:

Table 4 — Overview of remedial actions according to type of ethical impacts

Type of ethical impact	Type of remedial action
Ethical impact due to technology being developed in the R&I project (e.g. big data analytics)	Design interventions (medium-scale, large-scale EIA)
Broad social impacts due to R&I activities (e.g. changing economic paradigms)	Societal recommendations (all scales of EIA)
Impacts due to malfunctioning of organisations (e.g. risks of conflicts of interest)	Organisational recommendations (all scales of EIA)
Impacts due to regulatory or conventional deficiencies (e.g. risk of corruption)	Regulatory recommendations (medium-scale, large-scale EIA)
Impacts due to insufficient policy support (e.g. environmental risks)	Policy recommendations (medium-scale, large-scale EIA)

8.4 Formulate and implement design interventions

The EIA team should formulate and implement design interventions targeted at technical aspects of the project and innovation activity. Value-sensitive design interventions are those that resolve ethical impacts and follow the following three stages of investigations:

— **conceptual investigation** define the values that ought to be addressed for the technology and its context of use into workable concepts This stage can draw from the ethical impact evaluation;

— **empirical investigations** identify the interactions between humans and the expected project outputs using methods for empirical research, such as interviews, surveys and ethnographic methods. This stage can draw from stakeholder engagement exercises in the ethical impact identification [6];

— **technical investigations** formulate and implement design interventions. This stage can draw from the value conflicts identified in the evaluation stage [7.5]. The researchers alter the design to do justice to each value that ought to be inscribed in the technology.

8.5 Formulate recommendations

The EIA team should formulate recommendations on a broad scale:

— **societal recommendations** addressing impacts on societal values, public trust, public concerns. The research project team is responsible for implementation and engagement with other societal actors such as civil society organisations, media and other special interest groups;

— **organisational recommendations** addressing how an organization identifies, responds to, addresses, manages, avoids or minimizes ethical issues. The organization conducting the research or innovation activity is responsible for implementing the recommendations;

— **regulatory recommendations** offering guidance on how to meet legal and ethical obligations. The legislators and regulators are responsible for implementation;

— **policy and public policy recommendations** for decision-making authorities. Politicians and public authorities are responsible for addressing these recommendations.

8.6 Present the recommendations for remedial actions

The EIA team should present the recommendations for remedial actions. It should be clear to whom recommendations are directed. The remedial actions can be presented in different ways, according to the action type:

— **design interventions:** can be presented in the form of a report with the proposed design interventions and/or surveys for stakeholders. If a survey takes place before and after the design interventions, the effectiveness of the interventions can be assessed;

— **societal and organisational recommendations** are presented in the form of a simple report consisting of a short review, if possible, of societal and organization recommendations from other projects, complemented by the ones specific to the R&I project in which the EIA takes place;

— **regulatory recommendations** are presented in the form of legal proposals. Such proposals generally consist of (i) an explanation of the context and rationale of the proposed regulations, (ii) an explanation of how the proposed regulations fit in with the existing relevant regulatory framework, (iii) a presentation and explanation of the proposed regulations;

— **policy recommendations:** these are presented in the form of green- or whitepapers. Such papers generally consist of (i) an explanation of the purpose and context of the policy, (ii) the function of the policy, (iii) the procedures involved in its implementation and (iv) a roadmap for implementation.

9 Review and audit of the EIA

9.1 Objective

The review and audit stage of an EIA ensures independent evaluation of the EIA process and, if necessary, independent intervention. The review and audit stage:

— provides constructive feedback and guidelines for improving the the EIA process;

— guards agreed milestones and key performance indicators of the EIA process.

9.2 Procedure

The review and audit stage has the following steps:

— at the start of the EIA: set the key milestones and review criteria for the review and audit process;

— during the EIA process: evaluate the conduct and documentation of the EIA process;

— at the end of the EIA process: review the EIA process.

Review and audit procedures should be standardized to decrease their administrative burden, for instance, through an online entry system for presenting findings and uploading documentation.

9.3 Who performs the review and audit

The assessor for review and audit of the EIA depends on the funding source for the R&I project, the ethics assessment unit, the funding body or company responsible. The assessor performing the review and audit of an EIA and the person reviewing the EIA plan [5.3] could be the same.

Research-funding organisations should set up an independent body for conducting the review and audit of EIAs.

