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European foreword

This CEN Workshop Agreement (CWA) has been drafted and approved by a Workshop of representatives of interested parties on 22 May 2017, the constitution of which was supported by CEN following the public call for participation made on 1 August 2015.

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

The formal process followed by the Workshop in the development of the CEN 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 the CEN Workshop Agreement or possible conflict 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.

The final review round for this CWA was started on 15 September 2016 and was successfully closed on 30 November 2016.The final text of this CWA was submitted to CEN for publication on (date).

This CEN Workshop Agreement is publicly available as a reference document from the National Members of The following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN-CENELEC Management Centre.

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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 harmonising 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.

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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 harmonise 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

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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.

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[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]

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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

2.19
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.

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2.20
research
form of systematic inquiry that aims to contribute to a body of knowledge or theory

2.21
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]

2.22
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.

2.23
scenario
predicted sequence of events that might possibly occur in the future

[SOURCE: Jackson, Practical Foresight Guide, 2013]

2.24
scenario planning
strategic planning method that e.g. organisations use to make flexible long-term plans.

[SOURCE: Jackson, Practical Foresight Guide, 2013]

2.25
social responsibility
principle for raising awareness of the societal impacts of research and innovation, including taking appropriate remedial actions if deemed necessary

2.26
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.

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2.27
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.
http://www.earto.eu/fileadmin/content/03_Publications/The_TRL_Scale_as_a_R_I_Policy_Tool_-_EARTO_Recommendations_-_Final.pdf

2.28
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]

2.29
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]

2.30
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]

2.31
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]

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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.

The EIA framework consists of the following steps:

— 1. conduct an EIA threshold analysis [chapter 4];

— 2. prepare an EIA plan if the threshold analysis concludes that ethical issues are involved [chapter 5];

— 3. identify ethical impacts [chapter 6];

— 4. evaluate the ethical impacts [chapter 7];

— 5. formulate and implement remedial actions [chapter 8];

— 6. review and audit the EIA [chapter 9].

Figure 1 provides a graphic presentation of the ethical impact assessment framework.

