CEN

WORKSHOP

AGREEMENT

CWA 17145-1

May 2017

ICS 03.100.02; 03.100.40

English version

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

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Ref. No.:CWA 17145-1:2017 E

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European foreword

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

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

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

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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 harmonizing and improving ethics assessment practices of research and innovation.

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

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

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

1 Scope

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

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

The CWA has two parts:

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

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

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

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

2 Terms and definitions

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

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

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

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

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

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

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

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

[SOURCE: Thompson, 1993]

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

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

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

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

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

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

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

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

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

[SOURCE: adapted from Wright, 2011]

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

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

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

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

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

[SOURCE: Oxford English Dictionary]

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

[SOURCE: SA TORI D1.1, 2015]

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

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

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

[SOURCE: adapted from SATORI D 1.1, 2015]

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

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

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

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

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

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

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

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

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

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

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

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

[SOURCE: adapted from Rawls, 1971]

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

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

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

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

[SOURCE: Beauchamp et al., 2011]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.35
responsible treatment of cultural heritage
principle of protecting and promoting ”the legacy of physical artefacts and intangible attributes of a group or society that are inherited from past generations, maintained in the present and bestowed for the benefit of future generations” and recognizing the shared aspects within human diversity and culture

[SOURCE: adapted from UNESCO, Cultural heritage]

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

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

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

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

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

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

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

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

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

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

3 Ethics committee

3.1 Role and responsibilities

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

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

— objects of assessment;

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

— scientific fields;

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

The ethics committee should determine whether it is part of its mandate to assess the scientific quality and adequacy of proposals, including the methodology proposed in them. Reasons in favour of considering scientific adequacy are that bad science is unethical, wastes resources and provides possibly false information, and that there may not be another committee that assesses scientific adequacy. Reasons against it include the fact that some may not hold it to be part of the mandate of an ethics committee, and that an assessment of scientific adequacy may require extra effort and expertise.

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

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

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

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

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

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

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

3.2 Competencies

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

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

The ethics committee should, where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken. Ethics training could be made more effective by incorporating it into other policies and procedures that require training. Training in dealing with ethical issues could be included in the quality assurance system [6].

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

3.3 Appointment of the ethics committee and its members

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

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

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

— the chairperson should be elected by the members;

— the organization should appoint qualified experts;

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

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

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

— in cases where a newly elected member of the ethics committee is replacing an outgoing member, there should be a transition period during which the new member acts as a regular substitute for the outgoing member, knowledge is transferred and training may take place.

Ad hoc members may be appointed to the ethics committee and either be treated as advisors who present their informed opinion of the activity under review, or as ad hoc members who participate in the ethics committee's full decision-making process. The term of office of ethics committee members, including the option of membership renewal, should be clearly prescribed, bearing in mind the need to maintain an appropriate balance between continuity of accumulated expertise and the appointment of new members. The position of chairperson of the ethics committee should rotate, over a fixed time period and through a democratic process, among members of the ethics committee who possess strong administrative competence.

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

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

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

3.4 Composition

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

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

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

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

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

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

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

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

— ethical expertise;

— legal expertise.

Additional expertise may be included:

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

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

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

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

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

Each ethics committee member should possess the following characteristics:

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

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

— personal commitment to the goals of ethics assessment;

— communication skills;

— ability to cooperate in a group;

— no apparent and or potential conflicts of interest;

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

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

3.5 Conflicts of interest of the ethics committee

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

— clear definition of conflict of interest (for instance, 2.5);

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

  - financial and non-financial conflicts of interest (e.g. ownership of shares in a company funding the proposed research, or an interest in attracting scientists into the research programme with which one is affiliated);

  - personal and professional interests and relationships (e.g. personal involvement in the proposed research, or competing research proposals associated with the ethics assessor and another researcher);

- institutional conflicts of interest (e.g. the research is proposed by the ethics committee's home institution or an institution with which an individual ethics committee member is affiliated);

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

— specification of the people to whom the policy applies. The policy should chiefly apply to: ethics committee members, ad hoc reviewers, consultants, guests and administrative staff;

— conflict of interest disclosure procedure, consisting of:

  - annual reports from the individual members and administrative staff of the ethics committee about their actual, possible or perceived conflicts of interest;

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

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

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

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

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

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

4 Ethical issues and principles

4.1 General

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

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

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

— **ethical guidelines for institutional responsibility and integrity** are ethical principles that concern the way in which the institutional setting for research and innovation ought to be constructed so as to support ethically sound research and innovation practices. These principles are not normally applied by ethics committees, although ethics committees sometimes address them in their work;

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

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

NOTE **Research integrity**, or scientific integrity, is about possessing and firmly adhering to the scientific and professional standards that govern the conduct of research. These standards, which are often specific to particular fields or disciplines, are provided by professional organisations and research institutions (in codes of conduct), and sometimes by the government or the public. In general, they call for the avoidance of data fabrication, manipulation, plagiarism and conflicts of interest, and for collegiality, among other things. Since research integrity is about the behaviour and conduct of the researcher rather than the research plans and activities themselves, matters of research integrity are generally handled by other committees than those that perform ethics assessment of research and innovation projects, proposals and practices; namely, they are handled by scientific integrity boards or professional ethics committees. Research integrity can, however, be assessed by ethics committees to the extent that there are potential individual or institutional conflicts of interest that are apparent in research and innovation proposals and activities. It is in the interest of good research ethics that ethics

committee members are at least aware of the core principles of research integrity, and ethics committees could take it upon themselves to inform researchers of research integrity standards (if there is no other unit that does this), and to observe and identify flaws in research plans and activities that could provide evidence of scientific misconduct.

The determination of ethical issues and principles is typically:

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

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

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

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

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

The ethics committee should resolve conflicts between ethical principles by means of arguments referring to more basic ethical views such as maximizing utility (utilitarianism) and respecting individual rights (deontological ethics). Annex B provides information on moral decision-making and resolving conflicts between ethical principles.

4.2 General and field-specific ethical principles

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

— general ethical principles that potentially apply to every major field of scientific research and innovation;

— ethical principles that apply only to specific fields of research and innovation – including the natural sciences, the engineering sciences, the medical sciences, the life sciences, the computer and information sciences, and the social sciences and the humanities. These principles primarily concern the context of the research, such as how experiments are performed or which research participants are involved, and the (future) impacts of the research, such as the environmental consequences of technological innovations resulting from research in the chemical sciences.

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

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

— social responsibility;

— protection and management of data;

— dissemination of research results;

— protection of researchers and the research environment;

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

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

— protection of and respect for human research participants;

— protection of and respect for animals used in research.