9.4 Review and audit criteria

Review criteria are usually framed in terms of the necessary documentation that shall be submitted to the auditor.

Audit criteria are usually framed in terms of the necessary minimum milestones or deliverables that need to be provided in order for the EIA process to be continued and funded.

EXAMPLE These criteria might include requirements for the presentation of EIA outcomes, such as reports or publications, or requirements for stakeholder engagement.

9.5 Intermediate review and audit

During the EIA, the assessor is responsible for documenting the EIA process and should organize:

— **Evaluation meetings:** The assessor should convene a meetings with the EIA team during which the EIA is evaluated, leading to feedback and recommendations for future EIA work;

— **Audit reports:** The assessor should provide the EIA team with audit reports, which state whether the agreed-upon milestones and/or deliverables have been met;

— **Review options:** The assessor should issue opinions about the continuation of the EIA. These opinions may be binding, for instance, in the case of a publicly-funded R&I project.

9.6 Final review and audit

The final review and audit typically includes the following activities:

— the assessor convenes a final review meeting with the EIA team to evaluate the EIA and document recommendations for future EIAs;

— the assessor writes a final review document, to be sent to the funding organization of the R&I project as well as to the relevant stakeholders;

— for medium-scale and large-scale EIA: the assessor conducts a short survey amongst the stakeholders who were involved in the EIA;

— the assessor makes a financial statement, with the cost of the EIA, and a portfolio of publications for the funding organization of the R&I project;

— the assessor convenes a final audit meeting with the EIA team at which leftover follow-up actions are agreed. These need to be performed in order to meet the audit criteria.

9.7 Presentation of the review and audit results

Depending on the different steps in the review and audit stage, the reviewer should present the results in the following ways:

— **At the start of the EIA:** The review and audit criteria are documented in the form of a contract that needs to be signed by both the assessor and the EIA team;

— **During the EIA:** Intermediate reviews and audits are presented as audit reports;

— **At the end of the EIA:** The review and audit at the end of the EIA process should be presented in the following way:

  - final EIA report, drafted by the EIA team;

- final review document, drafted by the assessor;
- financial statement;
- portfolio of reports and publications related to the EIA.

Annex A
(informative)

Ethical issues for the threshold analysis questionnaire

A.1 General

Annex A provides guidance in the selection of ethical impacts for the threshold analysis questionnaire.

A.2 Overview of ethical impacts

The relevant ethical impacts guide the construction of the threshold analysis questionnaire. The performer of the threshold analysis selects relevant ethical issues from the different types.

Three types of ethical impacts are the following:

— **impacts during research** concern research ethics, including the ethical impacts that the practice of research can have, such as harm to human subjects or scientific fraud. The impacts during research are usually taken into account during conventional ethics assessment procedures, and are therefore of less importance for the threshold analysis of the EIA;

— **impacts from technologies (innovation)** concern new or emerging technologies that result from R&I projects. This category consists of impacts due to:

  - issues related to human healthcare;
  - genetic modifications;
  - safety risks;
  - collection/processing of personal data;
  - accessibility restrictions;
  - interference with the environment;
  - targeting of vulnerable groups;
  - modification of distribution of means;
  - dual use.

— **impacts from research outcomes** concern with the research outcomes of projects that can have real life impacts. For example, climate models can have a strong impact on energy policies; new findings in the field of social psychology can have strong impacts on the value systems of certain cultures. This third category of impacts can be divided into the following sub-categories of impacts due to:

  - unpredictability of scientific models;
  - misuse or misrepresentation of cultural heritage;

- restriction of free speech and freedom of opinion;
- violation of intellectual property rights.

NOTE The impacts to be taken into account in an EIA are impacts of R&I. These impacts can occur despite *the researchers adhering to the ethical codes of conduct.* For instance, even though a nuclear researcher sticks to the professional ethical code, presents the research results honestly and limits harm to the animals used in the experiments, the *outcomes and applications* of the research nonetheless might have ethical impacts.

A.3 Design and complete the threshold analysis questionnaire

The following criteria should apply to any questionnaire for an EIA threshold analysis. Questionnaires should:

— **be guided by the concept of reasonable expectation***:* Questions should be aimed at asking about concrete aspects of the R&I project;

— **be as short and simple as possible, while still being comprehensive:** Since a threshold analysis is part of the overall process of writing an R&I project proposal and should not unnecessarily burden this process, its questions should be short and simple to complete;

— **leave room for free interpretation***:* Certain types of ethical impacts should be specifically mentioned in the questionnaire, in order to make it as inclusive as possible. However, in order to account for ethical impacts that arise with the development of innovations and emerging technologies, the questionnaire should also leave room for open-ended questions.

