SATORI

Outline of an Ethics Assessment Framework

May 2017

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European Commission

Outline of an Ethics Assessment Framework

V.2.0

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May 2017

Deliverable D4.2

This deliverable and the work described in it is part of the project:

Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation – SATORI – received funding from the European Commission's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 612231

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Initials and acronyms

CR: Corporate Responsibility

CSO: Civil Society Organisation

CSR: Corporate Social Responsibility

EA: Ethics Assessment

EAU: Ethics Assessment Unit

EI: Ethical Impact

EIA: Ethical Impact Assessment

EG: Ethics Guidance

EU: European Union

NEC: National Ethics Committee

NGO: Non-Governmental Organisation

NSA: National Science Academy

OECD: Organisation for Economic Cooperation and Development

PDCA: Plan-Do-Check-Act

QA: Quality Assurance

REC: Research Ethics Committee

RFO: Research Funding Organisation

R&I: Research and Innovation

TRL: Technology Readiness Level

SECTION 1 Introduction

This is a summary of a larger report (Deliverable 4.1) that presents the outline of an ethics assessment framework for research and innovation (R&I) in the European Union member states.[1] It roughly follows the organisation of the larger report.

In section 2, we analyse stakeholders' expectations about the intended goal of the SATORI project: an European framework for ethics assessment of R&I. This analysis is based on 153 interviews with different kinds of stakeholders, both ethics assessors and non-assessors. The benefits and obstacles are identified and listed in this section.

In section 3, we propose a framework of ethical issues and principles, many forms of scientific R&I. It describes a set of ethical issues and principles that apply to all types of research. It also specifies the principles and issues that apply to specific research contexts.

In section 4, we outline recommendations for best practice in Ethics Assessment Units (EAUs). These recommendations are structured around a series of parameters common to all EAUs that review R&I activity.

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

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

In section 7, we present recommendations for ethics assessment (EA), and ethics guidance (EG) by specific types of organisations: universities, civil society organisations, industry and research funding organisations.

In section 8, we outline proposals for the institutional structure of ethics assessment in the European Union and its constituent countries. They address the institutional setup of eight different types of ethics assessors at the European Union level.

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

SECTION
2

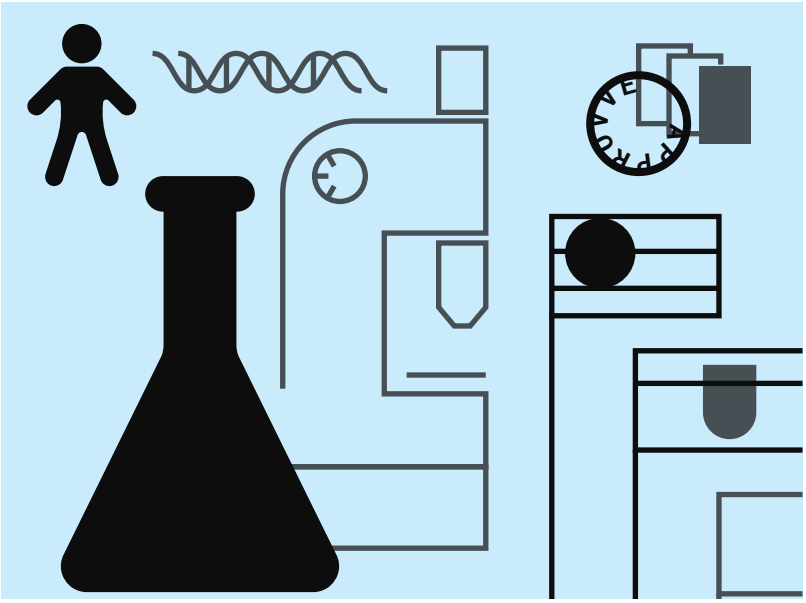
Ethics Assessment Organisations Expectations about a Joint Framework

This section analyses stakeholders' expectations about the intended goal of the SATORI project: an European framework for ethics assessment (EA) of research and innovation (R&I). This analysis is based on 153 interviews with different kinds of stakeholders, both ethics assessors and non-assessors, who were asked to share their opinions on the desirability and possibility of such a framework.[2] The interviews were conducted during the previous, fact-finding stage of the project, before the framework was developed.[3]

At the first level of analysis, the positions of the stakeholders on the prospect of a common approach to EA in R&I was identified. 51.6% of interview respondents thought it would be desirable to have a shared European framework. An additional 30% of respondents were conditionally positive on the desirability of the framework. These stakeholders would welcome the framework if it would be designed or implemented in a specific way. 9.2% of responses were negative, while another 9.2% were inconclusive.

The second level looked deeper into the interviews, identifying recurrent themes and major points provided by respondents, concerning the benefits and potential negatives of a common framework, the obstacles to its development and implementation, as well as advice on the framework's design.

Among the *benefits* of the common framework, respondents cited unification, harmonisation and convergence of EA principles and procedures. Many stakeholders also thought that the framework could be beneficial as a platform for discussion of ethical issues and exchange of best practices of assessment among a variety of stakeholders. A framework should preferably include wide stakeholder participation and dialogue, and be based on an inclusive decision-making process, rather than one that is top-down. Stakeholders would also welcome the use of the framework in international projects.



According to the majority of respondents, the biggest *obstacle* for creating the common framework is the differences between countries, cultures, ethical values and philosophies as well as between scientific fields. The awareness of the differences often led to the conclusion that the framework should be general and function at an aspirational level. At the same time, the stakeholders were acutely aware that a framework that does not strive to provide concrete answers could become useless or at least impractical. A possible solution is that countries and scientific fields should have the option to accommodate the general rules with some room to manoeuvre due to differences, similar to the "margin of appreciation" doctrine in the field of human rights. Some respondents warned that it would be hard to achieve buy-in or enforce the framework. Others feared the framework would increase bureaucracy or that it would be reduced to another check box formality.

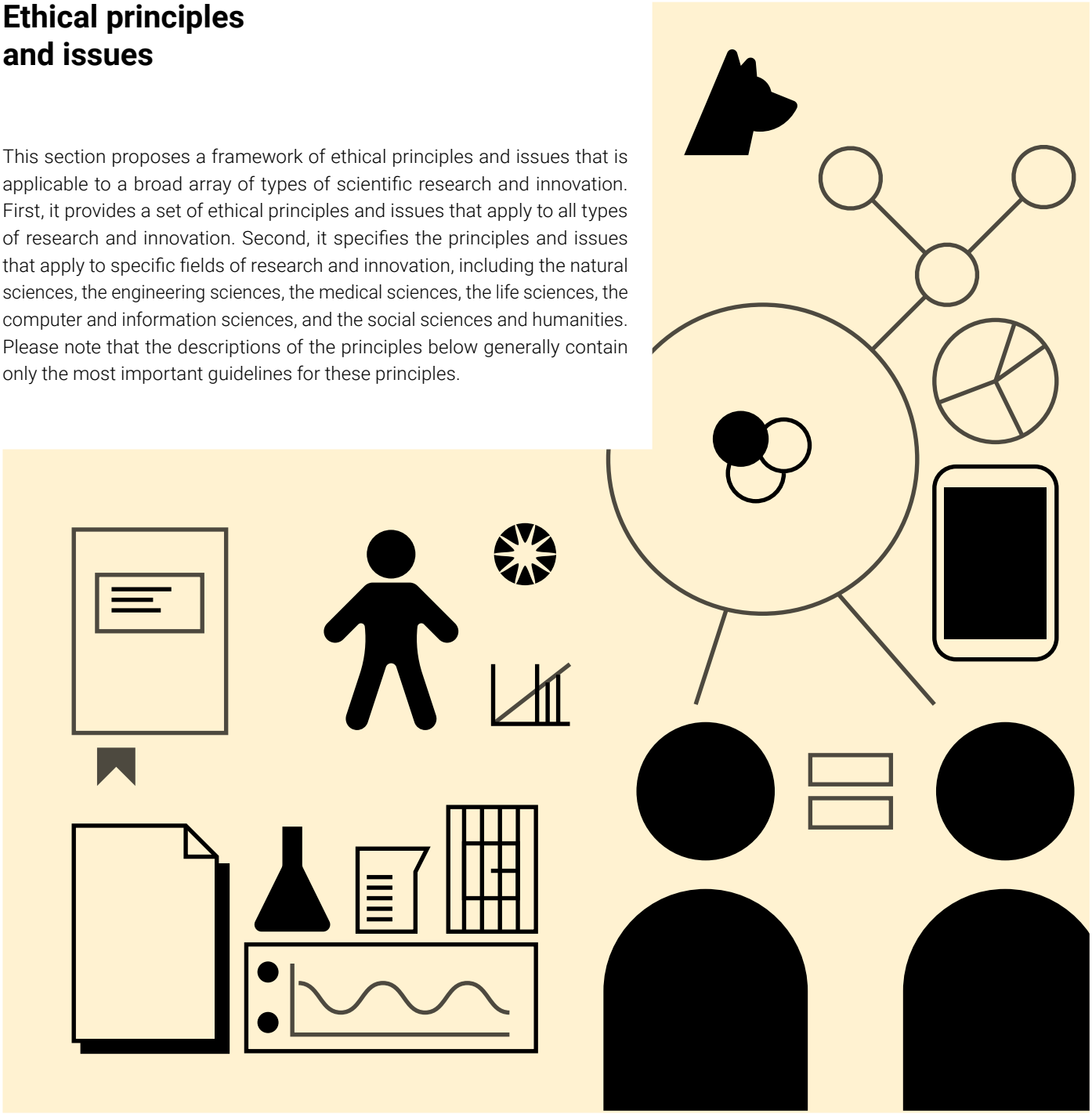
There are therefore three major challenges for the development of a common framework. The first challenge is to achieve harmonisation of ethical principles and procedures, while at the same time allowing for differences between countries and scientific fields. The second challenge is for the framework to function on a general, aspirational level, while at the same time providing useful tools for solving concrete ethical dilemmas. The third challenge is to achieve a wide acceptance for the framework.

SECTION
3

Ethical Principles and Issues

Ethical principles and issues

This section proposes a framework of ethical principles and issues that is applicable to a broad array of types of scientific research and innovation. First, it provides a set of ethical principles and issues that apply to all types of research and innovation. Second, it specifies the principles and issues that apply to specific fields of research and innovation, including the natural sciences, the engineering sciences, the medical sciences, the life sciences, the computer and information sciences, and the social sciences and humanities. Please note that the descriptions of the principles below generally contain only the most important guidelines for these principles.