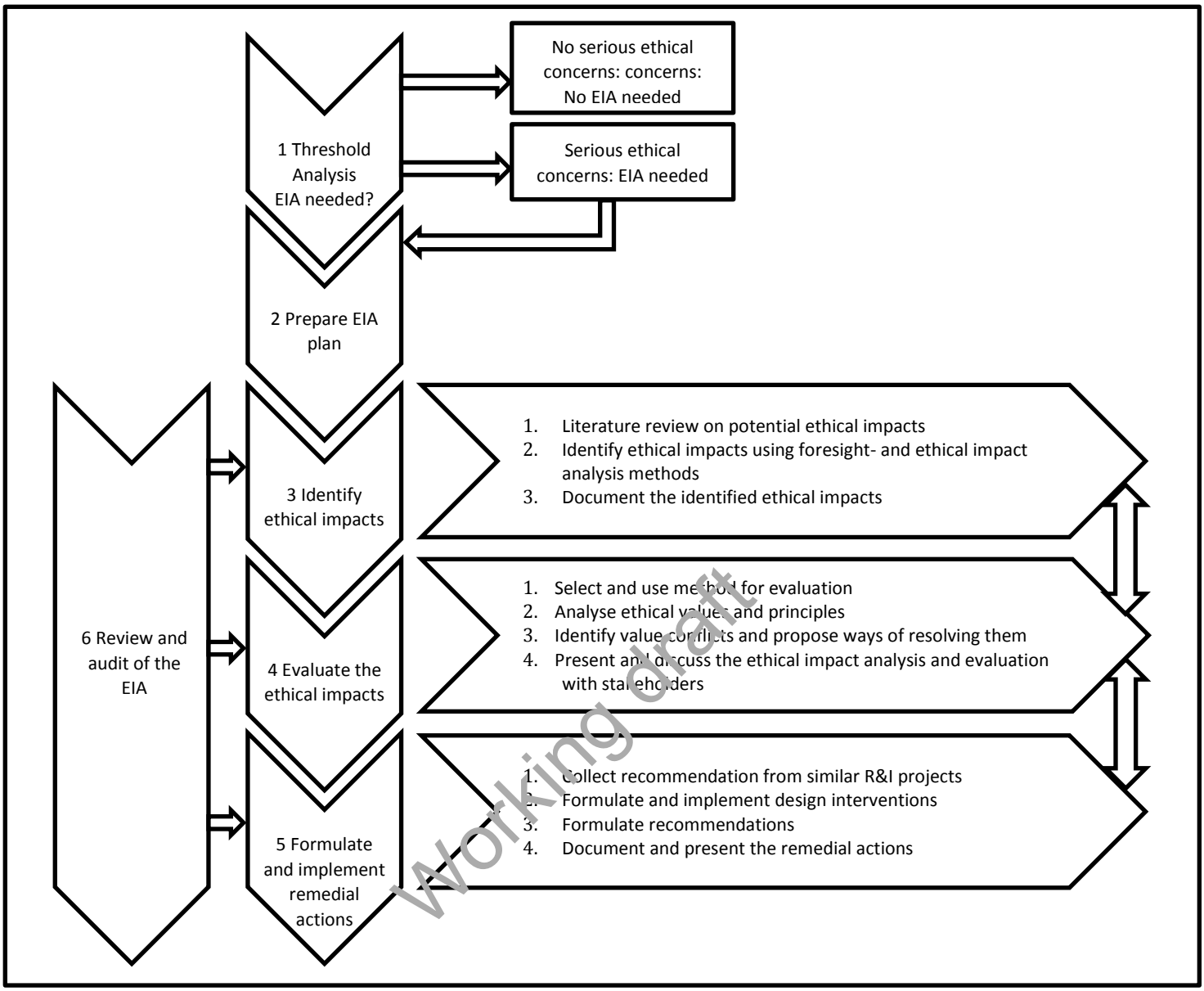

Figure 1 — Graphical presentation of the ethical impact assessment framework

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 organisation 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 organisation 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.

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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 is collected relating to health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.)*						
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.)*	
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.)*	

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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.

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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 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 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.

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5.3 Review and approval of the EIA plan

5.3.1 Who reviews and approves the EIA plan

Who reviews the EIA plan depends on the funding source and could be:

— **An ethics committee** in case a public research institution, such as a university, funds the project;

— **A funding body** in case a research-funding organisation funds, or partly funds, an R&I project;

— **A responsible entity in a company** in case a commercial entity funds an R&I project. An internal department, company association or consultant could review the EIA plan.

NOTE Research funding organisations should 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 organisation.

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.

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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 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 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.

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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], 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)*

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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.

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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 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 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.

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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 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 **I**n 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 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 **I**n 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:** organise 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 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.

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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 organise 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)

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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 organisation identifies, responds to, addresses, manages, avoids or minimises ethical issues. The organisation 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.

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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 organisation 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 standardised to decrease their administrative burden, for instance, through an online entry system for presenting findings and uploading documentation.

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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.

NOTE 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 organise:

— **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 organisation 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 organisation 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.

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Annex A
(informative)

Ethical issues for the threshold analysis questionnaire

Annex A provides guidance in the selection of ethical impacts for the threshold analysis questionnaire.

A.1 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.

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A.2 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.

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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.

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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 organisation 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 5 stipulates nine distinct levels for conducting a TRL assessment:

Table 55 — 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

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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

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.

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D.1 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 short workshop or a small survey.

D.2 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 organising thinking and questioning about the future. The futures wheel produces a graphical visualisation 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, synthesising 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.3 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.

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Annex E
(informative)

Methods for ethical impact analysis

The methods for ethical impact analysis differ in the type of analysis, level of EIA and type of moral issues.

E.1 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.

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E.2 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.

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