Outline of a Common Ethics Assessment Framework

September 2016

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V.01

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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 a common 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 the stakeholders' expectations about what is to be the outcome of the SATORI project: a shared 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. Furthermore, three main challenges are identified.

In section 3, we propose a framework of ethical issues and principles, applicable to a broad array of types of scientific R&I. In this section, the framework is structured according to the format of a flowchart. It provides a basis 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 Common Framework for Ethical Impact Assessment (EIA). This section can be used by governance bodies to set up 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; 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 specialized 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 a 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

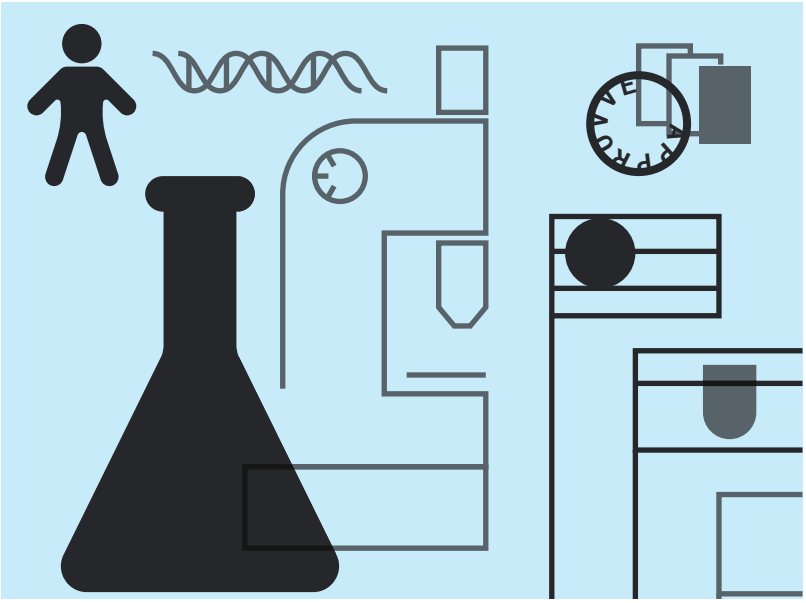
Ethics Assessment Organizations Expectations about a Joint Framework

This section analyses the stakeholders' expectations about what is to be the outcome of the SATORI project: a shared European framework for ethics assessment (EA) of research and innovation (R&I). The 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 done in 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 estimated. 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, not 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 known in 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.