Annex B
(informative)

Technology-scale ethical impact assessment

A technology-scale ethical impact assessment (EIA) is a type of EIA in addition to the regular (small-, medium- and large-scale) types. A technology-scale EIA is relevant when a new technological paradigm calls for a dedicated EIA that is not tied to a specific research project.

A technology-scale EIA will accompany developments in research and innovation that set the stage for a new scientific or technological paradigm that does not belong to a single project but can apply to a great variety of R&I projects in different fields. An example of such a situation has been the paradigm of nano-research that has instigated a separate discussion about the ethical impacts of any technological application at the nano-scale. Technology-scale EIAs are set up in such a way that they can inform the individual EIAs of projects that incorporate the novel type of R&I.

For the above-mentioned reasons, in contrast to the other types of EIAs, the initiation of a technology-scale EIA does not lie in the range of responsibilities of R&I projects but rather, it follows on from more general observations made by policy or standard-setting bodies. For instance, if an academy of sciences observes that there is the need for ethical assessment of a new technological paradigm across a scientific field, such as the nano-technologies paradigm, it might initiate a technology-scale EIA.

Organisations that are likely to be initiators of technology-scale EIAs include:

- national ethics committees;
- funding organisations;
- science academies;
- standards-setting bodies.

A technology-scale EIA follows the same procedure as full-scale EIAs, with the following differences:

- a technology-scale EIA should be carried out by a dedicated team not tied to a specific R&I research project;
- a technology-scale EIA should include the following activities that are not necessarily part of a full-scale EIA:
    - development of new conceptual frameworks to deal with the new technological paradigm;
    - development of new methodological frameworks to deal with the new technological paradigm;
    - recommendations for, and potentially development of, policy and law for dealing with new technological paradigms.

Annex C
(informative)

Technology readiness level (TRL) methodology

The Technology Readiness Level (TRL) refers to the technology readiness of outcomes from an R&I project.

In a TRL assessment, the EIA team should use the prospective outcomes of its research activities as the input for determining the TRL level. In some instances, the funding organization sets the TRL that proposals are expected to meet.

EXAMPLE An R&I project that aims at developing a demonstrator application for smart grid technologies probably ends up as TRL 6 or 7. However, a nano-technology R&I project that investigates the topology of certain materials would probably end up with a TRL based at levels 1, 2 or 3.

Table C.1 stipulates nine distinct levels for conducting a TRL assessment:

Table C.1 — Technology Readiness Levels (TRLs)

TRL level	Criterion
TRL 1	Basic principles observed
TRL 2	Technology concept formulated
TRL 3	Experimental proof of concept
TRL 4	Technology validated in lab
TRL 5	Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)
TRL 6	Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)
TRL 7	System prototype demonstration in operational environment
TRL 8	System complete and qualified
TRL 9	Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)
NOTE Source: European Commission Decision C (2014)4995, 22 July 2014; General Annexes	

Technologies that are at an early stage of development have a low TRL and bring with them a high level of uncertainty regarding their potential future ethical impacts, and thus require greater relative emphasis on foresight methodology. Technologies that have a high TRL, on the other hand, generally offer more certainty in terms of their potential impacts and therefore more attention will be paid to ethical impact analysis methods.

Annex D
(informative)

Foresight methods

D.1 General

The methods for ethical impact identification differ in the scale of EIA and in their reliance on sources of knowledge: evidence, expertise, interaction and creativity. Any selection of foresight methods used for ethical impact identification should ideally combine different sources of knowledge in order to decrease the chance of missing potential ethical impacts.

Expertise-based methods, such as *Delphi* or expert consultation, such as consultation of technologists or civil society organisations, are helpful in determining the most likely futures. Creativity-based methods, such as wildcard workshops and scenario writing, are useful in identifying low-chance, high-impact events that may challenge the occurrence of the most likely future scenarios. Interaction-based methods, such as expert-, stakeholder- and citizen panels, offer benefits by bringing together different experts and non-experts and enabling them to exchange views, form consensus opinions, and improve one another's understanding of future events. Evidence-based methods, such as a literature review and trend analysis, are helpful in understanding the factual state of development of a particular technology or field of research, as well as its developmental constraints.