1 General Ethical Principles for all Types of Research and Innovation

1. RESEARCH INTEGRITY

- Employ and faithfully apply appropriate research methods;
- Avoid fabrication, falsification and plagiarism of research materials and data;
- Avoid practices that undermine the integrity and trustworthiness of scientific research.

2. SOCIAL RESPONSIBILITY

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

3. 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;
- Be transparent about and disclose relevant financial ties and/or ideological, political or institutional influences and positions.

4. PROTECTION OF AND RESPECT FOR HUMAN RESEARCH PARTICIPANTS

- Obtain informed and voluntary consent from human participants (or their legal guardians);
- Treat human participants with due consideration for their autonomy and dignity, and minimise the risk of harm done to them in a research context;
- Fairly distribute benefits and burdens of research, and ensure that the potential benefits of research outweigh the risk of harm caused to research participants.

5. PROTECTION OF AND RESPECT FOR ANIMALS USED IN RESEARCH

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

6. PROTECTION AND MANAGEMENT OF DATA

- Obtain consent for the collection and use of personal data;
- Ensure the security of collected and stored data and information.

7. PROTECTION OF RESEARCHERS AND THE RESEARCH ENVIRONMENT

- Ensure that researchers and staff involved in conducting the research are not exposed to serious risk of physical or psychological harm or strain as a result of the research;
- Avoid harm to the local community as a result of any field work or experiments;
- Avoid or minimise harm to the local environment (including animals, plants, and natural and cultural heritage) caused by any field work or experiments, and ensure that any harm done can be justified by the (potential) benefits of the research.

8. DISSEMINATION OF RESEARCH RESULTS

- In the absence of compelling reasons to act otherwise, make research results publicly available (e.g. through open access publications). Openness regarding research findings is essential for ensuring verifiability, returning benefit to research participants, providing benefit to society, detecting misconduct, and ensuring a dialogue with fellow researchers, stakeholders and the public.

2 Additional Field-specific Principles for Research and Innovation

In addition to the general ethical principles for all types of research and innovation, there are additional field-specific principles for research and innovation as listed below. It must be noted that because ethical issues are frequently triggered by special conditions that often arise across multiple fields, it becomes important to identify applicable ethical principles on a case-by-case basis for each research and innovation project, while taking account of special provisions, conventions and regulation that may apply to specific fields.

1 The Natural Sciences

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

2 The Engineering Sciences & Technological Innovations

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

3 The Medical Sciences

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

4 The Life Sciences

- Ensure that the research, regardless of its potential applications, does not pose any direct or long-term risks of harm to public health and safety (e.g., by taking adequate precautionary measures against accidental release of hazardous biological agents);
- Consider how the research might lead to innovations that could harm human and civil rights, interests or the well-being of individuals and groups in society, or the common good, and how the research and innovation activity might be directed to enhance rights, well-being and the common good;
- Anticipate, assess and communicate how the research and innovations based on this research might pose risks to or harm biodiversity, the integrity of natural ecosystems, and the welfare of animals;

- Consider concerns about naturalness (authentic generation by nature without human interference) in relation to research into animal and plant breeding, cloning, and the (genetic) modification of biological organisms;
- Ensure that researchers and staff involved in conducting the research are not exposed to serious physical harm resulting from working with harmful biological, chemical, or radiological materials;
- Consider whether the research results might have military applications;
- Prevent or counter the effects of the potential misuse of security-sensitive biological, chemical, or radiological materials or knowledge (e.g., through the appointment of a security advisor, limitation of dissemination of the research results, training for staff).

5 *The Computer & Information Sciences*

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

6 *The Social Sciences and the Humanities*

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

SECTION 4

Ethics Assessment Procedures

This section outlines recommendations for best practice in ethics committees, which may be a part of a larger organisation or independent. These recommendations are structured around a series of parameters common to all ethics committees that review R&I activity: composition and expertise; appointment and training; procedures prior to assessment; procedures during assessment; procedures after assessment; supervision; quality assurance (QA); efficiency considerations; organisational and cultural factors. Specific national legislation may also impose additional requirements on ethics committees that go beyond the general recommendations presented here.

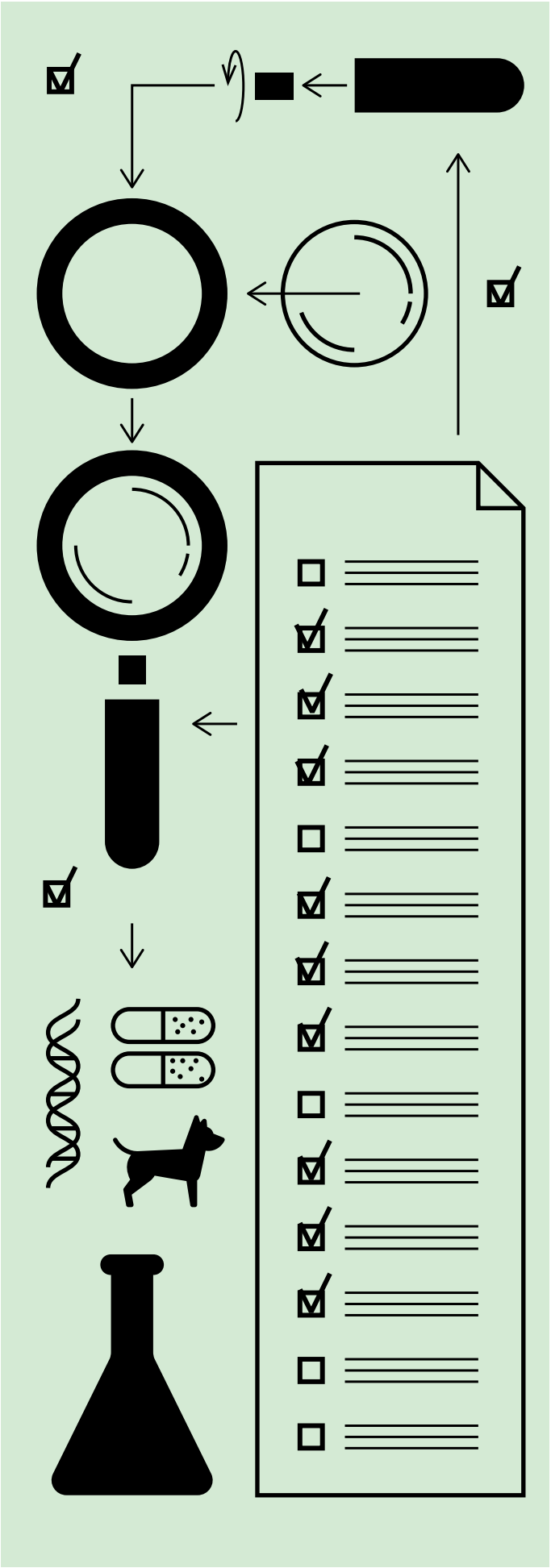
Composition and Expertise

The appropriate composition of and expertise within an ethics committee depends on the unit's goals, the scope of its work and the available resources.

- The number of members in an ethics committee may depend on any legislative requirements for the size of an ethics committee, the available resources, and the need to include a number of diverse perspectives on research while maintaining a manageable size to allow for fruitful discussion and deliberation.
- The membership of an ethics committee should be arranged so that it encourages rigorous discussion and evaluation of R&I activity. This is best achieved by a membership that is professional (technically, ethically, and administratively), independent of the researchers and the institutions involved, diverse in backgrounds and expertise, and *representative* of the communities affected by its decisions.
- The ethics committee chairperson should possess strong administrative competence, including good interpersonal skills for managing group decisions and good communication skills to convey the ethics committee's decisions to researchers and supervisors.
- Those with expertise relevant to the activity under review should be included among the ethics committee's members. However, persons without directly relevant expertise should be an equally important section of the membership.
- Ethics committee members should possess the following characteristics:
  - Relevant expertise (professional members) or an informed interest (non-professional members/lay persons, experts from other fields) in the R&I activity under assessment;
  - Good communication skills, both written and interpersonal;
  - An ability to evaluate the benefits, risks, and burdens associated with the specific research projects assessed;
  - An ability to engage in reasoned debate and discussion to reach and accept a balanced view of the research projects assessed;
  - Personal commitment to the goals of EA.
- Lay persons (i.e., persons without expertise relevant to the R&I activity, including members of the general public) should be included, and there should be a sufficient number of them to ensure that the expert members cannot ignore their views. Lay persons should also only be permitted to serve as ethics committee members for a limited time so that such members continue to provide an 'outside' perspective on research. They should be aware that their role is to view the R&I activity both as someone from outside the research community, and as someone belonging to a group of people who may participate in the activity.
- End users (e.g., patients or elderly), or representatives of end user organisations, should be included.
- Persons with ethical and legal expertise should be included.
- Ethics committee members with an apparent conflict of interest should not participate in discussions or decisions where that interest may affect their judgement.

Appointment and Training

- If the ethics committee is embedded in an organisation, the members of this organisation should elect the ethics committee chairperson. The organisation should appoint qualified experts. Members from outside the ethics committtee's parent organisation (e.g., stakeholder or CSO representatives) should be nominated by their own organisations in a transparent way and selected on the basis of their competency. Lay persons should not exclusively be selected by scientific experts. The chief executive of the organisation should not be a member of the ethics committee.
- If a newly elected member of the ethics committee is replacing an outgoing member, there should be a transition period in which the new member acts as a regular substitute for the outgoing member and during which knowledge is transferred and training may take place.
- The chairperson may select temporary or 'ad hoc' members in consultation with the ethics committee's supervisor. Temporary members may be appointed to the ethics committee and treated as advisors to



the ethics committee who present their informed opinion of the activity under review, or as temporary members who participate in the ethics committee's full decision-making process.

- Ethics training for ethics committee members without ethical expertise could be made more effective by incorporating it into other policies and procedures that require training.
- EA should be better integrated in political decision-making through education and training in ethical issues for decision makers and by including EA in decision-making procedures.