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

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

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

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

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

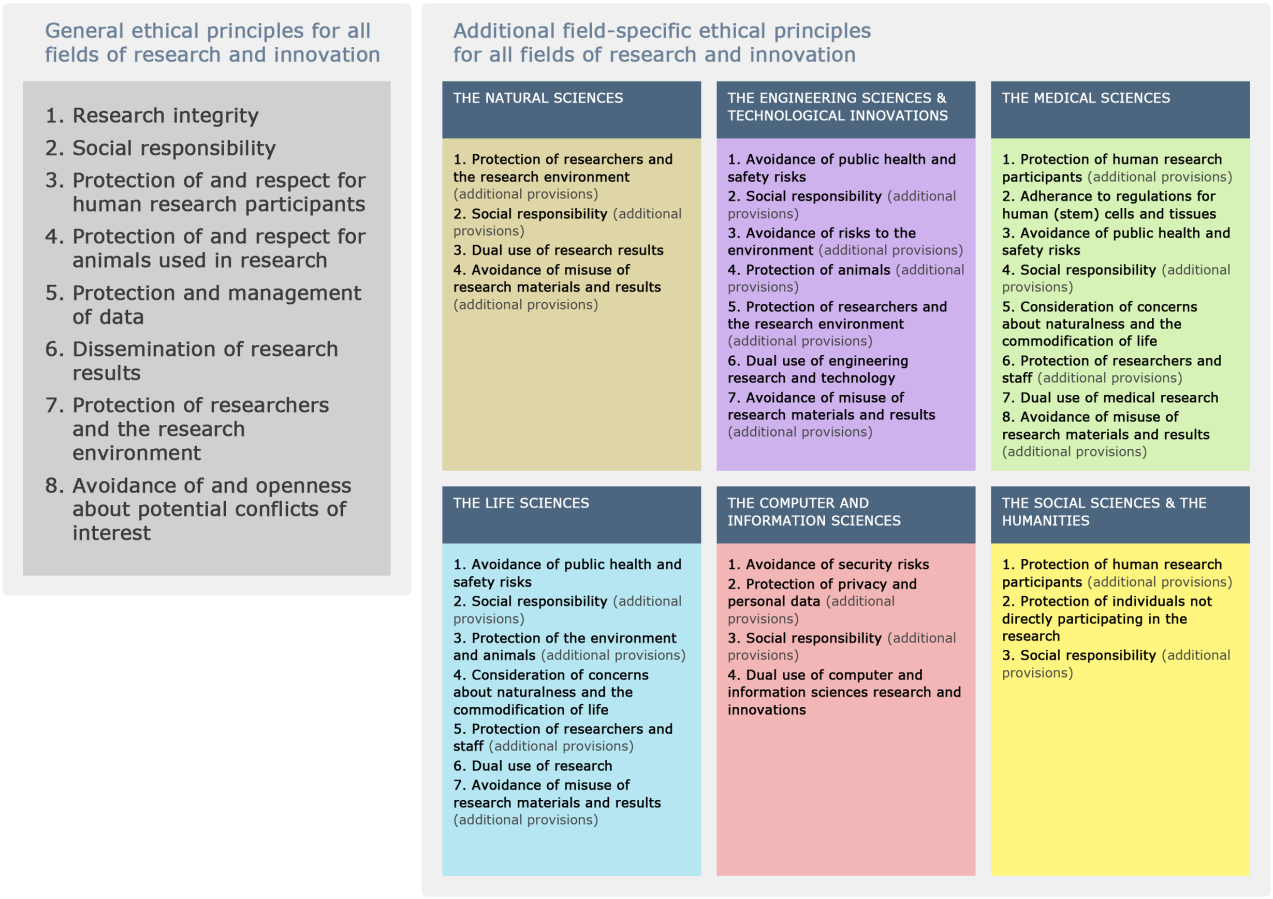

Figure 1 — Framework of ethical principles and issues in research

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

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

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

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

5 Procedures for ethics assessment

5.1 General

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

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

The ethics assessment procedures should as a minimum:

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

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

— determine if the research or innovation methods are appropriate;

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

— avoid unjustified duplication of ethics assessment.

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

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

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

The procedures typically include:

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

— procedures during assessment;

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

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

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

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

5.2 Procedures prior to assessment

Recommendations for procedures prior to assessment are the following:

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

  - person responsible for conducting the project;

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

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

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

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

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

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

5.3 Procedures during assessment

Recommendations for procedures during assessment are the following:

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

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

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

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

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

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

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

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

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

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

5.4 Procedures after assessment

Recommendations for procedures after assessment include the following:

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

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

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

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

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

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

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

— each decision made by the ethics committee should have a written justification. Minority voices or opinions should be included;

— the ethics committee should oblige researchers to provide annual reports, end-of-study reports, and reports on adverse events.

6 Quality assurance in ethics assessment

Quality assurance in ethics assessment can help determine and ensure that the ethics assessment is meeting its goals and expectations. Quality assurance can help correct any misinterpretations or misapplications of ethics policies and procedures. Quality assurance activities help foster communication between different agents involved in the ethics assessment process – i.e. those making the policy and those implementing it. Quality assurance can also help develop and strengthen best practice and tailor ethical policies and procedures to meet different requirements, e.g. in relation to different scientific fields.

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

The ethics committee should be supervised by a senior administrative or managerial level of the organization within which they operate. The supervision of ethics committees should not compromise their ability to be independent in their decision-making.

The ethics committee should consider the results of analysis and evaluation, from internal and external review, to determine if there are needs or opportunities that should be addressed as part of continuous improvement.

The ethics committee should continuously improve the suitability, adequacy, and effectiveness of their ethics assessment system.

A recommended approach to quality assurance is the Plan-Do-Check-Act (PDCA) approach. This approach is particularly relevant as it is a continuous improvement model. Using this approach could help ethics assessors plan their ethics assessment processes and interactions better, and ensure quality by enabling them to check that processes are adequately resourced and managed, and that opportunities for improvement are identified and acted on.

NOTE The PDCA approach is used in the ISO 9001 Quality management systems — Requirements.

The PDCA approach for ethics assessment has the following elements:

— **Plan:** establish the objectives of the ethics assessment and its processes, and the resources needed to deliver results in accordance with ethical requirements and the organization's policies;

— **Do:** implement what was planned;

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

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

Annex D provides guidelines for the use of the PDCA approach for ethics assessment.

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

Annex A
(informative)

General and field-specific ethical principles

A.1 General

This annex lists and operationalises ethical principles for ethics assessment for all of the major fields of scientific research and (technological) innovation. The lists are comprehensive, but may not be complete. Ethics committees and organisations that provide guidance for ethics committees are encouraged to further adapt and develop the principles for the particular fields that they cover, and to make adaptations to account for national legislation and regulations and for the particular institutional, social and cultural settings in which research and innovation activities are carried out. Ethics committees may develop specific protocols for the application of ethical principles. Further development of field-specific principles may include the introduction of principles, protocols or considerations for specific issues, methods and approaches in these fields and for specific subfields.

EXAMPLE For the social sciences and humanities, special principles and protocols could be developed for specific data collection methods, specific types of research involving human research participants and specific fields, e.g. psychology, anthropology or visual arts., internet research

Section A.2 lists general ethical principles that apply to every major field of scientific research and innovation. These principles should be incorporated in the ethics protocols for all fields, although an exception can sometimes be made for the principles concerning human research participants and research involving animals since there are fields in which such research activities are rare.

Sections A.3 through A.8 list ethical principles that apply only to specific fields of research and innovation – the natural sciences (A.3), the engineering sciences (A.4), the medical sciences (A.5), the life sciences (A.6), the computer and information sciences (A.7), and the social sciences and the humanities (A.8). These lists constitute field-specific additions to the general ethical principles in section A.2. For "hybrid" fields that combine elements of two or more of these fields (e.g. biomedical engineering, geo-information sciences), the ethical principles of all of the "parent" fields should be used. Multidisciplinary research should use the combined ethical principles of the participating fields.

The principles are intended to be used as guiding principles for research ethics committees and for the development of self-assessment forms and questionnaires for researchers who are preparing a request for assessment. The complexity of self-assessment forms should be proportional to the nature and size of the research and innovation projects that are being assessed. For example, for basic research and for smaller and more routine applied projects, the inclusion of only one or a few questions about social responsibility may be sufficient.

NOTE Examples of self-assessment forms will be posted on the SATORI project website, http://satoriproject.eu.

