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## Executive Summary

The purpose of this document is to propose a structured methodology for conducting an Ethical Impact Assessment (EIA), which reflects both the existing literature and the Research and Innovation (R&I) practice, tailoring it to the way R&I projects are organised. The methodology is both structured, by laying down clear steps and criteria, by providing options for structuring EIAs for different scales of R&I projects and for different contexts of these projects (e.g. both for publicly funded and privately funded projects).

In addition, the deliverable presents a Gender Equality Plan (GEP) which was defined based on the guidelines presented by the European Commission (EC) in the context of the new Horizon Europe program. This action plan sets out organisational priorities for addressing gender equality, and identifies activities and monitoring plans. This GEP legitimates and protects every strategy aiming to achieve gender equality in HYDROPTICS. GEP is devised according to national and European laws and aligns with national initiatives and actions focusing on: equality of women and men, rights, discrimination banning, equality treatment, harassment in workplace, social responsibility of organisations etc.

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## 1. Introduction

The increasing pace of technological advancements and societal impacts of resulting innovations in the contexts of genetic technologies, geo-engineering, Information and Communication Technologies (ICTs), complex innovations, and financial technologies "have catalysed an increasing willingness at a policy level to discuss, challenge and rethink linear models of science policy and the social contract for science". Thus, EIA is meant both to help ethicists to investigate ethical challenges and researchers, policy makers and relevant stakeholders to deal with the ethical impacts of R&I.

The need for methods for EIA arises out of the increasing focus on responsible R&I in policy contexts and in collaborative efforts of researchers, as well as from new legal regulations for R&I at the European level. Moreover, the increasing impact of R&I on society and the increasing pace of technological advancements call for a reflection on the impacts of these transformations on society. The EU, and notably the European Commission, has been a driving force behind the development of impact assessment practices, by incorporating the need for responsible R&I in its framework programmes.

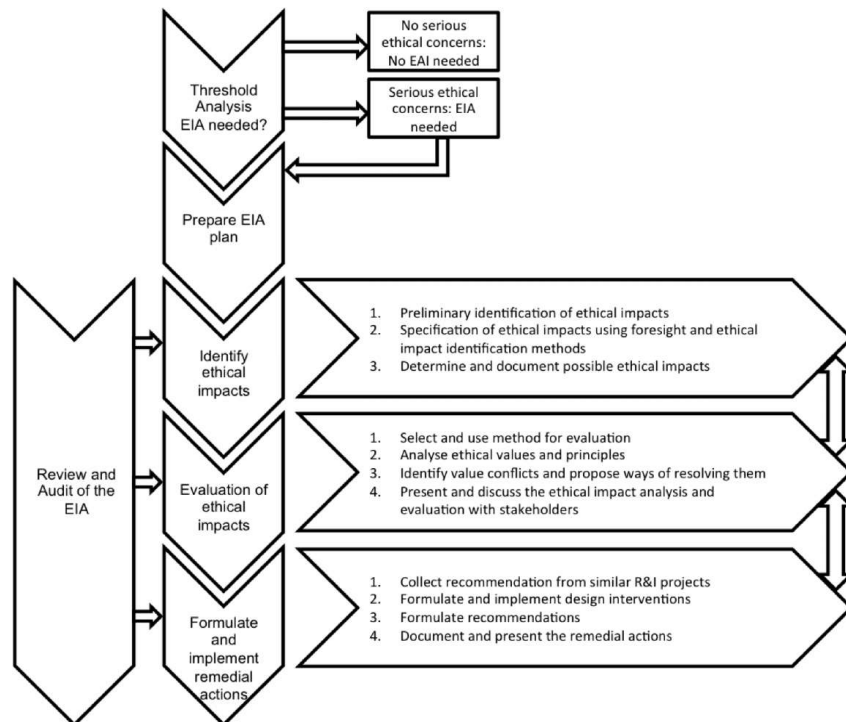
Research funding agencies such as the European Commission and funders at the national level could advocate the use of the EIA process proposed here as a good practice in research projects. Moreover, they could make having an ethical impact assessment built into an R&I project a condition of a project's successful funding. Academies of science could, as part of their role in promoting excellent science, help advocate the use of ethical impact assessment and also actively promote its use and encourage discussion about it. Policy makers and regulators could also help support the use of EIA by supporting them as a good practice measure in legislation and policy (as exemplified in the case of how data protection impact assessments are incorporated into the EU General Data Protection Regulation)<sup>1</sup>

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<sup>1</sup> Council of the European Union. Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), Inter-institutional File: 2012/0011 (COD), (OR. en) 15039/15, Brussels, 15 December 2015.

## 2. Ethical Impact Assessment

Below, both a schematic overview of the main procedural steps of the EIA<sup>2</sup> can be found as well as a table that explicated what the procedural steps entail in more detail. The figure below depicts the order of the different steps of the EIA, although some of these steps might chronologically overlap (e.g. the ethical impact anticipation and determination stage and the ethical impact evaluation stage). The review and audit stage runs separate from the other four stages, for it applies to the entirety of the EIA process.



**Figure 1. The six steps of the Ethical Impact Assessment (EIA)**

Below we summarise the concrete steps of each of the stages of the EIA. All these steps<sup>3</sup> will be further clarified in the following sections.

### 1. Conduct an EIA threshold analysis

- 1. i. Complete the EIA questionnaire.
- 1. ii. Send the finished documentation to the ethics assessor or conduct a self-assessment.
- 1. iii. The threshold analysis is either accepted, rejected or there will be a request for amendments.

### 2. Prepare and EIA plan

- 2. i. Assess the scale of the EIA.
- 2. ii. Allocate a budget to the EIA.
- 2. iii. Compose a team for the EIA.
- 2. iv. Review and approval of the EIA plan.
- 2. v. (Optional) Repeat the threshold analysis at different stages of the project, critically when there are significant changes in the project

<sup>2</sup> Wright, D. Ethical Impact Assessment. Ethics, science, technology and engineering (2<sup>nd</sup> ed.). Gengage Learning. 2014.

<sup>3</sup> Modeled on the EU's impact assessment guidelines: European Commission. Impact assessment guidelines. 2019

- vi. (Optional) Consult with relevant stakeholders to raise awareness of the project taking place and gather more details about possible ethical impacts

### • 3. Set up and execute an ethical impact identification assessment

- i. Assess the Technology Readiness Level (TRL) of the R&I project's outcomes.
- ii. Review existing work in the relevant R&I field.
- iii. Select appropriate methods for conducting the ethical impact identification based on the TRL and the threshold analysis.
- iv. Gather relevant data (evidence based, by consulting experts, by interacting with stakeholders, based on creativity).
- v. Determine possible, probable and/or preferable ethical impacts.
- vi. Document and present the ethical impacts.

### • 4. Evaluate the ethical impacts

- i. Decide which methods should be used (desk research, expert consultation or participatory method).
- ii. Conduct a contingency analysis to evaluate the likelihood of ethical impacts to occur.
- iii. Assess the relative importance of ethical impacts.
- iv. Identify potential or actual value conflicts and, if possible, aim at resolving these.
- v. Formulate workable conceptualizations of the relevant ethical impacts.
- vi. Document and present the ethical impacts evaluation.

### • 5. Formulate and implement remedial actions

- i. Gather relevant information about remedial actions proposed by other R&I projects.
- ii. Formulate and implement design interventions.
- iii. Formulate different types of recommendations.
- iv. Document and present the remedial actions.

### • 6. Review and audit the EIA outcomes

- i. At the beginning of the EIA: set the milestones and criteria for the review and audit process.
- ii. During the EIA: evaluate the EIA documentation and the agreed upon criteria and milestones.
- iii. At the end of the EIA: ensure proper documentation, follow-up and signing off of the EIA.
- iv. Document and present the review and audit outcomes.

## 2.1. Threshold Analysis

The threshold analysis stage of an EIA is aimed at determining whether an EIA is necessary in a R&I project. The determination could be done at the start of an R&I project but, if appropriate, also after the initiation of an R&I project. The purpose and setup of a threshold analysis will depend on the type of institution (public/private), the means of the institution initiating the project and the requirements of the oversight body (e.g. a funding body). Below, we outline specific practical steps and requirements for the threshold analysis of an EIA procedure i.e., its function, method, who performs it, who reviews it, and certain criteria.

### 2.1.1. Function

The two functions of the threshold analysis in the EIA process can be described in terms of their purposes in assessing the expected:

- Variety of ethical impacts.
- Severity of ethical impacts.

On the basis of this assessment, the analysis is to determine:



- ◆ What ethical impacts can be expected.
- ◆ Whether or not an EIA is needed.

### 2.1.2. Method

If followed correctly, a sequence of six procedural steps should lead to a successful threshold analysis of an EIA for an R&I project. The following table outlines these procedural steps:

#### Summary of key procedural steps:

- ◆ 1. Design a questionnaire for the threshold analysis
- ◆ 2. Fill in the questionnaire to determine the variety and severity of expected ethical impacts of the R&I project
- ◆ 3. Send the threshold analysis to the reviewer (e.g. funding agency, science academy)
- ◆ 4. The reviewer either accepts, asks for amendments or rejects the threshold analysis:
  - ◆ a. Acceptance: requirements for resource allocation and review are communicated.
  - ◆ b. Amendments: the project team is given feedback on the threshold analysis and is requested to revise it within a designated timeframe.
  - ◆ c. Rejection (optional): the ethics assessor deems the severity and variety of ethical impacts too great for conducting an EIA within the means of the project; the entire R&I project ought to be revised.
- ◆ 5. For some R&I projects, the ethics assessor should require to have the threshold analysis conducted in the course of the project. More specifically, samples cases are as follows:
  - ◆ a. The project works with emerging technologies, the character of which is likely to change rapidly within the project timeframe (such as ICTs).
  - ◆ b. The R&I project goals itself might be changed, depending on the research outcomes.

### 2.1.3. Who performs a threshold analysis?

Depending on the type of entity that engages in an R&I project, different types of people could perform the threshold analysis of an EIA. Three types of people are most likely to conduct a threshold analysis, depending on the institutional context. They are a third party's organisational representative, a designated administrator or a researcher within the R&I research team:

**Third party's organisational representative:** In the event that the threshold analysis is performed by an independent body that is principally impartial with regards to whether or not a certain R&I project is initiated (such as a research funding organisation or a science academy), a representative of such a body could be made responsible for conducting the analysis. In such a case, the contact person of the project is requested to deliver the relevant information (project proposal, budget) and the independent institution performs the threshold analysis.

**Designated administrator at a public research institute or a company:** For larger institutions or companies a designated administrator might be in charge of conducting the threshold analysis. For universities, this could be the person who is responsible for coordination of research funding proposals. For larger companies, this could be the corporate responsibility person.

**A researcher within the R&I project team:** In the event that an institution or a company (especially an SME) does not have a designated administrator who could perform the threshold analysis, a member of the R&I project team might be appointed to be responsible for it. It is recommended that public institutions provide the necessary funds so that researchers can apply for a grant that covers their activities while working on the threshold analysis.

### 2.1.4. Who could review a threshold analysis?

Depending on the funding source for an R&I project, the following stakeholders could be responsible for reviewing the threshold analysis:

- An ethics committee of public institution: In the event that a public research institution, such as a university, funds the R&I project, the body that is responsible for conducting the existing ethics assessment activities (e.g. for ethics clearance of experiments) should be in charge of reviewing the threshold analysis as part of the project proposal.
- Research funding organisation: In the event that a research funding organisation (partly) funds an R&I project (this could be the European Commission or a national research funding body), this organisation should review the threshold analysis.
- Reviewers for commercial parties: In the event that commercial entity funds an R&I project, different options exist. The company could assign an internal department, with sufficient conflict of interest protocols, to review the threshold analysis. Also, company associations or consultancies might be asked to review the threshold analysis.

### 2.1.5. Essential elements of a threshold analysis

Here, we present essential elements of any threshold analysis to be conducted for an EIA, disregarding the type of organization that conducts it or the nature of the EIA. We discuss the most important ethical impacts that need to be taken into account, the questionnaire that should be completed for a threshold analysis, and the criteria that can be used for assessing it.

