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Contents

European foreword

Introduction

The increasing pace of technological developments such as genetic technologies, geo-engineering, ICT and synthetic biology has been raising questions and discussion on the desirability and governance of the 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 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 of 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 to harmonize and improve ethics assessment practices of research and innovation.

Some of the SATORI project reports have been further developed into a CEN Workshop Agreement (CWA) on Ethics assessment for research and innovation. This CWA consists of two parts.

Part 1, outlines here, sets recommendations for the composition, role, functioning and procedures of an Ethics Assessment Unit. Organisations can use part 1 to strengthen and/or improve the ethics assessment of their research and innovation projects. Ethics Assessment Units 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 Assessment Units, regardless of their size scope or research and innovation area.

Part 2 provides researchers with guidance on ethical impact assessment. Ethics assessors and ethics assessment units will find this information useful as it describes ethical impact assessment in different stages of the ethical assessment. Part 2 is applicable to all researchers, regardless of the context they are working in or 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 has two parts:

— part 1: Ethics assessment units. This part provides recommendations for the ethics assessment units on practices and procedures;

— part 2: Ethical impact assessment framework. Part 2 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, 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 for respecting cultural diversity and pluralism, recruiting participants who are representative of the general population and using double-blind research methods where possible

2.2
avoidance of harm to human subjects
principle for minimizing the potential harms to research subjects as much as possible if the risk of harm is unavoidable with a main goal of reducing unnecessary suffering

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

2.3
beneficence
principle for acting to the benefit of society: 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 involved

[SOURCE: revised from SATORI project Deliverable 4 and Beauchamp and Childress, Principles of Biomedical Ethics, 2001]

2.4
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

Note to entry: 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.

[SOURCE: adapted from Shamoo and Resnik, 2003.]

2.5
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

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

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

2.6
ethical impact
impact that concerns or affects human rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good

2.7
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 translationing to a set of guidelines or recommendations for remedial actions aiming at mitigating ethical risks and enhancing ethical benefits, typically in consultation with stakeholders

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

[SOURCE: adapted from Wright, D. A framework for the ethical impact assessment of information technology]

2.8
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 to entry The EC perceives 'ethics' as including questions of legal and regulatory compliance as well as a branch of philosophy in European Commission. Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects.

[SOURCE: Oxford English Dictionary]

2.9
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: SATORI D1.1, 2015]

2.10
ethics assessment unit
institution or committee that performs 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]

2.11
ethical issues
issues that may be relevant for evaluating the ethical implications of maxims, principles, or particular courses of action

2.12
ethical principles
general principles that may be relevant for making ethical evaluations

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

2.13
honesty
principle for honestly reporting research practices and findings, for accurately reporting data in scientific communications and for acting in an honest fashion

2.14
human participants
subjects including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and foetuses, human tissue and bodily fluids, and human data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements)

[SOURCE: ESRC 2012, Framework for research ethics]

2.15
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.

2.16
informed consent
decision, 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

Note 1 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.

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 believed to create added value for society

[SOURCE: SATORI, D 1.1, p 17]

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

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

[SOURCE: Adapted from: Rawls, J. A theory of Justice. Harvard University Press. 1971]

2.19
lay person
person without affiliation to the research organisation apart from membership of the ethics assessment unit.

Note to entry This term is used in reference to a member of an ethics assessment unit.

2.20
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.

[SOURCE: Beauchamp, Tom L. and James F. Childress, Principles of Biomedical Ethics]

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

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: General Data Protection Regulation]

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

2.24
professionalism/respect for colleagues
principle for respecting fellow researchers and treating them fairly, rejecting discrimination, assisting to educate and mentor junior researchers, giving proper credit for conducted research and upholding the standards of the profession

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 for 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, for making provisions for the needs of vulnerable cultures, including those who cannot consent on their own behalf and to recognise the practices of traditional communities and knowledge and the avoiding their exploitation

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

Note 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 disciplined 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 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.

2.31
research practice
dimension in ethics assessment concerning how experiments are performed

EXAMPLE Which research subjects are involved.

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

2.33
respect for human subjects
principle for obtaining informed consent from human participants, minimizing 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 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 society

2.35
responsible treatment of cultural heritage
principle for 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 recognising the shared aspects within human diversity and culture

[SOURCE: adapted from UNESCO. Cultural heritage]

2.36
roadmapping
vision driven tool for presenting the path from the current state to the desired future state. It provides a graphical presentation 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.

