Cost-effectiveness and risk-benefit of ethics assessment

Compiled by: Rasmus Øjvind Nielsen (the Danish Board of Technology Foundation)

Contributors: Agata Gurzawska (University of Twente), Andrea Porcari (AIRI - Italian Association for Industrial Research), Dino Trescher (Constart), Doris Wolfslehner (Secretariat of the Austrian Bioethics Commission), Elvio Mantovani (AIRI - Italian Association for Industrial Research),Gregor Strle (ZRC SAZU), Julius Griessler (Secretariat of the Austrian Bioethics Commission), Lise Bitsch (the Danish Board of Technology Foundation), Nina Bryndum (the Danish Board of Technology Foundation), Rok Benčin (ZRC SAZU), Rosella Cardone (Ericsson),

Date of submission/publication

Deliverable D5.1

Contact details for corresponding author:
Rasmus Øjvind Nielsen, the Danish Board of Technology
rn@tekno.dk

This deliverable and the work described in it is part of the project *Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation - SATORI* - which received funding from the European Commission's Seventh Framework Programme *(FP7/2007-2013)* under grant agreement n° 612231

SATORI

Contents

ABSTRACT

This report explores how best to conceptualise and implement cost-effectiveness and risk-benefit evaluation of ethics assessment and ethics guidance in relation to European research and innovation (R&I). The report gives an overview over existing data about the effectiveness of ethics assessment and other organizational mechanisms for supporting a culture of ethics in R&I organizations. The report finally assesses current best practice in evaluating the cost-effectiveness of ethics assessment. The report builds on interviews, literature review, and case studies in addition to expert input reported in SATORI D5.3. The report lays the ground for D5.2. The underlying ambition of the three reports is to develop a framework for cost-effectiveness evaluation and risk-benefit analysis of ethic assessment practices and to allow for the enhancement of cost-effectiveness and the management of risks without compromising the quality of ethics assessment and guidance. Because of the inherent conflict between the ethical values and economic value, the report pays special attention to the limits of the approaches considered. From its findings, the report draws out the implications that: a) the costs, risks, effects and benefits of ethics assessment and ethics guidance should be evaluated in the context of broader ethics programs; b) since European R&I spans across many different organisation types, an evaluation framework should take into account that these organisation well bear different costs and risks while enjoying different benefits from ethics interventions; and c) that systematic evaluation of different forms of ethics interventions and their impact on behaviour could be part of the framework in D5.2, but that such evaluation would only provide data about a limited subset of the issues.

EXECUTIVE SUMMARY

This report explores how best to conceptualise and implement cost-effectiveness and risk-benefit evaluation of ethics assessment and ethics guidance in relation to European research and innovation (R&I). The report also explores existing data about the effectiveness of such ethics interventions and current evaluation practices.

The report is part of the SATORI project, which aims to construct a common European framework for ethics assessment of R&I. The aim of the project is that this framework shall be applicable across the many different disciplines that make up European R&I and be relevant for the many different types of organisation involved in the R&I sector.

The ambition of this report is to provide a stepping stone towards the development of a framework for cost-effectiveness evaluation and risk-benefit analysis of such ethic interventions that allows for the enhancement of cost-effectiveness and the management of risks without compromising the quality of ethics assessment and guidance. This framework will be presented SATORI D5.2.

To evaluate costs-effectiveness and analyse risk-benefit relations of ethics assessment and other forms of organizational mechanisms that are implemented to support ethical behaviour and ethical outcomes of R&I – such as ethics guidance, ethics training, etc. – involves the gathering of many different parts of the research and innovation value chain under a common calculus. Implementing cost-effectiveness and risk-benefit analysis approaches in such a broad context risks stretching the usefulness of these evaluation approaches beyond their

limits. This risk is enhanced by the inherent conflict between ethical values and economic value. The report therefore pays special attention to the limits of applicability of the different approaches to cost-effectiveness and risk-benefit analysis in this specific area.

The exploration in this report is based on the understanding that the costs, risks, effects and benefits of ethics interventions may be conceptualised in various ways. The report therefore takes the form of a 'narrowing down' of possible approaches towards a more limited range of approaches, which would provide relevant information to decision-makers considering the implementation of ethics assessment and guidance.

The report is furthermore based on an explorative research process consisting of a literature review, expert and stakeholder interviews, a handful of case studies, and an interdisciplinary expert workshop. The latter provided recommendations, which are reported in SATORI D5.3. Included in these recommendations are 'red flags' about the limits of applicability of cost-effectiveness and risk-benefit analysis to practice of ethics assessment. These 'red lines' are respected throughout this report.

The 'red flags', which this report inherits from D5.3 are:

- *It is impossible in principle to make exact comparisons of the cost-effectiveness of different purely conceptual approaches to ethical assessment, since the costs, risks, effects, and benefits of ethics assessment are only determinable in concrete cases where such concepts have been implemented. This is due to the empirically observed differences that exist between ethics assessment practices in different organization in terms of goals, mandates, and impacts; even where basic assessment concepts are largely similar.*

- *Even superficially identical assessment approaches may have very different effectiveness parameters, which depend not only on the assessment practice itself, but also on the effectiveness follow-up mechanisms such as risk management and value-chain management, and thus cannot be reliably compared in terms of monetary or otherwise quantified costs*

- *Adopting a cost-effectiveness perspective on ethics assessment should not lead to a narrow focus on operational costs, nor should it allow itself to be bogged down by the willingness-to-accept of those R&I actors who are subjected (or subject themselves) to ethics assessment. While it is important to also include considerations of the effects – positive and negative – of the assessment on research and innovation activities, it is equally important to take into account the effects of the research and innovation on society more broadly. The cost-effectiveness perspective thus should not be divorced from a broader risk-benefit perspective.*

Staying within these red lines demands that the recommendations of this work package with regard to the evaluation of the cost-effectiveness and risk-benefit relations of ethics assessment of R&I should stay clear of the pitfall of monetizing that which can be monetized and leave that which cannot be the side. Drucker's often cited warning that 'what gets measured gets managed' is particularly relevant in this context. Ethics assessment aims to avoid human rights violations, which is of absolute value, stakeholder backlash, and long-

term negative impacts to society. The costs of the things prevented are either difficult to measure or immeasurable, while the costs of ethics assessment are directly observable as the running costs of assessment units. The red lines set out by the participants in the workshop reported in D5.3 boil down to the clear demand that this work package should stay clear of a focus on how managers can tweak running costs and instead focus on the fundamental, but unquantifiable 'economic' relations (in the broad sense) that exist between the running costs of ethics assessment units and their practices, the commitments of European institutions to the protection of human rights, the impacts on R&I organizations of stakeholder backlash to unacceptable practices and outcomes, and the long-term impacts of R&I on society and nature. Ultimately, this report argues, because the cost of ethics assessment is dwarfed by the risks it aims to prevent, evaluations of ethics assessment practices should focus on means of achieving higher quality in the assessment rather than how they can best achieve the goals of ethics assessment.

Respecting these red lines, the conclusions of the report are:

Conceptualising cost-effectiveness of ethics assessment

- The cost of ethics assessment and the risk of missed opportunities that entail should be weighed against the medium-term risk of ethical breaches (violating absolute values) and stakeholder backlash from such breaches (causing economic losses) as well as the long-term benefits from ethically appropriate research and innovation (which is, however, undocumented)
- With regard to the management of medium-term risks, ethics interventions such as ethics assessment and guidance are best understood as **elements of ethics programs** that also include leadership commitment, ethics training, ethics hotlines, and other similar organisational interventions.
- The operational costs of ethics assessment and ethics guidance can meaningfully be categorized together as '**proactive prevention cost**s' integral to good risk management and should be weighed against 'reactive non-compliance costs' and the risks they represent to the R&I individual organization.
- Ethics programs should thus be seen as **an element of risk and quality management**.

Risks and benefits connected with ethics assessment

- Ethics assessment is generally held to **lower the risk of undesirable social consequences** from R&I, to **lower the risk of ethical breaches**, to **lower the risk of backlash from stakeholder perceptions**, but also to entail a risk of **missed opportunities.**

Documented effectiveness of ethics assessment and other ethics interventions

- Ethics assessment, perhaps unsurprisingly, stands out against a background of other types of assessment as being the **best able to identify ethical problems**.
- On their own, individual interventions such as ethics assessment or guidance may at best be **moderately effective** in preventing ethical lapses in organizations
- When implemented as part of organisation-wide ethics programs, even interventions that have no measurable effect on their own contribute to the **cumulative**

effectiveness of the program as a whole towards creating a 'culture of ethics' with a **high significance for the prevention of ethical lapses**.

- External regulation seems to have **very limited effects** on organisational culture.
- Our exploration indicates that the relationship between the short-term costs and the risks of missed opportunities associated with ethics assessment of R&I and the long-term effects of ethics assessment on the societal value and impact of R&I remains unexplored.

Current practices of cost-effectiveness and risk-benefit evaluation of ethics assessment

- **Monetized or otherwise quantified evaluation of cost-effectiveness and risk-benefit of ethics assessment is not done.**
- Most types of organizations that implement ethics assessment see the practice as intrinsically valuable.
- Industrial/business organizations seem in addition to value ethical assessment as a valuable addition to risk management.
- The scientific literature indicates that **the cost of gathering data for quantified analysis of ethics assessment would in itself be highly cost-inefficient**
- The scientific literature also indicates that **the costs associated with stakeholder backlash on unethical practices, unacceptable outcomes, or unintended impacts of R&I is disproportionately large in comparison with the costs of ethics assessment,** which makes ethics assessment
- Rather than focusing on the cost-effectiveness of ethics assessment and other types of ethics interventions, current practice is to focus on raising the quality of ethics assessment while staying within acceptable costs levels (with no strong link having been established between the two).
- Our exploration indicates that industrial organisations seem to be **leading the development of organisation-wide program approaches to ethics interventions** aiming to maximize the effectiveness of individual interventions (e.g. ethics assessment).
- Monitoring of ethics intervention effectiveness is almost only found in the field of ethics training, and even here it **is not done systematically.**

Some of the implications for the subsequent work on a framework for cost-effectiveness evaluation and risk-benefit analysis of ethics assessment and guidance are:

- The costs, risks, effects and benefits of ethics assessment and ethics guidance should be evaluated as part of a program approach.
- European R&I value chains span across many different organisation types, which will bear different costs and risks while enjoying different benefits from ethics interventions. This should be taken into account in an evaluation framework.
- Systematic evaluation of ethics interventions could be part of the framework, but it should be acknowledged that such evaluation would only provide data about a limited subset of the issues. Also, it is not known to which degree ethical breaches serve as good proxy indicators for medium-term risks such as stakeholder backlash to unacceptable practices and outcomes or long-term risks such as negative impacts on society and nature. The value of systematic evaluation should thus not be overstated.