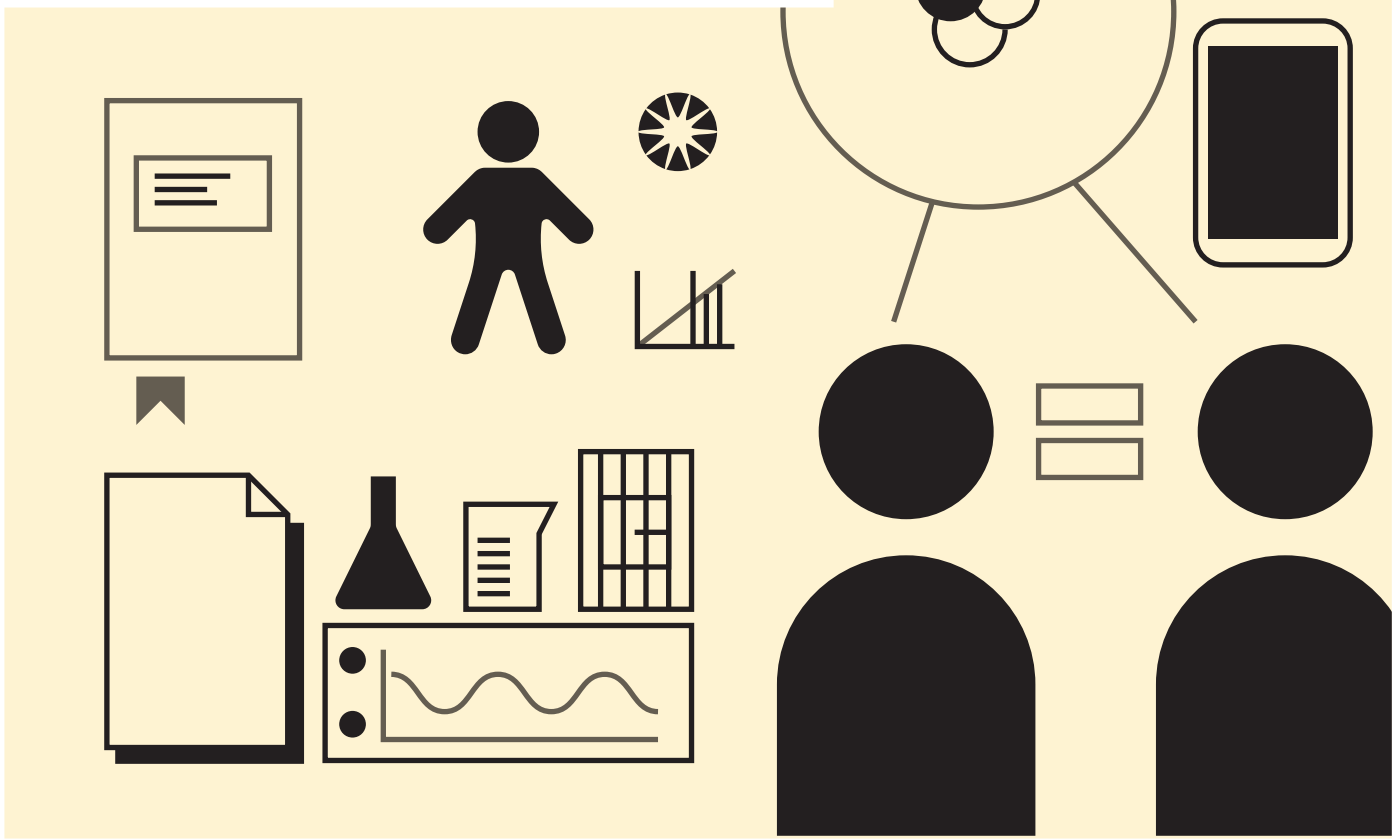
There are therefore three major challenges for the development of a common framework. The first challenge is to achieve harmonisation of ethical principles and procedures, while at the same time allowing for differences between countries and scientific fields. The second challenge is for the framework 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 issues and principles that is applicable to a broad array of types of scientific research and innovation. It is structured according to the format of a flowchart. First, it provides a basis of ethical issues and principles that apply to all types of research, following three dimensions: professional conduct, research practice and societal impacts. Secondly, it specifies the principles and issues that apply to specific research contexts: research aimed at technological innovations, research involving human subjects, personal data, animals, environmental risks or significant aspects of human society and culture.



1 *Shared Ethical Principles and Issues for all Types of Research*

Professional conduct

1. ACCOUNTABILITY

- Be cognisant of and take responsibility for actions in research. Be responsive in accordance with the duties of the researcher.
- Consider the potential impacts of behaviour and research outcomes and take action to avoid negative impacts. [4]

2. RESPECT FOR COLLEAGUES [5]

- Respect fellow researchers, recognizing their autonomy and dignity.
- Reject and prevent discrimination.
- Help to educate and mentor junior researchers and make an effort to place them in a secure position.
- Uphold the standards of the profession.

3. STEWARDSHIP

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

4. SCIENTIFIC FREEDOM

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

5. SCIENTIFIC INTEGRITY [6]

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

6. OPENNESS [7]

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

Research practice

1. RESPECT

- Treat any human subjects partaking in or directly impacted by research with respect, guaranteeing their informed consent and treating them never as merely means.[8]
- Treat communities partaking in or directly impacted by research with respect, taking into account their value-systems.