The sections of this annex offer descriptions of a number of key foresight methods that may be useful at different EIA scales.

D.2 Foresight methods for small-scale EIAs

Small-scale ethical impact assessments could focus on one or two foresight activities. The most obvious choice would be horizon-scanning and expert consultation:

— **exploration of existing work – horizon scanning (evidence-based):** Analysis of existing ethical impact identification and assessment studies in the field of the R&I project or in related fields can be performed through structured literature review or bibliometric analysis. Horizon-scanning is a suitable approach for exploring existing work.

  Horizon-scanning clarifies the big picture behind the issues to be examined. It primarily involves desk research with and information from a variety of sources, such as the Internet, research communities, databases, journals, newspapers, magazines, government agencies, non-governmental organisations, international organisations and companies. A small group of experts, at the forefront in the area of concern, could engage in horizon-scanning by sharing their perspectives and knowledge among themselves. A horizon scan can provide a background for strategic planning and decision-making;

— **expert consultation (predominantly evidence based):** Expert consultation is a basic method for stakeholder engagement in EIA. The EIA assessor or his team could consult a range of different experts, each having a different expertise and perspective on specific ethical issues. An expert consultation can take the form of interviews, a workshop or a survey.

D.3 Foresight methods for medium-scale EIAs

In medium-scale EIAs, the methods are more resource-intensive and time-consuming, yet rewarding, such as trend analysis, stakeholder brainstorming and roadmapping.

Some form of stakeholder involvement, including citizen engagement or participation, may be important in the foresight analyses of medium- and large-scale EIAs to identify stakeholder ideas and concerns about the future and to establish the legitimacy of the foresight process. In medium-scale EIAs, the assessor should used various foresight techniques in addition to the methods listed for small-scale EIAs:

— **trend analysis (predominantly evidence-based)** is the practice of collecting historical information on similar R&I projects, and the field to which they belong, attempting to find patterns from which one might predict the outcomes of the R&I project and its future consequences;

— **stakeholder brainstorming/futures wheel (predominantly interaction-based)** discusses specific aspects of the R&I project with stakeholders. The futures wheel is a tool for organizing thinking and questioning about the future. The futures wheel produces a graphical visualization of all the direct and indirect future consequences of a particular development in the R&I project;

— **roadmapping (predominantly creativity based)** is a plan that matches short-term and long-term goals of an R&I project with specific solutions to help meet those goals. Roadmapping consists of collecting, synthesizing and validating information about the expected and preferred R&I outcomes and detailing a trend line towards reaching the goals. Roadmapping has three major uses: (1) it helps reach a consensus about a set of needs and the R&I developments that are required to satisfy those needs; (2) it provides a mechanism to help foresee R&I developments; and (3) it provides a framework to help plan and coordinate R&I developments.

D.4 Foresight methods for large-scale EIAs

In large-scale EIAs, the methods for ethical impact identification are organisationally more difficult and time-consuming but offer high-quality information:

— **Delphi interviews (expertise based):** The Delphi survey technique involves multiple rounds of interviews, using questionnaires, with the same individuals, usually experts in a particular field and feeding back anonymised responses from earlier rounds to all participants. The underpinning concept is that this feedback loop will allow for better judgements to be made without there being undue influence from forceful or high-status advocates. There are three phases to conducting a Delphi: (1) selecting the topic, (2) designing the questionnaire, and (3) selecting the panel of experts;

— **citizen panels (predominantly interaction based):** Citizen panels collect input from important societal stakeholders. Panel discussions may take place during conferences, workshops or trainings at which stakeholders are invited to participate. The outcomes of citizen panels take the form of written feedback on the R&I project set-up, minutes of the meeting, or a collaborative report in which probable or preferable impacts of the R&I project are discussed and evaluated by the participating stakeholders;

— **scenario-writing (predominantly creativity-based):** Scenarios are like stories built around carefully constructed plots based on selected trends and events. They offer rich and detailed portraits of different plausible future worlds, such that one can clearly see and comprehend the problems, challenges and opportunities within them. Scenarios are often used in the design and selection of strategies, and are intended to make people aware of uncertainties, to open up their imaginations in terms of possible alternative futures, and to initiate learning processes. Scenarios are one of the most popular and persuasive foresight methods.