Procedures prior to assessment

The procedures that take place prior to the EA of R&I activity cover the dissemination of policies and procedures for EA to scientists and others, the actual submission of proposals or requested information to the ethics committee, and the procedures necessary for preparing the descriptions of R&I activity for ethics review. The following procedures are recommended as best practices for all types of ethics committees:

- Use of a standard application form, including:
  - information on the person responsible for the conduct of the project;
  - a description of the R&I activity including the scientific questions, and the overall aim and purpose of the research/experiment;
  - a detailed presentation of the proposed methodology;
  - the significance of the R&I/R&D activity and expected benefits achieved;
  - documentation describing the procedures for obtaining informed consent;
  - information on the social impact and context of the R&I/R&D activity;
  - information on documentation and data protection and/or how biological material is to be stored; and
  - information on identified stakeholders.
- Use of *self-assessment*: The research proposal should include the researchers' own description and assessment of the ethical considerations.
- Use of *pre-assessment/pre-screening*: Pre-assessment or -screening deals with the question of whether the ethical issues of the project have been addressed. They make ethics review both time-effective and enable a thorough EA for R&I activities that require it. The ethics committee will conduct the full assessment of R&I activity where such assessment is needed, e.g. when there is a high-risk project. The pre-assessment will involve:
  - a summary of the case,
  - a reflection on the ethical considerations that the researcher has identified as well as a reflection of how the researcher will deal with them,

- an analysis of other ethical concerns that the researcher may have not addressed, and
- the suggestion of a decision (for which the pre-assessor could give reasonable arguments).

- While the EA of R&I activity is in most cases proactive (i.e. it takes place before the research or innovation is conducted), there are at least two cases where ethics committees should assess on-going projects:
  - An application has already been approved but has undergone essential changes that may affect the risk of harm or other relevant ethical aspects. The researcher (or equivalent agent) should submit a proposal for amending the former application.
  - The application has not undergone ethics review but the researcher (or equivalent agent) identifies ethical issues that ought to undergo ethics review. Here the researcher (or equivalent agent) should submit a new application for ethics review. Any changes to the protocol must go to the ethics committee for approval.

Procedures during assessment

The following general procedures to take place during the EA of R&I activity are recommended as best practices for all types of ethics committees:

- All ethics committees should have an established decision procedure to promote transparency and to prevent decisions being made on an arbitrary basis. The decision procedure should be documented and made publicly available.
- The assessment procedure should be designed to ensure that the conducted R&I activity:
  1. protects stakeholders (e.g. individuals participating in research) from undue risk and harm,
  2. ensures that participation in research, trials and similar activities related to the R&I activity is voluntary,
  3. determines whether the research or innovation methods are appropriate, and
  4. aims to increase the awareness of the ethical impact (EI) of R&I.
- Some of these goals can be achieved by using a checklist for relevant and pressing issues.
- There should be a method for dealing with the issue of weighing the benefits of the research against the risk and harm. However, before weighing the harms against the benefits of the research, it should be considered whether there are ways to redesign the research study or the product to reduce the risk. Such methods should not only consider weighing benefits against harms towards individuals, but also harms against society, the environment and animals.
- The decision-making procedure should be made public for the sake of transparency, unless prevented by regulatory requirements and/or confidentiality considerations.
- In cases where the ethics committee finds information lacking, or where they identify ethical issues that can be avoided, they should ask the applicant to revise the application in accordance to their suggestions rather than reject the proposal.
- The ethics committee should establish mechanisms of communicating their decisions to the researchers.
- The ethics committee should provide ample motivation for the decisions.
- The ethics committee should establish procedures for dealing with conflicts of interest within the unit. Researchers should be required to state any potential conflicts of interest.
- The ethics committee may use ethical checklists in order to comprehensively check for the presence of ethical issues. There should always be a possibility to add new ethical principles and issues to the list. The use of ethical checklists should not preclude open discussion about ethical issues.

Procedures after assessment

The following general procedures after assessment are recommended as best practices for all types of ethics committees in order to deal with communicating the result of the assessment process, the possibility to appeal, and monitoring compliance:

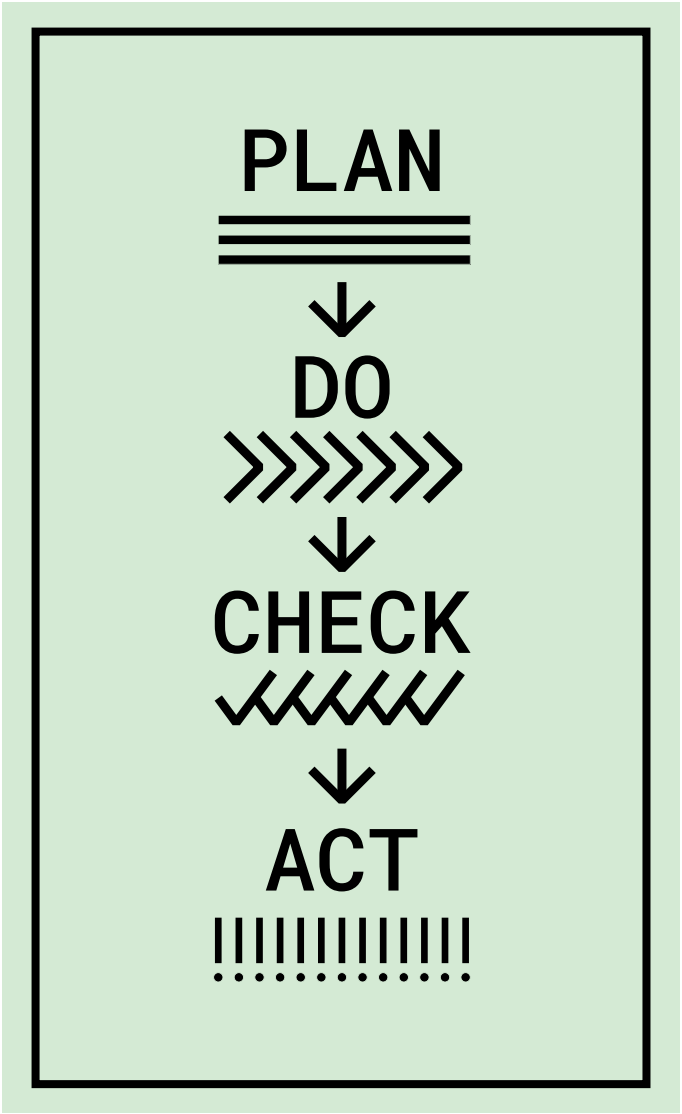
- The decisions of the ethics committee should be recorded for internal access and for external reference if required by legislation or auditing.
- After the review/decision, the ethics committee should provide the applicant with a written assessment that explains the reasons for the ethics committee's decision. If the decision is not unanimous, this should be noted in the decision. The decision may vary depending on whether the assessment is obligatory or non-obligatory. If approval has been given (in the case of an obligatory EA), a favourable report is issued. If minor amendments are necessary, the committee will ask the researcher to submit a revised proposal. Ideally there should be a dialogue between the ethics committee and the submitter of the proposal regarding the ethical issues and how to deal with them. In case of a non-obligatory assessment, the ethics committee will give a recommendation that the R&I activity should either proceed, be revised, or halted.
- The opportunity to appeal against the decision should be given. The procedure and timeframe for appeals should be specified when the decision is presented.
- There should be QA monitoring of both whether the researchers followed the ethics committees by either – if it has the resources available - the ethics committee itself or by another organisation (such as a RFO) involved in the research. There should also be QA monitoring of whether the researchers found the ethics committee effective. The ethics

committee should oblige researchers to issue annual reports, end-of-study reports and report on adverse events.

- If decisions (especially binding ones) are to be followed up, there should also be procedures for the measures to take in case of non-compliance.

Supervision

- Those responsible for the work performed by an ethics committee have the strongest interest in supervising their work and ensuring that it is of a high quality.
- Ethics committees should be supervised by a high administrative or managerial level of the organisation within which they operate (when they do operate within an organisation).
- The supervision of ethics committees should not compromise their ability to be independent in their decision-making. Using external auditors and performing QA of the ethics committee's work are both ways of demonstrating the quality of the ethics committee's work and that it is fair and unbiased.
- Policies should be put in place that require the supervisors of ethics committees to take the assessment of the ethics committee into account when deciding on whether to proceed with R&I activity.



Quality assurance

In EA, QA refers to activities (administrative, procedural or other) undertaken either by ethics assessors themselves or their agents to (systematically) study, evaluate, monitor, or measure and compare with established standards, or make recommendations (for improvement) in relation to the effectiveness of their EA process and procedures. We recommend that ethics committees consider using a modified version of the *Plan-Do-Check-Act* (PDCA) process[17] used in the internationally recognised ISO 9001 'Quality Management Systems — Requirements' standard. Our adapted version that incorporates relevant elements from existing QA of EA practice is presented below:

PLAN

This part envisages the implementation of the QA plan and ensuring that the arrangements therein are followed. This includes support actions, such as:[18]

1. the objectives of the QA,
2. the strategy and approach to QA,
3. the methods/techniques to be used and how performance shall be measured, and
4. who has the responsibility for QA.

DO

This part envisages the implementation of the QA plan and ensuring that the arrangements therein are followed. This includes support actions, such as:[18]

- Determining and providing the persons and resources necessary for establishing, operating, and revising the EA process (while considering the capabilities of, and constraints on, existing internal resources and also what needs to be obtained from external providers).
- Determining, providing and maintaining the infrastructure and environment necessary for the operation of processes to achieve quality of EA.
- Ensuring that the resources provided are suitable for the EA performed and are maintained to ensure their continuing fitness for their purpose.
- Retaining appropriate documented information as evidence of fitness for purpose of the EA process.
- Ensuring that relevant persons working under the organisation's control (e.g. ethics assessors, other staff) are aware of:

1. the quality policy;
2. relevant quality objectives;
3. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
4. the implications of not conforming with the EA process requirements.

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

CHECK

This part monitors and (where applicable) measures EA processes and the results against policies, objectives and requirements, and reports the results. Some key questions (based upon and adapted from the EC Better Regulation Guidelines on Evaluation and Fitness Checks)[19] that could help assess the quality of EA policy, practice or procedure are outlined below:

1. What is the current situation?
2. How effective has the EA policy, practice or procedure been?
3. How efficient has the EA policy, practice or procedure been?
4. How relevant is the EA policy, practice or procedure?
5. How coherent is the EA policy, practice or procedure internally and with other external actions?
6. What is the European Union added value of EA policy, practice or procedure?