A.2 Ethical principles and issues applicable to all fields of research and innovation

— **Research Integrity**

- Employ and apply appropriate research methods and take responsibility for the trustworthiness of results;
- Avoid unintentional bias in the selection of research methods and analysis of research data;

- Avoid the manipulation of research instrumentation, materials or processes and the omission or distortion of research data;
- Avoid the inclusion of data, observations or characterisations that did not occur in the gathering of data or running of experiments;
- Ensure autonomy of research and freedom of critical thinking from ideological bias and political pressures;
- Avoid conflicts of interest, and disclose financial and other conflicts of interest that could compromise the trustworthiness of one's work in research proposals, publications, public communications or review activities;
- Avoid representing the work of others as one's own, and cite all sources used;
- Avoid misrepresenting one's qualifications, experience or research accomplishments;
- Respond to and report irresponsible research practices by others.

NOTE 1 Research integrity, or scientific integrity, is not normally a principle of ethics assessment conducted by ethics committees. It concerns the behaviour and conduct of researchers, and is normally considered by scientific integrity boards that investigate cases of scientific misconduct. It is, nevertheless, in the interest of research ethics that ethics committee members, researchers and innovators are aware of the core principles of research integrity. It is also in the interest of research ethics that members of ethics committees are aware of field-specific codes of ethics for researchers and know how these relate to the ethics assessment that they perform for these fields.

NOTE 2 Relevant international guidance and regulations exist for scientific integrity, such as the *Singapore Statement on Research Integrity* (2010), the *European Code of Conduct for Research Integrity* (2017) and the *Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations* (2013). In addition, national guidelines exist in many countries.

— **Social responsibility**

The social responsibility principle applies to the assessment of research and innovation plans and practices, rather than the conduct of individual researchers or innovators:

- Anticipate and consider the potential consequences of the research and innovation project for society, including plausible future uses and applications of the results of project, and take appropriate remedial action to address any (potentially) negative societal and environmental impacts if such action seems justified;
- Consider whether and how the research or innovation activity could positively or negatively contribute to the interests, rights and well-being of individuals and groups, the common good or a just and peaceful world society;
- Consider whether the research or innovation promotes or is compatible with sustainable development, and how it could promote environmental sustainability;
- Acknowledge the economic and cultural value of local knowledge, pursue dialogue with local knowledge bearers, involve them in the research and let them share in the benefits. This

applies to research and innovation that directly builds on other types of knowledge, specifically local or traditional knowledge, and the skills and practices found in individuals and local communities;

- Avoid the misuse of research materials and results by considering whether the materials, methods, technologies, and knowledge involved in or generated during the research or innovation could serve, or be modified or enhanced to serve, alternative (unethical or ethically questionable) purposes that could harm individuals, animals, society and or the environment;

- Take into account the concerns of stakeholders when planning and conducting the research, and communicate important research results and (potential) societal consequences to relevant stakeholders and to the general public to ensure their proper interpretation, while explaining the degree of uncertainty involved. This applies specifically to research and innovation projects with significant potential consequences for society.

Special provisions for research involving low income or lower-middle income countries:

- Be responsive to the particular (research) needs of the country or community where the research is carried out;

- Share the benefits of research involving local research participants or resources with local stakeholders, including local research participants and local communities;

- Involve local researchers in the research – preferably as equal partners – to help build local research capacity;

- Minimize the diversion of local (human) resources towards the research if this could have detrimental effects on the local community;

- Show respect for local cultural traditions and value systems.

NOTE 1 Social responsibility is both a quality of individual researchers and of the research itself. When applied to researchers and innovators, it is part of their professional responsibility and is usually included in ethics codes for professional conduct. It includes anticipation of and taking responsibility for the effects on society and the environment of one's research and innovation activities, taking proper precautions to avoid negative effects, communicating one's activities and their consequences effectively to stakeholders and the public, and addressing concerns to superiors and acting as a whistle-blower, if necessary. Ethics committees do not normally consider the behaviour of individual researchers, but may consider whether a research design of activity includes proper precautions and actions to address issues of social responsibility.

NOTE 2 Local resources can include, among other things, animal or human tissue samples, genetic material, live animals, human remains, materials of historical or cultural value, endangered fauna or flora samples, and fossils. Most countries have regulations on these resources.

NOTE 3 Benefits of research for local stakeholders can include, among other things, development of research infrastructure, distribution of research results, publications, access to data, intellectual property, proper compensation for use of resources and services, and technology transfer.

NOTE 4 Relevant guidelines for human rights include the *Universal Declaration of Human Rights* (1948) and the *Charter of Fundamental Rights of the European Union* (2000). Relevant guidelines for benefit sharing and research involving low-income countries include the *Nagoya Protocol*, the *United Nations Declaration on*

the Rights of Indigenous Peoples, the *Ethical and Regulatory Challenges to Science and Research Policy at the Global Level* of the European Commission (2012) and the SATORI project deliverables D3.1 to D3.4

— **Protection of and respect for human research participants**

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

NOTE 1 The term 'research participant' refers to any or all of the following: *research subjects* (e.g. experiments), *research respondents* (e.g. surveys), *research informants* (e.g. anthropological studies) and *research participants* (e.g. interviews).

NOTE 2 The principle of protection of and respect for human research participants is relevant to most fields, but can be downgraded or removed in protocols for fields in which research involving human research participants is rare or non-existent, such as in the natural sciences.

NOTE 3 There is a debate on whether informed consent always requires explicit written and signed notification of consent. Many experts in research ethics now hold that for anonymous surveys and surveys that provide minimal risk to participants, a signed consent form is not necessary and a simple consent paragraph in the survey is sufficient. Some also hold that it is sufficient that the participant has been informed of risks, benefits and procedures in the study and has expressed consent in some way that can be verified, such as by text, on video or by returning a survey that contains a consent paragraph.

NOTE 4 Regarding the bullet point on the representativeness of one's pool of human research participants, it can be argued that the representativeness is part of proper research methodology rather than of research ethics. It need not be included in ethics assessment when a separate scientific evaluation takes place that can be expected to include the representativeness.

Special provisions for the protection of children, mentally disabled persons and other vulnerable groups:

- Only carry out research with children or other persons unable to give consent if there are no acceptable alternatives, if the risks and burdens to participants are minimal, and if substantial benefits will accrue to the participants or the group represented by the participants;

- If the participant is a child, obtain informed consent from the parent(s) or legally authorized representative(s), and obtain assent from the child if possible;

- If the participant is an adult who is judged as lacking the mental capacity to give consent, obtain informed consent from the legally authorized representative(s), and obtain assent from the participant if possible;

- Ensure that inducements, rewards or compensation for participating in the research do not threaten or challenge the ability of participants to provide genuine informed consent;

- Take special care in all aspects of the research where vulnerable individuals or groups are involved.

NOTE 5 Vulnerable people include, among others, children, persons unable to give informed consent, people with mental or physical disabilities, pregnant women, senior citizens, residents of retirement and assisted living facilities, patients with incurable diseases, people with addictions and problematic substance use, poor persons (including the homeless and people receiving welfare or social assistance), the unemployed, prisoners, first-generation immigrants, members of groups that face discrimination, persecution and exclusion, and persons in low or lower-middle income countries.

NOTE 6 No international regulations or frameworks for the protection of human research participants currently exist that cover all scientific fields. There are, however, frameworks that are specifically directed at the medical sciences and/or social and behavioural sciences.

— **Protection of and respect for animals used in research**

Respect for life (three Rs – replacement, reduction, refinement):

- Consider all possibilities for replacing animal experiments with research methods that are less harmful to animals;

- Make an effort to minimize the number of animals involved in the experiment;

- Minimize the suffering of animals during the experiment and in the context of animal keeping and breeding.