### 2.1.6. A three-item taxonomy of ethical impacts

This section presents a brief, three-item taxonomy of ethical impacts, based on the findings in the SATORI report on shared ethical principles and issues. The purpose of the taxonomy is to permit the construction of an outline for a questionnaire that enables the determination of the level of EIA that is required and, at the same time, includes sufficiently the types of possible ethical impacts.

Here, three types of ethical impacts are outlined. They include impacts during the research itself, impacts from the technologies being developed, and impacts from intangible research outcomes.

It is important to note at this point that the impacts that need to be taken into account in an EIA are impacts of R&I that can occur even if the researchers stick to their ethical codes of conduct. For instance, even though a nuclear researcher might stick to his/her professional ethical code and present his/her research results honestly and while limiting harm to the animals s/he uses in his/her experiments, the outcomes and applications of the research nonetheless might have severe ethical impacts.

#### 1. Impacts during research:

The first sub-category of impacts mostly has to do with research ethics, including the ethical impacts that the practice of research can have, such as harm to human subjects, or scientific fraud. These impacts of an R&I project are usually taken into account during conventional ethics assessment procedures (through, for example, an ethics clearance for the use of human subjects in experiments) and are therefore of less importance for the threshold analysis of the EIA and the EIA itself.

#### 2. Impacts from technologies (innovation):

The second sub-category of impacts has to do with new or emerging technologies that result from R&I projects, or tangible research outcomes. This category can be divided into the following nine, broad sub-categories. They are impacts that due to:

- 1. a. Application in the context of human healthcare
- 1. b. Genetic modifications
- 1. c. Safety risks
- 1. d. Collection/processing of personal data
- 1. e. Accessibility restrictions

- ◆ f. Interference with the environment
- ◆ g. Targeting of vulnerable groups
- ◆ h. Modification of distribution of means
- ◆ i. Dual use

### ◆ 3. Impacts from intangible research outcomes

The third sub-category of impacts has to do with intangible research outcomes of R&I projects that can have real life impacts. For example, climate models, though intangible, can have a strong impact on energy policies; new findings in the field of social psychology can have strong impacts on the value systems of certain cultures. This third category of impacts can be divided into the following sub-categories of impacts that due to:

- ◆ a. Unpredictability of scientific models
- ◆ b. Misuse or misrepresentation of cultural heritage
- ◆ c. Restriction of free speech/ freedom of opinion
- ◆ d. Violation of intellectual property rights

#### 2.1.7. The questionnaire

Below, we present three types of questions that could be posed in a questionnaire used for conducting a threshold analysis. Following this list of three sample question types, a series of ways of handling the questions is listed i.e., tick box responses or closed (yes/no) responses.

The following criteria should apply to any questionnaire for an EIA threshold analysis:

- ◆ Questionnaires should be guided by the concept of reasonable expectation: "Reasonable expectation" is a notion that fits the context-dependent nature of R&I projects and can be defined in contract law as "the objectively justified belief in the likelihood of some future event or entitlement". However, as a justification of normative beliefs, reasonable expectations can be derived from "previous experience and probability". When requesting researchers to perform a threshold analysis, an appeal is made to their ability to deal with uncertainties. (After all, at the stage of conducting a threshold analysis, the R&I project has yet to commence and, therefore, any ethical impact that might be at stake is hypothetical in nature.) In order to deal with the kinds of uncertainty that are at stake, reviewers of a threshold analysis can appeal to the concept of reasonable expectation. Thus, any threshold analysis is based on the presumption that researchers can hold reasonable expectations with regards to the ethical impacts of their planned R&I project. Questions should therefore be aimed at asking about concrete aspects of the R&I project about which any researchers should have reasonable expectations. Sometimes, therefore, performing a threshold analysis might require a certain level of previous experience with applied ethics.
- ◆ Questionnaires should be as short and simple as possible, while still being comprehensive: Since a threshold analysis will be part of the overall process of writing an R&I project proposal and should not unnecessarily burden this process, its questions should be short and simple to complete.
- ◆ Questionnaires should be specific but also leave room for free interpretation: Certain types of ethical impacts should be specifically mentioned in the questionnaire, in order to make it as inclusive as possible. However, in order to account for ethical impacts that arise with the development of novel innovations and emerging technologies, the questionnaire should also leave room for open-ended questions.

#### 2.1.8. Review of the EIA threshold analysis

Because the threshold analysis is set up to be simple and should require little time to complete, the review should be straightforward in a similar fashion. The only purpose of the review is to see whether the threshold analysis has been completed in a fair and reasonable way, to avoid for instance that researchers on purpose fail to report on crucial potential ethical impacts in order to avoid having to do an EIA.

The review of the threshold analysis focuses on the following aspects:

- Whether some ethical impacts that can be reasonably expected have not been taken into account.
- Whether the likelihood of ethical impacts has been underestimated in the threshold analysis.

For both these aspects, reviewers will have to provide reasons for their comments, explicitly stating which impacts could be expected, why they should have been included and what their likeness to occur would be.

### 2.1.9. Recommendations

Certain R&I projects could be exempt from conducting a threshold analysis, especially projects that are based on a research funding call that already includes substantive requirements for ethics.

An occasional peer-review process should be institutionalized, which means that independent researchers review on an periodic basis the threshold analyses of their peers in order to guarantee the independence of the reviewing institution (the university, funding organization, etc.).

The requirement for a threshold analysis should be included in research funding calls.

## 2.2. Preparation of the EIA Plan

Once a project team receives an acceptance of its threshold analysis, it will have to take care of the following three mandatory and two optional, preparatory steps. On a mandatory level, they relate to budget allocation, team composition, and review criteria; on an optional level, they refer to periodical threshold analyses and stakeholder consultations:

### 2.2.1. Function

The drafting of the EIA plan has the following functions:

- To ensure that the EIA is well structured.
- To ensure that the EIA will have sufficient institutional support.

On the basis of this plan, the following will be determined:

- The budget of the EIA.
- The team composition of the EIA.
- The review and audit criteria for the EIA.

### 2.2.2. Method

If followed correctly, a sequence of six procedural steps should lead to a successful formulation of an EIA plan for an R&I project. The following table outlines these procedural steps:

Summary of key procedural steps:

- 1. Assess the scale of the EIA: small-scale, medium-scale or large-scale.
- 2. Allocate a budget to the EIA, based on the scale and on the resources available to the overall R&I project.
- 3. Compose a team for conducting the EIA, based on the scale of the EIA and the expertise and seniority of assessors.
- 4. The EIA plan is reviewed.
- 5. For some R&I projects, the ethics assessor should require to have the threshold analysis periodically conducted in the course of the project. More specifically, samples cases are as follows:

- ♦ a. The project works with emerging technologies, the character of which is likely to change rapidly within the project timeframe (such as ICTs)
  - ♦ b. The R&I project goals itself might be changed, depending on the research outcomes
- ♦ 6. For some R&I projects (notably those having medium- and large-scale EIAs), the ethics assessor should require organising preliminary stakeholder consultations.

### 2.2.3. Essential elements of the preparation of the EIA plan

Here, we present essential elements of any formulation of an EIA plan, disregarding the type of organisation that conducts it or the nature of the EIA. We discuss the most important ethical impacts that need to be taken into account, the questionnaire that should be completed for a threshold analysis, and the criteria that can be used for assessing it.

### 2.2.4. Determination of scale of EIA

The EIA plan is based on the idea that an EIA can have different scales. For reasons of simplicity, the SATORI project proposes three scales for an EIA procedure. These three are small-scale, medium-scale and large-scale EIAs. The different levels for an EIA guide the assessment criteria.

The following three aspects need to be taken into consideration: outcome of the threshold analysis, resources of the R&I project and possible team composition.

The decision on the level of EIA that is required rests with the body or person responsible for the review of the EIA plan. However, the outcome of the threshold analysis guides this decision in the following ways:

- ♦ If a limited number (for example, simply 1-2) of the ethically significant uses of the activities and outcomes of the R&I project are identified and the risk of at least one of them is seen as only mildly severe (2 on the 5-point scale), then a small-scale EIA should be considered.
- ♦ If a substantial number (for example, 3-4) of the ethically significant uses of the activities and outcomes of the R&I project are identified and the risk of at least one of them is deemed substantially severe (3-4 on the 5-point scale), then a medium-scale EIA should be considered.
- ♦ If a large number (for example, 5 or more) of the ethically significant uses of the activities and outcomes of the R&I project are identified, and the risk of at least one of them is deemed severe (4-5 on the 5-point scale), then a large-scale EIA should be considered.

### 2.2.5. Budget composition for an EIA

The different levels of EIA will especially depend on the budget that is required. We roughly base possible team compositions on the H2020 budget document of EU Research. Almost all costs of an EIA will be direct personnel costs and some additional cost will be spent on other direct costs (e.g. workshop rooms, trainings). However, the more substantial an EIA is, the larger the percentage of other direct costs will be. Accordingly, the following estimations guide considerations for budget composition:

- ♦ An EIA should preferably require 1-10% of the budget of an R&I project, and maximally 20%
- ♦ A small-scale EIA will be based on a budget of approximately 90% direct personnel costs and 10% other (in)direct costs.
- ♦ A medium-scale EIA will be based on a budget of approximately 80% direct personnel costs and 20% other (in)direct costs.
- ♦ A large-scale EIA will be based on a budget of approximately 70% direct personnel costs and 30% other (in)direct costs.

### 2.2.6. Team composition for the EIA

Considerations of team composition are derived from the different types of academic researchers that might be involved in the EIA. This allotment may not be in line with the personnel costs of companies conducting an EIA, but we are not able to provide a realistic estimate of personnel costs for commercial entities here.

- The team composition is based on three main types of researchers who are involved in R&I proposals: research assistants, senior fellows and professors.
- The following minimum considerations apply to the different levels of EIA:
  - Small-scale: EIA mostly requires deskwork. The EIA team is led by a (research) assistant who is member of the R&I project team. This is a part time position.
  - Medium-scale: EIA requires setting up consultative and participatory processes. The EIA team is led by a (research) member (research fellow) in the R&I project. This is a full-time position.
  - Large-scale: EIA requires the use of a variety of participatory efforts, involving multiple stakeholders. The EIA team is led by a senior member (a professor) in the R&I project. This is a full-time position.

### 2.2.7. Formulating review criteria

The EIA will be submitted to a regular review, usually conducted or organised by the funding organisation. This review can be part of the overall project review, or it could be done separately if deemed necessary by the funding organisation. Certain review criteria could be agreed upon:

- Milestones: deadlines for reports in which the completed stages of the EIA are presented.
- Quality assurance standards: certain standards with regards to the form and content of the reports that need to be met.
- Original research: in the event that either medium-scale or large-scale EIA original research might be expected, this could be reflected in e.g. a publication target.

### 2.2.8. Review of the EIA plan

After the EIA plan has been reviewed, three different outcomes can be communicated (rejection, amendment, or acceptance):

- The reviewers might accept the EIA plan:
  - Definite requirements for budgeting and, if necessary, additional team composition are communicated to the project team.
- The reviewers might ask for amendments, including e.g.:
  - Identification of additional ethically sensitive uses of research activities and outcomes.
  - Different assessment(s) of the level of severity of ethical impacts.
  - The addition of ethical impacts that the project team did not include in their threshold analysis but that nonetheless could have been reasonably expected.
- The EIA plan might be rejected in the following cases:
  - When the plan calls for an EIA scale that does not fit the size of the project.
  - Some ethical impacts are deemed too severe for the means available to the project team.

### 2.2.9. "Technology scale" EIA

In addition to the regular types of EIAs, a "technology-scale" EIA might be required. This implies that a new technological paradigm is established that calls for a dedicated EIA that is not tied to a specific research project.

A technology-scale EIA will accompany developments in research and innovation that set the stage for a new scientific or technological paradigm that does not belong to a single project but can apply to a great variety of R&I projects in different fields. An example of such a situation has been the paradigm of nano-research that has instigated a separate discussion about the ethical impacts of any technological application at the nano-scale. Technology-scale EIAs are set up in such a way that they can inform the individual EIAs of projects that incorporate the novel type of R&I.

For the abovementioned reasons, in contrast to the other types of EIAs, the initiation of a technology scale EIA does not lie in the range of responsibilities of R&I projects but rather, it follows on from more general observations made by policy or standard- setting bodies. For instance, if an academy of sciences observes that there is the need for ethical assessment of a new technological paradigm across a scientific field (such as the nano-technologies paradigm), it might initiate a technology-scale EIA.