ACT

This part involves the review and continuous monitoring and improvement to improve the performance, adequacy and effectiveness of the EA process. This includes the following type of activities:

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

Efficiency considerations

The recommendations for QA are based on the Plan-Do-Check-Act (PDCA) process described in the ISO 9001 standard. According to this approach, planning for and ensuring efficient use of resources is already part of the QA of a project. The majority of elements relevant to efficiency in the adapted PDCA approach appear in the CHECK stage, and are listed below:

- To what extent have the objectives been achieved?
- What have been the (quantitative and qualitative) effects of the EA 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 EA policy, practice or procedure?
- What factors influenced the achievements observed?
- To what extent did different factors influence the achievements observed?
- Did evaluation or review policies/procedures allow for the addressing of things affecting the achievement of the objectives of the EA policy, practice or procedure?
- To what extent has the EA policy, practice or procedure been cost effective?
- To what extent are the costs involved justified, given the changes/effects that have been achieved?
- To what extents are the costs proportionate to the benefits achieved? What factors are influencing any particular discrepancies?
- What factors influenced the efficiency with which the achievements observed was attained? How affordable were the costs borne by different stakeholder groups, given the benefits they received?

Addressing cultural and organisational factors

- Cultural factors should only be used to justify stricter requirements than those imposed by national and international laws, and accepted international guidelines on research ethics.
- Ethics committee members with training and experience in applied ethics can assist in identifying and addressing cultural factors that might affect how the general community perceives the research.
- Legal requirements must take precedence over other considerations in the ethics committee's organisation and operation.
- The work of the ethics committee should recognise the goals of the organisation connected with the ethics assessor, without undermining the independence of the ethics committee's decisions.

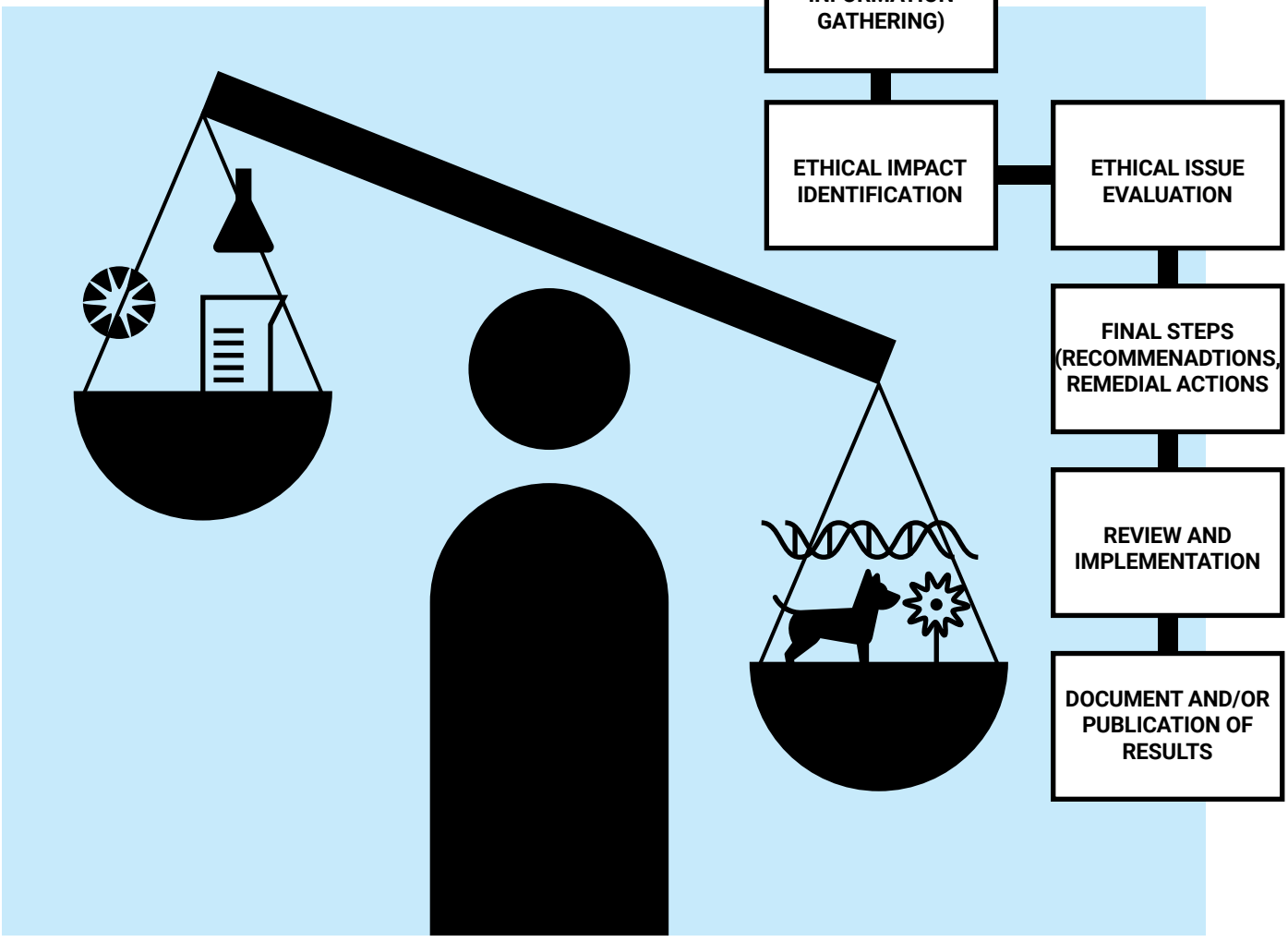
SECTION
5

Ethical Impact Assessment

This section offers a short overview of the framework for Ethical Impact Assessment (EIA). The framework can be used by the following organisations in the following ways::

- For governance bodies to set up new regulations with regards to EA in R&I;
- For research funding organisations (RFOs) to set up new procedures for conducting EIAs in the projects they fund;
- For local research organisations and companies for setting up internal procedures for conducting an EIA in the R&I projects they organise.

Our framework presents the EIA process as a series of six stages: the EIA threshold analysis stage, the preparation stage, the ethical impact identification stage, the ethical impact evaluation stage, the remedial actions formulation stage, and the review and audit stage. Below, we outline the functions, the essential elements, and the specific procedural steps of each of these stages.



1 CONDUCT AN EIA THRESHOLD ANALYSIS

1. Design the threshold analysis questionnaire
2. Fill in the threshold analysis questionnaire
3. Decide whether an EIA is needed

2 FORMULATE AN EIA PLAN

1. Assess the scale of the EIA
2. Review and approve the EIA plan
3. Communicate the review

3 IDENTIFY THE ETHICAL IMPACTS

1. Conduct preliminary identification of the R&I project's potential (future) ethical impacts through literature analysis of the impacts of similar R&I projects
2. Further specify and identify additional potential ethical impacts through the use of both (1) ***foresight methods*** and (2) ***ethical impact identification methods***
3. Document the results of the ethical impact identification activities

4 EVALUATE THE ETHICAL IMPACTS

1. Decide which methods should be used – desk research, expert consultation or participatory methods
2. Conduct a contingency analysis to evaluate the likelihood of any ethical impacts occuring
3. Assess the relative importance of ethical impacts
4. Identify potential or actual value conflicts and, if possible, aim to resolve them
5. Formulate workable conceptualisations of the relevant EIs

5 FORMULATE AND IMPLEMENT REMEDIAL ACTIONS

1. Gather relevant information about remedial actions proposed by other R&I projects
2. Formulate and implement design interventions
3. Formulate different types of recommendations
4. Document and communicate the remedial actions

6 REVIEW AND AUDIT THE EIA OUTCOMES

1. At the beginning of the EIA: set the milestones and criteria for the review and audit process
2. During the EIA: evaluate the EIA documentation and the agreed upon criteria and milestones
3. At the end of the EIA: ensure proper documentation, follow-up and signing off of the EIA

Table 1: Procedural steps of the ethical impact assessment process

1 *Threshold analysis*

The threshold analysis stage of an EIA determines the kind of EIA procedure that could be implemented in an R&I project.

Why conduct a threshold analysis?

- To determine whether or not an EIA is needed;
- To assess the expected number and severity of the ethical impacts.

Essential elements for a threshold analysis:

- An overview of relevant ethical issues and ethical principles;
- A questionnaire, based on this overview;
- Communication of the outcomes of the threshold analysis.

2 *EIA plan*

The EIA plan determines the scale of the EIA (small-, medium-, and large-scale), the budget allocated to the EIA, and the EIA team composition

Why create an EIA plan?

- To determine what resources need to be allocted the EIA;
- To adjust the design of the EIA to the outcomes of the threshold analysis.

Essential elements of the EIA plan:

- An appropriate budget for conducting the EIA;
- An outline of the composition of the EIA team;
- Review criteria for the EIA;
- An assessment of the scale of the EIA;
- Review and approval of the EIA plan.

3 *Ethical impact identification*

At the ethical impact identification stage, the persons involved in the EIA attempt to identify all ethical impacts that could occur in the context of the R&I project, and to connect them to relevant ethical principles.

Why conduct the ethical impact identification stage?

- To describe probable futures regarding the ethical impacts of the R&I project;
- To describe the relevant research outcomes that can lead to ethical impacts;
- To identify ethical values and principles and relevant stakeholder interests regarding these impacts.

Essential elements for the EI anticipation and determination stage:

- Review relevant literature and, if deemed necessary, conduct a *technology readiness level* (TRL) analysis to determine the balance between the use of foresight methods and ethical impact identification methods;
- Selection and use of foresight methods:
  - *For small-scale EIA, methods can include:*
    - Horizon scanning;
    - An expert consultation;
    - Stakeholder consultation.
  - *For mid-range EIA, methods can include:*
    - Trend analysis;
    - Stakeholder brainstorm/futures wheel;
    - Road mapping.
  - *For full-scale EIA, methods can include:*
    - Delphi interview;
    - Citizen panels;
    - Scenario writing.
- Selection and use ethical impact identification methods:
  - *Conceptual investigations:*
    - Ethical checklist approaches;
    - Use of ethical theories;
    - Situational approaches.
  - *Empirical investigations:*
    - Consolatory/consultative approaches (consulting stakeholders);
    - Techno-ethical scenario building (collaboratively come up with scenarios in which ethical impacts could occur).

4 *Ethical impact evaluation*

The ethical impact evaluation stage is aimed at assessing the relative severity of the potential ethical impacts, the likelihood of their occurrence, and any potential value conflicts that may arise.

Why conduct the EI evaluation stage?

- To assess the relative importance of ethical impacts that have been identified.
- To locate potential value conflicts and, where possible, to resolve them.
- To find workable conceptualisations of the EIs and the ethical values/principles that apply to them.