NOTE 7 This principle can be downgraded or removed in protocols for fields in which research involving animals is rare or non-existent. Research involving animals occurs most frequently in medical and life sciences, may also occur in behavioural sciences and engineering sciences, but is rarer in social and economic sciences, humanities, computer and information sciences and natural sciences.

NOTE 8 Potential causes of suffering or harm to animals include invasive procedures, disease and deprivation of basic physiological needs. Other sources of harm for many animals include social deprivation and loss of the ability to fulfil natural behaviours.

Respect for the welfare of animals:

- Ensure that the potential benefits of the animal experiment outweigh the (potential) harm caused to the animals involved;
- Provide reasonable accommodation for the species-specific characteristics, needs and behaviours of animals involved in experiments;
- Only use animals bred to have genetic diseases and defects or behavioural disorders if their use is deemed essential following careful ethical balancing.

Special provisions for the protection of non-human primates and wild animals and species:

- Avoid the use of non-human primates in animal experimentation;
- Only use animals captured in the wild or animals from species that live in the wild if their use is deemed necessary following careful ethical balancing.

Special provisions for the protection of animals in low or lower-middle income countries:

- Help in building local capacity for the humane conduct of animal experimentation;
- Only use endangered species if the experiment contributes to the conservation of the species in question.

NOTE 9 Relevant regulations for the protection of animals in research are the *Directive 2010/63/EU on the protection of animals used for scientific purposes* and the *United Nations Convention on Biological Diversity* (1992).

— **Protection and management of data and dissemination of research results**

Management of data and open data:

- Store all research data securely, and render them difficult to access or hard to use for unwanted third parties;
- Be aware of all actual and potential data flows;
- Ensure that the research data produced will be locatable by and accessible to other researchers, interoperable with other data and tools, and reusable in future research.

NOTE 10 Source of points 1–3 is the *FAIR Guiding Principles for scientific data management and stewardship*, 2016.

NOTE 11 General guidelines on open data are provided by the European Commission, *Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020*, 2016.

Protection of personal data:

- Ensure that all personal data that researchers plan to collect are necessary for the research;

- Obtain informed consent from research participants for the collection and use of their personal data, or verify that such consent has been given;
- Ensure that data related to identifiable participants are stored securely, and that such data are not stored any longer than is necessary to achieve the objective for which they were collected;
- Ensure that any personal data collected are not used for other research (secondary use) without the consent of the participants involved or proper justification if consent cannot be obtained;
- Ensure that, for any secondary use of data, the data in question are openly and publicly accessible or that consent for secondary use has been obtained;
- Consider and anticipate the effects that gaining access to personal information could have on third parties (e.g. persons related to the data subject).

Protection of personal data and ethics in Internet research:

- Consider whether publicly available information should actually be considered sensitive personal information and treated as such;
- Take precautions when merging multiple data sources to ensure that anonymity and or pseudonymity are maintained;
- Take special precautions to guarantee proper consent in cases where such consent is required. Specifically, special precautions should be taken to ensure that persons are not recruited who should not be participating in the study, such as children in studies targeted at adults. It is also important to ensure that subjects adequately and correctly understand the information provided concerning the research and why consent is requested if the information is communicated in writing only, and over the Internet;
- Inform participants in open online forums about systematic registration or reporting of information when possible;
- Take precautions to ensure anonymity when using information from Internet sources (since such information may be searchable);
- Researchers should not disguise their identity when communicating with research subjects electronically. This contravenes ethical principles concerning informed consent and openness about the nature and purpose of the research.

NOTE 12 A relevant regulation for data protection is the European Union *General Data Protection Regulation (GDPR) EU 2016/679.*

Dissemination of research results:

- In the absence of compelling reasons to act otherwise, make research results publicly available. Openness regarding research findings is essential for ensuring verifiability, returning benefit to

research participants, providing benefit to society and ensuring a dialogue with fellow researchers, stakeholders and the public;

- Wherever possible, strive towards open access publications, which provide free online access to any user;

- Where possible, make research results available to different audiences that may have an interest in them, using different formats and media. Aim to include the general public, if results may be of interest to them, and aim to include regions that are otherwise excluded for reasons of economic disadvantage.

NOTE 13 General guidelines on open access are provided by the European Commission, *Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020*, 2016.

— **Protection of researchers and the research environment**

- Ensure that researchers and staff involved in conducting the research are not exposed to serious risk of physical or psychological harm or strain as a result of the research;

- Take special precautions regarding the health and safety of (local) researchers and staff if (part of) the research is conducted in low income or lower-middle income countries;

- Avoid harm to the local community as a result of any field work or experiments;

- Minimize harm to the local environment (including animals, plants and natural and cultural heritage) caused by any field work or experiments, and ensure that any harm done can be justified by the (potential) benefits of the research.

— **Avoidance of and openness about potential conflicts of interest**

- Be aware of and as far as possible avoid actual or perceived conflicts of interest of the researchers and/or organisations performing the research;

- Disclose information about relevant financial ties (especially direct funding of the research, funding of the salaries of participating researchers, or funding of organisations participating in the research) that are relevant to judging potential conflicts of interest;

- Be transparent about and disclose relevant professional positions or other work that researchers have done in political, religious or other value-based organisations that could potentially negatively affect (the perception of) those researchers' objectivity in conducting the research;

- Ensure that, in the event of a potential conflict between different roles, it is clear whether a participating researcher is speaking as a researcher or in a different capacity.

NOTE 14 A relevant national guideline for conflicts of interest in research is chapter 7 of the *Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (2014).

A.3 Additional ethical principles and issues in the natural sciences

NOTE 1 For applied work in the natural sciences, see also A.4 on engineering sciences.

— **Protection of researchers and the research environment**

- Take special precautions to ensure that researchers and staff involved in conducting the research are not exposed to serious physical harm or strain as a result of working with harmful biological, chemical, radiological, nuclear, or explosive materials;
- Take special precautions to minimize any potential harm to the environment, animals, or plants caused by the use of harmful biological, chemical, radiological, nuclear, or explosive materials during the research.

NOTE 2 For applied work in the natural sciences, see also A.4 on engineering sciences.

— **Social responsibility**

(additional provisions specific to the natural sciences)

- Anticipate and consider the technological applications of the research and their potential positive and negative impacts on society and the environment;
- Take special care to communicate and ensure proper interpretation among stakeholders and the public of research and research results that have, or are could be perceived as having, potentially significant consequences or implications for society and/or the environment, such as research in climatology, astronomy and or astrobiology, experimental particle physics.

— **Dual use of research results**

- Consider whether the results of the research could have military applications;
- Consider whether the results of the research could contribute to the proliferation of weapons of mass destruction;
- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if the research has significant military applications or if it contributes to the proliferation of weapons of mass destruction.

— **Avoidance of misuse of research materials and results**

(additional provisions specific to the natural sciences)

- Take special precautions to prevent or counter the effects of potential misuse of security-sensitive chemical, radiological, or nuclear materials and knowledge (e.g. the appointment of a security advisor, limiting dissemination, classification, training for staff).

A.4 Additional ethical principles and issues in the engineering sciences and in technological innovation

— **Avoidance of public health and safety risks**

- Ensure that the technology that is developed, in terms both of the production and the societal use of any goods based on it, does not pose inherent direct or long-term risks of harm to public health and safety.

— **Social responsibility**

(additional provisions specific to the engineering sciences)

Respect for individual rights and liberties:

- Ensure the technology does not pose inherent risks to individual freedom, autonomy, authenticity or identity; or to individual privacy, human dignity, or human bodily integrity.

Protection and promotion of well-being and the common good:

- Consider how the technology could potentially harm or benefit the well-being and interests of individuals and groups in society;

- Consider how the technology could help to protect and promote important social institutions and structures, democracy, and important aspects of culture and cultural diversity.