2. JUSTICE [9]

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

3. BENEFICENCE AND NON-MALEFICENCE

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

Societal impacts

1. SOCIAL RESPONSIBILITY

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

2 *Ethical Issues and Principles for Research Aimed at Technological Innovations*

1. **Reduce dual use harms**
   - Be aware of potential malicious uses for new technologies.
   - Make an effort to minimise the malicious uses of new technologies while still maintaining their beneficial applications.
2. **Precaution**
   - Consider the likelihood of benefits and harms from new technologies during the innovation process.
   - Evaluate the environmental risks posed by the technology, and revise planned developments if the risks of environmental damage from it are significant.
3. **Fairness**
   - Consider how the technology may affect inequalities in society.
   - Make efforts to avoid or minimise unfair distributions of resources resulting from technological innovations.
   - Any inequality resulting from a technological innovation should as far as possible be arranged in such a way that most benefit goes to the least advantaged.

3 *Ethical Issues and Principles for Research Involving Human Subjects or Personal Data*

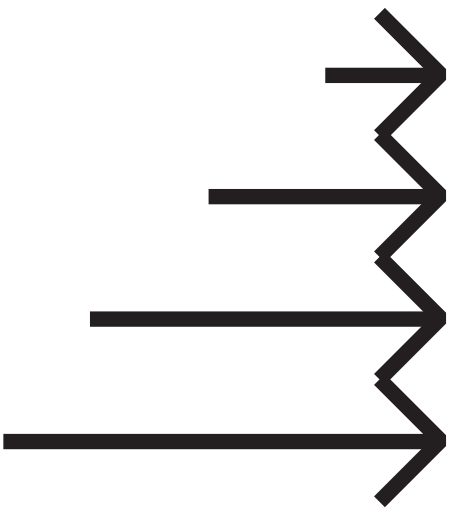
1. **Respect for human research subjects** [10]
   - Obtain informed and voluntary consent from human participants (or their legal guardians).
   - Treat human participants with due consideration for their autonomy and dignity and minimise the risk of harm done to them in a research context.
   - Ensure that the potential benefits outweigh the risk of harm caused to research participants.
   - Fairly distribute benefits and burdens of research.
2. **Respect of privacy**
   - Render identifiable information about research participants confidential.
   - Protect collected data from unauthorised access and store participant data securely.
3. **Avoid biases**
   - Incorporate practises that respect cultural diversity and pluralism.
   - Recruit participants who are representative of the general population except when the research demands a focus on a specific part of the population.
4. **Protect the vulnerable**
   - Take additional care in research that involves vulnerable individuals and groups to prevent them from exploitation.
   - Alternatives to informed consent must be sought and obtained if the participants are unable to give such consent themselves.

4 *Ethical Issues and Principles for Research Involving Animals*

1. **Respectful treatment of animals in experiments** [11]
   - Incorporate practices that reduce the use of animals as much as possible in experimental settings.
   - Incorporate practices that reduce suffering of animals by less invasive techniques and better living conditions.
   - Adhere to experimental procedures. [12]
2. **Care for animal research subjects** [13]
   - Be humane and considerate in the treatment of animal subjects.
   - Provide for proper care and housing of animals.
3. **Avoiding harm for animals**
   - Minimise harm caused to animals.
   - Ensure that the potential benefits outweigh the risk of harm caused to animals.
   - Consider all possibilities for replacing animal use in research with less harmful methods in research.