Essential elements for the EI anticipation and determination stage:

- Select the appropriate methods:
  - Desk-research approaches
  - Expert consultations
  - Participatory approaches
- Assess the relative importance of the ethical impacts:
  - *To evaluate the normative importance of ethical impacts:*
    - For basic EIA procedures: literature review and use of ethical theories.
    - For mid-range and full-scale EIA: Expert consultation and stakeholder engagement.
  - *To evaluate the risk of violation of ethical principles/values involved:*
    - For basic EIA: use outcomes of the contingency analysis.
    - For mid-range and full-scale EIA: consult experts for input on these outcomes.
  - *To evaluate the severity of EIs:*
    - For basic EIA: analyse factors of scale and intensity of ethical impacts.
    - For mid-range and full-scale EIA: consult experts for input on this analysis.
  - *Identify and resolve (if possible) value conflicts:*
    - Use five rules of thumb for determining appropriate procedures:
    1. Reference to ethical theories and/or widely acknowledged documents on human rights.
    2. Take the severity of EIs into account.
    3. Construct an ethical argument to resolve the value conflict.
    4. (Only for mid-range and full-scale EIA): consult stakeholders for balancing conflicting values.
    5. Formulate ways in which the EI can be avoided if negative, and promoted if positive.
  - *Construct workable concepts:*
    - Conduct a literature review.
    - Construct a definition of the relevant value/ethical principle.

5 *Remedial actions*

In the remedial actions stage, remedial actions may be designed and performed in response to the negative impacts found and analysed during EI anticipation & determination and EI evaluation stages.

Why conduct a remedial actions phase?

- To translate the earlier findings in the EIA into practical recommendations for the relevant stakeholders
- To translate the earlier findings in the EIA into design interventions at the project level
- To identify possible gaps between the earlier findings and practical possibilities for remedial actions and, if necessary, reiterate parts of the previous stages.

Essential elements of the remedial actions:

- Collect information about remedial actions from other R&I projects
- Formulate and implement design interventions:
  - Articulate the relevant values
  - Investigate the empirical context of technology deployment
  - Alter the technological design of R&I outcomes
- Formulate different types of recommendations:
  - Societal recommendations
  - Organisational recommendations
  - Regulatory recommendations
  - Policy recommendations

6 *Review and audit stage*

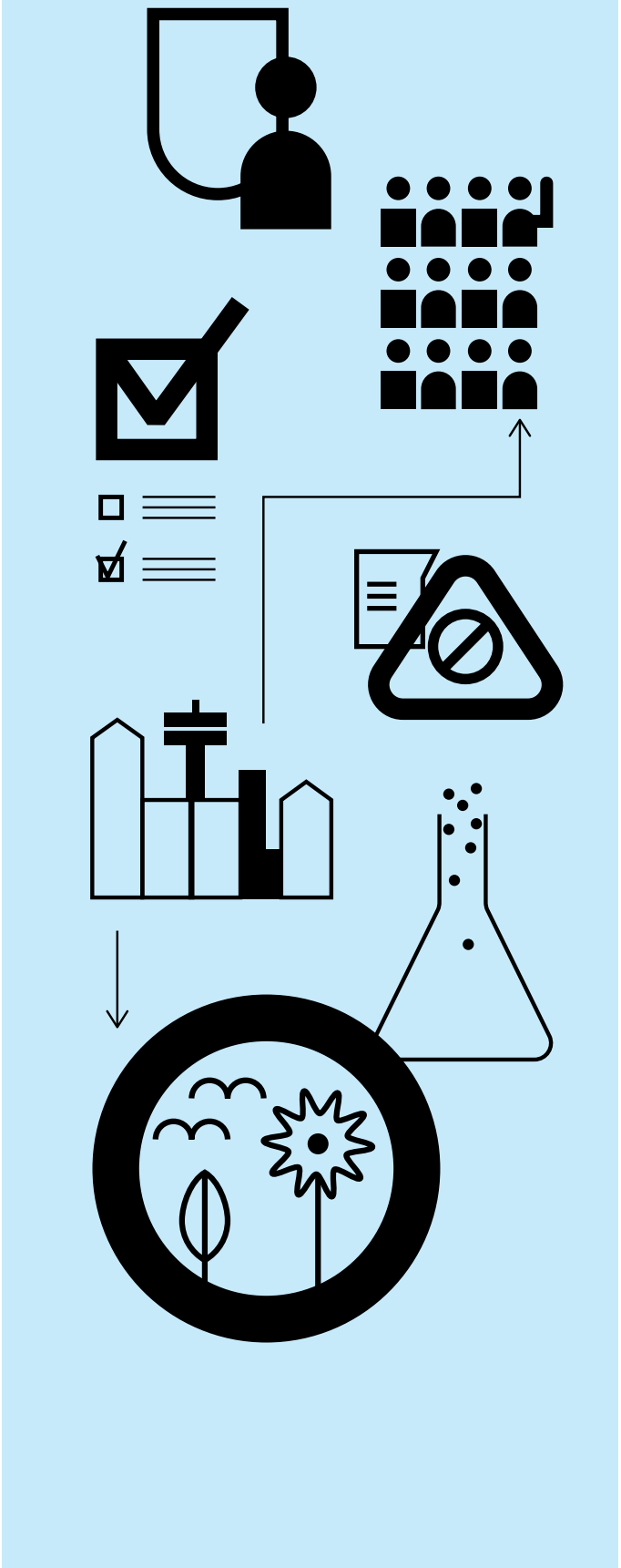
The review and audit stage of an EIA ensures independent evaluation of the EIA process and, if necessary, independent corrective intervention in it.

Why conduct a review and audit?

- To provide constructive feedback for improving the execution of the EIA process.
- To guard agreed-upon milestones and KPIs (key performance indicators) of the EIA process.

Essential elements of a review and audit:

- At the start of the EIA:
  - Formulate review and audit planning
  - Establish review and audit criteria (milestones, KPIs)
- During the EIA:
  - Intermediate review(s): monitoring, evaluation, management and communication of the EIA
  - Intermediate audit(s): review audit criteria and issue an opinion on the EIA progress
- At the completion of the EIA:
  - Conduct a final review, with final EIA and review reports
  - Conduct final audit, with financial statement, portfolio of publications and follow-up actions



SECTION
6

Specialised Forms of Ethical Assessment And Guidance

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

STANDARDS, TOOLS AND BEST PRACTICES FOR POLICY-ORIENTED ASSESSMENT AND GUIDANCE OF NEW DEVELOPMENTS AND PRACTICES IN R&I

In this subsection, we analyse how policy-oriented guidance, assessment and expertise is organised. We focus on policy-oriented assessment and guidance of three different types of stakeholders and formulate the following central recommendations:

1. Governmental organisations

- Recommendations for guidance:
  - Directly involve Civil Society Organisations (CSOs) in the ethics guidance (EG) process
  - Include community members and lay persons in the EG processes
  - Create greater public visibility of EG
- Recommendations for assessment:
  - Include non-ethicists in EA committees
  - Transparently align different legal regimes
- Recommendations for the role of experts:
  - Taking into account the value of democracy in the composition of EG and assessment bodies
- Voting of committee members amongst peers
- Allotment of lay people as representatives[21]

2. National ethics committees

- Recommendations for guidance:
  - National Ethics Committees (NECs) should develop reference principles according to the topic under scrutiny and should be transparent about the ethics framework applied.
  - NECs should aim at providing recommendations for the political level and at fostering public debate, education and public awareness of ethical impacts of R&I
- Recommendations for the role of experts:
  - NECs should be established as independent, multidisciplinary and pluralist (representing different ethical traditions) ethics bodies
- Recommendations for procedures:
  - NECs should, after the publication of an opinion, inform the responsible authority about their views and should actively disseminate their opinion to the public. Dissenting opinions should be published in the same document as the majority opinion.
  - In order to foster international debate, NECs should try to provide their opinions in a language understood by the international community

3. Civil society organisations

- Strengthen the CSOs mandate to have representatives in research ethics committees (RECs); encourage CSOs to participate in RECs (group of people formally appointed to review research proposals or initiatives to assess if the research is ethical)
- Ensure the participation of CSOs in institutionalised forms of EA or guidance and formal advisory panels; it would allow CSOs to develop expertise in the area of assessment and guidance. At the same time it is necessary to make sure the functioning of any mechanisms is transparent and remains open to interested parties.
- Strengthen the CSOs right to participate in decision-making – CSOs should be able to comment on policies, plans, programmes and proposals for R&I projects affecting the society; they should receive feedback

STANDARDS, TOOLS AND BEST PRACTICES FOR GUIDING, ASSESSING AND SUPPORTING ETHICAL PROFESSIONAL BEHAVIOUR BY SCIENTISTS AND INNOVATORS

The aim of this subsection is to summarise the recommendations regarding standards for guiding, assessing and supporting ethical professional behaviour by scientists and innovators. Ethical professional behaviour is defined as a part of research ethics, specifically aimed at ethical principles, applicable to the conduct of individual scientists and innovators (engineers). Proposals are made based on literature review and codes of ethics discussed in SATORI deliverables.

1. A proposal of ethical standards:

- *for professional researchers:*
  - Objectivity & impartiality
  - Truthfulness & transparency
  - Honesty & openness
  - Respect & fairness
  - Conformity to regulation, guidelines and good practices
  - Integrity in international cooperation
  - Social responsibility
- *for professional engineers:*
  - Honesty & integrity
  - Accuracy & rigour
  - Holding paramount safety, health and welfare of the public
  - Objectivity, impartiality and verifiability
  - Transparency & fairness
  - Promoting collaboration
  - Promoting engagement with the public and social responsibility
  - Continuing learning and professional development
  - Conformity to regulations and good practices

2. Recommendations for good ethical guidance of professional behaviour of researchers:

- *Recommendations for the research community:*
  1. The responsibility for ethical professional behaviour should be acknowledged by individual institutions that conduct research and employ researchers (universities, research institutes, companies), but also by other stakeholders in the research process, such as RFOs, academic journals, governmental organisations responsible for research policies, integrity boards, science academies and professional organisations.
  2. Stakeholders should strive to cooperate to achieve a research environment that encourages ethical professional behaviour on all levels (national-international, funding, research process, publishing) by creating international guidelines, national governance systems, forums for discussion and exchange of information, etc.
  3. The initiative to raise awareness on ethical professional behaviour and develop guidelines in a particular country or scientific field should be taken up by independent and representative institutions, such as science academies, professional associations, university associations, science foundations, etc.
  4. In order to embed ethical professional behaviour in the research cultures, institutions should review the ways in which they evaluate researchers' work, e.g. preferring quality over quantity, etc.
- *Recommendations for individual institutions:*
  1. Individual institutions should establish a body (e. g. committee, office) with a mandate and resources to:
     - develop a coherent and integral institutional research integrity policy, including the development of guidance, assessment procedures and strategies,
     - provide information services, awareness raising and other activities, aimed at encouraging the acceptance of developed guidelines and procedures and their integration into the research culture (if this is not possible due to the size of the institution or limited resources, institutions may refer to frameworks by professional associations, science academies or other institutions).
  2. In order to encourage ethical professional behaviour and prevent misconduct, universities should include ethics in curriculums and offer ethics classes and training sessions. Research institutions should offer training and organise workshops and conferences to raise awareness and discuss research integrity issues.