Protection and promotion of justice and equality:

- Consider how the technology could harbour biases or negative effects that disproportionally impact people in terms of age, gender, sexual orientation, social class, race, ethnicity, religion, culture or disability;

- Consider how the technology could contribute to the reduction of unjust biases, stigmatization or discrimination in society in terms of age, gender, sexual orientation, social class, race, ethnicity, religion, culture or disability;

- Consider how the technology could widen or help narrow social inequalities in terms of the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks or hazards;

- Consider how the technology could harm or benefit vulnerable, disadvantaged, or underrepresented individuals, groups, and communities in society or individuals, groups and communities in low-income and lower-middle income countries;

- Consider how the technology could harm or benefit future generations.

— **Avoidance of risks of harm to the environment**

(additional provisions specific to the engineering sciences)

Protection of the environment:

- Anticipate and assess potential risks of harm to the (urbanised or natural) environment as a result of the applications or uses of the technology, and take appropriate measures to address them during the innovation process;

- Consider the possibility of unforeseen or long-term environmental effects of the technology;
- Take special precautions to prevent environmental harms caused by the use of biological, chemical, radiological, nuclear, or explosive materials;
- Promote a clear understanding of the actions required to restore the environment once it has been disturbed as a result of the technology.

Promotion of environmental sustainability:

- Optimize the technology for effective and cost-efficient resource recovery (recycling);
- Take responsibility to search for technological solutions that lower the potential consumption of raw materials and energy;
- Take responsibility to search for technological solutions that lower the production of environmentally harmful wastes and lessen environmental pollution;
- Be conscious of the interdependence between eco-systems and the importance of bio-diversity.

Social environmental responsibility:

- Be conscious of, and engaged with, any (local) societal concerns and interests regarding the ways in which the technology could affect the environment.

— **Protection of animals (if the technology is intended for use around animals)**

- Ensure that the technology does not pose any unnecessary risks of harm to animals;
- Respect the characteristics, needs and behaviours of the animal species involved.

— **Protection of researchers and the research environment**

(additional provisions specific to the engineering sciences)

- Take special precautions to ensure that researchers and staff involved in conducting the research are not exposed to serious physical harm or strain as a result of working with harmful biological, chemical, radiological, nuclear, or explosive materials.

— **Dual use of engineering research and technology**

- Consider whether the technology could have military applications;
- Consider whether the technology could contribute to the proliferation of weapons of mass destruction;
- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if the technology has significant military applications or if it contributes significantly to the proliferation of weapons of mass destruction.

— **Avoidance of misuse of research materials and results**

(additional provisions specific to the engineering sciences)

- Take special precautions to prevent or counter the effects of potential misuse of security-sensitive chemical, radiological or nuclear materials and knowledge (e.g. the appointment of a security advisor, limiting dissemination, classification, training for staff).

NOTE 3 A relevant national guideline for the engineering sciences is the *Guidelines for Research Ethics in Science and Technology* by The Norwegian National Committee for Research Ethics in Science and Technology (2016).

A.5 Additional ethical principles and issues in the medical sciences

— **Protection of human research participants**

(additional provisions specific to the medical sciences)

- Take special precautions to ensure the participant has a full understanding of all the risks, including potential unforeseen risks, associated with participating in the research;

- Take special precautions to ensure respect for the participant's bodily integrity;

- Take special precautions to ensure the participant's long-term quality of life (including its physical, functional, psychological/emotional, and social/occupational aspects) is not negatively affected as a result of their participation in the research.

NOTE 1 Relevant frameworks and regulations for the protection of human research participants in the medical sciences are the following: the *Declaration of Helsinki* (1964, last amended 2013), WHO *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants* (2011), the *Oviedo Convention*, the UNESCO *Declaration of Bioethics and Human Rights,* CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2016), the *Nuremberg Code* and the *Belmont Report*.

— **Adherence to regulations for research involving human embryonic stem cells**

NOTE 2 Relevant regulations and guidelines for research involving human embryonic stem cells are: Declaration C 373/12 of the European Commission, the Council of Europe's *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings* and the International Society for Stem Cell Research *Guidelines for Stem Cell Research and Clinical Translation (*2016).

— **Adherence to regulations for research involving human cells and tissues**

NOTE 3 Relevant regulations for research involving human cells and tissues are: Directive 2004/23/EC of the European Parliament and of the Council of Europe's *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin* and the Council of Europe's *Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin*.

— **Avoidance of public health and safety risks**

- Ensure that the medical research, regardless of its potential applications, does not pose any direct or long-term risks of harm to public health and safety (e.g. take adequate preventative measures against accidental release of hazardous biological agents);
- Anticipate, assess, and communicate any potential direct or long-term public health and safety risks caused by the medical innovation.

— **Social responsibility**

(additional provisions specific to the medical sciences)

- Ensure that the medical research or innovation has an appropriate cost-benefit ratio;
- Avoid raising unrealistic expectations about the medical innovation in society;
- Ensure that applied medical research or innovation is a response to actuals health needs and priorities.

Respect for individual rights and liberties:

- Ensure that medical innovation does not pose inherent risks to human dignity, individual freedom, autonomy, authenticity, identity (and sense of self) or individual privacy.

Protection and promotion of the well-being of individuals and groups in society:

- Consider how the medical innovation could harm or promote the well-being of individuals and groups in society;

Protection and promotion of justice and equality:

- Consider how the medical research or innovation could exacerbate or help reduce social inequalities in terms of the distribution of primary goods, capabilities, risks or hazards;
- Consider how the medical research or innovation could harm or serve the interests of vulnerable, disadvantaged or underrepresented individuals, groups and communities in society;
- Consider how the medical research or innovation could harm or serve the interests of individuals, groups and communities in low-income and lower-middle income countries;
- Consider how the medical innovation could affect future generations.

— **Consideration of concerns about naturalness and the commodification of life**

- Have consideration for concerns about naturalness, *i.e.* authentic generation by nature without human interference, in relation to (aspects of) human genetics research, human enhancement research, and other subfields of the medical sciences;
- Have consideration for concerns about the commodification of life in relation to (aspects of) human genetics research and human reproductive technologies.

— **Protection of researchers and staff**

(additional provisions specific to the medical sciences)

- Take special precautions to ensure that researchers and staff involved in conducting the research are not exposed to serious physical harm or strain as a result of working with harmful biological, chemical, or radiological materials.

— **Dual use of medical research**

- Consider whether the research or innovation could have military applications;
- Consider whether the research or innovation could contribute to the proliferation of biological weapons of mass destruction;
- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if the research or innovation has significant military applications or if it contributes significantly to the proliferation of biological weapons of mass destruction. Even if publication is allowed, find a proper balance between security and freedom of publication.

— **Avoidance of misuse of research materials and results**

(additional provisions specific to the medical sciences)

- Take special precautions to prevent or counter the effects of the potential misuse of security-sensitive biological, chemical or radiological materials and knowledge (e.g. the appointment of a security advisor, limiting dissemination, classification, training for staff).

NOTE 4 The precautions in this bullet point are in conformity with the Declaration of Helsinki, the Nuremberg Code and the Belmont Report with regard to the requirement for ensuring the balance of risk and benefit in conducting medical sciences research on human subjects. They are in line with the UNESCO Declaration and the CIOMS Guidelines with regard to the responsibility for the protection of local and indigenous populations, especially in low-income and resource-poor countries. They draw from the CIOMS Guidelines and the Oviedo Convention, particularly with respect to concerns about the commodification of life, and special consideration of human tissue and embryonic cells. They also share concerns about future generation with the UNESCO Declaration of Bioethics and Human Rights. The emphasis on the priority of the interests of human beings (over the interests of science or society), the protection of human rights and dignity and the requirement for informed consent for medical science research and experimentation are universally shared across existing major international conventions and guidelines including the Nuremberg Code, the Declaration of Helsinki, the UNESCO Declaration, the CIOMS Guidelines and the Oviedo Convention. For medical research in European Union Member States, the above guidelines should be supplemented with the Oviedo Convention protocol, which is legally binding within the EU, as well as with other appropriate EU regulations and legislation.