1 INTRODUCTION

This report presents the findings of a study of conceptual and practical issues in the evaluation of cost-effectiveness and risk-benefit relations of ethics assessment; specifically ethics assessment of research and innovation (R&I). The operational aim of the report is to supply the necessary building blocks for developing a methodology for evaluating cost-effectiveness and risk-benefit relations in ethics assessment. This methodology will be presented in a subsequent report (SATORI T5.2).

In this report, the central issue to be examined is how existing tools for cost-effectiveness and risk-benefit evaluation can meaningfully be applied to ethics assessment of R&I in ways that do not lead to lowering the quality of ethics assessment in European organisations involved in R&I.

The basic approach taken in the report is to view ethics assessment as one organisational element among others that aim to ensure ethical behaviour and outcomes from R&I through ethics programs (endogenous ethics activities) and ethics regulation (exogenous ethics activities). The costs and risks, effects and benefits and the effectiveness of different approaches to ethics assessment will thus be viewed in a wider context that also includes ethics guidance, ethics training, and other ethics-oriented organisational activities as well as policies that seek to install ethical behaviour in organisations from the outside.

Taking this approach avoids the risk of not seeing the forest for the trees. Seeing different methods of ethics assessment as only one of a subset of ethics activities makes it possible to see the question of their cost-effectiveness and risk-benefit relations as only one aspect of a more general question of how to evaluate those issues in relation to ethics interventions on the whole. By taking this approach we hope to avoid getting caught up in debates over the merits of one specific ethics assessment approach over another and to focus on the more salient question of how best to achieve the outcomes that ethics assessment aims to contribute towards.

1.1 CONTEXT

The overarching goal of the SATORI project is to develop a common European framework of basic principles and joint practical approaches to ethical assessment of research and innovation. The ambition is to create a framework that will be useful to a range of different actors involved in the shaping and performance of research and innovation.

Work package 4 of the SATORI project will develop a detailed outline of a common European ethics assessment framework. The ambition of the project is that this framework should be applicable at multiple levels of R&I governance in the European Union, across the European Member States, in different areas of R&I, and in different types of organisations.

The framework outline developed in WP4 focuses both on ethics assessment and ethics guidance at these various levels, areas and types of organisations. The framework furthermore envelops attempts at influencing *behaviour* as well as *outcomes* of organized R&I.

The present report is the second report of work package 5 of the SATORI project. As a whole, this work package aims at developing a methodology for evaluating the cost-effectiveness and analysing the risk-benefit relations of ethics assessment, which will be useful for efforts later on in the project to achieve uptake and implementation of the SATORI framework developed in WP4. The considerations of the work package, of course, may also have its uses for institutional entrepreneurs or decision-makers interested in implementing other types of ethics interventions.

This report draws on lessons learned in SATORI T5.3, which consisted of an interdisciplinary expert workshop debating cost-effectiveness and risk-benefit analysis in relation to ethics assessment and ethics guidance, and it points forward to SATORI T5.2, which will propose a methodology for cost-effectiveness evaluation and risk-benefit analysis of ethics assessment and ethics guidance.

1.2 OBJECTIVES

The present report seeks to:

- Outline the **basic conceptual issues** that arise when attempting to understand the cost-effectiveness and risk-benefit ratios of ethics assessment and ethics guidance in terms of behaviour and outcomes of organized R&I.
- Provide an understanding of the **current best practice** of evaluating the costs, effects, risks and benefits of ethics assessment and ethics guidance in the broader context of organisational ethics interventions; both in terms of **conceptual approaches to evaluation** and **empirical comparisons** of costs, effects, risks and benefits that accrue from different ethics intervention; highlighting the adequacy of the evidence base, the challenges in collecting adequate evidence and ways of addressing those challenges.
- Put these considerations into relief by comparing ethics assessment to other forms of R&I assessment.

1.2.1 Deviation from SATORI's Description of Work (DOW) in terms of objectives

The objectives of the report have been reshaped by lessons learned along the way. Specifically, the workshop reported in SATORI D5.3 produced three 'red lines' that the experts and stakeholders present in the workshop warned the partners involved in the work package not to cross. (The red lines and their implications are listed on p. 4-5 above). The red lines set out by the participants in the workshop reported in D5.3 boil down to the clear demand that this work package should stay clear of a focus on how managers can tweak running costs and instead focus on how they can best achieve the goals of ethics assessment.

Compared to the objectives set out in SATORI's DOW, this learning-based reshaping of the objectives of this report can be listed as follows:

Objective as set out in the DOW	Objective as reshaped by learning
To examine the cost-effectiveness and risk-benefit of ethics assessment	To examine the basic conceptual issues that arise when attempting to understand the cost-effectiveness and risk-benefit of ethics assessment (among other ethics interventions)

To develop an evidence base demonstrating the cost-effectiveness and risk-benefit of ethics assessment, highlighting the adequacy of the evidence base, the challenges in collecting adequate evidence and ways of addressing those challenges.	Provide an understanding concepts and empirical findings from current best practice of evaluating the costs, risks, effects, and benefits of ethics assessment; highlighting the adequacy of the evidence base, the challenges in collecting adequate evidence and ways of addressing those challenges.
To carry out case studies, interviews and literatures studies in order to examine the cost-effectiveness and risk-benefit of ethics assessment.	To carry out case studies, interviews and literature studies in order to examine how the cost-effectiveness and risk-benefit of ethics assessment is currently conceptualized and what results such concepts have produced for researchers and practitioners in the field.
Compare ethical assessment to other science and technology assessment forms (drawing on results from the EST Frame project).	Unchanged.

1.3 METHODOLOGY

The study behind this report has gathered input to the conceptualization and empirical evaluation of the cost-effectiveness and risk-benefit relations in ethics assessment and ethics guidance though a range of interrelated activities. These activities were tied together in a interactive research design aimed at identifying keys issues through expert input and to flesh out these issues through studies of peer-reviewed literature. Please note that the report presents the results in a partially reversed order to enhance clarity. These activities and their interrelation are illustrated below:

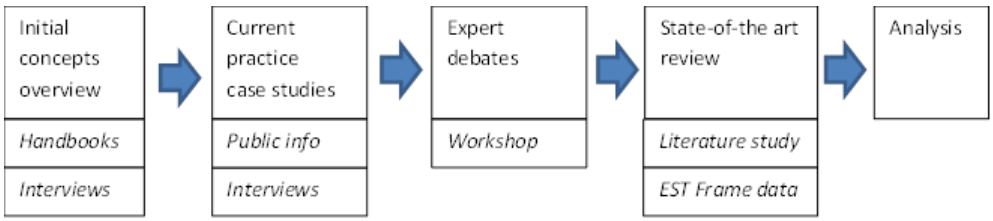

Table 1: Research approach followed in SATORI WP5

The five steps of the study were carried using the following methods:

1. **Initial concepts overview**
   The initial part of the study consulted leading handbooks of cost-effectiveness evaluation, risk-benefit analysis and program evaluation to outline the basic conceptual issues to be dealt with throughout the study. This issue identification was informed by five semi-structured expert interviews concerning the traditions of cost-effectiveness, risk-benefit analysis and the place of these traditions in the broader field of cost-benefit and risk assessment. Experts were specifically asked to think creatively about how best to address the cost-effectiveness and risk-benefit relations of 'soft' (non-technical; non-legal) interventions in organized R&I such as ethics assessment and ethics governance.

2. **Best practice case studies**
   To understand current practice in evaluating the cost-effectiveness of ethics assessment and ethics guidance as well as the risk-benefit relations involved, the study carried out case studies of these practices. The case studies comprised of six cases of intra-organisational (internal) practice in performing such evaluation specifically with regard to ethics assessment and guidance. The six case studies were selected so as to represent each of the six major organisational categories investigated by SATORI, i.e. research funding organisations, national science academies, research performing organisations, CSOs and industrial producers. As part of these case studies, eight semi-structured interviews were performed. These content of these interviews have been anonymized on the request of participants.

3. **Expert debates**
   To gather proposals for a methodology of cost-effectiveness evaluation and risk-benefit analysis of ethics assessment and ethics guidance, the study facilitated a two-day expert workshop held in Copenhagen, May 2016. The results of this workshop were reported in SATORI T5.3. More importantly, the results of this workshop markedly reshaped the objectives of this report as outlined in section 1.2.1 above. Recommendations from the workshop are listed with direct relevance for the overall conceptualization and practice to the present report are listed in section 2.4.

4. **State-of-the-art review**
   To explicate, structure and validate the inputs gathered in steps 1-3, the study performed a structured keyword-search of peer-reviewed literature on the costs, effects, risks and benefits that accrue to ethics assessment and ethics guidance in and outside R&I. The methodological details and results of this study are presented in section 3. Results from the EST Frame project were furthermore consulted for the comparative discussion in section 5.

5. **Analysis**
   The inputs gathered in steps 1-4 were gathered, categorised and structured for the purposes of this report.

1.3.1 Deviations from SATORI's Description of Work (DOW) in terms of methodology

1. **Repurposing of the workshop reported in D5.3**
   For SATORI work package 5 as whole, the most important change to the methodology is the central, co-creative role assigned to the expert and stakeholder workshop reported in D5.3. The original purpose of this workshop, as stated in the DOW, was to test a methodology for assessing cost-effectiveness and risk-benefit of ethics assessment; a methodology which would have been reported beforehand in D5.2. The workshop was repurposed. Instead of serving as a down-stream testing site, the event became instead a literal *work-shop* in which external experts and stakeholders worked with SATORI partners to set out the basics of a viable approach to cost-effectiveness and risk-benefit. The contributions of the workshop served both to demarcate 'red lines' that SATORI should avoid crossing, and to point the way to basic mechanisms

linking the running costs of ethics assessment, the values that ethics is there to protect, the risks that 'bad' organizations run in the medium-term, and the risks that irresponsible R&I imposes on the rest of society in the long-term. To be sure, the reverse themes of the positive contributions of ethics assessment and R&I were equally prevalent (see D5.3). This repurposing of the workshop was done for two reasons. Firstly, it was done because of a general scepticism on the part of the work package leader with regard to the linear approach to the development of the methodology, which was outlined in the DOW. Such a methodology ought to be useful to managers and other decision-makers in the field, and experiences from user-driven design show that usefulness and upstream involvement of users go hand in hand. Secondly, the interviewees of the first round of explorations warned unanimously against a simplistic approach to the quantification, measurement and evaluation of the cost-effectiveness and risk-benefit of ethics assessment. This made it even more urgent for the partners of the work package to engage with experienced experts and stakeholder in order to identify possible, more realistic approaches.