Organizations that are likely to be initiators of technology-scale EIAs include:

- ◆ National ethics committees.
- ◆ Funding organizations.
- ◆ Science academies.
- ◆ Standard setting bodies.

A technology-scale EIA would follow the same procedure as the large-scale EIAs, with the following differences:

- ◆ A technology-scale EIA should be carried out by a dedicated team that is not tied to a specific R&I research project.
- ◆ A technology-scale EIA would include the following activities that are not necessarily part of a large-scale EIA:
  - ◆ Development of new conceptual frameworks capable of dealing with the new technological paradigm.
  - ◆ Development of new methodological frameworks capable of dealing with the new technological paradigm.
  - ◆ Recommendations for, and potentially development of, policy and law for dealing with new technological paradigms.

### 2.2.10. Recommendations

Based on the above description of doing a threshold analysis as part of an EIA, we present a number of recommendations for implementing a threshold analysis in an appropriate way. It is recommended that:

- ◆ Public institutions should provide the necessary funds so that researchers can apply for a grant that covers their activities while working on the EIA plan. This would ensure that the EIA plan is not an unnecessary financial or resource burden for a project team working on an R&I project proposal.
- ◆ A ready-made format for EIA plans could be provided by R&I institutions, to speed up the process of setting it up.

## 2.3. Ethical Impact Identification

Once the threshold analysis has been completed and the EIA plan has been formulated, the first stage of an EIA as part of the R&I project that is conducted is the ethical impact identification stage. At this stage, the researchers involved in the EIA aim at mapping the ethical impacts that might occur in the context of the R&I project and at putting these in a temporal perspective (anticipating short/medium/long-term impacts). Researchers can gain knowledge about possible ethical impacts by consulting existing literature or ethical impact assessments of similar R&I projects. However, often a multitude of perspectives will be needed to assess both what kind of impacts of the R&I project can be deemed ethically problematic and to know what the likelihood of those impacts to actually occur. For this reason, the ethical impact identification stage often includes approaches for stakeholder involvement and consultation and for involvement of experts.

### 2.3.1. Function

The function of the ethical impact identification stage can be explained as follows:

- ◆ Describe possible and probable futures regarding the ethical impacts of the R&I project.
- ◆ Describe the relevant research outcomes that can lead to ethical impacts.
- ◆ Identify ethical values and principles and relevant stakeholder interests regarding these impacts.

### 2.3.2. Method

In order to complete the ethical impact identification stage, several procedural steps have to be followed. However, these steps can be carried out simultaneously, especially since findings in one step might benefit the work done in another. The following depicts the procedural steps of the ethical impact identification stage:

Summary of key procedural steps:

- ◆ 1. Assess the technology readiness level of the outcomes of the R&I project. For this, the widely used Technology Readiness Level (TRL) method can be used.
- ◆ 2. Review existing literature on foresight and determination (ethical analyses) of R&I projects with similar outcomes
- ◆ 3. Decide on which methods should be used:
  - ◆ a. Based on the technology readiness level and the EIA scale
  - ◆ b. Methods can be chosen according to their focus on expertise, interaction, creativity and evidence.

### 2.3.3. Who conducts the ethical impact identification?

The following types of people can be responsible for conducting the ethical impact identification stage.

- ◆ Researchers working within the R&I projects: Commonly, R&I projects appoint researchers that are part of the project (they appointed according to the team composition as a result of the threshold analysis) to conduct the ethical impact identification stage. However, under certain circumstances it might be possible that people outside the project conduct it.
- ◆ External experts: For R&I projects that produce outcomes that change rapidly and that can be implemented within a short-term timeframe, it can be desirable that external experts who have experience with managing rapid technological changes in societal settings assist the researchers in the R&I project with the ethical impact identification.
- ◆ Designated consultants: For commercial entities, it can be valuable to involve consultants who have experience in conducting ethical impact identifications. These consultants could work on a commercial basis or they can be provided by public organizations (e.g. by research funding bodies).

### 2.3.4. Essential elements of the ethical impact identification stage

The ethical impact identification stage should preferably start early in the R&I project so as to ensure that possible ethical impacts can be evaluated in a timely manner and be translated into recommendations and/or remedial actions. Below, we discuss the three essential steps of every ethical impact identification stage:

- ◆ Adjusting the EIA to the technology readiness levels applicable to an R&I project.
- ◆ Determining requirements and selection of EIA methods.
- ◆ Determining requirements and possible approaches for ethical impact identification.

### 2.3.5. Assessing the technology readiness level of R&I project outcomes

The first step in any ethical impact identification stage is the assessment of the technology readiness of the expected outcomes of an R&I project. For this, the Technology Readiness Level (TRL) methodology can be used.

This sub-section describes why a TRL assessment should be conducted, how this should be done and what the follow-up involves.

#### Why conduct a TRL assessment?

A TRL assessment should be conducted because the level of applicability of the outcomes of a R&I project influences significantly the extent to which concrete impacts can be anticipated. Therefore, for each EIA, the tentative rule



applies that the closer R&I outcomes are to being applied; the more the EIA should focus on ethical impact identification compared foresight studies.

EIA can be done in an R&I project in applied science: in the natural and life sciences, and the social sciences. An EIA for applied science is conducted in the same manner as an EIA is conducted for technological research and innovation. This means that it uses the same threshold analysis and stages of the EIA. EIAs can also be conducted for fundamental science in natural, life and social sciences. An EIA for fundamental science is always done at the level of research programs for new fields.

EIAs in fundamental science will often face the challenge of missing knowledge about potential applications and impacts of fundamental research. As a solution to this problem, the foresight stage is significantly expanded and allocated more financial and time-based resources relative to the EIA scales for technological research and innovation. Nonetheless, in conducting EIA for fundamental science, no matter how much time and effort are put into foresight, speculating on potential future applications and impacts of fundamental research has an increased likelihood that the predictions are wildly off the mark.

#### How to conduct a TRL assessment

To do a TRL assessment, the R&I project team should use the prospective outcomes of its research activities as the input for determining the TRL level. For instance, an R&I project that aims at developing a demonstrator application for smart grid technologies probably ends up as TRL 6 or 7. However, a nano-technology R&I project that investigates the topology of certain materials would probably end up with a TRL that is based at either levels 1, 2 or 3.

#### Follow-up of the TRL assessment

The outcomes of a TRL assessment should lead to a tentative and reasoned balancing of activities of foresight and ethical impact identification. No strict guidelines for this balancing are given. The reviewing organisation (e.g. the research funding organisation) can, however, expect that, with a TRL of 1, 2 or 3, more attention will be paid to the foresight activities whereas, with a TRL of 6 or 7, more attention will be paid to the ethical impact identification activities.

### 2.3.6. Methods for foresight studies

Once the TRL assessment has been completed, both the foresight studies and the overall ethical impact identification activities can start. These activities are often intertwined and therefore can be conducted at the same time. For instance, if in the ethical impact identification impacts on privacy are seen as a predominant area of concern in an R&I project, this probably directly influences the stakeholder involvement during the foresight studies (by choosing experts on privacy in the expert consultation or focusing on privacy issues in a citizen panel).

We outline the different foresight study methods that can be used. These methods can be categorised according four explicit features: focusing on expertise, interaction, creativity or evidence.

#### Methods involving evidence, expertise, creativity and interaction

The different methods are categorised according to their reliance on evidence, expertise, creativity and interaction. Methods can be classified based on their degree of reliance on expertise vs. interaction and on creativity vs. evidence. In order to obtain the widest range of analysis, it is helpful to combine methods that are different from one another in terms of these sources of knowledge. On the one hand, expertise-based methods (such as roadmapping and expert surveys), for example, may be helpful in determining the most likely futures, as well as the probabilities of possible futures. Creativity-based methods (such as wildcard workshops and scenario writing), on the other hand, can be useful in identifying wild card events that may challenge the occurrence of "highly probable" situations in the future. With interaction-based methods (such as expert and citizen panels), participants often gain considerably from being brought together and challenged to articulate ideas and exchange them with their peers (and indeed with the views of non-expert stakeholders). Evidence-based methods (such as a literature

review and trend analysis) are particularly helpful for understanding the actual state of development of the field to which the R&I project belongs.

### Basic methods for foresight studies

The basic methods for foresight studies are structured activities or approaches that need to be followed in any EIA. Therefore, these basic methods are the minimum ones to be applied in a small-scale EIA (as established in the threshold analysis). Application of these basic methods can be stipulated as requirements for the conduct of any EIA by a reviewing body (e.g. a research funding organisation).

#### 💧 (Evidence) Exploration of existing work - horizon scanning

- 💧 The EIA process should always start with an analysis and an assessment of existing foresight studies in the field or in related fields. This can be done in the form of a structured literature review or a bibliometrical analysis. Horizon scanning is a suitable approach for exploring existing work. Horizon scanning clarifies the big picture behind the issues to be examined. It is often carried out by doing desk research, which should involve data coming from a wide variety of sources, such as Internet repositories, research communities, online and offline databases and journals, ministries and agencies, non-governmental organisations, and publications of international organisations and companies. Also, a small group of experts who are at the forefront in the area of concern can undertake horizon scanning by sharing their perspectives and knowledge with each other. A horizon scan can provide the background for strategic planning and decision-making.

#### 💧 (Expertise) An expert consultation

- 💧 As the simplest and most basic level of stakeholder engagement, an expert consultation should be conducted in an EIA. An expert consultation can take the form of a number of interviews, a short workshop or a small survey. Experts are to be selected on the basis of their expertise with the specific ethical impacts at hand or the particular R&I field.

#### 💧 (Creativity) Roadmapping

- 💧 A basic way in which the future development of the outcomes of the R&I project can be captured is by constructing a roadmap. This consists of collecting, synthesising and validating information about the expected R&I outcomes, and representing the trends within graphical displays associated with support documents. The approach should be based on a light and modular process by using a "toolbox". The toolbox should contain different modules, depending on the roadmapping areas, issues, context and objectives. Roadmapping consists of three distinct steps: (1) defining the focus and timescale of the roadmap, (2) building the vision, (3) creating the roadmap contents (R&I outcomes).

### Methods for medium-scale foresight studies.

For medium-scale EIA procedures, expensive and time-consuming methods such as Delphi interviews and scenario writing will not be feasible. However, there are alternatives to these methods that require less time and resources so that comprehensiveness of the forecasting methods can be maintained in terms of knowledge sources used.

Thus, in addition to the basic methods the following may be a sequence of methods for a medium-scale EIA:

#### 💧 (Evidence) Trend analysis

- 💧 To investigate possible future impacts of R&I outcomes, researchers can aim to identify a trend in their area of R&I activities. A trend is a general tendency or direction that is already evident from past events, and hence is increasing or decreasing in strength of frequency of observation; it usually suggests a pattern. Three distinct features define the outlines of a trend analysis: (1) a specific time horizon, (2) the reach of impacts (regional/global, specific field/more general field) and (3) intensity of expected impact(s).

#### 💧 (Interaction) Stakeholder brainstorming/futures wheel

- 💧 As a form of stakeholder engagement focused on interaction, structured brainstorms can be organized in which specific aspects of the R&I project are discussed among stakeholders. The Futures Wheel is one way of organizing thinking and questioning about the future. It produces a graphical visualization of the direct and indirect future consequences of a change or development.

### Methods for large-scale foresight studies

For a large-scale EIA, the financial and time resources to be used for foresight studies are the greatest. There is room for methods that are organizationally difficult and time-consuming but offer high quality information, such as the Delphi method or scenario writing. Stakeholder involvement, and especially citizen engagement or participation, will be important at this level to identify public concerns about the future and to establish legitimacy of the foresight process. This means that it is useful to include citizen panels within the mix of methods. The

following four sets of methods may act as a sequence of methods in which the four sources of knowledge (i.e., expertise, interaction, creativity and evidence) are well represented:

💧 (Expertise) Delphi interviews

💧 The Delphi method is a survey technique that involves repeated polling of the same individuals, feeding back anonymized responses from earlier rounds of polling. The underpinning concept is that this feedback loop will allow for better judgements to be made without there being undue influence from forceful or high-status advocates. There are three phases to conducting a Delphi. These are: (1) selection of the topic, (2) designing the questionnaire, and (3) selection of the panel of experts. Guidance on each of these phases is available at the European Foresight Platform.