NOTE 5 While International ethical guidelines for research in the medical sciences tend to have a focus on research involving human research participants (note at the beginning of section A.4), many also address some other ethical issues in medical research, such as benefit sharing, the use of human cells and tissues, and dual use. For many specific topics (e.g. genetics research, epidemiological research, stem cell research, medical devices, clinical drug trials, biobanking, research on transplantation, experiments on animals) separate guidelines and directives exist either at international (including EU) or national levels. The US International Compilation of Human Research Standards, 2017 edition contains an exhaustive overview of legislation, guidelines and directives across the world relating to different topics in medical research and innovation.

NOTE 6 Ethical guidelines for medical research in low- or low-middle income countries are provided in the Nuffield Council of Bioethics report *The ethics of research related to healthcare in developing countries* (2014).

A.6 Additional ethical principles and issues in the life sciences

— **Avoidance of public health and safety risks**

- Ensure that the research, regardless of its potential applications, does not pose any direct or long-term risks of harm to public health and safety (e.g. take adequate preventative measures against accidental release of hazardous biological agents);

- Anticipate, assess, and communicate any potential direct or long-term public health and safety risks caused by the intended applications of the research.

— **Social responsibility**

(additional provisions specific to the life sciences)

Protection and promotion of justice and equality:

- Anticipate, assess, and communicate how innovations based on the research could affect social inequalities in terms of the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks, and hazards;

- Anticipate, assess, and communicate how innovations based on the research could affect vulnerable, disadvantaged or underrepresented individuals, groups, and communities in society, and individuals, groups, and communities in low income and lower-middle income countries;

- Anticipate, assess, and communicate how innovations based on the research could affect future generations.

Protection and promotion of rights, well-being and the common good:

- Consider how the research could lead to innovations that could harm human and civil rights, interests or the well-being of individuals and groups in society, or the common good, and how the research and innovation activity could be directed to enhance rights, well-being and the common good.

— **Protection of the environment and animals**

(additional provisions specific to the life sciences)

Protection of the environment:

- Take special precautions to prevent environmental harms caused by the use of biological, chemical or radiological materials during the research;

- Anticipate, assess and communicate how innovations based on the research could harm biodiversity and the integrity of natural ecosystems.

Protection of animals:

- Anticipate, assess and communicate how innovations based on the research could harm (or contribute to) the welfare of animals.

Social responsibility:

- Be conscious of, and engaged with, any societal concerns and interests regarding the ways in which innovations based on the research could affect the environment.

— **Consideration of concerns about naturalness and the commodification of life**

- Consider concerns about naturalness in relation to research into animal and plant breeding, cloning, and the (genetic) modification of organisms;

- Consider concerns about the commodification of life in relation to genetic patenting and research into animal and plant breeding, cloning, and the (genetic) modification of organisms.

— **Protection of researchers and staff**

(additional provisions specific to the life sciences)

- Take precautions to ensure that researchers and staff involved in conducting the research are not exposed to serious physical harm or strain as a result of working with harmful biological, chemical, or radiological materials.

— **Dual use of research**

- Consider whether the research results could have military applications;

- Consider whether the research results could contribute to the proliferation of biological weapons of mass destruction;

- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if the research has significant military applications or if it contributes significantly to the proliferation of biological weapons of mass destruction. Even if publication is allowed, find a proper balance between security and freedom of publication.

— **Avoidance of misuse of research materials and results**

(additional provisions specific to the life sciences)

- Take special precautions to prevent or counter the effects of the potential misuse of security-sensitive biological, chemical, or radiological materials or knowledge (e.g. the appointment of a security advisor, limiting dissemination, classification, training for staff).

A.7 Additional ethical principles and issues in the computer and information sciences

— **Avoidance of security risks**

- Ensure that new research concepts and innovations offer reasonable protection against any potential unauthorised disclosure, manipulation or deletion of information and against

potential denial of service attacks, e.g. protection against hacking, cracking, cyber vandalism, software piracy, computer fraud, ransom attacks, disruption of service;

- Ensure that new research concepts and innovations, by themselves or through their use in a system, do not pose inherent direct or long-term risks of harm to public health and safety, e.g. ICT innovations used in healthcare, ICT innovations used in the monitoring and control of public infrastructure, ICT innovations that could lead to addiction;

- Do not engage in research that involves attempts to make unauthorised access to telephone systems, computer networks, databases or other forms of ICT; such research is illegal and unethical, regardless of motivation;

- Treat with extreme caution the dissemination of research involving the identification of undiscovered security weaknesses in existing systems;

- Avoid practical experiments with computer viruses or perform them in a controlled environment, and exercise extreme caution in the dissemination of the results of paper-based (theoretical) computer virus experiments;

- Carry out any experiments in breach security on designated, standalone (offline) computers or on designated isolated networks of computers.

— **Protection of privacy and personal data**

(additional provisions specific to the computer and information sciences)

- Ensure that new research concepts and innovations do not pose any unjustified inherent risks to the right of individuals to control the disclosure of their personal data;

- If research concepts and innovations involve the combination of multiple data sources, carefully consider the effects on (informational) privacy;

- If research concepts and innovations involve the development of capabilities for, or the use of, data surveillance or human subject monitoring or surveillance, then invoke the requirement for informed consent, if appropriate. Strike an appropriate balance between the need to monitor and control personal information and the right of individuals to (informational) privacy and other human rights.

— **Social responsibility**

(additional provisions specific to the computer and information sciences)

Respect for freedom of expression:

- Ensure that new research concepts and innovations do not pose unjustified inherent risks to the freedom of individuals to express themselves through the publication and dissemination of information, or to their freedom of access to information;

- If research or innovation involves the use of censorship methods, strike an appropriate balance between the need for content control and the right of individuals to express themselves freely.

Respect for intellectual property:

- Ensure that new research concepts and innovations do not pose unjustified inherent risks to the intellectual property rights of individuals or organisations;

- Avoid research that could generate copyright issues, such as research involving peer-to-peer networking or file sharing and distribution.

Respect for other individual rights and liberties:

- Ensure that new research concepts and innovations do not pose inherent risks to autonomy, authenticity or identity. In particular, ensure that information systems do not unnecessarily or unjustifiably take away control from users by limiting their choices or making choices for them that they would prefer to make themselves;

- Ensure that decisions made by information systems that have significant social impact take into account the rights, values and interests of stakeholders, including users, and make efforts to ensure that the reasons for decisions made by information systems can be retrieved, so as to make the systems accountable;

- Take into account the issue of how responsibilities and liabilities are assigned between humans and machines when information systems are involved in decision-making.

Avoidance of harms to justice and equality:

- Consider how new research concepts and innovations could widen or narrow social inequalities in terms of the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks or hazards;

- Consider how new research concepts and innovations could harbour or counter unjust bias in terms of age, gender, sexual orientation, social class, race, ethnicity, religion or disability;

- Consider how new research concepts and innovations could harm or promote the interests of vulnerable, disadvantaged, or underrepresented groups and communities in society, including those in low income and lower-middle income countries.