2.37
safety
ethical principle for avoiding injury or other harm

2.38
scientific freedom
principle for freedom of thought and inquiry, not subject to political or institutional interference

2.39
scientific integrity
principle for careful and honest presentation of data, universalism and disinterestedness and giving proper credit to those who carried out the research

2.40
social responsibility
principle for raising awareness of the societal impacts of the research and innovation, including taking appropriate remediate actions if deemed necessary

2.41
stewardship
principle for wisely using resources, whether they are human, technological, or natural and the care taking of research sites, artefacts and collected samples

2.42
sustainability
principle for responsibility for care and use of natural resources, restoration of the ecology when damaged and responsibility for waste management

2.43
transparency
full, accurate, and open disclosure of relevant information

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

3 Ethics assessment unit

3.1 Role and responsibilities

The objective of an ethics assessment unit (EAU) is to assess, evaluate, review, appraise or valuate practices, products and uses of research and innovation that makes use of primarily ethical principles or criteria.

The EAU should determine its scope of operation. The scope of operation includes:

— 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;

— objects of assessment;

EXAMPLE The objects for assessment can be, but is 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.

The EAU should monitor and review the scope of its operation by considering stakeholders' interests and opinions.

An EAU might be part of a larger organisation 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 its decision-making, and independent of the researchers and institutions involved. Its work should be fair and unbiased.

EAUs associated with industry should take into account the corporate social responsibility goals of the industry and the research's potential impact to the business goals of the company. This consideration should not compromise the EAU's judgement and 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 and international laws, and accepted international guidelines on research ethics. Having members of the EAU with training and experience in applied ethics can assist in identifying and addressing cultural factors that might affect how the general community perceives the research.

3.2 Competencies

The EAU should determine the necessary competences of its membership. Members should be *competent* (technically, ethically, and administratively), *independent* of the researchers and the institutions involved, *diverse* in backgrounds and expertise, and *representative* of the communities affected by its decisions.

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

The EAU 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.

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

3.3 Appointment of the EAU and its members

Legal requirements must take precedence over other considerations in the organisation and operation of an EAU.

The processes by which EAU members are appointed and membership is renewed should be transparent and fair. The appointment process should establish the authority, independency and credibility of the EAU. It is recommended that:

— the chief executive of the organisation containing the EAU should appoint the EAU chairperson.

NOTE If the EAU is only responsible for reviewing the R&I activity of a specific branch of an organisation, such as a faculty within a university, the chief executive of that branch should be responsible for appointing the EAU members.

— the chief executive, based on recommendations made by that organisation's research administrators, may also appoint the other members.

— the EAU chairperson should be able to appoint temporary members with specific expertise if she believes that additional expertise is necessary to fairly assess particular R&I activity.

NOTE The chairperson may select the temporary members in consultation with the EAU's supervisor. Temporary members may be treated as advisors to the EAU who present their informed opinion of the activity under review, or as temporary members who participate in the EAU's full decision-making process.

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.

Managing possible conflicts of interests to preserve the independence of the ethics review process is necessary. As such, any potential EAU 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 responsibilities established by their appointment.

3.4 Composition

Members of an EAU should be able to recognise the ethical concerns raised by R&I activity during its planning, development and application. Its 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 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.

NOTE While appointing members belonging to the same organisation may reduce the appearance of the EAU's independence, this may be countered by appointing sufficient non-affiliated members, such as lay persons and outside experts, to provide balance.

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

The EAU should at least include one of each of the following expertise and or background:

- scientific or technical expertise preferably both expertise related to the field being reviewed and outside;
- lay person, end user, or representative of the end user organisation, for example patients or the elderly. Lay persons should be permitted to serve as an EAU member for a limited time so that such persons continue to provide an 'outside' perspective on research;
- 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 or affected by the research.

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 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.

The composition of the EAU should be a well-balanced representation of each of the above mentioned categories. Lay persons should be sufficient in number to ensure that their views cannot be ignored by members with directly relevant expertise.

Each EAU 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;
- communication skills;
- ability to evaluate the benefits, risks, and burdens of the specific research projects being assessed;
- ability to engage in reasoned debate and discussion to reach and accept a balanced view of the research projects assessed;
- personal commitment to the goals of ethics assessment;
- ability to cooperate in a group;
- no apparent and or potential conflicts of interests;

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

4 Ethical issues and principles

The EAU should determine and maintain the ethical issues and principles for consideration. There are basic ethical issues and principles that are applicable to all types of research regardless of the research field. In addition to the basic ethical issues and principles, the ethics assessment unit should determine and maintain field specific ethical issues and principles relevant to the scope of ethics assessment.