2. **Only four of six case studies are fully reported**

The work that went into this report contained six case studies, but of these six studies only four are fully reported. This is because for different reasons the remaining two failed to provide the in-depth practice descriptions that would have made them comparable to the rest. The first of the two was a case study dedicated to exploring current practices among CSOs of conceptualizing and evaluating the cost-effectiveness and risk-benefit of ethics assessment. Given the conclusions drawn in Annex 6 to SATORI D4.1[1], namely that CSOs are only rarely involved in ethics assessment performed by other organization and do not seem to perform ethics assessment on their own, the aim of this case study was always going to be difficult to reach. Having contacted five different CSOs, which were deemed to have the potential to have an internal ethics assessment practice, and having received upfront responses from representatives of those CSOs that a) no, these organizations did not in fact have a specific ethics assessment practice and 2) they had no position whether official or informal on how to conceptualize or evaluate the cost-effectiveness and/or risk-benefit of ethics assessment, further pursuit of the case study was halted in order to spend time one other issues. Nevertheless, this negative result is also a finding, which supports the overall conclusion of the case study comparison (see section 4). The second of the two cases studies was dedicated to current practices in a university. Here, however, the researcher carrying out the case study ran into the practical problem that the main interviewee, which had unique insight into the case and was therefore not replaceable, stopped responding so far into the case study process, that it was implausible to pursue a new case. Also here, however, indications early on indicated that the university in question – despite being highly esteemed for its ethics assessment practices – had no specific method for conceptualizing or evaluating the cost-effectiveness or risk-benefit of ethics assessment of R&I. With this negative finding supporting the overall conclusions of the case study comparison, the second case study was also abandoned, but the negative findings integrated as support for the overall conclusions of section 4.

[1] Warso, Z and Petrovic, D: *Models for ethics assessment and guidance at CSOs*, SATORI Deliverable 4.1, Annex 6, SATORI, https://satoriproject.eu/media/D4.1_Annex_6_Civil_Society_Organisations.pdf

1.4 STRUCTURE OF THE REPORT

To report is structured as follows.

Section 1 places this report in the context of the SATORI project, which aims to provide a common European framework to ethics assessment.

Section 2 gives a brief overview of basic conceptual issues in the relationship between ethics, cost-effectiveness and risk-benefit approaches and recounts expert recommendations about how to approach these issues.

Section 3 presents the results of a literature study of peer-reviewed research on the costs-effectiveness and risk-benefit relations of organisational ethics programs and ethics regulation.

Section 4 examines and compares four cases of how organisations evaluate the cost-effectiveness of risk-benefit relations of ethics assessment in practice.

Section 5 examines, based on the analyses of the EST Frame project, the ability of ethics assessment to provide early detection of societally problematic impacts of future and emerging technologies in comparison to other forms of R&I assessment.

In conclusion, **section 6** provides an overview of the findings of the report and draws out lessons to be implemented in a framework for evaluating the cost-effectiveness and risk-benefit relations of ethics assessment in an organisational context.

2 CONCEPTUALIZING COST-EFFECTIVENESS AND RISK-BENEFIT OF ETHICS INTERVENTIONS

In this section we seek to narrow down the overall conceptual and practical issues that a methodology for cost-effectiveness evaluation and risk-benefit analysis of ethics assessment and ethics guidance must be able to address.

Cost-effectiveness evaluation and risk-benefit analysis are analytical tools used in program and policy evaluation to inform decision-makers involved in the development of organisations and regulations. From an evaluation point of view ethics assessment and ethics guidance compete among a wide range of possible activities (constructive technology analysis, foresight, user oriented design, public participation, etc.) that may be implemented with the aim of influencing organisational behaviour and outcome in relation to the stakeholders and society in general. Cost-effectiveness evaluation and risk-benefit analysis of ethics assessment and ethics guidance aims to provide organisational and regulatory decision-makers with the evidence base necessary to assess the comparative value of implementing ethics assessment and guidance.

2.1 ETHICS INTERVENTIONS IN AN ORGANISATIONAL CONTEXT

When we talk about ethics assessment and the cost, effects, risks and benefits that accrue to it, what does this mean in an organisational context, and where do the recommendations made by SATORI as regards organisational and regulatory change fit in the picture?

Our first assumption about ethics interventions is that they are first and foremost practical. The literature on ethics assessment and guidance sometimes divides ethical approaches according to the underlying ethical theories (utilitarianism, deontology, consequentialism, virtue ethics, pragmatism, etc.)[2] However, when an organisation or regulator considers whether or not to implement ethics interventions and what kinds of alternative interventions to implement the crux of the decision-making problem is how these principles are translated into organized activities and the effects that these activities have. It is therefore realistic to assume that a given organization will mix and match ethics interventions that derive from different theoretical standpoints with little regard to the underlying theoretical commitments.

Our second assumption is that R&I *qua* organised activity functions much the same as other forms of organized activity and that R&I can learn from organisations in other fields. While the themes, methods and outputs of R&I may be unique compared to other areas of social production, the everyday of R&I is to a certain extent organized just as any other form of routinized production. We therefore see ethics interventions in R&I as a subset of ethics interventions in general. This generalized approach allows for inspiration from other forms of organisation and regulation.

[2] For example, Robertson C, Geiger S. Moral philosophy and managerial perceptions of ethics codes: Evidence from Peru and the United States. Cross Cultural Management: An International Journal. 2011 Aug 2;18(3):351-65.

The SATORI project has (in SATORI T4.2) provided a number of recommendations for organisational or regulatory ethics interventions in specific types of organisations involved in R&I. To respond in an appropriate manner to the challenge of evaluating the cost-effectiveness and analysing the risk-benefit relations pertaining to ethics assessment and assessment guidance, we need as a minimum to be able to outline principles and procedures for such evaluation with relation to these intervention suggestions.

The core of the SATORI framework is a set of interlinked procedures for *threshold analysis* of the necessity of ethics assessment in relation to concrete R&I-related activities and projects, for *ethical impact anticipation and determination*, for *ethical impact evaluation*, for the design and implementation of *remedial actions* and follow-up procedures for ongoing *ethics review and audit*.

The recommendations made by with regard to establishing a common European framework for ethics assessment range from the large to the small and from the general to the concrete. Some recommendations pertain specifically to the implementation of the SATORI framework, while others are more general recommendations for organisational or regulatory change to support ethics in R&I in general.

Reporting on the work described above, the SATORI consortium made the following specific recommendations for organisational or regulatory interventions (see also SATORI D4.2):

- **Implementation of the SATORI framework** through:
  - New **regulation** to govern the standards of ethical assessment of R&I
  - New **demands** for ethics assessment from research funding bodies to research performing organisations (RFOs),
  - New ethics assessment **procedures** to be established within research performing organisations (RPOs).
- **Development of in-house ethics assessment capacity** beyond legal compliance in RFOs
- Implementation of **codes of conducts** in universities
- **Representation of vulnerable groups** in research ethical councils (RECs) through the participation of civil-society organisations (CSOs) in their assessment activities
- **Organisation-wide implementation of ethics assessment** in industrial firms
- **Establishment of best-practice networks and forums** for ethics assessment in university associations, national science academies, as well as other academic and professional
- **Broadening the assessment mandates and guidance activities** of national ethics committees to include all forms of R&I
- **Establish national ethics committees** in Member States where they do not exist

The breadth of these recommendations show that implementing ethics assessment and achieving the ends, which such assessments seeks to achieve, is about much more than simply choosing the ‘best’ or ‘most cost-effective’ *single method* for ethics assessment. Ethics assessment is part of a field of ethics interventions and ethics-oriented practices and is performed by a multiplicity of organisations with different roles in the framing, funding, performance and evaluation of R&I.

This indicates that a methodology for the cost-effectiveness and risk-benefit analysis of ethics assessment, ethics guidance and other ethics interventions must be able to take into account this complex context.

In the following, we attempt to reframe this challenge in terms that relate directly to the basic concepts of and institutionalized systems for cost-effectiveness evaluation and risk-benefit analysis of organisational and policy interventions.

2.2 RELEVANT APPROACHES TO COST-EFFECTIVENESS AND RISK-BENEFIT ANALYSIS

Cost-benefit analysis is historically linked to the emergence of welfare state programs and the need to base decision-making about such programs on rational considerations of social benefits[3]. The basic aim of a cost-benefit evaluation is to enable decision-makers to decide between different equally appealing programs for investment or regulation based on a calculus of overall utility for the body social. This rational ideal has, of course, been subject to much criticism, and a number of methodological variants have emerged as a result. Among these disciplinary descendants this report focuses on cost-effectiveness evaluation and risk-benefit analysis for reasons to be outlined below.

The relevance of cost-effectiveness evaluation of ethics interventions in R&I

Cost-effectiveness analysis is a variant of cost-benefit analysis that specifically addresses situations where a decision has already been made about pursuing a specific outcome and where only the operational question remains about how to achieve this aim at the lowest possible cost[4]. We assume – and will justify this assumption in sections 3 and 4 – that ethics interventions such as ethics assessment are often implemented on the unexamined belief that such interventions will produce more ethical behaviour and outcomes. Lacking a clear operational argument for why one alternative produces is more likely to achieve such outcomes than another, this belief risks inviting pressure to adopt the least costly intervention option. In this context, cost-effectiveness evaluation draws attention to the potential for quality loss as a consequence of cost-cutting at the same time as it allows for the revelation of bloated, ineffective intervention programs. On this basis, cost-effectiveness evaluation would seem to be a more direct way of getting at one set of immediately useful results than would a broader cost-benefit analysis where the aims to be pursued are more open. We will, however, return to the question of the benefits of ethics assessment in comparison with other assessment forms in section 5.