Promotion of well-being and the common good:

- Consider how the research or innovation activity could harm or promote the general well-being of individuals and groups in society (e.g. effects on the quality of work or quality of life);

- Consider how the research or innovation activity could harm or promote the social skills and behaviour of individuals, and how it could harm or promote the learning or exercising of important virtues, such as patience and empathy;

- Consider whether and how the research or innovation activity could harm or promote important social institutions and structures, democracy, and important aspects of culture and cultural diversity.

Promotion of environmental sustainability:

- Optimize technologies for effective and cost-efficient resource use (including raw materials and energy), for resource recovery (recycling), and for lowering the production of environmentally harmful wastes and environmental pollution.

— **Dual use of computer and information sciences research and innovations**

- Consider whether new research concepts and innovations could have military applications;
- Consider whether new research concepts and innovations could contribute to the proliferation of weapons of mass destruction;
- Consult proper authorities before publishing and adhere to relevant national and supra-national regulations if a technology has significant military applications or if it contributes significantly to the proliferation of weapons of mass destruction. Even if publication is allowed, find a proper balance between security and freedom of publication.

NOTE An example of ethics guidelines for computer and information sciences is the 2013 publication *Applying Ethical Principles to Information and Communication Technology Research* by the US department of Homeland Security.

A.8 Additional ethical principles and issues in the social sciences and the humanities

— **Protection of human research participants**

(additional provisions specific to the social sciences and the humanities)

- Take into account cultural differences when approaching potential participants for informed consent, and seek alternatives to written and signed consent when such consent is culturally foreign to participants;
- Only consider exceptions to the requirement for informed consent in cases where the research cannot be effective if the participants are formally notified in advance of the topic of the research;
- Do not ascribe irrational or unworthy motives to participants without providing convincing documentation and justification. Show respect for the values and views of research participants, including those that deviate from those generally accepted by society.

— **Protection of individuals not directly participating in the research**

- Avoid conducting covert research unless it is the only method by which information can be gathered to fulfil a research aim of high societal importance;
- When conducting research on public individuals, communities, and organisations who are not directly participating in the research, strike an appropriate balance between consideration of the effects of the research on their reputations and privacy on the one hand and the societal benefit of such research on the other hand;
- Act with due consideration of the effects of the research on their posthumous reputations, when conducting research on deceased persons.

— **Social responsibility**

(additional provisions specific to the social sciences and the humanities)

- Acquire knowledge of local traditions, traditional knowledge and social matters and enter, as far as possible, into a dialogue with local inhabitants, representatives of the culture and local authorities when conducting research on other cultures, either in other countries or in minority cultures;
- Avoid using classifications or designations that allow for unreasonable generalisations when conducting research on other cultures.

Respect for individual rights and liberties:

- Consider how the research could contribute to a better understanding of, and better protections for, basic human rights, such as freedom, autonomy, human dignity, and privacy;
- Strike an appropriate balance between the recognition of cultural differences and the recognition of basic human rights.

Protection and promotion of justice and equality:

- Ensure that the research is conducted with respect for all groups and communities in society, regardless of age, gender, sexual orientation, social class, race, ethnicity, religion, culture, and disability;
- Consider how the research could contribute to the reduction of unjust biases, stigmatization, and discrimination in society in terms of age, gender, sexual orientation, social class, race, ethnicity, religion, culture, and disability;
- Consider how the research could contribute to the reduction of social inequalities in terms of the distribution of opportunities, powers and capabilities, civil and political rights, economic resources, income, risks or hazards;
- Consider how the research could help to protect and promote the interests of vulnerable, disadvantaged, or underrepresented groups and communities in society, including those in low income and lower-middle income countries.

Protection and promotion of well-being and the common good:

- Consider how the research could help to protect and promote the general well-being of individuals and groups in society;
- Consider how the research could help to protect and promote important social institutions and structures, democracy, and cultural diversity;
- Protect and promote the responsible treatment of the physical artefacts and intangible attributes of a group or society that constitute cultural heritage, including sites, monuments, artefacts, texts, archives, remains, and information about the past.

NOTE Several ethics guidelines and regulations for the social sciences and humanities exist, such as the EU *Code of Ethics for Socio-Economic Research* (2012), the Norwegian *Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology* (2016), the USA *Federal Policy for the Protection of Human Subjects* (2015), the British *Code of Human Research Ethics* (2010) and the Canadian Tri-Council Policy Statement on *Ethical Conduct for Research Involving Humans* (2014).

Annex B
(informative)

Conflict between ethical principles

B.1 Ethical principles in moral decision-making

Moral decision-making involves considering both the relevant facts, such as the potential outcomes of different decisions and the likelihood of these outcomes, and the application of value judgements. Value judgements can be justified by appealing to ethical principles. These principles help to explain why particular aspects of research and innovation activity could be of ethical concern and assist in communicating and justifying these concerns to others. Examples of ethical principles are listed in Annex A.

Ethical principles guide moral decision-making by emphasizing particular moral aspects of the possible outcomes of the decision. For example, non-maleficence calls for avoiding harm. Applying this principle to an evaluation of research and innovation activity would involve examining how the various outcomes could cause harm, and to whom, and whether it is possible to reduce or avoid the potential harm from these outcomes.

B.2 Resolving conflicts between ethical principles

Ethical principles could provide conflicting guidance when applied to some issues. This requires a choice to be made about which principle should be given priority over another. Which principle should take precedence is a matter of judgement and will depend on the context in which the research and innovation activity takes place. For example, the principles of beneficence (promoting well-being in others) and non-maleficence (avoiding harm) could conflict in medicine, where a medical procedure that could cause temporary harm is necessary to improve a patient's long-term health. In this case, the likelihood of the procedure's success in promoting future well-being would need to be considered against the degree of harm and discomfort caused by the procedure.

There are a variety of methods for deciding how a conflict between ethical principles should be resolved. Four such methods are the *utilitarian calculus*, *libertarian side-constraints*, *prima facie principles* and *specification*. An ethics committee may use one or more of these methods to assist in its decision-making.

— Utilitarian calculus

  The utilitarian calculus uses the concept of utility to decide between possible actions. Utility is usually understood as desirable consequences for those affected by an action, including happiness, pleasure, and well-being. If the positive consequences of an action outweigh the undesirable consequences (such as harm or pain) then the action has positive utility and should be performed. The differences in the utility of various outcomes can be compared to decide which action has the greatest likelihood of producing positive utility.

— Libertarian side-constraints

  Libertarian side-constraints emphasize the rights of those affected by an action and the importance of protecting these rights against violation. The rights of individuals, such as the rights to life and liberty, serve as constraints on the permissible actions of others.

— *Prima facie* principles

The *prima facie* approach sees ethical principles as valid only if they do not conflict with each other. In other words, these principles create *prima facie* duties that may be overridden by the requirements of another principle. When principles conflict with each other, the moral intuitions and experience of the decision-makers can help direct them in deciding which of the conflicting principles should take precedence over the others.

— Specification

The method of specification seeks to resolve conflicts between ethical principles by recognizing that such principles are understood as being valid 'in general', and may be made more specific to handle particular cases and to recognize the priority of other principles. For example, a potential conflict between the principle of beneficence and the individual's right to liberty could be avoided by specifying the principle of beneficence as the duty to increase the health and well-being of others in accordance with their right to choose their actions for themselves.

Annex C
(informative)

Risk-based thinking in ethics assessment

C.1 Risk-based thinking

Risk-based thinking enables to determine the factors that could cause a project's activities to deviate from the planned results, to put in place preventive controls to minimize negative effects, and to make maximum use of opportunities. This annex briefly explains the following steps in risk management:

communication and consultation;

— establishing the context;

— risk assessment;

— risk treatment.