💧 (Interaction) Citizen panels

💧 In order to gain the input from stakeholders during the foresight studies process, citizen panels or focus groups can be organised. These panels might take place during conferences, workshops or trainings at which stakeholders are invited to participate actively. The outcomes of citizen panels can take the form of written feedback on the R&I project setup, minutes of the meeting, or a collaborative report in which probable or preferable impacts of the R&I project are discussed.

### 2.3.7. Steps for the ethical impact identification

The ethical impact identification activities take place in sequence with the foresight studies, meaning that both activities can and usually should be conducted at the same time. The ethical impact identification stage includes (1) a description of the R&I outcomes (e.g. the technologies that are being developed) and preliminary ideas of ethical impacts, (2) a description of the expected impacts of the R&I outcomes (in congruence with the foresight outcomes) and (3) a determination of ethical values and principles that are at stake for the given impacts.

#### Describing the technology and preliminary ethical impacts

In order to conduct the ethical impact identification, the assessor (and his/her team, if s/he has one) first prepares a description of the technology and an initial identification of ethical values and principles and, possibly, relevant interests of stakeholders. The assessor investigates if features of the technology are likely to impact moral values or principles negatively. In some analyses, identification of the interests of different stakeholders can be chosen and these can be related to ethical principles. This investigation results in a structured list of ethical issues that may emerge if certain future technological or social options are realised as a result of the project being conducted. As the EIA progresses, the assessor (and possibly stakeholders who may participate in the process) can identify additional values and principles impacted by the proposed technology.

#### Methods for ethical impact identification

After the preliminary investigation, methods for conducting the ethical impact identification need to be selected. This selection will depend on the level of the EIA (as established in the threshold analysis), but also on some additional factors.

First of all, the ethical impact identification can be conducted by a conceptual analysis (e.g. determining ethical impacts based on explicit ethical principles) or by an empirical analysis (e.g. determining ethical impacts by consulting experts).

Secondly, during the identification stage, ethicists may do two types of identification. A first type is that of explicit moral issues, where a technological or social option potentially violates a moral principle, value or norm. For example, in the identification stage, it may be concluded that developments in robotics may result in certain types of robots that violate people's autonomy or privacy. A second type is that of intuitive moral issues, where a technological option has certain characteristics or implications that intuitively feel morally problematic or controversial, even though it is not immediately clear how and whether the option violates any moral value or principle.

Below, the two different methods are presented according to their conceptual or empirical basis and according to whether they focus on explicit moral values or intuitive moral issues. Also, their relative advantages and disadvantages are outlined.

#### Ethical impact identification through conceptual investigations

Method(s) focusing on explicit moral values:

💧 Ethical checklist approaches (for a basic EIA)

💧 Ethical checklist approaches offer practical and comprehensive ways to determine ethical impacts and can be used in any EIA. When using an ethical checklist approach, a list of ethical principles or values is cross-referenced with the technological options that were identified during the foresight studies. If the ethical checklist is drawn up adequately, this approach has the advantage of being thorough because it ensures that all relevant values or principles are checked upon. It also has a disadvantage, which is that it does not allow for the identification of intuitive moral issues. In addition, it is difficult for any checklist to be suitably comprehensive, so that it covers all moral values or principles that may be at issue with a certain technology.

💧 Use of ethical theories (for medium-scale and higher EIAs)

💧 In the event that the assessors conducting the EIA have an expertise in ethics, they can use ethical theories to determine the ethical impacts of the R&I activities. The most frequently and well-known ethical theories are (a) consequentialism, (b) deontological ethics and (c) virtue ethics. Other approaches, such as care ethics or value-ethics, might be used, depending on the field of research under development (i.e. care ethics would be an appropriate approach for research related to healthcare).

Method(s) focusing on intuitive moral issues:

💧 Situational approaches (for a large-scale EIA)

💧 Situational approaches are those in which the analyst does not start out with a list of moral principles or values but screens the research and innovation options by drawing on his or her moral intuitions. This leads to a collection of technological options that are found to be morally problematic from an intuitive point of view.

Ethical impact identification through empirical investigations

Method(s) focusing on explicit moral values:

💧 Consolatory / consultative approaches

💧 Consolatory approaches are approaches in which the assessor reviews previous ethical analyses (and possibly other analyses that may contain ethical observations, such as policy analyses) in order to collect ethical issues that have been identified by others, or interviews experts to collect their opinions and evidence on possible ethical issues. The assessor does not identify any ethical impacts him- or herself in this approach, although he or she has to be able to recognize those issues identified by others and place them in order.

Method(s) focusing on intuitive moral issues:

💧 Techno-ethical scenario building

💧 By constructing descriptive narratives (scenarios) about the way a technological innovation might impact society, a more comprehensive analysis of the ethical impacts of research and innovation can be obtained. This method uses a three-step methodology: (1) it provides a descriptive account of the present situation (both regarding the technology and existing ethical controversies) to ground the analysis, (2) it explicates potential moral controversies by means of the ethics of New and Emerging Science and Technology (NEST) approach) that considers technological expectations, critical objections to the technology, and patterns of arguments among stakeholders, and (3) it permits closure by judging plausible resolutions of the ethical controversies.

**2.3.8. Presentation of ethical impact identification results**

After the ethical impact identification and foresight studies have been initiated, the assessors need to make sure that the outcomes of their activities are documented frequently and in a comprehensive manner. In the event that a periodic review is conducted in the EIA, the reviewing bodies might set certain milestones with regards to the presentation of the results. The following types of presentations of results might typically be requested or required:

💧 For a small-scale EIA: a report, outlining the activities that have been undertaken in the Ethical impact identification stage, the R&I outcomes that can be expected and the consequent ethical impacts that have been identified is required. This report will generally have the following structure:

- 💧 o Introduction.
- 💧 o Description of expected R&I outcomes (e.g. the technology being developed).
- 💧 o Overview of methods used and activities conducted o Overview of anticipated ethical impacts o Conclusion and Discussion.

- ◆ For a medium-scale EIA: Additional to the report, a number of academic publications or public deliverables might be requested or required that explore the ethical impacts that have been identified and share the findings with the broader (academic) community.
- ◆ For a large-scale EIA: Additional to the report and academic publications, it might be requested or required to present the outcomes of the EIA publicly, especially those resulting from stakeholder engagement.

### 2.3.9. Recommendations

Based on the above description of the ethical impact identification stage of the EIA, we present three recommendations for implementing this stage in an appropriate way:

- ◆ A repository of documentation of the ethical impact identification stages for R&I projects would be very useful, in order to avoid duplication of the same activities.
- ◆ If the impacts of an R&I project remain uncertain, more resources of the EIA should be allocated to the foresight studies and fewer resources to the ethical impact identification.
- ◆ In the event that periodic reviews of the EIA take place, the assessor(s) might be requested or required to work on certain milestones with regards to the presentation of the EIA outcomes (e.g. a report, publications or public presentation of the results).

## 2.4. Ethical Impact Evaluation

The ethical impact evaluation stage of an EIA is aimed at evaluating the relative severity of ethical impacts that have been determined, as well as the likelihood of occurrence of these impacts and potential value conflicts that may be at stake.

Here we take the example of a proposed project on the Internet of Things (IoT). For instance, in the ethical impact identification stage, the assessor may have determined that behavioural profiling by IoT systems presents privacy issues. In the evaluation stage, the assessor determines the threats, vulnerabilities and risks, the advantages and disadvantages, their impacts, the permissibility of allowing the violation of privacy by these technologies, how privacy may conflict with other values in the use of IoT technologies (such as autonomy, security and well-being), and on what grounds such conflicts could, and should, be resolved.

### 2.4.1. Function

What is ethical impact evaluation?

- ◆ Ethical impact evaluation comprises the assessment of the relative importance, the likelihood of occurrence and the possible value conflicts of ethical impacts that have been determined earlier.

The function of the ethical impact evaluation stage in the EIA process can be explicated as follows:

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

### 2.4.2. Method

In order to complete the Ethical impact evaluation stage, five procedural steps have to be followed. The following depicts the procedural steps of the Ethical impact evaluation stage:

#### Summary of key procedural steps:

- ◆ 1. Decide which methods should be used; base this decision on the EIA level.

- ◆ 2. Conduct a contingency analysis to evaluate the likelihood of ethical impacts to occur.
- ◆ 3. Assess the relative importance of ethical impacts:
  - ◆ a. Based on the contingency analysis.
  - ◆ b. Based on the methods applied.
- ◆ 4. Identify potential or actual value conflicts and, if possible, aim at resolving these
  - ◆ a. If value conflicts cannot be solved, this should be explicitly recognized/
- ◆ 5. Clarify the ethical impacts and the related ethical values/principles and formulation of workable conceptualizations.

#### 2.4.3. Who conducts the ethical impact evaluation?

To determine who should work on the ethical impact evaluation, roughly the same arrangement as in the ethical impact identification stage can be used. That is to say, ethical impact evaluation can be conducted by researchers within the R&I project, by external experts, or by designated consultants. Who will perform the ethical impact evaluation will ultimately depend on the desirability or an external review and on the resources available.

#### 2.4.4. Essential elements

##### Deciding on methods for ethical impact evaluation

Similar to the ethical impact identification stage, the assessor will have to decide on the methods to deploy for working on the ethical impact evaluation. The choice of these methods will largely depend on the scale of the EIA that was decided upon by means of the threshold analysis. Basically, methods can be distinguished for three types of inquiries: methods in (1) desk-research approaches, (2) for conducting expert consultations or (3) in participatory approaches.

- ◆ Desk-research approaches: Desk-research approaches form the basis of all activities undertaken to conduct the ethical impact evaluation stage. These include reviews of existing evaluation of ethical impacts in related R&I projects and the deployment of certain conceptual framework, for instance when trying to resolve conflicts of values.
- ◆ Expert consultation: Because some activities in the ethical impact evaluation stage might call for ethical expertise or expertise in other specific areas (e.g. for field-specific expertise when conducting the contingency analysis), methods for expert consultation might be selected. For this, similar methods as those mentioned in the ethical impact identification stage can be selected (e.g. an ethical Delphi). However, the focus will be different (not inquiring about possible or probable ethical impacts, but about e.g. the relevant importance of already determined ethical impacts).
- ◆ Participatory approaches: If the scale of the EIA and the available resources allow this, then selecting participatory approaches for conducting parts of the ethical impact evaluation stage is preferred. These focus on stakeholder engagement, in the form of e.g. focus groups or citizen panels.

#### 2.4.5. Conducting a contingency analysis

A contingency analysis is a detailed analysis of the way in which the very occurrence and strengths of occurrence of the ethical impact depends on various factors, such as the presence of certain technological features or configurations, aspects of the social and institutional context in which the technology is used, aspects of users or user groups, and particular ways of using the technology.

A contingency analysis can therefore be seen as a continuation of the foresight studies, but with a focus on different aspects of the context in which the ethical impact occurs instead of on determining the impact itself. For instance, an assessor might first anticipate the ethical impact of violation of someone's privacy. However, whether and to what extent internet cookies violate user privacy clearly depends on many factors: the type of information contained in the cookie, policies that regulate the use of such cookies, the browser's support of privacy settings,

the behavioural patterns of internet users, and so forth. In a contingency analysis, many such contingencies are laid bare. A contingency analysis can be conducted in the following way:

- Conducting an extensive desk-review in which certain factors derived from the context of an ethical impact are laid bare
- Conducting a horizon scanning for each of the identified factors, determining the likelihood of it changing in the future (e.g. current technologies in the development stage being put on the market)
- Constructing short scenarios for the ethical impacts that have been determined in the ethical impact identification stage.

#### 2.4.6. Assessing the relative importance of ethical impacts

Based on the contingency analysis, and additional desk-research, expert consultations or participatory processes, the relative importance of the ethical impact under study can be tentatively arrived at. This relative importance will depend on at least three factors: the normative importance of the value or principle that may be violated (either arrived at through the use of ethical theories or stakeholder consultation), the likelihood that it will be violated, and the intensity by which it may be violated.