When it comes to non-technical interventions such as ethics assessment and ethics guidance, there are challenges with regard to the application of cost-effectiveness evaluation techniques. To calculate cost-to-effectiveness ratios for different intervention options, two kinds of data must be available: reliable cost figures and comparable effectiveness measures.

[3] McDavid, James C., Irene Huse and Laura R. L. Hawthorn. *Program Evaluation and Performance Measurement. An introduction to practice*, SAGE Publications. London, 2011.
[4] Leven, H. M., McEwan P. J., *Cost-Effectiveness Analysis: Methods and Applications*. Sage Publications Inc., Thousand Oaks, London, New Delhi, 2001

Of these two, cost figures are the easiest to come by, at least as long as 'costs' are limited to operational costs related directly to the ethics intervention in question. However, there are also less easily quantifiable costs. For example, one concern that was often mentioned by the stakeholders engaged in preparation of this report is that ethics interventions in R&I, may also have longer-term costs, such as the prevention of promising research projects from being carried out. How to assess such losses is not immediately obvious. Such losses, of course, are most often assumed to be outweighed by the gains (or prevented losses) from hindering social or environmental damages from occurring as a consequence of the application of R&I outcomes. Estimating the balance between lost gains and prevented damages, which may be an indirect consequence of ethics interventions, goes beyond the scope of cost-effectiveness assessment of the ethics intervention in itself. Such longer-term consideration would instead fall under the rubric of impact assessment, which SATORI takes up in WP6. Readers are referred to forthcoming deliverables from that work package.

Effectiveness is even more difficult to measure. This difficulty stems from the diversity of goals that are to be achieved by ethics interventions. For example, the most immediate goal of ethics assessment is often defined as the identification of ethical issues in relation to specific future or on-going activities. But given the uncertainties and cultural differences involved in such assessment, it is not immediately obvious how one would measure the success rate (effectiveness) of any given approach to ethics assessment. Furthermore, and continuing with the example of ethics assessment, the underlying assumption is often that the rational identification of ethical problems and means of addressing them will lead to changes in the activity in question. But how are such changes to be gauged? In many central cases, such as research involving human subjects, ethical behaviour is a goal in itself. In such cases, it will be necessary to have observable criteria and means of observation put in place to gain data about the effectiveness of a given assessment intervention. But in other cases, such as research that may impact future generations, the link between behaviour now and consequences later is less obvious. For such cases, some research assumes that ethical behaviour during research serves as a proxy for ethical impacts downstream, while others indicate that long-term empirical studies are needed for the link between early warnings and long-term effects to be established[5]. These considerations show that there are many different possibilities for conceptualising the effects of ethics assessment and that many important potential effects are not easily quantifiable. These difficulties are important to bear in mind when considering the cost-effectiveness of ethics interventions; the effects that we can quantify are not necessarily good proxies for the effects that we intent.

Even if we limit ourselves to measuring the effectiveness of ethics interventions in identifying ethically problematic issues and in changing behaviour – making no assumptions about the secondary consequences of such changes – quality in ethical assessment as well as changes in organized behaviour are not immediately observable. They demand operationalization and means of monitoring, which in themselves may be costly. Considering the relevance of cost-effectiveness evaluation in relation to ethics assessment must therefore take into account the relationship between the costs going to the ethics intervention and the costs going to the downstream monitoring of impacts. We will address these concerns in some detail in section 2.3 below.

[5] For example: European Environment Agency. *Late lessons from early warnings: the precautionary principle 1896-2000*. Office for Official Publications of the European Communities, 2001.

Of course, an organisation may decide to learn from already established cost-effectiveness data when considering which type of ethics intervention (e.g. which approach to ethics assessment) to implement. The plausibility of such an approach given the existing literature on the subject is one of the questions that the literature review in section 3 will seek to address.

The relevance of risk-benefit analysis in relation to ethics interventions in R&I

In a complex organisational setting such as European R&I, the risks of incurring costs or other types of loss will not necessarily be borne by the same actors that reap the benefits of the intervention. For such a setting, risk-benefit analysis holds the promise of giving an overall measure of the benefits to be reaped by the sector as a whole. While a risk-benefit perspective would therefore seem to be obviously useful in such a setting, it is equally important to be aware of limitations to the approach as described in the following.

Risk-benefit analysis is a variant of the cost-benefit analysis which "consists of evaluating a proposed action in terms of monetary values assigned to each of the various risks and benefits associated to the action" [6]. To be more specific, each monetary assignment is made by calculating the "compensation variation" (CV) associated with a particular risk or benefit. The CVs is the amount of money whose loss or gain, respectively, would perfectly compensate a person for the benefits or risks associated with the hazardous activity (ibid.). The maths of this concept is that if the CVs of the gainers (those who benefits from an action) are added to those of the losers, and if the resulting sum is positive, then the benefits outweigh the costs and risks, and the economic action (e.g. building a new airport or doing medical research) is usually judged as acceptable. If the resulting sum is negative, the proposed action is usually judged questionable.

A number of difficulties in applying risk-benefit arise from a number of assumptions that form the basis of risk-benefit analysis (ibid.).

Firstly, risk-benefit analysis is formed around the idea that gains and losses can be expressed numerically, on the basis of market prices. However, in relation to ethical interventions it should be obvious that even as, for instance, ethical treatment of human research subjects may benefit an organisation in terms of bettering its reputation – a benefit that might be expressed in terms of the market value of marketing activities – the inherent 'value' in the moral sense of the word of ethical behaviour is precisely inexpressible in market terms; hence the notion of intrinsic value.

Secondly, risk-benefit analysis assumes that the distributive effects can be ignored, provided that overall benefits exceed risks/costs. However, in lieu of a political decision to make certain ethics interventions mandatory, winning the argument for a implementing a certain type of ethics intervention in a setting such as European R&I demands that those organisations or individuals that bear the costs and risks should be equally convinced by the argument as those that reap the benefits.

[6] Naagarazan, R. S,. *Textbook on Professional Ethics and Human values.* New Age International (P) Ltd, 2006.[p. 103].

Thirdly, the risk-benefit analysis discipline assumes that benefits and risks can be defined in terms of individual preferences. But when it comes to maintaining a certain level of ethical standards in a societal sector as a whole, the preferences of individual organisations or researchers may precisely go against the overall interests of the sector as a whole. In relation to ethics interventions in the way that R&I works there may thus be cases where immeasurable 'value' would outweigh measurable risks and costs. For example, recent European data regulation imposes both measurable direct costs of data security management and risks of secondary costs in the form of lost opportunities on European researchers and research performing organisations in the name of enhanced privacy, which, as a human right, is good in-itself with only its secondary effects being quantifiable. Even a negative risk-benefit analysis of the total monetary effects on the European economy would therefore not have provided a compelling counterargument against the legislation.

Even taking these difficulties into account, risk-benefit analysis – even if it could not be applied in an off-the-shelf manner to ethical interventions in R&I – could nevertheless provide an important heuristic in terms of identifying precisely those areas where the measurable and immeasurable clash and call for reflective rather than monetary judgment. Invoking the special privileges of ethics in a blanket fashion with regard to all costs and risk incurred by those who seek to comply with ethical principles would risk souring the relationship of organized R&I with ethics as a field. Being honest and open about precisely where those areas of friction between different orders of value occur, would instead focus the debate and the decision-making process concerning ethics intervention implementation and could thus benefit the cause of ethical standard setting in European R&I in the long run.

2.3 Red Flags Raised by Experts

An interdisciplinary group of experts gathered to debate the use of cost-effectiveness and risk-benefit analysis in relation to ethics assessment and ethics guidance (see SATORI D5.3) raised the following red flags.

- *It is impossible to make direct comparisons of the cost-effectiveness of different forms of ethical assessment due their differences in terms of goals, mandates, and impacts.*

- *Even superficially identical assessment approaches may have very different effectiveness parameters and thus cannot be compared in terms of monetary costs*

- *Adopting a cost-effectiveness perspective on ethics assessment should not lead to a narrow focus on operational costs. It is important to also include considerations of the effects – positive and negative – of the assessment on research and innovation as well as effects of the research and innovation on society more broadly. The cost-effectiveness perspective thus should not be divorced from a broader risk-benefit perspective.*

These red flags corroborate the attention paid in the preceding section to the limitations that apply to the use of the two evaluation forms in relation to ethics interventions. These red flags serve as signposts for the search for an improved understanding of the costs, effects, risks, and benefits that pertain to ethics assessment and ethics guidance in the remaining part of this report.

3 LITERATURE STUDY: COSTS AND EFFECTS OF ETHICS PROGRAMS

The following section outlines what is known and what has been proposed in the peer-reviewed research literature regarding the conceptualisation of cost-effectiveness and risk-benefit analysis of ethics assessment and other ethics interventions in organised R&I.

The literature study is reported as follows:

- Literature search results
- Framework proposals
- Empirical comparisons of intervention alternatives

3.1 LITERATURE SEARCH RESULTS

The literature study was performed as a keyword search using two major search engines for peer-reviewed research literature (Web of Science and Google Scholar). The keyword search produced the following results.

	Web of science		Google Scholar		Total relevant
	Results	Relevant	Results	Additional	
Cost-effectiveness + ethics assessment	0	-	0	-	0
Cost + ethics assessment	0	-	0	-	0
Effectiveness + ethics assessment	1	0	2	0	0
Cost-effectiveness + ethical assessment	2	0	0	-	0
Cost of ethic*	3	(1*)		-	0
- … of ethics	-	-	8	0	0
- … of ethical	-	-	11	0	0
Effectiveness of ethic*	25	19			19
- … of ethics	-	-	22	7	7
- … of ethical	-	-	13	3	3
Risk-benefit + ethics assessment	1	0	0	-	0
Risk + ethics assessment	3	0	1	0	0
Benefits + ethics assessment	3	0	0	0	0
Risks incurred + ethic*	2	0	0	0	0
Negative impact of ethic*	2	1	0	0	1
Benefits of ethic*	12	3			3
- … of ethics	-	-	5	1 (2*)	1
- … of ethical	-	-	4	0	0
Total	54	23	66	11	34

'Relevant' results are defined as results that deal specifically with: the cost-effectiveness or risk-benefit ratios of ethics assessment, or ethics guidance, or more broadly with the costs involved in ethical assessment or guidance; the effectiveness of forms of ethics assessment or guidance; the risks that stem from ethical assessment or guidance; and the benefits that may be gained from ethical assessment or guidance.