NOTE ISO 31000 provides requirements and recommendations for risk management.

C.2 Communication and consultation

Communication and consultation with external and internal stakeholders should take place during all stages of risk management. The R&I project members should identify, record and take stakeholder views into account in the decision-making process.

C.3 Establishing the context

To establish the context, the R&I project members should articulate the project's objectives, define the external and internal parameters to be taken into account when managing risk, and set the scope and risk criteria for the project.

The external context is the external environment in which the R&I project members seek to achieve project objectives and includes specific details of legal and regulatory requirements, stakeholder perceptions and other aspects of risk specific to the scope of the project.

The internal context is the internal environment in which the R&I project members seek to achieve project objectives and includes the project's culture, processes, structure and strategy. Internal context is anything within the project that influences risk management.

C.4 Risk assessment

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

— **Risk identification:** Risk identification involves identifying sources of risk, areas of impact, events including changes in circumstances, and their causes and potential consequences. The aim of this step is to generate a comprehensive list of risks based on those events that could create, enhance, prevent, degrade, accelerate or delay the achievement of objectives. It is important to identify the risks associated with not pursuing an opportunity. Risk identification should include examination of consequences and cumulative effects;

— **Risk analysis:** Risk analysis involves developing an understanding of the risk. Risk analysis involves consideration of the causes and sources of risk, their positive and negative consequences, their likelihood, and the timeframe in which the consequences could occur. Factors that affect consequences and likelihood should be identified. The combination of consequences, likelihood and timeline determines the level of risk and sensitivity to preconditions. Factors such as divergence of opinion among experts; uncertainty; the availability, quality, quantity and relevance of information, or limitations on modelling should be stated and can be highlighted;

— **Risk evaluation:** Risk evaluation involves comparing the level of risk with the objectives and context. The purpose of risk evaluation is to assist in making decisions, based on the outcomes of risk analysis, about which risks need treatment and the priority for treatment implementation.

C.5 Risk treatment

Risk treatment involves selecting one or more options for modifying risks, and implementing those options. Risk treatment involves a cyclical process of:

— assessing a risk treatment;

— deciding whether residual risk levels are tolerable;

— if they are not tolerable, generating a new risk treatment;

— assessing the effectiveness of that treatment.

Risk treatment options are not necessarily mutually exclusive or appropriate in all circumstances. The options can include the following:

— avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk;

— taking or increasing the risk in order to pursue an opportunity;

— removing the risk source;

— changing the likelihood;

— changing the consequences;

— sharing the risk with another party or parties (including through contracts and risk financing);

— retaining the risk by informed decision.

Selecting the most appropriate risk treatment option involves balancing implementation costs against benefits, with regard to legal, regulatory and other requirements, such as social responsibility and protection of the environment. Some risks warrant risk treatment but this is not justifiable on economic grounds, e.g. severe (high negative consequence) but rare (low likelihood) risks.

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

Annex D
(informative)

Guidelines for the use of the Plan-Do-Check-Act approach (PDCA) for ethics assessment

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

PLAN The ethics committee should adequately plan for quality assurance (QA) in their ethics assessment. The ethics committee should develop a quality assurance plan that typically includes the following: — the objectives of QA; — the strategy and approach to QA; — the methods and or techniques to be used and how performance is to be measured; — who has the responsibility for QA.
DO DO envisages the implementation of the QA plan and ensuring that its arrangements are followed. The ethics committee should, for example: — Determine and provide the *resources* needed for the establishment, implementation, maintenance and continual improvement of the ethics assessment process (while considering the capabilities of, and constraints on, existing internal resources and what needs to be obtained from external providers); — Determine and provide the *persons* necessary for the effective implementation, operation and control of its ethics assessment processes; — Determine, provide and maintain the *infrastructure*[1] necessary for the operation of processes to ensure the quality of ethics assessment; — Determine, provide and maintain the *environment* necessary for the operation of its ethics assessment processes; — Determine and provide the resources needed to ensure valid and reliable results in the ethics assessment process; — Ensure that the resources provided: • are suitable for the specific type of ethics assessment being undertaken; • are maintained to ensure their continuing fitness for purpose. — Retain appropriate documented information as evidence of the fitness for purpose of the ethics assessment process. — Determine the knowledge required for the operation of its ethics assessment processes. — Ensure: • the required level of competence of person(s) doing work under its control where this affects the performance and effectiveness of the ethics assessment process; • that these persons are competent on the basis of appropriate education, training, or experience;

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

- where applicable, taking actions to acquire the required level of competence, and evaluating the effectiveness of the actions taken;
- the retention of appropriate documented information as evidence of competence.

— Ensure that relevant persons working under the organization's control (e.g. ethics assessors, other staff) are aware of:
- the quality assurance policy;
- relevant quality objectives;
- their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- the implications of not conforming with the ethics assessment process requirements.

— Determine the internal and external communications relevant to the ethics assessment process (what, when, with whom, how);

— Maintain the documented information that the organization has determined necessary for the effectiveness and quality of the ethics assessment process.

CHECK

To facilitate the CHECK stage, the ethics committee should assess the quality of ethics assessment policy, practice and procedure:

Typical example questions include:

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

— How effective has the ethics assessment policy, practice, or procedure been?
- To what extent have the objectives been achieved?
- What have been the (quantitative and qualitative) effects of the ethics assessment policy, practice, or procedure?
- To what extent do the observed effects correspond to the objectives?
- To what extent can these changes/effects be credited to the ethics assessment policy, practice, or procedure?
- What factors influenced the achievements observed?
- To what extent did different factors influence the achievements observed?
- Did evaluation or review policies and procedures enable researchers to address things affecting achievement of the objectives of the ethics assessment policy, practice, or procedure?

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

— How relevant is the ethics assessment policy, practice or procedure?
  - To what extent is the ethics assessment policy, practice or procedure still relevant?
  - To what extent have the (original) objectives proved appropriate for the ethics assessment policy, practice or procedure in question?
  - How well do the (original) objectives (still) correspond to the needs within the EU?
  - How well adapted is the ethics assessment policy, practice or procedure to subsequent technological, scientific, societal or other advances? Issues related to the specific policy could be included here.
  - How relevant is the ethics assessment policy, practice or procedure to individuals or citizens?
— How coherent is the ethics assessment policy, practice, or procedure internally and with other external actions?
  - To what extent is the ethics assessment policy, practice or procedure coherent with other ethics assessment policies, practices or procedures that have similar objectives?
  - To what extent is the ethics assessment policy, practice or procedure coherent internally?
  - To what extent is the ethics assessment policy, practice or procedure coherent with wider EU or national policy?
  - To what extent is the ethics assessment policy, practice or procedure coherent with international obligations?
— What is the EU added value of the ethics assessment policy, practice,or procedure?
  - What is the additional value resulting from the EU ethics assessment policy, practice, or procedure, compared to what could be achieved by Member States at national and/or regional levels?
  - To what extent do the issues addressed by the ethics assessment policy, practice, or procedure continue to require action at EU level?
  - What would be the most likely consequences of stopping or withdrawing the existing EU intervention?

ACT

The ACT part envisages review and continuous monitoring and improvement to improve the performance, adequacy and effectiveness of the ethics assessment process. The ethics committee should take actions to improve the ethics assessment policy, practice and procedures and correct undesirable effects (e.g. the passing of a highly unethical project with detrimental effects on society). These includes following type of activities:

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

NOTE The key questions in the CHECK section are based upon and adapted from the EC Better Regulation Guidelines on Evaluation and Fitness Checks. http://ec.europa.eu/smart-regulation/guidelines/ug_chap6_en.htm.

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