5 *Ethical Issues and Principles for Research Involving Possible Environmental Risks*

1. **Safety**
   - Be aware of safety requirements and regulations.
   - Anticipate possible risks for direct harm and take necessary measures to avoid these.
2. **Social responsibility**
   - Recognize the duty to address the possible, foreseeable environmental effects of research.
   - Incorporate practices that protect the environment, biosphere, and biodiversity.
   - Incorporate practices that serve the public interest with regard to their environment.
   - Be aware of the societal interest in environmental values.
   - Be engaged with the societal concerns regarding the environment.
3. **Sustainability**
   - Incorporate practices that restore aspects of the ecology when damaged in research.
   - Take responsibility for care and use of natural resources.
   - Ensure responsible waste management.
4. **Responsible conduct of research**
   - Disclose information about research aspects that can have harmful side effects to those likely to be affected by them.
   - Prevent environmental violations involving the use of radioactive, biologic, or chemical materials.
   - Be conscious of the possibility of uncertainty/unforeseen consequences and potential short and long-term effects.



6 *Ethical issues and principles for research involving significant aspects of human society and culture*

1. **Freedom and independence of research**
   - Avoid ideological bias and resist political pressures.
2. **Scientific integrity**
   - Respect rival theoretical or methodological approaches.
3. **Respect biodiversity and cultural diversity**
   - Recognise the value of cultural diversity and biodiversity and the means for preserving them when conducting research.
4. **Protection of communities**
   - Consider risks and benefits of research for participants from vulnerable groups and communities and use appropriate means of obtaining and maintaining voluntary and informed consent at all stages of research.
   - Recognise the practices of traditional communities and knowledge and avoid their exploitation.
5. **Responsible treatment of cultural heritage**
   - Protect and promote "the legacy of physical artefacts and intangible attributes of a group or society that are inherited from past generations, maintained in the present and bestowed for the benefit of future generations."[14]

SECTION 4

Ethics Assessment Procedures

This section outlines recommendations for best practice in ethics assessment units (EAUs), which may be a part of a larger organisation or independent. 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 (QA); efficiency considerations; organisational and cultural factors.

It should be noted that specific national legislation may also impose additional requirements on EAUs that go beyond the general recommendations presented here.

Composition and Expertise

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

- The number of members in an EAU may depend on any legislative requirements for the size of an EAU, the available resources, and the need to include a number of diverse perspectives on research while maintaining a manageable size to allow for fruitful discussion and deliberation.
- The membership of an EAU should be arranged so that it encourages rigorous discussion and evaluation of R&I activity. This is best achieved by a membership that is competent (technically, ethically, and administratively), independent of the researchers and the institutions involved, diverse in backgrounds and expertise, and *representative* of the communities affected by its decisions.
- The EAU chairperson should possess strong administrative competence, including good interpersonal skills for managing group decisions and good communication skills to convey the EAU's decisions to researchers and supervisors.
- Those with expertise relevant to the activity under review should be included among the EAU's members. However, persons without directly relevant expertise should be an equally important section of the membership.
- EAU 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 an balanced view of the research projects assessed;
  - Personal commitment to the goals of EA.
- Lay persons (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 EAU 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.
- Persons with ethical and legal expertise should be included.
- EAU members with an apparent conflict of interest should not participate in discussions or decisions where that interest may affect their judgement.

Appointment and Training

- In general, the chief executive of the organisation containing the EAU, when the EAU is contained in an organisation, should appoint the EAU chairperson.[15] The chief executive, based on recommendations made by that organisation's research administrators, may also appoint the other members.[16] If the EAU is only responsible for reviewing the R&I activity of a specific branch of an organisation (such as a single faculty within a university), the chief executive of that branch should be responsible for appointing the EAU members.
- The EAU chairperson should be able to appoint temporary members with specific expertise if additional expertise is necessary to fairly assess particular R&I activity. The chairperson may select temporary or 'ad hoc' members in consultation with the EAU's supervisor. Temporary members may be treated as advisors to the EAU who present their informed opinion of the activity under review, or as temporary members who participate in the EAU's full decision-making process.
- Ethics training for EAU 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 EAU, 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 EAUs:

- 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 and pre-screening make ethics review both time-effective and enable a thorough EA for R&I activities that require it. Pre-assessment will only deal with the question of whether there are any ethical issues that have not been adequately addressed. The EAU 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 EAUs 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 EAU 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 EAUs:

- All EAUs should have an established decision procedure to promote transparency and to prevent decisions being made on an arbitrary basis.
- 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 EAU 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.