'Irrelevant' results include results that deal with: the ethics of cost-effectiveness and risk-benefit analysis; the use of cost-effectiveness or risk-benefit analysis in ethics assessment; the use of cost-effectiveness or risk-benefit analysis in achieving ethical priority setting; discussion of the ethics of certain objects or interventions (medicines, treatments, technologies, policies, or others) based on cost-effectiveness or risk-benefit analysis of that object or intervention; ethics assessment of a particular cost-effectiveness or risk-benefit study; activities that take place at the cost of ethical standards; discussions that doubt, but do no examine, the effectiveness of ethics; discussion of the effectiveness of ethics as an explanatory framework; studies of the quality of ethics training *qua* training rather than its effectiveness *qua* ethics guidance; discussion of factors strengthening or hindering the effectiveness of ethics assessment bodies without examining such effectiveness; studies dedicated to ethical leader behavior, ethical consumption, ethical trading schemes; ethical relationships; studies that discuss, but do not examine, the benefits of ethical conduct in research.

The 34 relevant articles discovered by the keyword search are listed in section 7 of this report.

The following results (marked *) were **unavailable** via the resources available for the study:

- Lavoie, F., "High Cost of Ethics", *Machine Design*, 1974, Vol. 46, No. 21, 1974, p.109..
- Rosenson, B.A., "The Costs and Benefits of Ethics Laws", in Denis Saint-Martin and Fred Thompson, *Public Ethics and Governance: Standards and Practices in a Comparative Perspective*, Elsevier, 2006 [pp. 135-154].

3.2 Categorizing Literature Search Results

The 34 relevant articles cover a number of different perspectives on the cost-effectiveness and risk-benefit relations of ethics interventions in organisational and regulatory contexts. The table below gives an overview of the prevalence of different types of research contributions, different focuses as regards types of ethics interventions, different organisational areas, and geographical scope within the set of articles.

In the listed 'types of contribution' we use the term 'evaluation' to refer to any type of evaluation that falls within the scope of the keyword search, i.e. evaluations under any form of costs, effects, risks, and benefits that derive from ethics interventions, and we use the word 'program' to refer to a broad selection of ethics interventions viewed as a combined organisational effort. Under 'organisational context' we list all organisational focus areas as well as all other areas found within the set of articles (marked *). Note that prevalence is counted non-exclusively, i.e. the total share of articles under each header is more than 100% since some articles include more than one of the perspectives listed under each header.

	Number of articles	Share of articles (%)
Type of contribution		
Evaluation of single intervention type	17	50
Comparative evaluation of alternative interventions	8	24
Program evaluation framework	9	26
Intervention types		
Ethics assessment	4	12
Ethical guidance	15	44
Ethics training	18	53
Ethics legislation	4	12
Organisational context		
Research Ethics Committees	0	0
National Ethics Committees	0	0
Governmental Organisations	0	0
Research Performing Organisations	6	18
Research Funding Organisations	0	0
National Science Academies	0	0
Civil Society Organisations	0	0
Standards Organisations	0	0
Industry	9	26
*Public health organisations	9	26
*Public sector organisations	5	15
*Higher education organisations	2	6
*Sports organisations	2	6
*Military	1	3
Country		
EU Member State	12	35
Non-EU country	27	79

This categorization, along with scrutiny of the articles and keyword search statistics, reveals a number of things about the state-of-the-art of research into the costs, effects, risks, and benefits related to ethics interventions.

Firstly, already the keyword search statistics show that costs and effects are the dominant concerns of the set of articles, while the risks that accrue from ethics implementation – while they are discussed in the content of some of the articles – have not become a separate research area.

Secondly, ethics assessment is not a very prevalent intervention focus. Not only do only 12% of the articles deal with ethics assessment, only one (#15) of these four articles has ethics assessment as its main focus, namely ethics reviews of research involving human subjects. The other three articles that deal with ethics assessment do so as part of broader attempts at program evaluation.

Thirdly, the most prevalent intervention focuses are ethics training (53%) and ethics guidance (44%). While in the articles that adopt a wider program perspective these types of interventions occur alongside ethics assessment, the strong focus on training and guidance gives the impression that these are the types of interventions that interest researchers and organisations the most.

This third observation demands further explanation. Scrutiny of the articles further gives the impression that ethics guidance and ethics training are in most cases seen as part of a continuum. Ethics training is typically training *in* the codes of conduct, standards of ethical practice, and similar guidance products with the purpose of *ensuring implementation* throughout an organisation. So in reality the sum total of the articles dealing with these topics indicate that 97% of the articles deal in one form or the other with aspects of *implementation* of ethics rather with only 12% dealing with its assessment. From an organisational point of view, the reasons for this may be found in the relative costs of each. While ethics assessment activities typically involve only a group of assessors and their interactions with other members of an organisation or a network of organisations (e.g. RFOs and RPOs) and thus only runs up relatively minor costs (depending on the size of the support organisation) the implementation of ethics guidance in each part of an organisation involves not only training of staff, but also ongoing interventions and report on the part of middle management. While in a small research project the two costs may be comparable, the difference in costs for a large may be on a scale of 1:1000 or more. Consequently, it makes sense for researchers to focus their efforts on the costs and effects of different forms of guidance and training interventions.

Fourthly, none of the specialised ethics institutions considered in the SATORI project (RECs, NECs, etc.) serve as focus areas for any of the articles. Instead industry in general (not specifically R&I-performing companies) shares first place with public health organisations. Research performing organisations is the third most prevalent organisation type (18%) followed closely by public sector organisations (15%).

Finally, just as ethics assessment is not a very prevalent intervention focus, neither is ethics regulation. In fact the two share a last spot in terms of prevalence (12%). This can be explained again by a pressing interest in the costs and value that derive from ethics implementation in organisations with only minor interest being paid to supportive functions such as assessment (internal ethics support) and regulation (external ethics support).

Overall this means that while very little evidence and conceptualization work exists, which takes into account ethics assessment, and while the question of risks that may derive from ethics assessment and guidance is only treated as a subordinate topic, research into the costs and effects of broader ethics interventions aimed at organisational implementation has produced relatively mature evidence on the costs and effects of different interventions types as well as ethics programs overall do exist. These conceptual contributions and this evidence are presented in the following.

3.3 FRAMEWORKS FOR EVALUATING COSTS AND EFFECTS OF ETHICS I+NTERVENTIONS

Some of the most recent articles discovered in the keyword search are also those that take the most comprehensive views of ethics interventions in an organisational and regulatory context. A fourth (9) of the articles thus seek in one way or the other to provide a framework for evaluating the costs and effects of ethics interventions.

In the following we focus mainly on the three articles that seek to conceptualise costs and effects of ethics intervention and which take into account both ethics assessment and ethics guidance, specifically articles #3, 20 and 33. Our presentation of their arguments is supplemented by points from articles that seek to conceptualise the role of ethics regulation as a supplement to intra-organisational ethics programs.

Conceptualizing overall cost categories

Article #33 from 2005 provides a number of definitions and distinctions useful for considering the costs and effects of ethics interventions. The article sums up much of the research produced at the time and thus provides a mature starting point for current discussions of the subject.

The major aim of the article is to provide a framework for scrutiny of costs and effects derived from ethics interventions in support of organisational decision-makers involved in designing intra-organisational ethics programs. The article's authors recommend the basic approach that ethics programs should be embedded in the organisation's management control systems to achieve integration of ethical considerations with other organisational goals.

To conceptualise costs, the article adopts a cost-of-quality approach, which divides costs into the two major categories of *proactive compliance costs*, which accrue to organizations that implement ethics interventions and thereby avoid ethical breaches (assuming this is the case), and *reactive non-compliance costs*, which may accrue to organizations that make no such interventions and thus experience ethical breaches.

Proactive compliance costs are in turn divided into prevention activities and appraisal activities. The article cites staff training in the application of codes of conducts and ethical standards as a major example of preventive costs. Ethical assessment is in turn cited as a major example of an appraisal cost aimed at detecting actual or possible ethical lapses.

Reactive non-compliance costs are in turn divided into internal costs, such as reduced productivity due to low moral and ethical conflict, and external costs, such as loss of reputation among organisational stakeholders and customers and the costs of lawsuits. The latter example show that the taxonomy of costs provided by the article in the end comes into close contact with regulation.

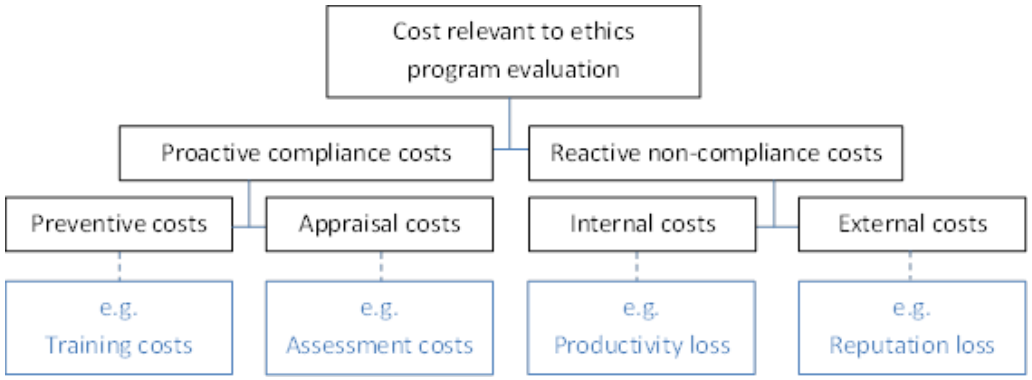

Table 2: Cost categories relevant to ethics interventions. Article 33 (full reference in section 7)

The article leaves the concrete measurement and calculation of costs-effect relationships up to the individual organisation, but the basic approach – the suggestion to view ethics interventions from a program perspective and the cost categories provided – provide a qualified starting point for discussion costs and effects of ethics interventions in an organisational context. Furthermore, the article makes one important note concerning the costs of ethics programs over time, namely that the costs of implementation will be greatest in the beginning but will eventually level out as ethical behaviour becomes part of the organisation's culture. This consideration is especially important to bear in mind in inter-organisational network contexts, such as that of European R&I; the implication being that stability of ethics programs is crucial for achieving cost-effectiveness and that the cycle of ongoing reforms that characterize institutional environments would tend to work against cost-effectiveness of such programs.