For example, a new neuro-technology may be massively deployed in the future, which radically undermines the ethical principles of human autonomy. By arguing that autonomy is an essential value, we could conclude that the ethical impact raised by this technology is very significant. The three factors mentioned actually define different scales of importance of ethical impacts:

- 1. A scale on which moral values and principles could be ranked for their importance (which is, however, bound to be controversial).
- 2. A scale to assess risks of occurrence (that a value or principle is violated).
- 3. An intensity scale (which assesses the expected strength and scope of the violation, if it is to occur).

These three scales inform the methodologies that can be used for conducting the assessment of relative importance of ethical impacts:

- For basic EIA procedures (in all cases):
  - 1. Evaluate the relative importance of the ethical impacts identified by: (1) conducting a desk-review to assess which ethical principles and values are brought into consideration for an ethical impact in the literature, considering and identifying the appropriate contexts where certain principles may take priority (e.g. security and privacy when considering ethical impacts of an ambient technology) and (2) evaluate them by using an ethical theory (such as consequentialism, deontology or virtue ethics).
  - 2. Use the contingency analysis to assess the likelihood of the ethical principles or values to be violated.
  - 3. Assess the severity of impacts by considering factors of scale and intensity such as (1) the number of people that might be harmed, (2) the severity of the harm, (3) the spread of the impacts through space (e.g. considering the area being impacted) and time (e.g. considering the speed at which impacts can occur).
- For medium-scale or large-scale EIA procedures (in addition to the basic procedures):
  - 1. Evaluate the relative importance of the ethical impacts identified by: (1) conduct an expert consultation to gather opinions on the relative importance of the ethical principles and values at stake or (2) organise participatory stakeholder engagement such as focus groups or citizen panels to gather opinions.
  - 2. Conduct an expert consultation to get additional inputs and feedback on the contingency analysis. Balance the opinions of the experts and the outcomes of the contingency analysis to determine the likelihood of the ethical principles and values to be violated.
  - 3. Utilise the same expert consultation to gain additional opinions about the severity of possible ethical impacts, based on the same parameters as used for the basic EIA procedures.

#### 2.4.7. Identification and resolution of value conflicts

Once the relative importance of the ethical impacts has been evaluated, the ethical principles and values that are at stake when considering these ethical impacts need to be evaluated as well. That is to say, especially the

relationships between these ethical principles and values need to be evaluated, which can be done by identifying possible value conflicts and aiming to overcome them.

It will rarely or never be the case that a particular technological artefact or scientific application has an impact on one value and is neutral with respect to all the others. It will normally support, to a greater or lesser extent, certain values or principles, while violating or harming others. An attempt to mitigate the violation of one principle may result in the violation of another principle. This creates a value conflict. For example, CCTV cameras are intended to provide security, but in doing so, they potentially violate privacy. Removing the cameras protects privacy, but runs the risk of compromising security.

In order to identify and resolve value conflicts, the assessor can resort to the following five rules of thumb that also explicate the different types of procedures that can be used.

- ◆ 1. A first rule of thumb is to follow the conviction in many ethical theories that that some values are fundamental, in two senses. They (1) are fundamental in the sense of not being reducible to other values, and (2) in that it is normally very important (considering public consensus) to uphold them. At least in the West, fundamental values include autonomy, freedom, dignity (including the right to life), justice and well-being. There are other candidates as well, such as privacy, equality, security and bodily integrity. Normally, fundamental values will get precedence over non-fundamental values in value trade-offs. Often, however, value conflicts will occur between two or more values that are both considered to be fundamental. In such cases, people will often have different reasons or moral intuitions for giving priority for one value over the other. So how to proceed?

- ◆ Procedure: Refer to (i) fundamental values as they are discussed in ethical theories and/or (ii) fundamental values as they are agreed upon in authoritative, widely accepted documents such as the declaration of human rights.

- ◆ 2. A second rule of thumb is that when fundamental values conflict, it is taken into account how severe the violation of one value is when the other is given priority to, and to choose that action that least compromises a fundamental value, understood in terms of the degree to which and scale at which a violation takes place. For example, if the choice is between a mild violation of autonomy, in which informed consent is partially but not fully realized, and a large injustice, in which thousands of people are denied opportunities that others have, then based on the degree of violation, the fundamental value is given priority that would be violated most. This kind of assessment requires an understanding of the circumstances in which the violations occur in order to assess the severity of violation.

- ◆ Procedure: Take into account the evaluation of the severance of the ethical impact, looking at the values at stake in this evaluation.

- ◆ 3. A third rule of thumb, in cases in which two fundamental values seem to be equally violated, a solution is to project one's moral intuitions onto the situation to determine which value appears more important in the particular situation, and to also employ moral reasoning to explore pros and cons for giving priority for one value over the other. This is, however, a process for which there is no sure method. It can be taken into account, though, that particular types of situations or contexts favour some values more than others. For example, in an airport context, the value of security is generally thought to be more important than the value of privacy, since the stakes for security are so high.

- ◆ Procedure: Construct an ethical argument, based on moral intuition, to favour one value over another.

- ◆ 4. A fourth rule of thumb is that conflicts of moral values can be resolved through deliberation and negotiation between different parties, who ideally constitute or represent a representative sampling of stakeholders in the situation.

- ◆ Procedure: (only for medium-scale and large-scale EIA processes): organise a stakeholder consultation to use their inputs for balancing the values that are at stake. 5. A fifth rule of thumb is that one can attempt to avoid the value conflict altogether by thinking up reconfigurations of the situation in which the value conflict will not occur. It is often possible to avoid value conflicts by avoiding situations in which they occur. Some examples will be discussed in the sections concerning the recommendation and the remedial action stages.



#### 2.4.8. Constructing workable concepts for relevant principles and values

Once the relative importance of the ethical impacts has been evaluated and possible value conflicts have been identified and, if possible, resolved, all the needed information is present to proceed to the final stages of the EIA (the recommendation and the remedial action stages). However, the ethical principles and values that are at stake are ethical concepts that may require conceptual clarification. For example, “*what is freedom?*”, “*what kinds are there?*” and “*what is the importance of and justification for each?*”. These questions can be answered in a conceptual analysis. Conceptual analysis may also be used to clarify non-moral concepts that play an important role in an analysis. For example, in a moral evaluation of cloning, it may be necessary to clarify the concept of cloning, or that of genetic engineering.

To conduct this conceptual analysis, the assessor can follow the following steps:

- ◆ A literature review of definitions of the respective ethical principle or value
- ◆ Constructing a definition of the respective ethical principle or value by drawing relationships between its concept and related concepts

#### 2.4.9. Presentation of ethical impact evaluation

After the ethical impact evaluation activities have been initiated, the assessors need to make sure that the outcomes of these activities are documented frequently and in a comprehensive manner. In case a periodic review is applied to the EIA, the reviewing bodies might set certain milestones with regards to the presentation of the results. The following types of presentations of results might typically be requested or required:

- ◆ For small scale EIA: a report, similar to the report written for the ethical impact identification stage with the following structure:
  - ◆ Introduction.
  - ◆ Overview of methods used.
  - ◆ (If applicable) outcomes of expert consultations and/or stakeholder engagement.
  - ◆ Outcomes of contingency analysis.
  - ◆ Discussion of the relative importance of ethical impacts.
  - ◆ Discussion of the value conflicts and possible resolutions for these conflicts.
  - ◆ Discussion and presentation of workable concepts o Conclusion and Discussion.
- ◆ For medium-scale and large-scale EIA: The same guidelines can be followed as for the ethical impact identification stage. Results of the ethical impact evaluation might be expected to be published and presented to the public.

#### 2.4.10. Recommendations

Based on the above exposition of the ethical impact evaluation as part of the EIA, we present a number of recommendations for implementing this stage in a proper way:

- ◆ Because of the controversial nature of deciding on the relative importance of ethical impacts, assessors should be required to be nuanced in conducting this evaluation.
- ◆ Since certain knowledge of ethical theories would be a prerequisite, it would be recommended to provide for sufficient training for the assessor in order to ensure the assessor's sufficient knowledge in this area.
- ◆ A knowledge repository with documents relevant for the ethical impact evaluation stage (such as widely acknowledged lists with ethical principles and human rights declarations) would be very useful for assessors in order to reduce the amount of time spend on activities such as desk review.

## 2.5. Remedial Actions

### Introduction

The remedial actions stage of an EIA is aimed at formulating and executing so-called "remedial actions" that are based on the foresight and ethical impact evaluation stages. These remedial actions can take the form of (i) recommendations and (ii) design interventions. The purpose of remedial actions is to overcome the ethical impacts that have been identified and evaluated in earlier stages of the EIA. The evaluation stage lays the basis for remedial actions by identifying the importance of certain ethical principles and by proposing how they should be balanced against each other. However, the evaluation stage only contains general, de- contextualised recommendations. In the remedial actions stage, the assessor uses these, with other considerations, to arrive at practical recommendations for the involved stakeholders in the project or program and at design interventions to deal with ethical impacts at the technology level.

#### 2.5.1. Function

*What are remedial actions?*

Remedial actions are follow-up activities based on the earlier findings in the EIA process that are aimed at overcoming the relevant ethical impacts. These actions can both be aimed at internal intervention into the design of the R&I outcomes and at external recommendations for future R&I efforts.

The function of the remedial actions stage can be explicated as follows:

- ♣ 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.

#### 2.5.2. Method

We explicate the method of a remedial actions stage of an EIA by describing a sequence of procedural steps that, if followed correctly, should lead to successful formulation and implementation of remedial actions for an R&I project. The following depicts these procedural steps:

#### Summary of key procedural steps:

- ♣ 1. Gather relevant information about recommendations and design interventions proposed by other related R&I projects
- ♣ 2. Formulate and implement design interventions, as appropriate regarding the earlier identified ethical impacts and according to three distinct steps:
  - ♣ a. A conceptual stage, at which the relevant values are transformed into workable concepts.
  - ♣ b. An empirical stage, at which the interactions between humans and the R&I outputs are investigated.
  - ♣ c. A technical stage, at which the researchers, possibly together with stakeholders, formulate and implement design interventions.
- ♣ 3. Formulate different recommendations, classified according to the following typology:
  - ♣ a. Societal recommendations.
  - ♣ b. Organizational recommendations.
  - ♣ c. Regulatory recommendations.
  - ♣ d. Policy and public policy recommendations.
- ♣ 4. Present the remedial actions in an appropriate manner:

- ♣ a. For design interventions: in the form of a report with the proposed design interventions or a survey for stakeholders
- ♣ b. For different types of recommendations:
  - ♣ i. *Societal & organizational recommendations: these are presented in the form of a simple report.*
  - ♣ ii. *Regulatory recommendations: these are presented in the form of legal proposals.*
  - ♣ iii. *Policy recommendations: these are presented in the form of green/white papers.*

### 2.5.3. Who performs the remedial actions?

Who performs the remedial actions will depend largely on the type of remedial actions that are selected to be implemented in line with the earlier findings of the EIA. For each of the below mentioned types of remedial actions, the following people can work on them:

- ♣ For design interventions: Design interventions are usually undertaken by the researchers in the R&I project, in collaborations with the project's assessor(s). This implies that a coordinated effort needs to be made to think about the outcomes of the R&I project with assessors that have some knowledge of ethics and researchers that know about the technicalities of the R&I outcomes.
- ♣ For societal and organizational recommendations: The assessor(s) in the R&I project usually work on formulating societal and organizational recommendations.
- ♣ For regulatory and policy recommendations: The assessor(s) in the R&I projects usually collaborate with experts in the areas of law and policy making to formulate regulatory and policy recommendations.

### 2.5.4. Essential elements

Based on the findings in the earlier stages of the EIA, the assessor can engage in different types of remedial actions.

### 2.5.5. Design interventions

Design interventions are any kinds of changes in the design of the R&I outcomes in order to resolve identified ethical impacts. Thus, unlike recommendations, design interventions are internal to the workings of the R&I project. They are usually targeted at technical aspects of the project and innovation activity. Since not many approaches have as yet been developed to organize and structure design interventions that are aimed at resolving ethical impacts, the EIA framework incorporates the most prominent existing approach: value sensitive design.

#### Value sensitive design

One of the main approaches to incorporate ethical concerns in the design of technologies is the "value sensitive design" approach, which was initiated by Batya Friedman and consequently developed by scholars such as Jeroen van den Hoven. It was initially developed specifically for information technologies, but has also been applied to different engineering sciences and can in principle be used for many kinds of technology development. The method "employs an integrative and iterative tripartite methodology, consisting of conceptual, empirical, and technical investigations".