Procedures after assessment

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

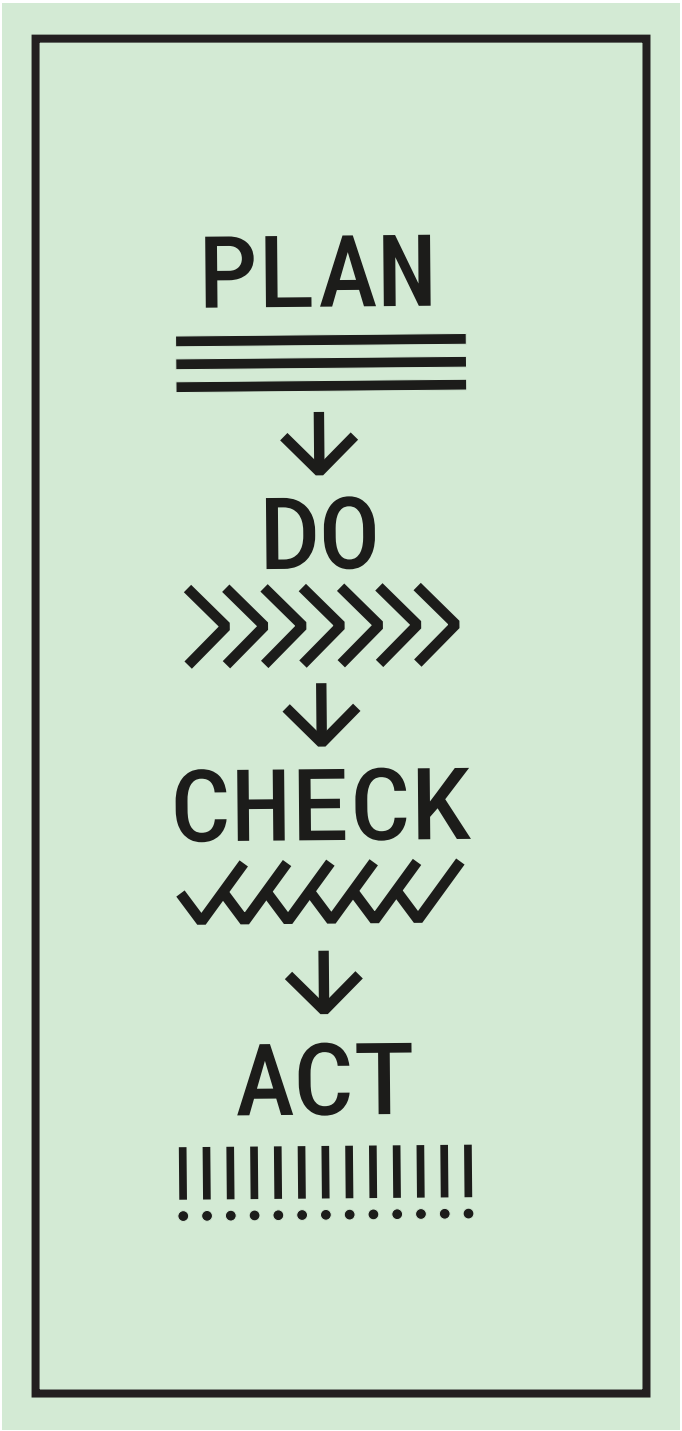
- The decisions of the EAU should be recorded for internal access and for external reference if required by legislation or auditing.
- After the review/decision, the submitter should receive a written judgment/opinion regarding the ethical issues. The decision may vary depending on whether the assessment 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 EAU and the submitter of the proposal regarding the ethical issues and how to deal with them. In case of a non-obligatory assessment, the EAU 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 EAU's by the EAU itself if it has the resources available to do so or by another organisation (such as a RFO) involved in the research. There should also be QA monitoring of whether the researchers found the EAU effective.
- 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 EAU have the strongest interest in supervising their work and ensuring that it is of a high quality.
- EAUs 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 EAUs should not compromise their ability to be independent in their decision-making. Using external auditors and performing QA of the EAU's work are both ways of demonstrating the quality of the EAU's work and that it is fair and unbiased.
- Policies should be put in place that require the supervisors of EAUs to take the assessment of the EAU 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 EAUs 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