3. Recommendations for good ethical assessment of professional behaviour of researchers

- *Recommendations for the research community:*
  1. A national system of assessment of professional behaviour is advisable since it reduces the risks of internal institutional assessments (e.g. conflict of interest, misconduct) and allows for the development of more efficient assessment procedures and practices
- *Recommendations for individual institutions:*
  1. Institutions that conduct research should establish fair and transparent procedures for assessment of ethical behaviour of scientists and innovators.
  2. Research institutions should take measures so that researchers and innovators are aware of what constitutes misconduct and are well informed of the assessment procedures.
  3. Each research institution should have a contact person for professional research behaviour whose contact details are publically available, easily accessible and who could be contacted concerning any suspicions of misconduct.

STANDARDS, TOOLS AND BEST PRACTICES FOR ETHICS ASSESSMENT OF INNOVATION AND TECHNOLOGY DEVELOPMENT PLANS

This subsection outlines our proposals for the specific adaptation of the SATORI ethical impact assessment approach to ethics assessment of innovation and technology development plans.

In innovation and technology development, three main stages can be distinguished: 1) basic research, 2) applied research, 3) innovation and development. While research is understood as "the conception or creation of new knowledge, products, processes, methods and systems", development is a "systematic use of knowledge or understanding gained from research." However, taking recourse to the chain-linked model of technological innovation (CLM) by Kline & Rosenberg (1986), it should be emphasised that the innovation process has a non-linear character, as "science is part of the process, but not necessarily the initiating step."

In the first main stage of the innovation and technology development plans, the basic research, research is conducted as an end in itself; without any plans of application. EA, in this stage, should contain a significantly expanded foresight stage as the possible (later) applications are not yet determined and hence even more applications are to be considered.

In contrast, the second main stage, applied research, is conducted to gain knowledge or understanding necessary for meeting a specific need. EIA at this stage is similar to the one in the third stage, innovation and development. However, EIA in applied research should focus more on the foresight stage and therefore also resembles the EIA of the first stage. This is an indicator of the blurring line between basic and applied research.

The end product of the third main stage, innovation and development, can be categorised as (1) structures and spaces, (2) products and (3) applied systems and processes. Every category benefits from a different focus in the EIA. EIA of structures and spaces benefits from an increased stakeholder participation, as structures and spaces have a large impact on communities. For products, the EIA can be principle-driven, as it is more cost- and time-efficient. Finally, as product-type goods are produced by commercial businesses, EIA should be incorporated in strategies for corporate responsibility tools (CR).

SECTION 7

Ethics Assessment and Ethics Guidance by Specific Types of Organisations

This section discusses recommendations regarding ethics assessment and guidance in the context of four specific types of organisations: universities, CSOs, industry and RFOs.

UNIVERSITIES

Within the higher education sector, the major instruments for EA and guidance are codes of conduct and practice (i.e. codes of ethics), and integrity boards. Codes of ethics offer guidance to university members on the expected standards of behaviour within their organisation, while integrity boards investigate reported instances of ethical failures and assess whether unacceptable behaviour has occurred.

Codes of ethics

Individual universities should develop a code of ethics that explicitly addresses their conduct in R&I. A code of ethics in R&I should be general rather than focused on one specific discipline. This allows for a discussion by RECs in diverse fields. However, if further clarifications are needed (e.g. in medicine), specific forms of conduct may be added to the general code of ethics.

Codes of ethics should not be published and then forgotten. They should be implemented in the curriculum and institutional strategies. Research integrity boards (described below) are helpful for enforcing these codes. The code of ethics should also be revised and updated on a regular basis. It should be regarded as a 'living document' that is open to change, to help identify problems with the code and allow them to be addressed.[22]

Integrity boards

Integrity boards investigate alleged breaches of the codes of ethics by researchers performing R&I activity. The structure and operation of an integrity board must encourage the trust of both the research community and the public in the fairness and accuracy of its decisions. Investigations of alleged misconduct must strive for fairness and credibility, so that the decisions made based on the evidence gathered during the investigation process will themselves be fair and credible.[23]

The independence of those investigating alleged misconduct should be guaranteed so that their investigation is fair and impartial. The integrity board should be separate from the research-performing sections of the university. Conflicts of interest (real and apparent) must be avoided, and the integrity board should have the necessary resources to perform its work without having to rely on other sections of the university.[24] The processes for investigating, adjudicating, and appealing against allegations of misconduct should also be distinct from each other in order to promote fairness in each stage of the process.[25]

CIVIL SOCIETY ORGANISATIONS

Few CSOs were established to perform the function of ethics assessors. Therefore most of them would lack resources, both in terms of financing or staff as well as in terms of EA related expertise that would be required in order to perform full-fledged EA. Additionally, there may be a lack of trust in CSOs opinions as ethics assessors, since they may be seen as leaning towards a specific set of values that defines and shapes their agendas.

In the case of some CSOs, however, it seems justified to recommend their further involvement in RECs as representatives of a specific vulnerable group (e.g. consumers or patients) or spokespeople for a specific interest (e.g. the animal welfare). This involvement would be legitimate if acting on behalf of these groups was defined in the CSOs statutes as one of their key objectives. Such a model ensures that the perspective of those affected by the research is taken into consideration and contributes to a greater diversity of views within RECs. Moreover, CSOs who are involved in R&I more directly should consider establishing structures (codes of conduct and procedures) for internal EA.

At the same time, CSOs that can be identified as those who perform informal EA in the course of their other activities should be offered training in order to increase the awareness of ethical issues, as well as tools such as checklists and general guidelines that can be easily used on an on-going basis in different types of projects.

Another way of strengthening CSOs' capacity to deal with ethical issues in R&I could be building EA related CSO networks. Bearing in mind the disparities between different states with regard to the level of civil society involvement in EA of R&I (concerning for example the existence of dedicated organisations, or the level of involvement of the public in debates about the societal aspects of R&I), there is a need to exchange best practices between organisations and groups from different states.

INDUSTRY

EA by industry is closely related to the concept of corporate social responsibility (CSR), which is well-established in the business world. While studies show that there are

several drivers for industry to undertake EA, including key business factors such as improving competitiveness, branding and costs, it also pinpoints important challenges and bottlenecks, including additional costs, bureaucracy, failures of self-regulation mechanisms.

References for EA and CR in the business sector derive from existing normative frameworks and regulations, as well as various types of voluntary initiatives, ranging from codes of practices, frameworks for CR, general and sectorial standards, and company specific initiatives.

Interestingly, the specific concept of R&I is not addressed by these tools in a comprehensive manner, with few or no actions designed explicitly for this issue. Therefore, the work of SATORI could provide an added value to these tools by introducing a strategic EA model explicitly devoted to R&I activities that would be integrated within a broader CR framework.

Approaches might be different in terms of the scope and themes considered, but there are several common procedures, tools and experiences emerging by the report analysis. We want to emphasise the following common procedures, tools and experiences as good practices:

- Define the domains of influence and responsibility of an organisation over its impacts
- Identify the relevant topics and prioritise the most important ones for the organisation
- Apply a due diligence process in the evaluation of impacts
- Ensure commitment of executives to EA
- Set a strategy for EA, based on a structured, step-by-step, procedure (e.g. the Plan, Do, Check, Act cycle).
- Ensure a flexible, modular, incremental process (tailored to the organisation type and needs)
- Define responsibility for EA along the entire hierarchy of the organisation
- Ensure credibility of actions:
  - ensure transparency and accountability of the EA process
  - engage with stakeholders to evaluate and review impacts and actions; adopt multi-stakeholder approaches
  - regularly communicate results on EA
  - provide ways for third part evaluation, external assurance of EA
- Promote training and capacity-building on EA

RESEARCH FUNDING ORGANISATIONS

The recommendations for EA by RFOs can be divided into three categories: those concerning the criteria for EA, those concerning the organisational structure of such assessment, and those on the procedures for conducting EA.

Criteria for ethics assessment

RFOs should verify whether the research proposal meets the national legislation and ethics requirements of the country in which the research will be performed. They should also go beyond the minimum standards provided by law in evaluating ethical issues. In addition, the evaluation should be based on ethical principles that are specific to particular kinds of research such as research involving human subjects, research involving animals, and research involving possible environmental risks.

Research conduct should be evaluated in a proactive manner. Evaluation should include the following aspects: research integrity, scientific misconduct, policy criteria such as usefulness of science, open-access strategies, gender issues, transparent communication, benefit sharing, and promotion of the social good. Finally, RFOs should verify whether the research proposal describes possible implications of results in a satisfactory manner relating in particular to individuals and society.

Organisational structure of ethics assessment

RFOs should establish procedures for in-house EA going beyond EA provided by law. EA should be included in regular project selection procedures, and RFOs should provide regular training activities in the field of ethics for staff members engaged in project selection procedures.

Ethics panels should be organised for full ethics review for all projects that have been identified as ethically problematic in a pre-screening phase by staff members involved in project selection of the respective RFO who have received prior training in the field of ethics. Ethics panels should be independent, multidisciplinary and pluralist by including members from different research fields and ethical traditions that are consistent to the goals of ethics assessment.

Procedures for ethics assessment

Transparent procedures for ethics review should be established. These procedures should consist of different phases. Before the start of the project they should include a self-assessment phase, pre-screening phase, and a full ethics review, if applicable. Guides on the EA procedure, including forms for the self-assessment phase clarifying which ethical principles and issues will be regarded as being of particular importance, should also be made available. During the implementation of the project, monitoring should also include aspects relating to research integrity, and scientific misconduct.

RFOs should also hold a permanent structured exchange with their national counterparts in order to discuss ethics in regard to new technologies. The procedures, related guides, and the regular reports of their exchanges with their national counterparts should be published by RFOs on their official website

SECTION 8

Proposals for the Institutional Structure of Ethics Assessment in the European Union and its Constituent Countries

This section outlines proposals for the institutional structure of EA in the EU and its constituent countries. The following recommendations address the institutional setup of eight different types of ethics assessors on an EU level. These types are universities, national science academies, RFOs, RECs, NECs, academic and professional organisations, CSOs, and companies. Additionally, some recommendations are made regarding the national level of some EU countries. All recommendations are based on previous SATORI reports, especially the annexes of Deliverable 1.1 on the respective types of ethics assessors and some subtasks of Work Package 4, concerning models for EA and guidance in some of the named types of ethics assessors. For general recommendation (indicated by a numeral), actions (indicated by a letter) are listed that should be taken by specific actors.