The following three distinct steps can be followed in order to incorporate values in technology design:

- ♣ 1. The conceptual stage: At the conceptual stage, both the technology in question, the values that ought to be inscribed in it and its context of use (e.g. stakeholders involved) are conceptualised in a philosophically rigorous manner. For instance, if trust ought to be inscribed in a certain IT system, a philosophically informed working definition of trust is provided. For this stage, the assessor can extensively draw from earlier work done in the ethical impact evaluation stage (arriving at workable conceptualisations).
- ♣ 2. The empirical stage: Methods for empirical research such as can be found in the social sciences are used to inform the human context in which the technology at hand will be used. Such can be for instance interview methods, survey methods and ethnographic methods. This stage should establish how different stakeholders apprehend their values in an interactive context mediated by the respective technology. In conducting this

stage, the stakeholder can therefore extensively draw from the stakeholder engagement exercises in the Ethical impact identification stage.

- ◆ 3. The technical stage: At the technical stage, trade-offs between certain values in the technology design (such as between privacy and security) are identified. To do so, the assessor can draw from the value conflicts as identified in the evaluation stage. Accordingly, the design should be altered in order to foster alternative designs that do more justice to each value that ought to be inscribed in the technology.

### 2.5.6. Types of recommendations

Next to undertaking remedial actions that are internal to the R&I project, in the sense of intervening in the design of the R&I outcomes, the EIA might be used to formulate recommendations that are to be implemented on a broader scale (e.g. as industry standards, regulations, policies). Assessors may make different types of recommendations (as applicable to the project, or innovation activity):

- ◆ Societal recommendations: these include advice on societal aspects such as impact on societal values, public trust, public concerns. Responsibility for implementation: research project team, in engagement with other societal actors such as non-profit and civil society organizations (NGOs and CSOs), media, representatives from industry trade associations and trade unions, and other special interest groups.
- ◆ Organizational recommendations: these include recommendations for how an organization identifies, responds to, addresses, manages, avoids or minimizes ethical issues. Responsibility for implementation: the organization conducting the research or innovation activity.
- ◆ Regulatory recommendations: these are aimed at two types of stakeholders. The first are regulators who might need to put in place new regulations addressing particular ethical issues. The other types of stakeholders are those who would be subject to regulatory strictures. Such recommendations could offer specific guidance on how to meet legal, ethical obligations. They could specify how regulation might need to be put in place or revised to take into account the ethical impact of a particular research or innovation activity. Responsibility for implementation: legislators and regulators.
- ◆ Policy and public policy recommendations: these include policy advice for any group with decision-making authority and public policy influence. Responsibility for implementation: government organizations, politicians, and public authorities.

### 2.5.7. Presentation of the remedial actions

Firstly, as a general guideline, Wright recommends that "the assessor should be clear to whom his or her recommendations are directed" - the responsibility for implementing the recommendations should be clearly demarcated and we have provided some examples of the responsibility for the different types of recommendations (these are by no means intended to be exhaustive).

Secondly, the remedial actions can be presented in different ways, according to the action type. These different ways of presenting remedial actions are categorized as follows:

- ◆ For design interventions: these are presented in the form of a report with the proposed design interventions and/or a survey for stakeholders. The survey would need to take place before and after the design interventions have been implemented, in order to assess the effectiveness of the interventions.
- ◆ For societal and organizational recommendations: these are presented in the form of a simple report. This report can be based on a short review of societal and organization recommendations that resulted from other projects; complemented by the ones that are specific to the R&I project in which the EIA takes place.
- ◆ For regulatory recommendations: these are presented in the form of legal proposals. Such proposals generally consist of (i) an explanation of the context and rationale of the proposed regulations, (ii) an explanation of how the proposed regulations fit in with the existing relevant regulatory framework, (iii) a presentation and explanation of the proposed regulations.

- ♦ For policy recommendations: these are presented in the form of green/white papers. Such papers generally consist of (i) an explanation of the purpose and context of the policy, (ii) the function of the policy, (iii) the procedures involved in its implementation and (iv) a roadmap laying down the implementation trajectory.

### 2.5.8. Recommendations

Based on the above exposition of the remedial actions stage as part of the EIA, we present a number of recommendations for implementing this stage in a proper way:

- ♦ The value sensitive design approach would need to be developed further in order to make it fit with actual R&I practices. At this point, the framework offers only a fairly abstract groundwork on how to implement value sensitive design.
- ♦ Overall, recommendations should be viable and implementable. It would also be good to get experts or other external stakeholders to review draft recommendations before their finalization.
- ♦ More concrete frameworks for the way in which recommendations can be drafted should be proposed, primarily with the aim of increasing the communicability of the EIA outcomes as well as giving reviewers of the EIA better criteria for assessing the EIA's effectiveness.

## 2.6. Review and Audit

### *Introduction*

The review and audit stage of an ethical impact assessment (EIA) aims at ensuring independent evaluation of the EIA process and, if necessary, of independent intervention. It especially focuses on the finalisation of the EIA, by reviewing and assessing whether the process has been successfully conducted and whether the assessor has ensured follow-ups of the relevant findings. However, the review and audit stage also plays a role during the entire EIA process, for it can steer the process in the right direction and help correcting mistakes if they occur. The extent to which reviewers are able to steer the EIA process will depend on the type of R&I project (public or private) and the EIA scale.

### 2.6.1. Function

What is the review and audit stage of an EIA?

The review and audit stage evaluates and, if necessary, steers the EIA process. The review process entails an iterative evaluation of the process with the aim of generating feedback. The audit process entails the evaluation of certain measurable milestones that the assessor and the reviewer agreed upon.

The function of the review and audit stage in the EIA process can be explicated as follows:

- ♦ 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.

### 2.6.2. Method

We explicate the method of a review and audit stage of an EIA by describing a sequence of procedural steps that, if followed correctly, should lead to a successful threshold analysis for an R&I project. The following depicts these procedural steps:

#### Summary of key procedural steps:

- ♦ 1. At the beginning of the EIA process: set the key milestones and review criteria for the review and audit process, as part of the R&I project's proposal
  - ♦ a. Agree upon review and audit moments during the project's execution.

- b. Agree upon remedial actions that can be undertaken once certain review or audit criteria are not met.
- 2. During the EIA process: at the agreed upon review and audit moments, the reviewer evaluates:
  - a. The documentation of the EIA process.
  - b. The agreed upon criteria and milestones.
- 3. At the end of the EIA process: during the final review and audit moment, the reviewer ensures:
  - a. Proper documentation of the findings of the EIA.
  - b. Proper planning of follow-up measures of the EIA.
  - c. Proper signing-off of the EIA at the appropriate level.
- 5. Present the review and audit in an appropriate manner:
  - a. In a "milestone report", which explains how the main criteria and milestones have been attained.
  - b. In a general final report, which reflects on the findings of the EIA, the remedial actions and which identifies recommendations for future EIAs.

### 2.6.3. Who performs the review and audit of an EIA?

Depending on the funding source of an R&I project, the following stakeholders could be responsible for reviewing the threshold analysis:

- When the research is funded by a public research institution: For R&I projects funded and executed at the level of a research institution, the review and audit can take place at the same level. This means that the local EAU (for instance, the university's ethics committee) should be made responsible for reviewing and auditing the EIAs that are conducted.
- When the research is funded by a research-funding organisation: For R&I projects that are funded by external research-funding organisations, such as the European Commission, the responsibility for conducting the review and audit of the EIAs lies with these funding organisations.
- When the research is funded by a company: For commercially funded research, the review and audit can be done by different organisations. Generally, an internal body within the commercial body can do the review and audit, or an external organisation such as a consultancy.

### 2.6.4. Essential elements of the review and audit stage

The review and audit process for EIAs that is described in this proposal is partially based on existing procedures and best practices as discussed for the follow-up, review and audit of environmental impact assessment<sup>3637</sup>. The purpose of the review and audit is to provide an assurance about the effectiveness of the EIA process and extent of the implementation of the recommendations. A review might also highlight new information that changes the basis of the original recommendations; this might necessitate repeating the EIA process or taking additional remedial actions, if necessary. The procedural steps focus on three distinct stages of the review and audit: at the start of the EIA, during the EIA and at the finish of the EIA.

#### At the start of the EIA

At the start of the EIA, after the threshold analysis has been completed, the assessor responsible for executing the EIA and the EIA reviewer need to reach a consensus regarding the review and audit planning as well as the review and audit criteria. Even though this planning and these criteria will be decided upon on a case-to-case basis, the following guidelines can assist in determining them:

- Review and audit planning:
  - For small-scale EIAs: only a final review and audit will be required; a mid-term review will be optional (the reviewer might initiate one if deemed necessary).
  - For medium-scale EIAs: A mid-term and a final review and audit will be required; additional reviews will be optional (the reviewer might initiate some if deemed necessary).

- For large-scale EIAs: Yearly reviews and audits as well as a final review and audit are required.

#### • Review and audit criteria:

• Review criteria: these are usually framed in terms of the necessary documentation that needs to be delivered before every review takes place. Criteria might include:

- The types of documentation needed for each stage of the EIA.

• The minimum period of time before the review date before which the assessor needs to communicate the necessary documents with the reviewer.

• Audit criteria: these are usually framed in terms of the necessary minimum milestones or deliverables that need to be provided in order for the EIA process to be continued and funded. These criteria might include:

- The finalization of certain stages of the EIA at certain moments in time in the duration of the R&I project.

• Requirements for the presentation of the EIA outcomes, such as:

- *Reports of the EIA stages.*

- *A number of academic publications.*

• Requirements for stakeholder engagement, such as:

- *A log with the stakeholders engaged in the EIA.*

#### During the EIA

During the EIA the reviewer might conduct intermediate review and audit activities, depending on the scale of the EIA and the overall progress of the EIA. When the reviewer has the impression that essential activities in the EIA are delayed, an intermediate review and audit might be requested. The following activities might be part of the intermediate reviews and audits:

#### • Intermediate review

• Monitoring: The reviewer will request the assessor to communicate the documentation of the current progress of the EIA. This documentation will be used as the basis of monitoring the progress of the EIA process.

• Evaluation: The reviewer will convene a meeting with the assessor during which the EIA as a whole is evaluated. Based on this evaluation, the reviewer will issue certain feedback that can be incorporated in the future EIA work.

• Management: The reviewer will also evaluate the project management of the EIA, including issues such as:

- Proper division of tasks within the EIA team

- Proper financial management

• Communication: The reviewer will ensure that sufficient communication is established between the assessor and the R&I project funding body.

#### • Intermediate audit

• The reviewer will request a short audit report from the assessor, which states whether the agreed upon milestones and/or deliverables have been met and which provides for proper evidence to support these claims.

• Based on the intermediate audit, the reviewer will issue an opinion about the continuation of the EIA. This opinion might be binding, for instance in the case of a publicly funded R&I project but is not necessarily so. The opinion can take the following forms: (i) acceptance of EIA without revisions, (ii) acceptance of EIA with minor or major revisions and (iii) rejection of current EIA progress with the need of re-initiating the EIA process.

#### At the finish of the EIA

Once all the steps of the EIA have been finished, a final review and audit will be organized. An EIA is complete after remedial actions have been taken, the review and audit stage has been completed and the EIA report is approved and signed off at a level appropriate to the project or innovation activity. The following activities might be part of the final review and audit of and EIA:

#### • Final review

- The reviewer convenes a final review meeting with the assessor. During this meeting, the entire EIA is evaluated and recommendations for future EIAs are documented.
- The assessor writes a final EIA report, which includes the main findings of the EIA and a description of the remedial actions.
- The reviewer writes a final review document, which will be send to the funding organisation of the R&I project as well as to the relevant stakeholders.
- For medium-scale and large-scale EIAs: the reviewer conducts a short survey amongst the stakeholders that were involved in the EIA.

#### • Final Audit

- o During the final audit, the reviewer makes sure that the following actions are undertaken:
  - A final financial statement is made, explicating the final cost of the EIA.
  - A final portfolio of publications (internal & external) is presented & send to the funding organization of the R&I project.
- o The reviewer convenes a final audit meeting with the assessor, at which:
  - Leftover follow-up actions are agreed upon. These need to be performed, even if they fall outside of the EIA budget, in order to meet the audit criteria.