Basic ethical principles follow three dimensions:

— **Professional Principles and Codes of Conduct**: certain ethical issues and principles specifically concern the working context of the researcher; e.g. the research practice and the way (s)he treats his or her colleagues.

NOTE Assessment of code of conduct is not the responsibility of the ethics assessment unit.

— **Research Assessment and Practice**: certain ethical issues and principles specifically concern the context of the research: depending on how experiments are performed, which research subjects are involved, etc.

— **Impacts of the Research and Innovation**: certain ethical issues and principles specifically concern the (future) impacts of the research that is done; for instance environmental consequences of technological innovations resulting from research in the chemical sciences.

Annex A provides an overview of basic ethical principles.

In addition to the basic ethical principles the ethics assessment unit should determine and maintain field specific ethical principles relevant to the scope of ethics assessment:

— **technological innovations** typically include the following field specific ethical principles: awareness of dual use, precaution and justice;

— **research involving potential environmental risks** typically includes the following field specific ethical principles: safety, social responsibility, sustainability;

— **research involving aspects of human culture** typically includes the following ethical principles: respect for biodiversity and cultural diversity, responsible treatment of cultural heritage and protection and preservation of communities;

— **research involving human subjects or data analysis** typically includes the following field specific ethical principles: respect for human subjects, privacy, avoidance of harm to human subjects, avoidance of bias and protection of the vulnerable;

— **research involving animals** typically includes the following field specific ethical principles: respectful treatment of animals in experiments, care for animal research subjects and avoidance of harm to animals;

— **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.

Annex B provides an overview of field specific principles.

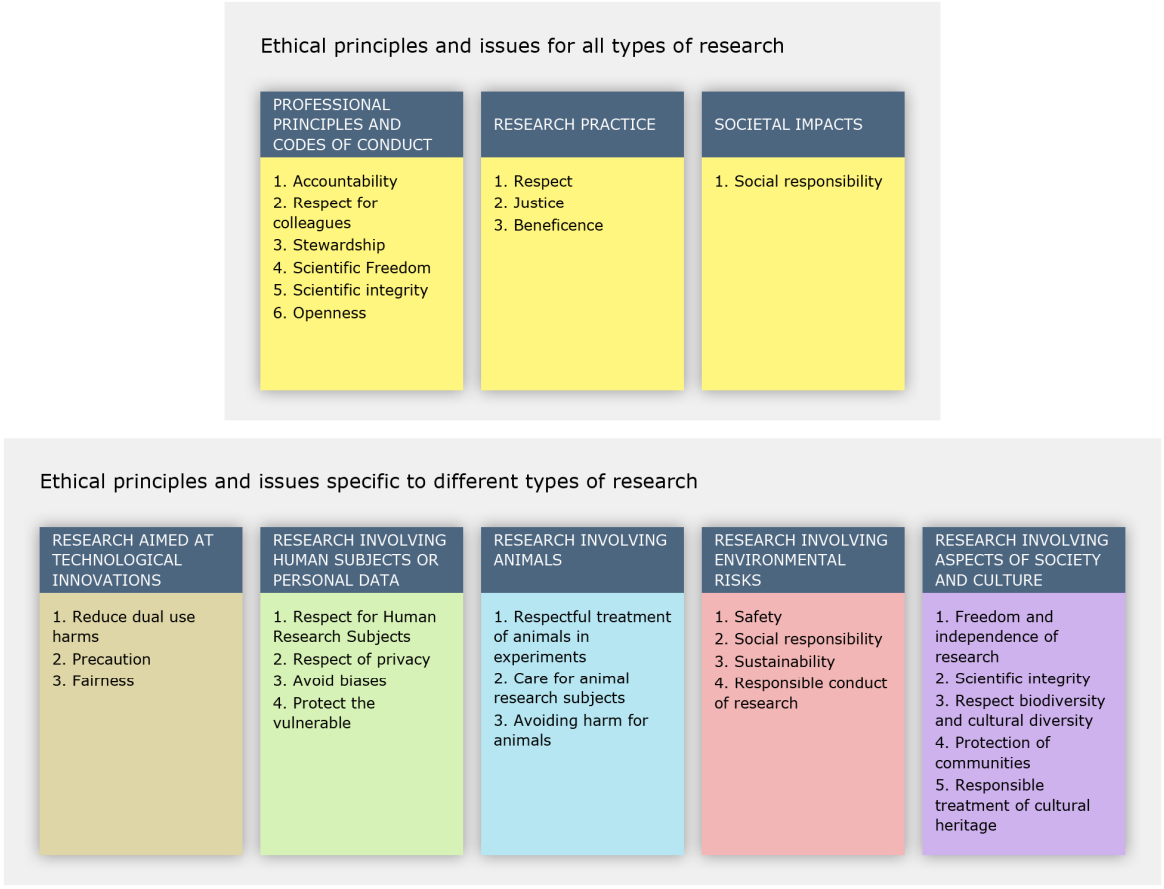

Figure 1 — Framework of ethical principles and issues in research

The ethical principles as mentioned in figure 1 can be used as a benchmark for setting the *minimum* requirements for ethical issues and principles. Additional principles and issues might be added.