Establish the objectives of the EA and its processes, and the resources needed to deliver results in accordance with ethical requirements and the organisation's policies. They should develop a QA plan showing:

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 previous section on QA presented recommendations for QA 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.
- EAU 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 EAU's organisation and operation.
- The work of the EAU should recognise the goals of the organisation connected with the ethics assessor, without undermining the independence of the EAU's decisions.

SECTION
5

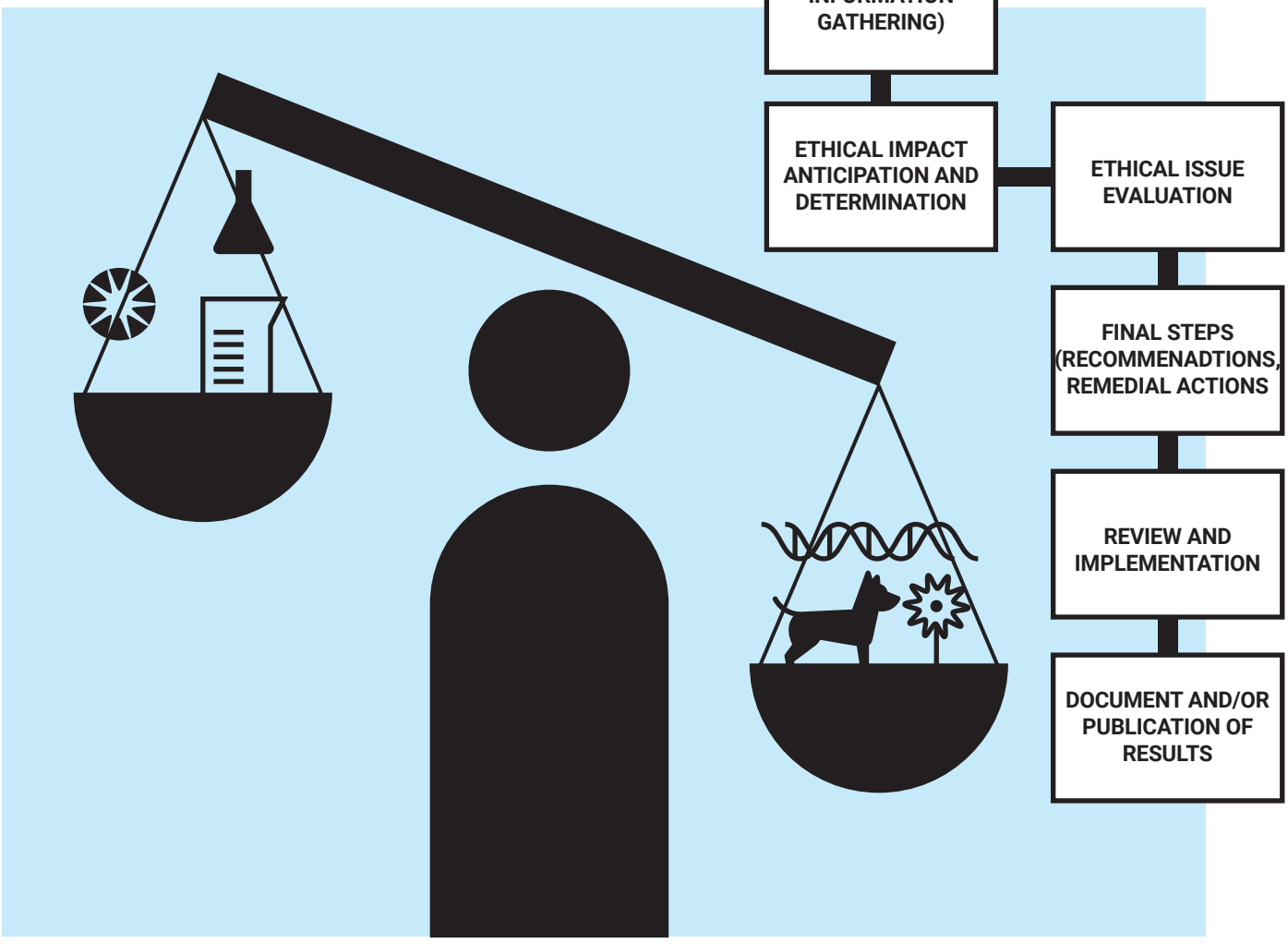
Ethical Impact Assessment

This section offers a short overview of the common 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 five stages: the EIA threshold analysis stage, the ethical impact anticipation and determination stage, the ethical impact evaluation stage, the remedial actions 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. Write a project proposal for the R&I project
2. Complete the EIA questionnaire
3. Send the finished documentation to the ethics assessor or conduct a self-assessment
4. The threshold analysis is either accepted, rejected or there will be a request for amendments
5. Complete preparatory steps: budget allocation, HR allocation, road mapping
6. (Optional) Repeat the threshold analysis at different stages of the project, critically when there are significant changes in the project

2 SET UP AND EXECUTE AN ETHICAL IMPACT ANTICIPATION AND DETERMINATION ASSESSMENT

1. Assess the Technology Readiness Level (TRL) of the R&I project's outcomes
2. Review existing work on EI anticipation and determination in the relevant R&I field
3. Select appropriate methods for conducting the EI anticipation and determination based on the TRL and the threshold analysis
4. Gather relevant data (evidence based, by consulting experts, by interacting with stakeholders, based on creativity)
5. Determine possible, probable and/or preferable EIs
6. Document and present the EIs

3 EVALUATE THE EIs

1. Decide which methods should be used (desk research, expert consultation or participatory method)
2. Conduct a contingency analysis to evaluate the likelihood of EIs to occur
3. Assess the relative importance of EIs