### 2.6.5. Presentation of the review and audit

Depending on the different moments of the review and audit stage, it is presented in the following ways:

- At the start of the EIA: The review and audit criteria are documented in the form of a contract that needs to be signed by both the reviewer and the assessor. This contract can be part of the overall contract between the assessor, as part of the R&I project and the research funding organization.
- During the EIA: Intermediate reviews and audits are presented as audit reports, that are put together by the reviewer; which are to be send to the research funding organization.
- At the finish of the EIA: The review and audit at the end of the EIA process is presented in the following ways:
  - o A final EIA report, drafted by the assessor
  - o A final review document, drafted by the reviewer
  - o A final financial statement.
  - o A final portfolio of publications related to the EIA.

### 2.6.6. Recommendations

Based on the above exposition of the review and audit stage as part of the EIA, we present a number of recommendations for implementing a threshold analysis in a proper way:

- Research funding organisations should consider setting up a body that is responsible for conducting the review and audit of EIAs.
- An independent body might need to be installed for ensuring the independence of the review body. This might for instance be a watchdog organisation at the EU level.
- Review and audit procedures should preferably be standardised as much as possible to decrease their administrative burden, for instance by providing for an online entry system in which the assessor can present the necessary EIA outcomes.



### 3. Initial Ethical and Societal Concerns in HYDROPTICS

As a first preparatory step in EIA, we have identified some preliminary Ethical concerns based on empirical data and the input to the questions presented below:

1. According to you, what will be the claimed benefit for the user of the technology and the society? Please update the description from the Project Proposal if necessary.
2. Are there possible safety risks for the users related to the use of the technology?
3. Do you think using this technology might lead to stigmatization or discrimination of any kind?
4. What technical and organizational measures can be taken to ensure and increase safety of the technology for end-users?
5. What technical measures might be implemented to assist end-users in better and faster familiarization with technology?
6. What measures can be taken to ensure the right and efficient use of the technology?
7. What other technical and organizational measures can be taken to increase trust of the society and individuals in the use of the technology?
8. Do you foresee any ethical issues related to the use of the technology? If yes, please describe them.

Ethical concerns in HYDROPTICS can arise out of different factors and their combinations: use of new technologies, their acceptance by the society and trust; the necessity to balance between different fundamental rights and vital interests of different groups of people.

In what follows below we describe ethical and societal concerns that might arise in HYDROPTICS out of the mentioned factors. While HYDROPTICS is in commencement phase and continues to develop, the ethical and societal concerns in this section are described in a general way and will be further discussed through the further stages of HYDROPTICS project.

The core of HYDROPTICS project is making use of novel advances in photonics, to provide a set of such devices and tools, which allow the reliable, accurate and cost-effective monitoring of produced water quality involved in up- and downstream processing in the oil industry. An important precondition for the adoption of new technologies is a trust. HYDROPTICS recognizes that the need to consider ethical issues is crucial especially during the development and deployment of new technologies. It's an accepted fact that Ethics is an unchanging principle in any activity, but technology can change.

Although it is difficult for technologists to take ethical concerns into account, however, adopting an ethical approach can help HYDROPTICS partners increase confidence that they are 'doing the right things' with technology. Ethics translates moral philosophy into practical principles so it can help businesses to focus on the good they can do with technology, as well as avoid potential harms or unintended consequences.

Ethical issues in technology need to be outlined and controlled with consideration of all the parties involved in HYDROPTICS project as both people and the environment must be considered in any technological advancement.

The preliminary ethical and societal risks that might arise out of the HYDROPTICS project and the measures to mitigate them are described in the table below.

The probability of risk to occur has been rated using a three-grade scale:<sup>4</sup>

**Remote** - Risk nature is known but no known occurrences of the risk happened in similar activities. Depending on the nature of the risk, the risk can be ignored, although a preventive action may still be proposed.

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<sup>4</sup> [https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics\\_en.htm](https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm)

**Possible** - Risks of similar nature have happened in similar activities or the situation may be conducive to the occurrence of the risk. A response plan should be suggested in case the risk manifests.

**Probable** - There is a significantly high chance that risk will occur, or the situation is favourable to occurrence of risks. Mitigating actions should be discussed and monitored.<sup>5</sup>

The identified risks may have an impact with respect to social, legal, ethical and privacy issues. The scale used to rate the impact is the following:<sup>6</sup>

**Minimal** - In case of occurrence, the risk does not hinder on any relevant interests, e.g., safety, or the rights and freedoms of the individual, thus no modification or adaption is needed. It is also possible that the occurrence of the risk only requires minor adaptations.

**Significant** - In case of occurrence, interests, rights and freedoms of the individual are affected, thus hindering the goals of the project. Significant revision and reorientation may be necessary.

**Severe** - In case of occurrence, interests, rights and freedoms of the individual are severely affected, meaning that the project will not achieve one or more goals. The activity or the functionality may be unlawful or contrary to ethical principles. This warrants for substantial revision and re-orientation of the project.<sup>7</sup>

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<sup>5</sup> Ibid.

<sup>6</sup> Ibid.

<sup>7</sup> Ibid.

**Table 1. Ethical and Societal Risks**

ETHICAL AND SOCIETAL RISKS						
<u>Risk ID</u>	<u>Name</u>	<u>Description</u>	<u>Probability of occurrence</u>	<u>Impact</u>	<u>Risk response plan</u>	<u>Responsible partner</u>
E.1	Lack of trust in the use of new technologies from the side of volunteers	Being trained and used to apply the defined scope of tools in their activities, end users might avoid using novel technologies developed in HYDROPTICS	Remote	Significant	End users involved in the HYDROPTICS project currently working in large oil industries within the EU. They have a solid informational background and skills. These end users have been actively involved in the project since the start of the project, giving feedback on the development of the tools. In this way, they ensure they help to create tools that are actually useful within their organizations. As full partners, they understand the project aims to increase efficiency, through the use of new technologies. They are motivated to participate and contribute to achieving the project's goals. Additionally, all end users will be trained on the use of new technologies during the development and final stages of the project.	End users
E.2	Lack of trust in the technologies by the society	Lack of trust in new technologies is the common issue as people do not fully understand how the technologies work and what might be the side effects.	Remote	Significant	It is unlikely that wide groups of population will be affected during the project's lifespan. HYDROPTICS will engage limited amounts of volunteers who will be informed on the aims of the project and the means to achieve these goals. This will enable volunteers (representing the society) to understand the importance of the use of new technologies in the oil industry.	End users
E.3	Affecting the fundamental rights of people	Disasters in oil industry involve different groups of people which can have different negative impacts (health, life, dignity, privacy, autonomy)	Remote	Severe	It is unlikely that during HYDROPTICS activities fundamental rights will be affected as all pilots are well prepared in advance ensuring lack of dangerous situations for the people involved. However, should the contrary be the case, a balancing exercise is needed. Both the benefits and negative impacts for groups concerned shall be weighted.	DBC+all

## 4. Gender Equality Plan in HYDROPTICS (GEP)

This action plan sets out organizational priorities for addressing gender equality and identifies activities and monitoring plans. Equality of opportunity is core to HYDROPTICS mission and gender balance is a critical component for the project to ensure fair access and equity for our research, managerial and support staff. In HYDROPTICS partners are committed to follow international, community and internal standards, to the promotion of equality of opportunities between women and men in its principles and priorities.

This GEP legitimates and protects every strategy aiming to achieve gender equality in HYDROPTICS. GEP is devised according to national and European laws and aligns with national initiatives and actions focusing on: equality of women and men, rights, discrimination banning, equality treatment, harassment in workplace, social responsibility of organizations etc. Specific articles, policies and directives can be found below:

### 4.1. European Union Law

#### TFEU

**Article 157 TFEU** states:

1. Each Member State shall ensure that the principle of equal pay for male and female workers for equal work or work of equal value is applied.
2. For the purpose of this Article, 'pay' means the ordinary basic or minimum wage or salary and any other consideration, whether in cash or in kind, which the worker receives directly or indirectly, in respect of his employment, from his employer. Equal pay without discrimination based on sex means:
  - (a) that pay for the same work at piece rates shall be calculated on the basis of the same unit of measurement;
  - (b) that pay for work at time rates shall be the same for the same job.
3. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure, and after consulting the Economic and Social Committee, shall adopt measures to ensure the application of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation, including the principle of equal pay for equal work or work of equal value.
4. With a view to ensuring full equality in practice between men and women in working life, the principle of equal treatment shall not prevent any Member State from maintaining or adopting measures providing for specific advantages in order to make it easier for the underrepresented sex to pursue a vocational activity or to prevent or compensate for disadvantages in professional careers."

#### **Chapter of Fundamental Rights of the EU**

- 💧 Article 21(1) states: "Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited".
- 💧 Article 23 states: "Equality between women and men must be ensured in all areas, including employment, work and pay. The principle of equality shall not prevent the maintenance or adoption of measures providing for specific advantages in favour of the under-represented sex".

#### **Directives**

- 💧 Directive (EU) 2019/1158 of the European Parliament and of the Council of 20 June 2019 on work-life balance for parents and carers and repealing Council Directive 2010/18/EU.
- 💧 Council Directive 2010/18/EU of 8 March 2010 implementing the revised Framework Agreement on parental leave concluded by BUSINESSSEUROPE, UEAPME, CEEP and ETUC and repealing Directive 96/34/EC (Text with EEA relevance).

- ◆ Directive 2010/41/EU of the European Parliament and of the Council of 7 July 2010 on the application of the principle of equal treatment between men and women engaged in an activity in a self-employed capacity and repealing Council Directive 86/613/EEC.
- ◆ Directive 2006/54/EC of the European Parliament and of the Council of 5 July 2006 on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation (recast).
- ◆ Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation.
- ◆ Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin.
- ◆ Council Directive 96/34/EC of 3 June 1996 on the framework agreement on parental leave concluded by UNICE, CEEP and the ETUC.
- ◆ Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
- ◆ Council Directive 79/7/EEC of 19 December 1978 on the progressive implementation of the principle of equal treatment for men and women in matters of social security.
- ◆ Council Directive 76/207/EEC of 9 February 1976 on the implementation of the principle of equal treatment for men and women as regards access to employment, vocational training and promotion, and working conditions.
- ◆ Council Directive 75/117/EEC of 10 February 1975 on the approximation of the laws of the Member States relating to the application of the principle of equal pay for men and women Greek Law.

## Laws

- ◆ Act 4808/2021, 'On the protection of the work - Establishment of the Independent Authority "Labour Inspectorate"- Ratification of International Labor Organization Convention 190 on the Elimination of Violence and Harassment in the world of work - Ratification of International Labor Organization Convention 187 on the Framework for the Promotion of Safety and Health at Work- Implementation of Directive (EU) 2019/1158 of the European Parliament and of the Council of 20 June 2019 on the balance between work and private life, other provisions of the Ministry of Labor and Social Affairs and other urgent arrangements', OJ A 101/19.6.2021,
- ◆ Act 4604/2019, 'On the promotion of substantive gender equality etc.', OJ A 50/26.3.2019,
- ◆ Act 4443/2016, '1) Transposition of Directive 2000/43/EC on the implementation of the principle of equal treatment between persons irrespective of racial or ethnic origin, of Directive 2000/78/EC establishing a general framework for equal treatment in employment and occupation and of Directive 2014/54/EU on measures facilitating the exercise of rights conferred on workers in the context of freedom of movement for workers (...)', OJ A 232/9.12.2016 [replacing Act 3304/2005 which had initially transposed Directives 2000/43/EC and 2000/78/EC], OJ A 16/27.1.2005].
- ◆ Act 4097/2012, 'Implementation of the Principle of Equal Treatment of Men and Women Engaged in an Activity in a Self-Employed Capacity - Harmonisation of the legislation with Directive 2010/41/EU of the European Parliament and the Council', OJ A 235/3.12.2012 (Directive 86/613/EEC had not been transposed).
- ◆ Act 4075/2012, Articles 48-54, 'Incorporation into Greek Law of Directive 2010/18/EU of the Council of the EU Implementing the Revised Framework Agreement on Parental Leave Concluded by BUSINESSEUROPE, UEAPME, CEEP and ETUC and Repealing Directive 96/34/EC', OJ A 89/11.4.2012.
- ◆ Presidential Decree 80/2012, 'Granting of Parental Leave and Leave of Absence to Workers under a Contract of Maritime Work on Vessels Bearing the Greek Flag, in accordance with Directive 2010/18/EU', OJ 138/14.6.2012.