In any case the cost framework provided by article #33 covers a different scope than the methodology to be developed in SATORI 5.2. Cost categories overlap to some degree with risk categories, but must be further elaborated. At the same time, the effect categories implied by the framework (compliance) - which by the way overlap to some degree with categories of benefit – must also be further specified. This necessary expansion of the framework from article #33 is taken up again in the conclusions to this section of the report.

Perceived effectiveness of ethics interventions

Article #20 from 2011 begins to establish an empirical basis for discussions of the effects of ethics programs in the context of good governance in public organisations in Europe. The article draws on existing research on ethics implementation as well as novel data on the opinions of government officials across the EU gathered through qualitative interviews in 26 Member States and the European Commission. The article thus provides a synthesis of experience-based judgments of practitioners with regard to the cost-effectiveness of various forms of ethics interventions.

The article posits ethics interventions as an element of human resource management, but at the same time describes a field of ethics interventions consisting of intra- and inter-organisational interventions. Ethics interventions are thus viewed as an element of public sector reform and as an issue that cuts across multiple organisations at once. The implication is that no one organisation can be expected to deliver fully ethical conduct if the surrounding

environment does not support such behaviour through explicit legislation, general incentive structures, and culture.

When asked to rate the effectiveness of different types of interventions in sustaining ethical behaviour, the article's respondents produced the following prioritised list.

1. Leadership
2. Openness, transparency
3. Laws and regulations
4. Training, incl. dilemma training
5. Codes
6. Protection of whistle-blowers
7. Registration of financial interests
8. Integrity officers providing counselling
9. Strict gift policies
10. Post-employment rules.

Interestingly, this list does not include ethics assessment at all, but from their interviews the authors do conclude that while the respondents in general view ethics assessment (including ethics climate surveys and ethics self-assessments) as ineffective with regard to directly effecting behaviour, they do see such interventions as having positive side-effects. Also of interest is the observation that training and guidance (codes) rank lower than leadership, organisational transparency and hard/soft regulation in terms of effecting behaviour.

While they are informative, the value of the data provided by article #20 should not be overstated since the qualitative surveying is not triangulated by other means of observation. While the study thus provides relatively reliable evidence of the *perceptions* of professionals regarding the effectiveness of ethics interventions, these perceptions may as much express cultural biases as factual relations between interventions and effects.

The authors of the article confirm this weakness as they conclude that as per 2011 not enough evidence – especially long-term longitudinal studies of the impacts of ethics programs – was available to draw sharp conclusions regarding the relative effectiveness of each of the listed intervention types. However, they did recommend continuation of work on conceptualizing and measuring the effectiveness of ethics interventions, since such evidence proves to be needed in relation to decision-making process concerning ethics implementation in EU and Member State institutions.

Empirical effectiveness of internal ethics interventions

Article #3 from 2015 provides precisely such evidence with regard to intra-organisational ethics programs, albeit from a different context. The article is based on a large-N survey (5,065 respondents) of employees working in U.S. organisations with more than 200 employees. The study examines statistical correlations between the implementation of nine different types of ethics interventions and observations by employees of unethical behaviour. The underlying assumption is that effective interventions would lead to lower frequencies of unethical behaviour.

The article provides strong support for viewing ethics interventions as a continuum of activities that make up ethics programs rather than stand-alone 'silver bullet' interventions.

The first major result of the article is the identification of *five ethics interventions that are significantly related to lowering of unethical behaviour*. In order of significance, these are:

- Code of ethics
- Training and communication
- Monitoring and auditing
- Accountability policies
- Investigation and corrective policies

The article also identifies four ethics interventions which *are not* significantly related to drops in ethical behaviour, namely: ethics officer; ethics report line; pre-employment screening; and incentive policies.

This prioritisation of ethics interventions in terms of effectiveness regarding the reduction of unethical behaviour is highly relevant for our purposes as the prioritization counters the perceptions of European stakeholders on several counts. Monitoring and auditing, for instance, takes a prominent place in the ranking whereas the respondents in article #20 did not rank such interventions at all. The prominence of codes of ethics is also much higher in article #3 than in #20. Finally, the significance of leadership commitment and engagement in realizing codes of ethics throughout the organisation through internal and external dialogue (grouped by article #3 under 'communication'), is ranked slightly lower, but still high, confirming the perceptions of stakeholders in article #20.
The importance of leadership commitment and dialogue is further confirmed by article #30, which concludes that "to maximize an ethics code's probability of creating a moral culture that yields value for al stakeholders […] management must be careful to ensure that the code itself is developed in a systematic, comprehensive, inclusive, and strategic manner" (p. 34).

The second major result of article #3 is that *the effectiveness of ethics interventions accumulates as more interventions are put in place in parallel.*

From a 65% likelihood of observed unethical behaviour within the last 12 months, the articles study shows that this likelihood drops significantly with the number of interventions put in place in the organisation. With nine ethics interventions (the maximum number investigated in the article) the likelihood of observed unethical behaviour drops to 15.87%. This relation between the number of ethics interventions and their accumulated effectiveness is illustrated below.

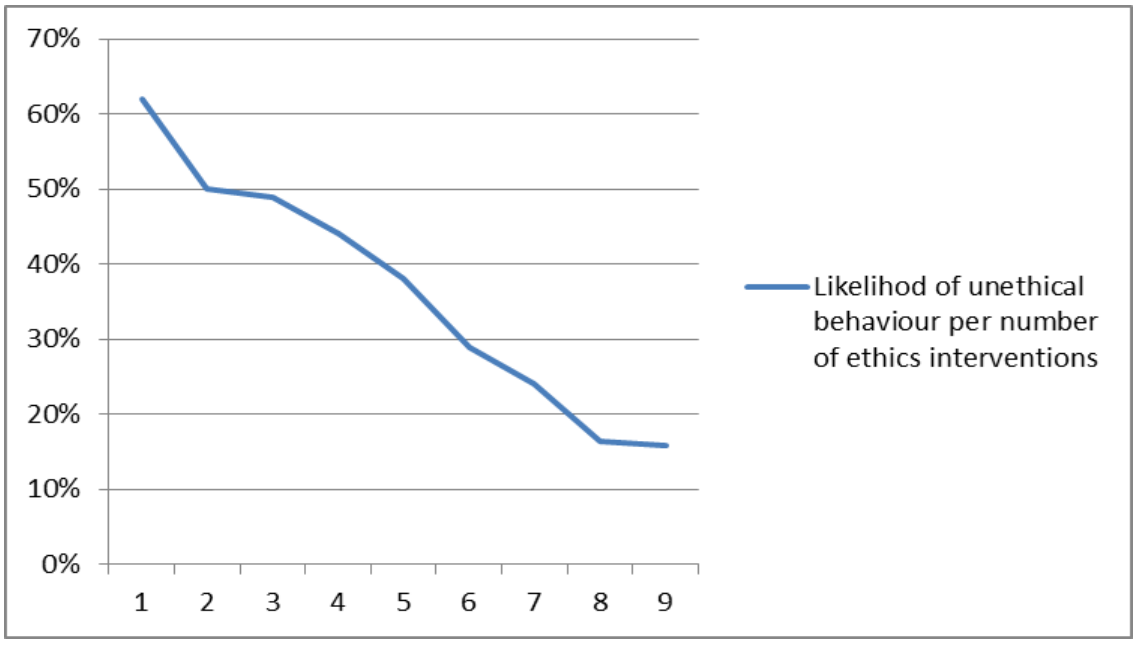

Table 3: Likelihood of unethcial behavior per number of ethics interventions. Source: Kaptein M. The effectiveness of ethics programs: The role of scope, composition, and sequence. Journal of Business Ethics. 2015 Dec 1;132(2):415-31.

With regard to advancing beyond the perceptions of stakeholders recorded in article #20 the data provided by article #3 does not investigate the two types of interventions rated second and third highest by European stakeholders, namely transparency and external regulation (including laws). Two of the relevant articles discovered by our keyword search study the effects of external regulation on attitude regarding ethical behaviour. The results of these articles are outlined below. No evidence was found among the relevant articles regarding the effects of transparency on ethical behaviour.

Effectiveness of external regulation

With regard to the effectiveness of external legislation in producing ethical behaviour, article #6 and article #25 take very different roads to arrive at the same answer, namely that *external regulation and strict compliance monitoring have little effect on attitudes and is less cost-effective in changing behaviour than ethics training*. This is relevant for the purposes of SATORI because it speaks for the necessity of ethics assessment and other forms of embedded ethics interventions and against the effectiveness of external regulation, which article #20 shows that many decision-makers believe to be a highly efficient means of achieving ethical behaviour.

Article #25 studies the effects of ethics legislation on the attitudes of members of Parliament (MPs) in Ireland. Based on a survey of the ability of 68 MPs to judge hypothetical behaviours as inside or outside the red lines constituting corruption, the authors conclude that "it appears that the ethics legislation has had a limited effect on members' perceptions of corrupt activities" and that "the influence of legislators' constituency role remains strong" (p. 109). This last remark means that external legislation – unsupported by monitoring and/or training –

is unable to break 'habits' learned in an organisational context that may in fact constitute unethical behaviour from the point of view of the external regulator.

Article #6 studies the effects of the U.S. Sarbanes-Oxley act on ethical behaviour in firm management. The Sarbanes-Oxley Act seeks to counter 'rogue' behaviour by firm management in relation to shareholders through strict regulation of management behaviour and intensive reporting and monitoring. Through the construction of a mathematical model that relates the degree of 'ethicalness' of managers to the cost, efficiency and effectiveness of monitoring activities, the article concludes that (1) is cases where managers already possess high personal ethical standards, minimal monitoring – which may imply some small degree of rogue behaviour – is still more cost-effective than expensive monitoring and that (2) in cases where managers act as highly independent (rogue) agents, ethics education and training would still provide a more cost-effective solution than tight monitoring.