4. Identify potential or actual value conflicts and, if possible, aim at resolving these
5. Formulate workable conceptualisations of the relevant EIs
6. Document and present the EIs evaluation

4 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 present the remedial actions

5 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
4. Document and present the review and audit outcomes

Table 1: Procedural steps of the ethical impact assessment process

1 *Threshold analysis*

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.

Why conduct a threshold analysis?

- To determine whether or not an EIA is needed, what level of EIA is required (small-scale, mid-range, or full-scale) and what the available budget and human resources will be.
- To assess the expected number and severity of EIs as well as the available resources of an R&I project to conduct an EIA.

Essential elements for a threshold analysis:

- An overview of relevant EIs.
- A questionnaire, based on this overview.
- Assessment criteria for the questionnaire, for:
  - Determination of the level of the EIA
  - Budget composition
  - Team composition
- Communication of the outcomes of the threshold analysis.

2 *Ethical impact anticipation & determination*

In the EI anticipation and determination stage, the persons involved in the EIA try to map the ethical impacts that might occur in the context of the R&I project and put them on a timeline (short-term, medium-term, and long-term impacts).

Why conduct the EI anticipation and determination?

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

Essential elements for the EI anticipation and determination stage:

- Conducting the TRL assessment, based on explicit criteria
- Select and use methods for EI anticipation: [20]
  - *For small-scale EIA, methods can include:*
    - Horizon scanning
    - An expert consultation
    - Road mapping
  - *For mid-range EIA methods can include:*
    - Trend analysis
    - Stakeholder brainstorm/futures wheel
  - *For full-scale EIA methods can include:*
    - Delphi interviews
    - Citizen panels
    - Scenario writing
- Select and use methods for EI determination:
  - *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)

3 *Ethical impact evaluation*

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

Why conduct the EI evaluation?