The determination of ethical issues and principles typically is:

— based on a global discussion among a variety of stakeholders;

— 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 on scientific integrity.

The EAU should resolve conflicts between ethical principles with arguments referencing to more basic ethical views such as maximising utility (utilitarianism) and respecting individual rights (libertarianism). Additional arguments may entail right-based and consequential considerations. Annex C provides information on moral decision making and resolving a conflict between ethical principles.

5 Procedures for ethics assessment

5.1 General

The EAU 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 assessment unit should have the mandate to select topics and issues the ethics assessment unit itself finds pressing.

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 research) from undue risk and harm;

— determine if the research or innovation methods are appropriate;

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

In shaping their procedures the EAU should consider available good practices, operating procedures and voluntary harmonisation procedures at national and international levels. Operating procedures include both general and field specific procedures.

EXAMPLE Several European Institutes have published good practices on ethics assessment procedures. Examples are Economic and Social Research Council (ESRC), Framework for research ethics 2015; Association or 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's requirement of an ethics-ready proposal 2014.

The procedures typically include:

— procedures prior to assessment. The procedure prior to assessment typically includes a self assessment by the researcher or applicant;

— procedures during assessment;

— procedures after assessment. The procedures after assessment typically include procedures for dissemination, appeal and follow up for an ongoing research.

The ethics assessment unit should determine, implement and maintain the criteria and conditions when 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 EAU should also keep the applicants informed about the progress of the assessment.

5.2 Procedures prior to assessment

Recommendations for procedures prior to assessment are:

— **use of a standard applications form** with 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 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 an aim of ethics review.

— **use of pre-assessment**: Pre-assessment, or screening, deals with the question whether the ethical issues have been addressed. One or two persons from the EAU 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;
- suggestion, with argument, for a decision.

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

5.3 Procedures during assessment

Recommendations for procedures during assessment are:

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

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

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

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

NOTE Information on Chatham house rule in https://www.chathamhouse.org/about/chatham-house-rule.

5.4 Procedures after assessment

Recommendations for procedures after assessment are:

— the decisions of the EAU should be recorded for internal access and for external reference if required by legislation or auditing;

— the EAU should provide the applicant with a written assessment. The decision may vary:

  — In case of obligatory assessments the EAU should:

  - approve the R&I activity;
  - call for amendments: There should be a dialogue between the EAU and the submitter regarding the ethical issues and how to deal with them;
  - reject the proposal and halt the R&I activity.

  — In case of non-obligatory assessments the EAU should recommend that the R&I activity should either proceed, be revised, or halted.

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

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

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

  NOTE Non-compliance seriously can affect the reputation of the organisation.

6 Quality assurance in ethics assessment

Quality assurance of 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 practices and tailor ethical policies and procedures to meet different requirements, e.g. in relation to different scientific fields.

The ethics assessment unit should self-evaluate the suitability, adequacy and effectiveness of their ethics assessment policies and procedures on a defined, regular basis. The evaluation should include views of relevant stakeholders. Third party evaluation and accreditation are recommended to demonstrate the quality of the EAU's work.

EAUs should be supervised by a high administrative or managerial level of the organisation within which they operate. The supervision of EAUs should not compromise their ability to be independent in their decision-making.

The ethics assessment unit 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 assessment unit should continuously improve the suitability, adequacy and effectiveness of the 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, ensure quality by

enabling them to ensure processes are adequately resourced and managed, and that opportunities for improvement are identified and acted on.

NOTE 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 organisation's policies;

— **Do:** implement what was planned;

— **Check**: Monitor and (where applicable) measure ethics assessment processes and the results against policies, objectives and requirements and report the results;

— **Act:** Take actions to improve performance, as necessary.

Annex E provides guidelines for the use of the PDCA for ethics assessment.

The EAU should regularly provide sufficient information about their work – ethics review, research follow-up, and other activities – to their appointing institution or authority. The information should not reveal confidential details of the research or its participants. The information, in entirety or in the form of an executive summary, should be made publicly available.