- ◆ Act 1756/1988, Code on the Status of Judges, OJ A 35/2.2.1988.
- ◆ Act 3896/2010, 'Implementation of the Principle of Equal Treatment of Men and Women in Matters of Employment and Occupation. Harmonisation of Existing Legislation with Directive 2006/54/EC of the European Parliament and the Council', OJ A 207/8.12.2010.
- ◆ Act 3769/2009, 'Implementation of the Principle of Equal Treatment of Men and Women Regarding Access to Goods and Services and Their Supply', transposing Directive 2004/113/EC, OJ A 105/1.7.2009, as amended by Article 162 of Act 4099/2012 implementing the CJEU Test-Achats judgment, OJ A 250/20.11.2012.
- ◆ Act 3488/2006, 'Implementation of the Principle of Equal Treatment of Men and Women Regarding Access to Employment, Professional Training and Evolution and Terms and Conditions of Work', transposing Directive 2002/73/EC, OJ A 191/11.2006.
- ◆ Presidential Decree 105/2003, 'Adaptation of Domestic Law to Directive 97/80/EC on the Burden of Proof in Cases of Sex Discrimination,' OJ A 96/23.4.2003; repealed by Article 30(5) of Act 3896/2010 transposing Directive 2006/54/EC.
- ◆ Presidential Decree 87/2002, 'Implementation of the Principle of Equal Treatment of Men and Women in Occupational Social Security Schemes in Compliance with Directives 96/97/EC and 86/378/EEC'; repealed by Article 30(5) of Act 3896/2010 transposing Directive 2006/54/EC.
- ◆ Presidential Decree 176/1997, 'Measures for the Improvement of the Safety and Health at Work of Pregnant Workers and Workers Who Have Recently Given Birth or are Breastfeeding in Compliance with Directive 92/85/EEC', OJ A 150/15.7.1997, as amended by Decree 41/2003, OJ A 44/21.2.2003.
- ◆ Act 1483/1984, 'Protection and Facilitation of Workers with Family Responsibilities', as amended by Article 25 of Act 2639/1998, OJ A 205/2.9.1998 implementing Directive 96/34/EC and by Article 46 of Act 4488/2017,7 and Article 54(1) of Act 4075/2012 transposing Directive 2010/18/EU.
- ◆ Act 1414/1984, 'Implementation of the Principle of Equal Treatment of the Sexes in Employment Relationships', transposing Directives 75/117/EEC and 76/207/EEC, OJ A 10/2.1984.
- ◆ Presidential Decree 1362/1981, 'Replacement of Paragraph 1 of Article 33 of Act 1846/1951 "on Social Security" in compliance with Directive 79/7/EEC', OJ A 339/30.12.1981.
- ◆ National General Collective Agreements (NGCAs).

## 4.2. Objectives

The HYDROPTICS GEP has eight tangible objectives, towards:

- ◆ Embedding a gender aware culture in the project by shifting traditional perceptions.
- ◆ Improving the research quality of the project by having heterogeneous research groups.
- ◆ Practicing excellence through female staff (researchers, managers and support) career development and training.
- ◆ Making decision-making more inclusive by inviting women in the process thus ensuring diversification of views.
- ◆ Strengthening links with industry by encouraging females to work in businesses and translate their research into tangible products.
- ◆ Becoming an attractive research project for female digital experts and talents.
- ◆ Contributing to the European needs for female digital experts.

To achieve those objectives HYDROPTICS will focus on six key areas, following the guidelines of the European Institute for Gender Equality (EIGE) aiming to "identify and implement innovative strategies to promote cultural change and equal opportunities in Universities and Research Centers" (EIGE, <http://eige.europa.eu>). These areas are:

- ◆ **Key Area 1:** *Governance and decision making*
- ◆ **Key Area 2:** Recruitment, Selection procedures, and Career Progression
- ◆ **Key Area 3:** *Flexible and Agile Working*
- ◆ **Key Area 4:** *Gender Strategy in Research*
- ◆ **Key Area 5:** *Gender in events and activities*
- ◆ **Key Area 6:** *Gender in Organisation Culture*

The selected Key Areas, comprise sets of objectives, measures, targets and KPIs, where the gender dimension will be studied and monitored, the respective timeline, the personnel responsible for each action. Through these Key Areas HYDROPTICS will aim to contribute to reducing the Digital Gender Divide at a project level.

### 4.3. The Digital Gender Divide

Both men and women use digital technologies and need to be involved in building our digital future. 53% of European companies trying to recruit ICT (Information and Communication Technologies) specialists report difficulties in finding qualified people. This translates into a lack of around 1 million digital specialists. Considering that this field is male dominated we can see that by recruiting more women will help meet Europe's increasing demand for digital experts. Women's active participation is crucial in order to shape a sustainable, fair and equitable digital economy and society. Unfortunately, women are underrepresented in digital economy and as EU statistics reveal, only 1 in 6 ICT specialists is a woman, while only 1 in 5 becomes an ICT entrepreneur.

The organization in HYDROPTICS are privileged to be mostly dedicated to ICT ((Information and Communication Technologies) as it recruits researchers with a genuine interest in digital technologies. It is a mandate for us to train them, retain them and help them become experts in cutting edge research fields, in order to excel in research and be employable by industry, meeting the high standards set nationally and on a European level.

With the gender oriented measures and interventions it proposes, HYDROPTICS will aim to contribute to reducing the Digital Gender Divide observed. It will empower female researchers in ICT and provide them with the necessary resources to advance their careers.

### 4.4. Methodology

Despite the fact that the plan has been formally established in 2021 work towards monitoring gender aspects within the project started more than a year ago. Therefore, in the tables below where the Key areas are presented, we have included actions that have been maturing since 2020.

Following the methodological steps of *Understanding — Planning — Implementing — Monitoring [EIGE]* for each Key Area, we have begun to undertake initial work to understand and analyse the current situation with the aim to address imbalances.

Key area 1: Governance and Decision Making				
Objectives	Measures	2020	2021	2022
I. Gender balance in all key decision-making bodies  II. Creation of structures to support gender equality  III. Oversight of organizational processes in relation to gender	1. Seek equality expertise for managerial positions	✓	✓	✓
	2. Establishment of Gender Equality Board		✓	✓
	3. Monitor the application of the Gender plan		✓	✓
	4. Equality, diversity and inclusion principles embedded into to governance and Strategic Planning		✓	✓
<b><u>Who is responsible:</u></b>  1. HR of organisations and Gender Equality Board (GEB) 2. Executive Board (EB) 3. GEB 4. EB	<b><u>KPIS and Targets:</u></b>  1. To the maximum extent possible 2. Completed in 2021 3. In progress 4. In progress			



Key area 2: Recruitment, Selection procedures and Career Progression				
Objectives	Measures	2020	2021	2022
I. Career advancement interventions for female professional, managerial and support staff  II. To gender proof recruitment selection  III. Monitor pay gaps  IV. Attract female applicants in senior posts	1. Analysis of applications vs admissions data to assess gender balance ratio		✓	✓
	2. Sharing career good practices and training female role models			✓
	3. Offering attractive packages for highly skilled females	✓	✓	✓
	4. Monitoring retention rate (RR) of female staff, substitution practices and career progression		✓	✓
	5. Existence of a person in charge of implementing the equality policies		✓	✓
	6. Existence of a person in charge of implementing the equality policies		✓	✓
<b>Who is responsible:</b> 1. GEP and HR of organisations 2. GEB and Researchers 3. EB 4. GEB and HR of organisations 5. GEB 6. GEB	<b>KPIs (Key Performance Indicators) and Targets:</b> 1. Variable ratios for professional, management and support staff 2. 1 event per year 3. Increase offerings (quality/quantity) 4. Average RR 5. Over a certain amount to have equal number of applicants 6. 1 article/announcement per year			

Key area 3 : Flexible and Agile Working				
Objectives	Measures	2020	2021	2022
I. Structures for supporting staff members with caring responsibilities	1. Flexible working models (part time/remote working etc)	✓	✓	✓
	2. Encouragement of men to take parental leaves	✓	✓	✓
II. Promote integration of work with family and personal life	3. ICT based systems for improving staff member connectivity when on leave	✓	✓	✓
III. Creation of guidelines for work life balance				
<p><b><u>Who is responsible:</u></b></p> <ol style="list-style-type: none"> <li>EB and GEB</li> <li>GEB and HR of organisations</li> <li>GEB</li> </ol>	<p><b><u>KPIS and Targets:</u></b></p> <ol style="list-style-type: none"> <li>In place since 2020</li> <li>In comply with all applicable EU and national laws and Directives</li> <li>In place since 2020</li> </ol>			

Key area 4 : Gender Strategy in Research				
Objectives	Measures	2020	2021	2022
I. Gender monitoring in research processes	1. Monitoring applications' gender balance received in research positions		✓	✓
II. Women hired in research Positions	2. Applying for funding in European calls targeting female researchers		✓	✓
III. Women career development	3. Promoting women in open posts for the project	✓	✓	✓
IV. Connection with industry /women practice	5. Facilitating access to funding, computer time, enabling research group set up	✓	✓	✓
V. Better access to resources	6. Supporting women returning from maternity leave	✓	✓	✓
<p><b><u>Who is responsible:</u></b></p> <ul style="list-style-type: none"> <li>• GEB</li> <li>• GEB</li> <li>• GEB</li> <li>• EB</li> <li>• HR of organizations and GEB</li> </ul>	<p><b><u>KPIS and Targets:</u></b></p> <ol style="list-style-type: none"> <li>1. In progress</li> <li>2. In progress</li> <li>3. To the maximum extend possible</li> <li>4. Offering extra resources – This is up to the participating organizations</li> <li>5. Sessions with the HR of the partners</li> </ol>			

Key area 5 : Gender in events, courses and activities				
Objectives	Measures	2020	2021	2022
I. Participation of balanced number of men/women in events, etc	1. Monitoring participation M/F in the project events/campaigns/info days	✓	✓	✓
	2. Appoint women in leading positions of research and communication activities	✓	✓	✓
II. Visibility of women in the activities of the Institute	3. Assign women mentors to students carrying out research/courses	✓	✓	✓
III. Exposure of women in media and social media.	4. Make visible women and their contribution to the results and success of the project in the website/ center screens/ local press.		✓	✓
	5. Participation of women in events targeting female access to R & I	✓	✓	✓
<p><b>Who is responsible:</b></p> <ol style="list-style-type: none"> <li>GEB</li> <li>GEB</li> <li>GEB and EB</li> <li>GEB</li> <li>GEB and EB</li> </ol>	<p><b>KPIS and Targets:</b></p> <ol style="list-style-type: none"> <li>To the maximum extent possible</li> <li>To the maximum extent possible</li> <li>To the maximum extent possible</li> <li>Biannual newsletter flagging the contribution of outstanding research of woman in the Institute</li> <li>To the maximum extent possible</li> </ol>			

Key area 6 : Gender in Organisation Culture				
Objectives	Measures	2020	2021	2022
I. Diffusing /publishing current plan II. Create event on sensitive topics III. Encourage women report incidents IV. Designated area for women and child care	1. Publication of current plan and future versions on website		✓	✓
	2. Organisation of events on diversity and gender for raising awareness			✓
	3. Offering a support service for the prevention, detection and report of discrimination and behaviors of harassment or violence based on gender		✓	✓
<p><b>Who is responsible:</b></p> 1. GEB 2. GEB 3. HR and GEB	<p><b>KPIS and Targets:</b></p> 1. 1 update per year 2. 1 per year 3. Board of 3 members (Gender Equality Board) and yearly evaluation of services by the Institute			

## Conclusion

The deliverable presented a methodology for conducting an Ethical Impact Assessment (EIA). The methodology will be followed in the next period of the project. Some preliminary ethical/societal concerns/issues were also presented and are expected to affect the technical developments of the Hydroptics solution. Last but not least, a first draft of the Hydroptics Gender Equality Plan was presented and strongly suggested to be followed by all the beneficiaries part of the project. The next and final deliverable of the corresponding tasks will mainly present the outcome of the EIA, the final ethical plan (risks/mitigation actions) and the results from the application of the proposed Gender Equality Plan.