Annex E
(informative)

Methods for ethical impact analysis

E.1 General

The methods for ethical impact analysis differ in the type of analysis, level of EIA and type of moral issues.

E.2 Ethical impact conceptual analysis

Conceptual investigation can make use of the following methods:

— **Method(s) focusing on explicit moral issues**:

- **Ethical checklist approaches**, for small-scale EIAs, offer practical ways to systematically identify the ethical impacts of an R&I project. In these approaches, comprehensive lists of widely accepted and documented ethical principles or values are cross-referenced with the technology's future capabilities and applications (as identified during, for example, a foresight analysis). The ethical checklist ensures that all relevant values or principles are being considered in the ethical impact identification stage. The ethical checklist does not allow identification of intuitive ethical issues and issues based on (future) ethical principles that are not yet recognized;

- **Ethical theories**, for medium-scale and large-scale EIAs, offer more in-depth ways to identify and describe the ethical impacts of the R&I project. Well-known ethical theories are consequentialism, deontological ethics and virtue ethics. Other approaches, such as care ethics or value ethics, might be used, depending on the field of research in question;

— **Method(s) focusing on intuitive moral issues:**

- **Situational approaches**, for large-scale EIAs, do not involve the use of well-known ethical theories of lists of accepted moral principles or values. Rather the approaches screen the research and innovation options by drawing on moral intuitions. The situational approach leads to a collection of technological options that may be morally problematic from an intuitive point of view.

E.3 Ethical impact empirical analysis

— **Method(s) focusing on explicit moral values:**

- **consultative approaches,** for small-, medium-, and large-scale EIAs, are approaches in which the EIA team reviews previous ethical analyses (and possibly other analyses that may contain ethical observations, such as policy analyses) or interviews experts to collect their opinions and evidence on potential ethical issues. These approaches can often be used at the very beginning of the ethical impact identification stage;

— **Method focusing on intuitive moral issues:**

- **techno-ethical scenarios approach**, for large-scale EIAs, is about constructing descriptive narratives (scenarios) about the way a technological innovation could impact society. Rather than through independent ethical analysis, it identifies ethical issues primarily through the analysis of public moral controversies. For this, it uses the ethics of new and emerging science and technology (NEST) approach, which analyses expectations of the technology, critical objections to the technology, and patterns of arguments among stakeholders.

Bibliography

Brey, Philip, Wessel Reijers, Philip Jansen, Rowena Rodrigues, David Wright, Raija Koivisto, Anu Tuominen, Lise Bitsch, SATORI WP4 report *A reasoned proposal for Ethical Impact Assessment*, 2016

EEROLA A., JØRGENSEN B.H. *Technology Foresight in the Nordic Countries*. Risø National Laboratory, Roskilde, 2002

EURESEARCH. *Horizon 2020 – How to Budget My Project Costs*. 2014

European Commission. *Ethics Issues Table – Checklist*. 2014

EUROPEAN COMMISSION. *Impact assessment guidelines*. 2009. http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

EUROPEAN COMMISSION. *Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects.* 2012. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf

European Parliament and the Council. *Regulation (EU) No 2014/536 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*

European Parliament and the Council. *Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)*

European Parliament and of the Council. *Regulation (EU) 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*

FRIEDMAN B., KAHN P.H., BORNING A. Value Sensitive Design and Information Systems. In: *Human-Computer Interaction and Management Information Systems: Foundations*, (HIMMA K.E., TAVANI H.T., eds.). John Wiley & Sons, Inc, 2006., http://doi.org/10.1145/242485.242493

Global foresight – glossary, http://www.globalforesight.org/glossary, 2016

VAN DER HELM R. The vision phenomenon: towards a theoretical underpinning of visions of the future and the process of envisioning. *Futures*. 2009, **41** (2)

JACKSON M. *Practical Foresight Guide*. Chapter 11. Foresight Glossary. Shaping Tomorrow, 2013., http://www.shapingtomorrow.com/media-centre/df-ch11.pdf

OWEN R., MACNAGHTAN P., STILGOE J. Responsible research and innovation: From science in society to science for society, with society. *Sci. Public Policy*. 2012, **39** (6)

WRIGHT D. Ethical Impact Assessment. In: *Ethics, Science, Technology and Engineering: A Global Resource*, (HOLBROOK J.B., MITCHAM C., eds.). Macmillan Reference, Farmington Hills: Second Edition, 2015