Annex A
(informative)

Basic ethical principles

A.1 Professional Conduct

The following principles are to be considered in the conduct of individual researchers:

— **Accountability**

- Be cognisant of and take responsibility for actions in research. Be responsive in accordance with the duties of the researcher.
- Consider the potential impacts of behaviour and research outcomes.

NOTE Source: Singapore Statement on Research Integrity, 2010.

Recognising the role of researchers and organisations involved in research and innovation necessitates appreciating the responsibility shouldered by each individual and group involved. Part of the responsibility is to consider how the actions, both the behaviour of the groups and the outcomes of the research, will result in potential impacts within the localised setting and greater society, as well. Accountability extends beyond responsibilities, as researchers and organisations should recognise their role and the expectations that are attached while being responsive to the duties attached to the responsibilities.

— **Respect for colleagues**

- Respect fellow researchers, recognizing their autonomy and dignity.
- Reject and prevent discrimination.
- Help to educate and mentor junior researchers.
- Uphold the standards of the profession.

NOTE Source: Singapore Statement on Research Integrity, 2010.

Since all research is in some way situated within a research community, be it in a university setting, a corporate setting or a research institute setting, each researcher engages with her colleagues, or research peers. Since mutual respect strengthens research communities, all researchers should always treat their fellow researchers with consideration for their autonomy and dignity.

— **Stewardship**

- Use resources wisely, whether they are human, technological, or natural.
- Take care of research sites, artefacts, and collected samples.

The principles of stewardship specifically attains to the principles of wisdom and care for our environment and surroundings. Since all research, either local or global, is situated within a greater world, society and natural environment and since it has the potential to affect this context for better or worse, wisdom and care regarding the effects of research is needed.

— **Scientific Freedom**

- Ensure that freedom of thought and inquiry should not be subject to political or institutional interference.

All research runs the risk of being subjected to financial, institutional and political pressures. However, these pressures can obstruct the freedom of the researchers to conduct their research in accordance with rigorous academic standards. Such pressures should therefore always be minimised and freedom of thought and inquiry ought to be promoted.

— **Scientific integrity**

- Ensure careful and honest presentation of data and research findings;
- Practice universalism and disinterestedness;
- Ensure that institutions act according to their purpose, in a transparent and accountable way.

NOTE Source: European Science Foundation (ESF), and All European Academics (ALLEA). The European Code of Conduct for Research Integrity.

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

— **Openness**

- Share data, resources, and procedures;
- Be willing to consider new ideas.

NOTE Source: Shamoo and Resnik, Responsible Conduct of Research.

A university is a public place devoted to the quest for knowledge. Sharing, openness and transparency are all intrinsic values of research and can be used to avoid scientific misconduct. When research is presented and discussed at regular seminars the result is accessible and open for critique. Through open and public motivations for peer-reviews regarding publications, research funding etc., criteria are known and biases and corruption can be avoided. Collegial loyalty should not prevent critique of unethical behaviour.

A.2 Research Practice

The following three principles are to be upheld in the consideration of the research context, which might involve research participants.

— **Respect**

- Treat any subjects partaking in or directly impacted by research with respect; guaranteeing their informed consent and treating them never as merely means;
- Treat communities partaking in or directly impacted by research with respect; taking into account their value-systems.

NOTE Source: European Science Foundation (ESF), and All European Academics (ALLEA), The European Code of Conduct for Research Integrity, 2011.

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

— **Justice**

- Treat each person involved in or impacted by research (both participants and researchers) as having equal rights as all others.
- Arrange any inequality arising from research practices in such a way that it bring about the greatest benefit for the least advantaged.

NOTE Source: Adapted from Rawls, A Theory of Justice.

The principles of justice can be understood as the obligation to treat others in accordance to what is morally right and proper. It includes the preservation of the rights and welfare of the individuals and communities involved and ensuring the research is responsive to the needs and desires of those involved or to be impacted by the outcomes of the research.

— **Beneficence**

- Ensure that risks involved for people involved in or impacted by research are proportional to the expected benefits of the research.
- Avoid harm for people or the environment resulting from research.

The International Ethical Guidelines for Biomedical Research Involving Human Subjects states that beneficence 'gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons…' It also extends to avoiding deliberately inflicting harm on the environment.

NOTE Source: Council for International Organisations of Medical Sciences (CIOMS). International Guidelines for Ethical Review of Epidemiological Studies.

A.3 Societal Impacts

The following principle is to be upheld in the consideration of research impacts for society:

— **Social responsibility**

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

The principle of social responsibility in a very broad sense designates the responsibility of researchers towards society as a whole, situating research in the broad context of institutional and cultural life. As such, researchers are expected to be aware of the possible societal ramifications of their work, to be transparent about these ramifications and to take appropriate actions if necessary.