UNIVERSITIES

The main instruments for EA in universities are scientific integrity boards and RECs. For both instruments, the recommendations aim at transparency, consistency and effectiveness.

Scientific integrity boards

1. There must be clarity in the legal framework regarding which organisations are responsible for particular aspects of the inquiry and investigation processes.[26] Different entities should handle the investigation, adjudication/sanctions and appeal phases of an allegation of misconduct.[27]
   - The relevant body at the national level should establish clear guidelines on investigating scientific misconduct, including overarching principles and standard procedures. It should also decide upfront whether different organisations or bodies within or outside the research organisation are responsible for different categories of allegation of wrongdoing, to ensure that all are covered.[28]
2. The independence of those investigating alleged misconduct should be protected. Conflicts of interest (real and apparent) must be avoided, and the integrity board should have the necessary resources to perform its work without having to rely on other sections of the institution.[29]
   - The relevant body should make the integrity body separate from the research-performing institution and write out explicit rules aimed at avoiding conflicts of interest.[30]
   - The relevant body should have all investigators and staff make a "Conflict of interest declaration" both when hired and thereafter on a yearly basis.[31]
   - Investigators of alleged scientific misconduct should not report to the research management under investigation[32] and they should have an independent budget.[33]

RESEARCH ETHICS COMMITTEES (RECs)

1. University associations and national academies of sciences should, with the help of professional organisations, establish and commit to a joint framework that would set general standards at a national level regarding RECs in the higher education system.[34] For that framework, an official committee should be established.
2. Accreditation committees, in the course of evaluating teaching programmes, should assess whether research ethics are a part of the curricula and based on and reflective of the general standards adopted by the institution, ensuring their quality.
3. EA in institutions of higher education should be organised into one or more RECs. In order to address discipline-specific issues in project evaluation, the principle of interdisciplinarity and independence should be respected in committee membership.
   - Each institution should decide, based on its size and volume of research, whether it should have multiple standing committees or one committee that has the authorisation to form sub-committees as needed.[35]
   - Committees should consider appointing a chairperson who is not from the focus field for the committee or the institution, to ensure minimal bias.
4. The institutions' governing bodies should appoint members of RECs. They should not be picked by current members of the committee, but rather be suggested by community leaders. When choosing members, persons with a potential conflict of interest should be avoided. Finally, the committee should be allowed to seek the advice from outside experts.

NATIONAL SCIENCE ACADEMIES

National science academies (NSAs) usually have an influential position in science and society. The following recommendations focus on how NSAs can use these positions in ethics assessment.

1. In the majority of cases, there is no systematic monitoring of compliance with NSA recommendations. Therefore, monitoring and compliance programs should be incorporated into National Science Academies.
    - NSAs should establish a compliance officer to monitor the number of mentions and citations of Academy results by policy, decision, and public actors.
2. Too often, the decision-makers do not accept/follow recommendations established by academic committees or see the need to conduct EA, and try to avoid difficult topics.
    - NSAs should try to develop closer connections, while retaining their autonomy, to work in conjunction with policy and decision makers by establishing liaisons or programs to work alongside decision-makers.
3. Another pressing challenge is the lack of necessary resources (administrative staff, budget).
    - The EC should encourage the establishment of NSAs as a part of its requirements for countries to receive funding for R&Is projects.
    - Governments (i.e., EU, UN, OECD and potentially other organisations) should create a multi-stakeholder platform on a global level, in which the UN, OECD, and the EU could collaborate in pursuit to harmonised NSA objectives. This platform can build upon the existing work of associations that currently exist.

RESEARCH FUNDING ORGANISATIONS

RFOs widely ask funding applicants for EA, but the EA itself is mostly outsourced and not based on a broad set of criteria. To secure the high quality of EA, an in-house EA should be considered.

1. Large RFOs (spending more than 100 million Euros a year) should themselves be responsible for conducting EAs of research proposals submitted to them. Smaller RFOs (usually privately funded NGOs) can continue to rely on external EA.
    - Large RFOs should institute in-house ethics panels for conducting full ethics review of all project proposals that have been flagged as ethically problematic during a pre-screening phase. Staff members of the RFO who are involved in project selection and who have received prior training in the field of ethics would conduct this pre-screening phase.
2. RFOs should organise an on-going structured exchange with their international counterparts to discuss (good practices in) EA in response to new and emerging technologies. They should also do more to raise awareness of ethics among researchers who submit research project proposals.

RESEARCH ETHICS COMMITTEES

RECs are not only important in universities, but can operate on various levels outside universities. It is therefore crucial to clarify the legal conditions under which RECs are operating.

1. It should be clear in a legal sense when RECs are to be included in the practice of EA.
    - Local and national governments should make the necessary legal provisions at the appropriate level - whether institutional, local, regional, or national - for when RECs are to be included in the EA practice.
2. For the sufficient funding of the REC, including any necessary secretariat or administrative staff, means of accomodating the costs of the REC should be established. They can be either directly funded by the government or a respective institution, or incorporated into the research project proposals.
3. RECs should have representatives that participate in (e.g. national) forums directed at the discussion and guidance of emerging ethical issues and guidelines. This participation is to ensure harmony with international trends, but also to provide input in their developments.

NATIONAL ETHICS COMMITTEES

NECs usually focus on bioethics and could benefit from broadening their focus. As they are supposed to advise national governments, stakeholders should participate in the EA process.

1. NECs should broaden their focus to encompass all other scientific fields besides the medical and life sciences. In order to do so, NECs should institute special sub-committees for different disciplines.
2. NECs should create an organisational structure that allows for the consultation of citizens, CSOs, external experts and possibly other external groups. To investigate how this might be achieved, individual NECs should institute a temporary sub-committee.
3. NECs should establish a special committee that monitors for compliance with the ethical guidance they offer to ethics assessors.
4. NECs should be more actively involved in ensuring the quality of the EAs made by REC members and other ethics assessors, e.g. by offering training programs.

ACADEMIC AND PROFESSIONAL ORGANISATIONS

As academic and professional organisations often work together with NSAs, the three recommendations for NSAs also apply to them.

1. Academic and professional organisations should create forums for consolidating developments in EA, which produce unambiguous results that can be implemented and monitored by membership groups.
2. Academic and professional organisations should utilise their positions as membership-granted organisations to train members to instil responsible research and practices through the development of partnerships with universities and other research conducting organisations that account for its membership group.
    - The EC should recognise academic and professional organisations as potential conduit points for the implementation of training programmes for responsible research.

CIVIL SOCIETY ORGANISATIONS

Recommendations for CSOs focus on making their two ways of participation in EA more effective: 1) to participate in RECs, and 2) to cooperate with each other to build their own structures for EA.

1. CSO representatives should make efforts to be involved in RECs as representatives of a specific vulnerable group (e.g., consumers or patients) or spokespeople for a specific interest (e.g., the animal welfare).
2. There should be support at the EU level for the development and exchange of EA related CSO networks. These networks could vary in terms of structure, level of interdependence, aims etc. The purpose of networking would be to exchange information (knowledge and experience) and learn from each other (through sharing best practices, coordinating activities, obtaining common funding, organising advocacy campaigns, influencing the adoption of new regulative acts, etc.).

INDUSTRY

This section provides recommendations for meeting the challenges in the institutional structures of EA in industry.

1. A broad institutional structure of corporate responsibility (CR) including R&I should be formed as a cross-sectoral approach based on collaboration.[36]
2. The institutional structures should enable engagement with stakeholders to evaluate and review impacts and actions. Multi-stakeholder approaches should be adopted.
3. CR (including R&I activities) should be based on an appropriate mix of bottom-up and top-down approaches to promote CSR, also taking into account local context and values.
4. The institutional structures for EA of R&I for industry should be incorporated with already existing general CR institutional structures, e.g. by businesses, the EU and the UN.
5. For the benefits of stakeholders, the institutional structures for EA of R&I should promote recognition of the companies as their members, e.g. via certificates and rewards.
6. The EU should enforce the currently existing legislation.
7. The membership of a company in the institutional structures should not be granted indefinitely. The adherence to the ethical requirements should be verified regularly (e.g. annual or biennial verification).
8. The institutions for the EA of R&I in industry should respond to the needs of different types of businesses.

NATIONAL INSTITUTIONAL STRUCTURES FOR ETHICS ASSESSMENT

In this section, recommendations are given for EA on the national level, including national level coordination, networking between RECs, ethical guidance and training, EA in non-medical fields and institutional problems.

1. In countries without a NEC, governments should establish a NEC to coordinate RECs, and to develop EA and guidance procedures. The NEC should also provide a platform for discussion and cooperation.
2. NECs should expand to include special sub-committees for different fields and disciplines, perhaps in cooperation with professional associations, which can provide insight into field-specific research practices and their ethical issues.
3. Institutions with the knowledge, experience and authority to provide ethical guidance are NECs and REC networks as well as national academies and professional associations in specific fields and disciplines. These institutions, especially NECs, should provide training programs.
4. Governments should take actions towards a functioning national system of EA, providing the necessary funding and impetus to national-level institutions as well as to take measures to implement national regulations.

SECTION
9

Assessing the Compatibility of Existing Ethics Assessment Frameworks with the SATORI Framework

In this section, we assess the compatibility of existing ethics assessment frameworks with the SATORI framework.

The SATORI framework does not have any clear areas of conflict with international regulations or guidelines. General human rights guidelines helped guide the development of formal EA, and SATORI draws heavily on the notion of human rights issues and principles as a basis for EA and guidance. Therefore, there is an obvious compatibility between them. Even though international regulations may operate in different fields, the procedures they offer for their own implementation affirm the type of approach that SATORI suggests. Regulations such as the Cartagena Protocol outline a process that includes reviews of decisions, simplified procedures, risk assessments and public education and awareness.[37] There is an accepted importance of the need to train, monitor and follow through on initial recommendations.[38] The organisational structures outlined in international regulations differ in subject matter from SATORI but show a shared approach, e.g. multiple international regulations mandate the creation of a national-level action plan or committee to ensure the regulations are properly implemented and monitored.[39] The regulations also advocate for policy discussions to include all relevant stakeholders, including local actors, private industry, NGOs and diverse community members (in terms of race and gender).[40] As with SATORI, several international regulations create specific bodies to organise this conversation between the public, private and government.