- To assess the relative importance of EIs, which have been identified.
- To locate potential value conflicts and, where possible, to resolve these.
- 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
- Conduct the contingency analysis:
  - Conduct extensive desk review
  - Horizon scanning for identified factors
  - Construct short scenarios for the EIs
- Evaluate the relative importance of the EIs:
  - *To evaluate the normative importance of EI:*
    - For basic EIA procedures: desk 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 EIs.
  - 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.

4 *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:

- Select the appropriate types of remedial actions, according to the types of EIs
- Conduct design interventions by implementing value sensitive design:
  - 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

5 *Review and audit stage*

The review and audit stage of an EIA is aimed at ensuring 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 provide guidelines for successfully finalising 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:
  - Set review and audit planning
  - Establish review and audit criteria
- 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

Specialized Forms of Ethical Assessment And Guidance

In this section, we present recommendations for specialized 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 service, 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 consider.

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 - 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 – development, can be categorized 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 disparity 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 organizations 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 the study shows 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 emphasize 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 prioritize 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. Our recommendations are presented below.

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, 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 effectivity.

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 organizations) should create a multi-stakeholder platform on a global level, in which the UN, OECD, and the EU could collaborate in pursuit of harmonized NSA objectives. This platform can build upon the existing work of associations that currently exist.

RESEARCH FUNDING ORGANISATIONS

RFOs widely ask the research proposers 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 accommodations 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 set up a special committee that monitors for compliance with the ethical guidance they offer to ethics assessors.
4. NECs should be more actively involved 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 organizations should create forums for the consolidation of developments in EA, which produce unambiguous results that can be implemented and monitored by memberships 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 where a NEC is missing, 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. 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

SECTION
10

Summary of Recommendations

This report has presented 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 specialized tools and toolkits for specific types of organizations 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 Organizations' Expectations about a Joint Framework

In the report, we first presented the results of our analysis of stakeholders' expectations about a shared 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 key ethical issues and principles that apply to all types of research, following three dimensions: professional conduct, research practice and societal impacts. Examples of shared ethical issues and principles are accountability, respect for colleagues, stewardship, scientific freedom, scientific integrity, openness, beneficence, and social responsibility. Secondly, our framework specifies the principles and issues that apply to specific research contexts: research aimed at technological innovations, research involving human subjects, personal data, animals, environmental risks or significant aspects of human society and culture. The issues and principles in these categories include: reduction of dual use harms, precaution, fairness, respect for human research subjects, respect for privacy, avoidance of bias, protection of vulnerable people, respectful treatment of animals in experiments, care for animal research subjects, avoidance of harm towards animals, safety, social responsibility, sustainability, responsible conduct of research, freedom and independence of research, scientific integrity, respect for biodiversity and cultural diversity, protection of communities, and responsible treatment of cultural heritage.

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 Common Framework for Ethical Impact Assessment. This framework can be used by governance bodies to set up new regulations in relation to ethical impact 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 in order to set up 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 anticipation and determination 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 (small-scale, mid-range, or full-scale EIA). In the EI anticipation and determination stage, the persons involved in the EIA try to map the ethical impacts that might occur in the context of the R&I project and put them on a timeline (short-term, medium-term, and long-term impacts). The EI evaluation stage is aimed at evaluating 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 EI anticipation & determination and EI 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.

Specialized Forms of Ethical Assessment and Guidance

Next, we presented recommendations for specialized 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 generalized 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 organizations create forums for the consolidation of developments in ethics assessment. Lastly, with regard to national institutional structures, we recommended, for example, that in countries where a NEC is missing, 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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