The process of deliberation (of which the process of ethical impact assessment is a part) is an implicit principle within this framework. The use of these principles supposes that the relevant actors involved in research and innovation are engaged in a process of ethical reflection over the activities that are being conducted.

Annex B
(informative)

Field specific ethical principles

B.1 Ethical issues and principles for research on technological innovations

Technological innovations have the potential to significantly affect the lives of those who use them and those affected by the social and environmental consequences of their use. Reflecting on how the principles of precaution and justice might arise from technological innovations offers a way of considering these effects before they occur. These issues should not be considered in isolation. Almost all technologies have malicious uses, emphasis on precaution should be balanced with the benefits of the new technology, keeping in mind that technologies often have unforeseeable social impacts. These issues allow identifying potential concerns and the remedial actions how these concerns may be addressed.

Principles:

— **Avoid dual use harms**

- Be aware of potential malicious uses for new technologies;
- If possible, minimise the malicious uses of new technologies while still maintaining their beneficial applications.

— **Precaution**

- Consider the likelihood of benefits and harms from new technologies during the innovation process;
- Evaluate the environmental risks posed by the technology, and revise an innovation trajectory if the risks of environmental damage from it are significant.

— **Fairness**

- Consider how the technology may affect inequalities in society;
- Avoid or minimise unfair distributions of resources resulting from technological innovations;
- Any inequality resulting from a technological innovation should be arranged in such a way that most benefit goes to the least advantaged.

B.2 Ethical issues and principles for research involving human subjects or personal data

Human research subjects, whether they are direct participants in research or are the sources of analysed data, should be respected through the research process. This respect is best demonstrated by aiming to reduce unfavourable outcomes for subjects, either through physical or psychological harm caused by participating in the study, or by embarrassment and humiliation through the exposure of personal information collected during research. To protect participants in medical research, the Charter of Fundamental Rights of the European Union requires 'the free and informed consent of the person concerned, according to the procedures laid down by law' in medicine and biological research. Individual rights over the collection and use of personal data are also included within the Charter. It states that '[e]veryone has the right to the protection of personal data concerning him or her', and that

'[s]uch data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.'

NOTE Source: European Parliament and the Council, Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, article 3 and article 8.

Principles:

— **Respect for Human Research Subjects**

- Obtain informed consent from human participants;
- Treat human participants with due consideration for their autonomy and dignity while minimising the risk of harm done to them in a research context;
- Ensure that the potential benefits outweigh the risk of harm caused to research participants;
- Fairly distribute the benefits and burdens of research.

NOTE The Nuffield Council on Bioethics, The Ethics of Research Involving Animals, May 2005.

— **Respect of privacy**

- Render identifiable information about research participants confidential;
- Protect collected data from unauthorised access and store participant data securely.

— **Avoid bias**

- Incorporate practises that respect cultural diversity and pluralism;
- Recruit participants who are representative of the general population.

— **Protect the vulnerable**

- Take additional care in research that involves vulnerable individuals and groups to prevent them from exploitation;
- Alternatives to informed consent must be sought and obtained if the participants are unable to give such consent themselves.

B.3 Ethical issues and principles for research involving animals

Research involving animals is predominantly used in medical and life sciences, parts of natural sciences (e.g. chemistry), and parts of social sciences (e.g. experimental psychology). Animal testing within laboratory settings is invasive and often causes suffering and a reduced quality of life. The general discussion of ethical issues on this topic typically revolves around harm vs. benefit, whether potential benefits outweigh harm caused to the animals (e.g. developing new medicines, safety testing of chemical compounds, etc.). Hence, one of the criteria involves the consideration of alternatives and justifications for the research involving animals. In the laboratory setting, the 'three Rs' principle of replacing, reducing and refining the use of animals in experiments (see below) has been put forward in EU legislation. In general, the ethical principles of avoiding harm, proper treatment, care and respect for animal research subjects apply.

NOTE 1 Source: The Nuffield Council on Bioethics, The Ethics of Research Involving Animals, May 2005.

NOTE 2 Source: 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.

Principles:

— **Respectful treatment of animals in experiments**

- Incorporate practices that reduce the use of animals as much as possible in experimental settings;
- Incorporate practices that reduce suffering of animals by less invasive techniques and better living conditions;
- Adhere to experimental procedures.

NOTE 1 Source: 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.

NOTE 2 Source: Guidelines for Ethical Conduct in the Care and Use of Nonhuman Animals in Research, American Psychological Society (APA).