While the underlying data value of these two studies should not be overestimated (especially in the case of article #6 which only makes indirect use of empirical studies) their results tend to confirm that external ethics legislation is even less likely than codes of ethics to have significant effects on behaviour if they are not supported by other interventions such as training, communication, leadership commitment, auditing, and monitoring. This indicated result furthermore gels well with the findings of article #30 cited above, which indicated that codes of ethics (or in this case ethics regulation) are most effective when supported by leadership commitment.

Altogether, the results cited above indicate that the often cited distinction between a 'culture of ethics' and a 'culture of compliance' can in fact be operationalized. Not only is it impossible for 'check-box' monitoring of compliance with ethics codes or external regulation to produce a culture of ethics – no one ethics intervention can achieve this result on its own. Promoting a culture of ethics demands that multiple ethics interventions be implemented throughout an organisation – the more, the better. Key among such interventions are: clear codes of ethics, ethics training, ongoing internal and external communication, leadership commitment, and on-going ethics audits and monitoring. But other types of interventions, when implemented as part of a battery of interventions (an ethics program) contribute significantly as well to achieving ethical behaviour.

3.4 Effectiveness Studies of Specific Elements of Ethics Programs

Even given the findings cited above that ethics interventions gather effectiveness when packaged in an ethics program consisting of multiple intervention types, the cost-effectiveness of alternative forms of individual interventions is still an important factor for the overall cost-effectiveness of such ethics programs. In the following we therefore cite some findings regarding the effectiveness of alternatives in ethics guidance and ethics training.

Empirical studies of factors influencing the effectiveness of codes of ethics

Among the relevant articles discovered by our keyword search only **article #27** deals empirically with the effects of codes of ethics in isolation from ethics training. Set in the area of professional U.S. sports clubs, the transferability of the results from the study to that of

organized R&I may be subject to certain limitations with regard to organisational structure, the nature of collaboration in the organisation, and others. At the same time, the increasingly competitive nature of R&I means that some of the same social and economic pressures apply.

Thus study concludes that the mere presence of a code of ethics has no significant effect on moral judgment and moral among members of the organisation, but that the intention behind the adoption behind the code makes a significant difference. Thus, if the code of ethics is adopted with the explicit goal of achieving a culture of ethics, the presence of the code makes a positive contribution, while if the code of ethics is adopted as a matter of compliance to professional norms, the effect is negative. This finding is corroborated by two case studies performed in **article #30**, which indicate that 'ethics code commitment' from top leadership in organisation has some degree of significance for ethics code effectiveness.

According to the study, other modifiers with positive significance on the effectiveness of codes of ethics seem, according to the study, to be:

- The involvement of management and staff in the creation of the code
- Explicit address of management behaviour in the code of ethics
- Introduction of the code of ethics when new staff joins the organisation
- Protection of whistle-blowers against retaliation

Empirical studies of factors influencing effectiveness of ethics training

Among the relevant articles, several deal with the effectiveness of various approaches to ethics training. We focus here on two meta-studies that cover most of the ground investigated by the rest of the relevant articles dealing with the subject.

Article #11 explores the effectiveness of different ethics training approaches in the sciences ranging from theory-based courses in moral reasoning to case-based training in moral reasoning and dilemma-solution. The article takes the form of a meta-study of 20 empirical studies that were available in 2009. Among these studies the reported effects varied widely, but on average the effectiveness of ethics training was judged to be 'fairly effective' (producing a 48% learning increase compared to a baseline scenario). We should mention that this result was confirmed by a yet-to-be published meta-study regarding the effectiveness of responsible conduct of research training (Watts et. al., in press). Based on their meta-analysis of the results reported in the cohort of studies, the authors found indications that ethics training is most effective when it is:

- Of a *high pedagogical quality*
- Focuses on *cognitive training in ethical decision-making* rather than moral development.
- Supports this focus with *social-interactional training* rather than lecture-style teaching or online-only instructions and tests.
- Makes use of *concrete, contextualized cases* rather than decontextualized, thought-up examples.
- Raises *awareness of reasoning errors* (e.g. hasty decisions, black-and-white categories, etc.)

- Brings together *older and younger researchers*
- Is *mandatory and separate from other training activities.*

However, the meta-study also found that the evidence base at the time was of medium to low reliability. Effectiveness studies make use of a wide range of different effect criteria, which makes comparability with regard to training technique difficult. Also, the size of the measured effects depends very much on the type of evaluation design deployed. Too many training evaluations are conducted by the authors of the training program under scrutiny, which introduces not only conceivable, but also measurable bias in the results. The average effect identified in the meta-study is thus likely to be exaggerated.

On the basis of their assessment of the quality of existing studies, the authors recommend that future effectiveness studies increasingly use combined pre- and post-tests with control groups, and that evaluations make their data openly available for learning across different studies. This same recommendation was reiterated by **article #2,** which – published in 2016 – found that most studies use proxy indicators such as trainee evaluations, whereas only 3% of the data compiled in the study cohort was gathered on the basis of empirical observation of actual conduct.

3.5 Conceptualizing Ethics Interventions from a Risk/Benefit Perspective

Our keyword search produced only two articles that link ethics interventions to issues of risk. Neither of these articles poses the question of risks arising from the interventions themselves. Instead, they both deal with ethics interventions as a means of risk management.

Article #31 explicitly frames ethics programs as an element of risk management strategy for private companies. The article describes organisational benefits of implementing ethics programs, which overlap with the category of 'external non-compliance costs' identified by article #33 (see 3.3 above). These include avoiding lawsuits, 'earning surprises', reputation damage, and damaged relationships with stakeholders and customers. The article furthermore stresses (in line with article #3 cited above) that ethics measures aiming strictly to achieve the minimal compliance needed to avoid liability – invites moral hazard and thus – even as they may avoid legal judgment – nevertheless invites the moral judgment of the public.

Article #39 looks more narrowly at the impact of ethical climate on moral distress, a specific subcategory of staff morale. This issue overlaps partly with the category of 'internal non-compliance costs' identified by article #33, but also extend into the broader area of human resource management and organisation. The article thus concludes that of a number of different factors investigated, lack of time and resources was the most significant factor influencing the frequency of moral distress. This would seem to indicate that ethics programs could – as was also suggested by articles #31 and #33 – be seen as an element of quality and risk management.

Although the evidence base is not broad enough to draw any firm conclusions, the two articles together indicate that taking a risk/benefit perspective on ethics interventions is unlikely to produce radically different categories from a discussion of costs and effects as long as the perspective – as is the case for these articles – remains tied to the interventions in themselves and their effects on the organisation in which they are implemented.

To be sure, expanding the scope to the more complex question the effects of ethics interventions on risk management in terms of R&I outcomes could – due to the long-term and multi-tiered chains of cause and effect involved in R&I – produce more complex categories of consideration. But this would not be unique to the risk/benefit perspective – this would be the case for any type of impact assessment with such a wide scope. We shall take up this wider perspective in section 5, but deeper discussions of such wider impacts and how ethics interventions relate to them fall outside the scope of this report. We recommend that readers consult upcoming deliverables from SATORI WP6 about these issues.

3.6 Literature Study Conclusions

Based on the existing literature we may conclude that existing work has already provided: useful means of conceptualising the costs of ethics interventions; consolidated ways of categorising the immediate effects of ethics interventions; and emerging data about the most effective ways of implementing ethics interventions (as part of an organisation-wide program).

We may also conclude, however, that with regard to ethics assessment specifically, almost no relevant data exists to judge the effectiveness of alternative assessment approaches. To begin the conversation on this issue, the following section presents reports of four concrete case studies. The long-term effects of ethics assessment on R&I outcomes are also generally unexplored. This remains an issue to be considered in SATORI WP6 on the impacts of ethics assessment.

4 CASES OF COST-EFFECTIVENESS AND RISK-BENEFIT EVALUATION OF ETHICS ASSESSMENT

In this section we report four case studies exploring how actual organisations conceptualise and operationalise cost-effectiveness and risk-benefit perspectives on ethics assessment. Whether these cases qualify as examples of best practices is a matter of one's perspective and expectations; a point which we will begin by elaborating.

If one approaches these cases looking for best practice in systematic evaluation in quantitative terms of the effectiveness of ethics assessment practice in achieving its various goals such as prevention of ethical breaches, prevention of stakeholder backlash, and prevention of negative effects on society, one would come back disappointed. But this is not necessarily a fault of these cases. Because if one comes to these cases from another perspective, they do in fact seem to present if not exceptional practice then current examples of well-balanced practice. For these cases share the characteristic that the organizations involved do not focus too much on tweaking the operating costs of ethical assessment units and ethical assessment practice. Rather, each of the organizations studied seem to focus on achieving the highest possible assessment quality within budget frames that are not closely linked to performance metrics.

Of course, the sample of cases studied here is small, and as such they do not in themselves provide conclusive evidence that systematic evaluation of the cost-effectiveness of ethics assessment is not performed anywhere. However, when considered in the context of the expert and stakeholder feedback received and reported in D5.3 as well as the results of the systematic literature survey reported above, we believe that the conclusions reached here will prove to be valid for many, if not all, cases.

This decoupling of the question of quality from the question of cost is allowed for different reasons. In some organizations, 'ethics' in the broad sense is seen as having intrinsic value, with ethics assessment being a common-sense measure to realize ethical behaviour in the organization. Implicit is the notion that the values that ethics assessment is there to defend are absolute. The case studies also give the impression that the organizations implicitly see the installation of an evidence-gathering routine for measuring the effectiveness of ethics assessment as overkill and as disproportionate to the possible gains. There are also other reasons for allowing ethics assessment to develop without strict monitoring of cost-effectiveness. The industry case stands out in this regard. Here, ethics assessment is seen as an essential element of the case organizations' risk assessment and risk management apparatus. Here, the value of ethics assessment lies both in its ability to avoid stakeholder backlash and negative impacts on society and in its usefulness in zooming in on the development pathways that are able to circumnavigate those risks and to reach the aim of contributing positively to society. Also from this viewpoint, the costs avoided and the potential gains are seen to be of dimensions that dwarfs the running costs of ethics assessment staff and their practices. While the industry case thus provides a somewhat more sophisticated conceptual take on the cost-effectiveness and risk-benefit of ethics assessment, in practice the end result is the same: the organization focuses on achieving the highest possible quality within a budget, which is not closely linked to performance.