Nonetheless, national priorities may produce EA priority conflicts with the SATORI approach. For example, a desire to maintain historical (high) levels economic growth may conflict with present-day ethical considerations. Some developing countries argue that the necessity for growing the economy and opportunity outweigh the ethics principles and issues that govern sustainable environmental policy and that more developed countries benefited from a laxer environmental focus, so fairness dictates a right to develop using the same methods.

As regards the first of the two non-EU countries studied in the SATORI project, the SATORI framework is compatible with the U.S. approach to EA. This compatibility is due to the fact that many of the principles adopted by the SATORI framework are implicitly based in the ethical assessment framework of the U.S., such as the Belmont Report. The places where the SATORI framework differs from that in the U.S. arise from factors specific to the U.S., including the decentralised R&I system. They do not, however, suggest conflicts of the core values of the system. Research in the U.S. does not always face the level of EA desired by the SATORI framework, which has specific outlines for organising RECs and conducting uniform, transparent EAs.[41]

As far as China is concerned, even though currently it does not have a strongly developed infrastructure for EA, it is rapidly developing one. The major differences between the SATORI framework and Chinese approach to EA primarily arise from the China-specific factors including the political system or low engagement of CSOs. The Chinese and the SATORI frameworks align to some extent, particularly concerning the key issues and principles underlying EAs for research aimed at technological innovations, research involving human subjects and research involving possible environmental risks. Ethical review in relation to biomedical research involving human subjects in China is well covered by various national guidelines that adhere to international standards.[42] However, the ethical review is limited to biomedical research.[43]

SECTION
10

Summary of Recommendations

This report presents the condensed results of our efforts to create an ethics assessment framework for European Union member states. At the core of our efforts has been the development of proposals for good practices for ethics assessment, including the development of ethics assessment units and the protocols of these units. We have developed a general toolkit for such assessment, as well as specialised tools and toolkits for specific types of organisations and scientific fields. In addition, we have developed recommendations for the general institutional structure of ethics assessment in the EU and its member states.

Ethics Assessment Organisations' Expectations about a Joint Framework

In the report, we first presented the results of our analysis of stakeholders' expectations about an European framework for ethics assessment of research and innovation. The analysis was based on 153 interviews with different kinds of stakeholders, both ethics assessors and non-assessors, who were asked to share their opinions on the desirability and possibility of such a framework. Of all interview respondents, 51.6 percent thought it would be desirable to have a shared European framework, and 30 percent were conditionally positive on the desirability of the framework. Many interviewees cited as potential benefits the unification, harmonisation and convergence of EA principles and procedures. They also highlighted two major challenges for the development of a common framework. The first is to achieve harmonisation of ethical principles and procedures, while at the same time allowing for differences between countries and scientific fields. The second is for the framework to function at a general level to account for differences between countries, cultures, ethical values, philosophies, and scientific fields, while at the same time providing useful tools for solving concrete ethical dilemmas.

Ethical Principles and Issues

We subsequently proposed a framework of ethical issues and principles that is applicable to a broad range of R&I activities. This framework firstly lists eight key ethical principles that apply to all types of research, each of which is operationalized through a set of guidelines. These eight principles are: research integrity, social responsibility, avoidance of and openness about potential conflicts of interest, protection of and respect for human research participants, protection of and respect for animals used in research, protection and management of data, protection of researchers and the research environment, dissemination of research results. Second, the framework specifies additional issues and principles that apply to specific fields of research and innovation, including the natural sciences, the engineering sciences, the medical sciences, the life sciences, the computer and information sciences, and the social sciences and humanities. It was noted that because ethical issues are frequently triggered by special conditions that often arise across multiple fields, it becomes important to identify applicable ethical principles on a case-by-case basis for each research and innovation project, while taking account of special provisions, conventions and regulation that may apply to specific fields.

Ethics Assessment Procedures

Next, we outlined recommendations for best practices in Ethics Assessment Units. These recommendations are structured around a series of parameters common to all EAUs that review R&I activity: composition and expertise; appointment and training; procedures prior to assessment; procedures during assessment; procedures after assessment; supervision; quality assurance; efficiency considerations; organisational and cultural factors. For example, we recommended that the membership of an EAU be arranged so that it encourages rigorous discussion and evaluation of R&I activity – which could best be achieved by including members who are competent (technically, ethically, and administratively), independent of the researchers and the institutions involved, diverse in backgrounds and expertise, and representative of the communities affected by their

decisions. Another recommendation holds that the assessment procedure be designed to ensure that the conducted R&I activity (1) protects stakeholders from undue risk and harm, (2) ensures that participation in research, trials and similar activities related to the R&I activity is voluntary, (3) determines if the research or innovation methods are appropriate, and (4) aims to increase the awareness of the ethical impact of R&I. Finally, to highlight one last recommendation, we have proposed that EAUs consider using a modified version of the Plan-Do-Check-Act (PDCA) process for quality assurance of ethics assessment.

Ethical Impact Assessment

We then presented an overview of SATORI's Framework for Ethical Impact Assessment. This framework can be used by governance bodies to establish new regulations in relation to ethical impact assessment in R&I; by research funding organisations to establish procedures for conducting EIAs in the projects they fund; and by local research organisations and companies in order to establish internal procedures for conducting an EIA in their R&I projects. Our framework presents the EIA process as a series of five stages: the EIA threshold analysis stage, the ethical impact identification stage, the ethical impact evaluation stage, the remedial actions stage, and the review and audit stage. The threshold analysis stage of an EIA is aimed at determining the kind of EIA procedure that could be implemented in an R&I project (i.e., small-scale, mid-range, or full-scale EIA). In the ethical impact identification stage, the persons involved in the EIA try to identify any ethical impacts that could occur in the context of the R&I project and to put these on a timeline (i.e., short-term, medium-term, and long-term impacts). The ethical impact evaluation stage assesses the relative severity of the potential impacts, the likelihood of their occurrence, and any potential value conflicts that may arise. In the remedial actions stage, remedial actions may be designed and performed in response to the negative impacts found and analysed during the ethical impact identification and evaluation stages. The review and audit stage of an EIA, finally, is aimed at ensuring independent evaluation of the EIA process and, if necessary, independent corrective intervention in it.

Specialised Forms of Ethical Assessment and Guidance

Next, we presented recommendations for specialised forms of ethics assessment and guidance. Specifically, we outlined standards, tools and best practices for (1) policy-oriented assessment and guidance of new developments and practices in R&I; (2) guiding, assessing and supporting ethical professional behaviour by scientists and innovators; and (3) the ethics assessment of innovation and technology development plans. With regard to policy-oriented assessment and guidance, we recommended, for example, that governmental organisations directly involve CSOs and non-ethicists or lay persons in the ethics assessment and guidance processes, and that they take into account the value of democracy in the composition of ethics guidance and assessment bodies. In relation to guiding, assessing and supporting ethical professional behaviour by scientists and innovators, we recommended, for example, that researchers abide by ethical standards that include principles such as objectivity and impartiality, truthfulness and transparency, honesty and openness, respect and fairness, conformity to regulation, guidelines and good practices, integrity in international cooperation, and social responsibility. Finally, with regard to ethics assessment of innovation and technology development plans, we proposed, among other things, increased stakeholder participation in the EIA process for building projects in urban areas (given their large potential impacts on communities), and an EIA that is more principle-driven for (consumer) product development.

Ethics Assessment and Ethics Guidance by Specific Types of Organisations

We subsequently discussed ethics assessment and guidance in the context of four specific types of organisations: universities, CSOs, industry and RFOs. We recommended that universities develop generalised codes of ethics (not focused on any specific discipline) which explicitly address researcher conduct in R&I, that these codes be implemented in their curricula and institutional strategies, and that research integrity boards investigate alleged breaches of the codes of ethics in an independent, fair and credible way. For CSOs, we recommended increased involvement in RECs as representatives for specific vulnerable groups or interests, and the creation of ethics-assessment-related CSO networks for the exchange of best practices. For industry, we outlined as number of good practices, which include defining responsibility for ethics assessment along all levels of the organisation, setting a company-wide strategy for ethics assessment based on a structured, step-by-step procedure (e.g., the Plan, Do, Check, Act cycle), and ensuring transparency and responsibility in the ethics assessment process. Finally, we recommended that RFOs establish procedures for in-house ethics assessment going beyond what is required by law, and focus their evaluations on issues and principles specific to the field of research to which the proposal under consideration belongs, among other things.

Proposals for the Institutional Structure of Ethics Assessment in the European Union and its Constituent Countries

We then outlined proposals for the institutional structure of ethics assessment in eight types of ethics-assessment-performing organisations in the EU member states: universities, national science academies, RFOs, RECs, NECs, academic and professional organisations, CSOs, and companies. In addition, we presented recommendations for the institutionalisation of ethics assessment for selected European countries. We recommended, for example, that university associations and national academies of sciences should, with the help of professional organisations, establish and commit to a joint framework that would set general standards at

a national level regarding RECs in the higher education system. In addition, we recommended that NECs broaden their focus to encompass all other scientific fields besides the medical and life sciences, thus instituting special sub-committees for different disciplines. We further recommended that academic and professional organisations create forums for the consolidation of developments in ethics assessment. Lastly, with regard to national institutional structures, we recommended, for example, that in countries without a NEC, governments establish a NEC to coordinate RECs, develop EA and guidance procedures, and provide a platform for discussion and cooperation on ethics assessment.

Assessing the Compatibility of Existing Ethics Assessment Frameworks with the SATORI Framework

Finally, we argued for the compatibility of existing ethics assessment frameworks with the SATORI framework. Our framework does not seem to have any clear areas of conflict with international regulations or guidelines. General human rights guidelines helped guide the inauguration of formal ethics assessment, and SATORI draws heavily on the notion of human rights issues and principles as a basis for ethics assessment and guidance. Therefore, there is an obvious synergy between them. And even though international regulations may operate in different fields, the procedures they offer for their own implementation affirm the type of approach that SATORI suggests. As with SATORI, the regulations advocate for policy discussions to include all relevant stakeholders, including local actors, private industry, NGOs and diverse community members (racially and by gender). Even so, national priorities may produce priority conflicts with the SATORI approach, such as the drive to grow economies in line with historical precedents for industrialization that may not account for current ethical considerations. Where this issue arises, the ethical deliberation principles advocated by the SATORI framework can be applied to provide a conduit for addressing the underlying issues and principles.

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