— **Care for animal research subjects**

- Be humane and considerate in the treatment of animal subjects;
- Provide for proper care and housing of animals.

NOTE Shamoo and Resnik. Responsible Conduct of Research.

— **Avoiding harm for animals**

- Minimise harm caused to animals;
- Ensure that the potential benefits outweigh the risk of harm caused to animals;
- Consider all possibilities for replacing animal use in research with less harmful methods in research.

B.4 Ethical issues and principles for research involving possible environmental risks

Ethical principles and issues related to the environmental risks are most prominent in the areas of engineering, natural sciences, and medical and life sciences. In these areas the results are continuously applied in practical contexts and thus have a strong impact on the society and the environment. For this reason, the ethical issues related to the environment are beyond the scope of the professional behaviour of a scientist and a part of a wider context of economic and socio-political decision-making.

There are three general sets of ethical issues regarding environmental risks: a) research misconduct (e.g. non-disclosure of information with potential harmful side effects, violations of use of radioactive, biological, or chemical materials), b) societal/environmental impacts (due to the complexity of effects of climate engineering, consumption of natural resources and energy, hazardous waste, and impacts on future generations), and c) uncertainty/unforeseen consequences due to the difficulty in establishing long-term effects (e.g. of exposure to chemicals) and the effects of current development on the environment (e.g. climate change), as a result of the growing complexity of man-made systems, chemical compounds, etc.

Principles:

— **Safety**

- Be aware of safety requirements and regulations.

- Anticipate possible risks for direct harm and take necessary measures to overcome these.

— **Social responsibility**

- Recognize the duty to address the possible, foreseeable environmental effects of research;
- Incorporate practices that protect the environment, biosphere, and biodiversity;
- Incorporate practices that serve the public interest with regards to their environment;
- Be aware of the societal interest in environmental values;
- Be engaged with the societal concerns regarding the environment.

— **Sustainability**

- Incorporate practices that restore aspects of the ecology when damaged in research.;
- Take responsibility for care and use of natural resources;
- Ensure responsible waste management.

— **Responsible conduct of research**

- Disclose information about research aspects that can have harmful side effects;
- Prevent environmental violations involving the use of radioactive, biological, or chemical materials;
- Be conscious of the possibility of uncertainty/unforeseen consequences and potential short and long-term effects.

B.5 Ethical issues and principles for research involving significant aspects of human society and culture

Ethical principles and issues related to research involving significant aspects of human society and culture can be applicable to numerous fields of research, from clinical trials to social sciences and humanities, especially when considering the physical location of research projects. Principles of respecting cultural differences and diversity as well as excluding bias based on gender, race, religion, etc., should be considered in any field of research. In fields, such as the social sciences and the humanities, that specifically place society and culture as their objects of research, additional ethical considerations should be in place. Issues concerning the protection of research participants differ from the ones in the biomedical field, since the risk of harm is rarely physical but rather psychological, linked to the problem of how cultures and behaviours of individuals or groups are represented in the community (risk of discrimination, stigmatisation). The reversal of power relations should also be considered in some types of research; since social science and humanities are often critical towards established practices in society, researchers can find themselves under political pressure.

Principles:

— **Freedom and independence of research**

- Avoid ideological bias and resist political pressures.

— **Scientific integrity**

- Respect rival theoretical or methodological approaches.

— **Respect biodiversity and cultural diversity**

- Recognise of the value of cultural diversity and biodiversity and the means for preserving them when conducting research.

— **Protection of communities**

- Ensure that research being conducted is responding to the needs of specific groups or communities and is of value and in the interest of those affected and involved.
- Consider risks and benefits of research for participants from vulnerable groups and communities and use appropriate means of obtaining and maintaining voluntary and informed consent at all stages of research.
- Recognise the practices of traditional communities and knowledge and avoid their exploitation.

— **Responsible treatment of cultural heritage**

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

NOTE Source: UNESCO. Cultural Heritage.

Annex C
(informative)

Ethical principles

C.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 by applying 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 may be of ethical concern and assist in communicating and justifying these concerns to others. Examples of ethical principles include *beneficence* (described in 2.3 and A.2), *justice* (2.18 and A.2), and *non-maleficence* (2.20), and those listed in Annexes A and B.

Ethical principles guide moral decision making by emphasising 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 may cause harm and to whom, and if it is possible to reduce or avoid the potential harm from these outcomes.

C.2 Resolving conflicts between ethical principles

Ethical principles may give conflicting advice when applied to some issues. This requires a choice to be made over which principle should be given priority over another. Which principle should take precedence is a matter of judgement and will depend on the context that the research and innovation activity takes place. For example, the principles of beneficence (promoting well-being in others) and non-maleficence (avoiding harm) may conflict in medicine, where a medical procedure that may 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 assessment unit may use one or more of these methods to assist in their 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, and includes 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 emphasise 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. While principles conflict with each other, the moral intuitions and experience of the decision makers can 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 recognising that such principles are understood as being valid 'in general', and may be made more specific to handle particular cases and to recognise the priority of other principles. For example, a potential conflict between the principle of beneficence and the individual's right to liberty can 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 D
(informative)

Risk based thinking in ethics assessment

D.1 Risk-based thinking

Risk-based thinking enables an R&I 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. This annex shortly explains the following steps:

— communication and consultation;

— establish the context;

— risk assessment;

— risk treatment.

NOTE ISO 31000 provides requirements and recommendations for risk management.

D.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 should identify, record and take stakeholder views into account in the decision making process.

D.3 Establishing the context

To establish the context, the R&I project should articulate its 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 seeks to achieve its objectives and includes specific details of legal and regulatory requirements, stakeholder perceptions and other aspects of risks specific to the scope of the project.

The internal context is the internal environment in which the R&I project seeks to achieve its objectives and includes the R&I project's culture, processes, structure and strategy. Internal context is anything within the R&I project that can influence the way in which an R&I project will manage risk.

D.4 Risk assessment

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

— **Risk identification:** The R&I project 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. Risk identification should include examination of the 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 that the consequences can occur. Factors that affect consequences and likelihood should be identified. The combination of consequences, likelihood and timeline determines a level of risk and sensitivity to preconditions. Factors such as divergence of opinion among experts, uncertainty, 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.

D.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:

— assess a risk treatment;

— decide whether residual risk levels are tolerable;

— if not tolerable, generate a new risk treatment;

— assess 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 contracts and risk financing);

— retaining the risk by informed decision.

Selecting the most appropriate risk treatment option involves balancing the costs and efforts of implementation against the benefits derived, with regard to legal, regulatory, and other requirements such as social responsibility and the protection of the natural environment. Decisions should also take into account risks which can warrant risk treatment that is not justifiable on economic grounds, e.g. severe (high negative consequence) but rare (low likelihood) risks.

A number of treatment options can be considered and applied either individually or in combination. The R&I project can normally benefit from the adoption of a combination of treatment options.

Annex E
(informative)

Guidelines for the use of PDCA for ethics assessment

Table 1 — Guidelines for the use of PDCA for ethics assessment

PLAN The ethics assessment unit should adequately plan for quality assurance of ethics assessment. The ethics assessment unit 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 measured; — who has the responsibility for QA.
DO DO envisages the implementation of the QA plan and ensuring that the arrangements therein are followed. The ethics assessment unit should support actions such as: — 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 and for the operation and control of its processes; — Determine, provide and maintain the infrastructure[1] necessary for the operation of processes to achieve 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 their purpose. — Retain appropriate documented information as evidence of fitness for the purpose of the ethics assessment process. — Determine the knowledge necessary for the operation of its ethics assessment processes. — Ensure: • the necessary competence of person(s) doing work under its control that affects the performance and effectiveness

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

of the ethics assessment process;
- that these persons are competent on the basis of appropriate education, training, or experience;
- and where applicable, taking actions to acquire the necessary competence, and evaluating the effectiveness of the actions taken;
- the retention of appropriate documented information as evidence of competence.

— Ensure that relevant persons working under the organisation's control (e.g. ethics assessors, other staff) are aware of:

- the quality 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 documented information determined by the organisation as being necessary for maintaining the effectiveness and quality of the ethics assessment process.

CHECK

To facilitate the CHECK aspect, the ethics assessment unit 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 allow for the addressing of things affecting the 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 oreffects that have been achieved?
- To what extent are the costs proportionate to the benefits achieved? What factors are influencing any particular discrepancies?
- What factors influenced the efficiency with which the achievements observed 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 proven to have been 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 ethics assessment policy, practice or procedure coherent with other ethics assessment policy, practice or procedures that have similar objectives?
- To what extent is the ethics assessment policy, practice or procedure coherent internally?
- To what extent is the ethics assessment policy, practice or procedure coherent with wider EU or national policy?
- To what extent is the ethics assessment policy, practice or procedure coherent with international obligations?

— What is the EU added value of 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 assessment unit should take actions to improve the ethics assessment policy, practice and procedures and correct undesirable effects (e.g. 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

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