4.1 DESCRIPTION OF CASE STUDIES AND APPROACH

The four cases explore openly the connections made by actors involved in the cases studied between categories of cost, risk, effect and benefit and the ethics assessment interventions. The case studies are based on semi-structured interviews and publically available information about the cases. The case studies all reported descriptions of the assessment procedures, the types and sizes of costs involved, the intended effects, risks associated with assessment as well as non-assessment, the perceived benefits, the methods used for cost-effectiveness evaluation (if any) and the perceived cost-effectiveness of the ethics assessment approach. The results of the four case studies are gathered and discussed in section 4.2.

4.1.1 Case Study 1 – Ethics Committee in a Research Funding Organisation (RFO)

This case study deals with the institutional setting of a research funding organisation (RFO). It analysis how the Seed- and Preseedfinancing-Programme in the framework of the Austrian Economic Service (Austrian Wirtschaftsservice) deals with questions of cost effectiveness of and risk / benefit analysis in ethics assessment.

Ethics assessment in the Seed- and Preseedfinancing-Programme is performed by an ethics committee which was established in 2012. The committee consists of five members, who are appointed by the Federal Ministry of Science, Research and Economy. They represent the fields of ethics, medicine, animal research, and law. The committee is responsible for the review of projects regarding research in humans, human embryo research, processing of sensible data, and animal research.[7]

The applicant is asked to fill in the ethics declaration in the proposal submission-phase. In case the ethics declaration does not indicate any ethically relevant areas, which is checked by the Austrian Economic Service, the project is not submitted to ethics evaluation. In case ethical issues are identified in the ethics declaration, they need to be elaborated further in the ethics section in respect to the aim of the research, the methodology, possible implications of the results of the research, and compliance with national legislation. The Ethics Committee can:

- Give ethics clearance: the applicant does not have to fulfil further ethical requirements;
- Formulate ethics requirements: the applicant needs to fulfil the requirements formulated. The Austrian Economic Service is tasked to check compliance with ethics requirements according to an ethics requirement plan which is established in the meetings of the Ethics Committee.
- Reject the proposal on ethical grounds. The applicant needs to rewrite the proposal (ibid.)

As regards methodology the case study is based on a qualitative interview with an expert within the respective Research Funding Organisation.

[7] See http://satoriproject.eu/media/4.a-Country-report-Austria.pdf

Cost effectiveness

For our case the guiding questions mentioned above are restructured as follows:

- Why has the Ethics Committee been established and which changes have taken place since its establishment?
- How are costs calculated for the Ethics Committee?
- To what extent are the costs involved justified, given the changes/effects, which have been achieved?

Why has the Ethics Committee been established?

By setting up an Ethics Committee, the risk of a public scandal in regard to possible ethical implications of a particular project has been addressed. Due to the experience of public debate of a research project including pigs, the public authorities who tasked the Research Funding Organisation with the micromanagement of the Seed- and Preseedfinancing-Programme stopped a procedure regarding a research project including non-human primates.

Concurrent with the decision to stop procedures regarding the project including research in non-human primates, the scientific advisory board was downsized and restructured for reasons of cost effectiveness. From then on the pool of experts consisted of auditors, tax advisors, experts in software development, marketing experts in the field of information technology, and experts in biotechnology and was reduced to three persons per committee meeting. In addition the selection procedure of the experts for each committee meeting was changed. Before it used to be a standing committee, which reviewed projects in a certain scientific field: at present, the members of the committee are appointed from an expert pool representing the professions named above by drawing lots. The guiding idea behind this change in procedures was to make the expert selection procedure more transparent. According to the interviewee this, however, led to a tremendous loss of quality of the decisions of the board, as focus shifted more towards the economic potential of a given project. In addition the appointed experts are not necessarily experts in the scientific field of the project under review, which makes it impossible to do a sound review of the project.

The ethics committee was able to fill that gap produced by the restructuring of the scientific review board based on cost effectiveness considerations.

The ethics committee guarantees a simple but nonetheless focused process that allows the employees of the RFO to focus on their job in full knowledge that they have an experienced ethics committee that is able to deal with potential ethical questions. This allows them to fund projects in ethically grey areas, projects which public authorities are usually not keen on funding. With the ethics committee in place the public authorities can rely on its members' abilities and experience, which results in the fact that the public authorities leave the micromanagement of project selection to the research funding organisation allowing a broader range of projects and more freedom for the RFO. According to the interviewee the costs imposed by the ethics committee is money well spent.

The interviewee did not report any difficulties, obstacles or barriers in the establishment of the ethics committee.

How are costs calculated for the Ethics Committee?

The RFO set up a system of cost calculation depending very much on the amount of projects which are reviewed. The RFO pays 200 Euro to each committee member attending the meeting per assessed project. In 2015 around 20,000 Euro were spent for ethics assessment. For 2016 about 25,000 Euro were budgeted for ethics assessment. The total yearly budget can therefore be estimated through the following equation:

Projects = p
Members present at the meeting = m
Yearly budget = yb

P x m x 200€ = yb

The public authorities do not provide budget to cover for increased spending caused by the Ethics Committee. The interviewee reported that costs for the ethics committee are provided for by the regular budget of the RFO.

To what extent are the costs involved justified?

The interviewee does not report on any other ways of measuring costs or on any plans to cut costs for the ethics committee. From that it can be deducted that he estimates that the costs involved are justified. He rather made clear that the money spend on the ethical committee is indispensable for conducting their business.

Neither does the interviewee report on whether there is any other kind of best practice available. In fact he recommends that practice as a best practice model as the procedure is light, which allows the Research Funding Organisation to take their funding decisions fast, which is of utmost importance for applicants.

Risk / benefit analysis in regard to the setting up of an Ethics Committee

By setting up an ethics committee, the risk of a public scandal with regard to possible ethical implications of a particular project has been addressed. Due to the experience of public debate of a research project including pigs, the public authorities who tasked the Research Funding Organisation with the micromanagement of the Seed- and Preseedfinancing-Programme stopped a procedure regarding a research project including non-human primates.

On one hand, this led to a lengthy procedure that is neither in the interest of the applicants nor in the interest of the RFO. On the other hand, this carried the risk that only low risk projects could be financed by the RFO. This however is counterproductive in regard to the aim of the Seed- and Preseedfinaning-Programme, which implies that the projects have a particular high innovative character and therefore carry a certain amount of intrinsic risk.

The interviewee reported that establishing an ethics committee was as a benefit as trust in ethical acceptability of projects financed by the RFO was re-established. This had an impact on procedures as the public authorities did no longer intervene in project selection and left the micromanagement of project selection to the RFO. In this micromanagement the RFO was

thus able to concentrate again on fast procedures and on the high innovative character of projects.

The interviewee did not report on any indicators regarding impact or performance of the ethics committee. He however explained that the importance of the ethics committee for procedures in project selection can be deducted from the fact that the public authorities have not allocated additional budget for the ethics committee. The RFO however sees that much added value in the work of the ethics committee that funds were earmarked for the work of the ethics committee out of the regular budget.

Risk / benefit analysis in regards to the chosen procedure

The ethics committee consists of five experts from the fields of ethics, medicine, animal research, and law, and is responsible for the review of projects regarding research in humans, human embryo research, processing of sensible data, and animal research.

The interviewee does not report on any risks regarding the knowledge base that is represented by these experts and relates to research in humans, human embryos, processing of sensible data, and animal research. These fields are seen as those including a risk of ethical misconduct in regard to the project lines offered by the RFO. The perception of ethical misconduct mainly relates to possible individual vulnerabilities, which are addressed through ethics review.

Neither does the interviewee report on any risks regarding the expert selection, as expert selection is in line with the predefined possible ethically problematic areas. As a benefit he reports the interdisciplinary of the ethics committee, which brings added value in the discussion of the projects, as each expert brings in the experience from his/her particular field which adds up to an opinion which is not only the sum of individual opinions, but represents a higher reflection level than individual opinions.

The methods used by the ethics committee on the one hand rely on a positivist mind-set of experts in regard the observation of legal safeguards by applicants. On the other hand, members of the ethics committee bring in personal expertise that does not relate to hard facts. This carries the risk that applicants, who mostly do not want to be kept back in their work, have a hard time accepting recommendations formulated by the ethics committee in case they cannot be deducted from legal provisions. Risks addressed by experts usually relate to the research method of the project, project aims, future implications of the project, and individual vulnerabilities of research participants (including animals).

The RFO however insists on implementing the recommendations of the ethics committee, as they have made the experience that projects gain quality if the recommendations are respected, which adds to the final aim of funding projects of the highest possible quality. The RFO has therefore already built internal knowledge in how to best guide applicants in the implementation of recommendations. In addition, the RFO tries to draw attention to ethical issues from the very start of the application procedure in order to raise awareness for ethics from the start, thus preventing conflicts at a later stage of the procedure.

The ethics committee does not use participatory methods in its review. The interviewee reports that the RFO is only responsible for the micromanagement of the particular project

lines. The project lines as such are proposed by the public authorities who are responsible for the underlying policy.

Observations

In regard to cost effectiveness of ethics assessment at the level of setting-up an ethics committee the case study demonstrates that ethical assessment enabled the RFO to fund projects in ethically grey areas which it could not have done that easily without the establishment of the ethics committee. The increased spending due to the establishment and upkeep of the ethics committee is not seen as problematic since its advantages outweigh its financial burden.

In regard to risk/benefit analysis in ethics assessment at the level of setting-up an ethics committee the case study demonstrates that ethics assessment helped to re-establish trust in ethical acceptability of projects financed by the RFO, which had an impact on procedures as the micromanagement of project selection was left to the RFO. The research funding organisation was thus able to concentrate again on fast procedures and on the high innovative character of projects.

With regard to the risk/benefit analysis in ethics assessment at the level of the chosen procedures, the case study demonstrates that in a pre-defined setting, such as a given research priority under which the RFO is tasked to fund projects, no risk in regard to knowledge base or chosen experts are reported. Benefits are reported in regard to the interdisciplinary of ethics review. In addition, the case study demonstrates that the work of an ethics committee in going beyond a positivist mind-set of evaluation of hard facts, such as the observation of legal safeguards by applicants, is seen as an added value by the RFO.

4.1.2 Case Study 2 – Responsibility Committee in a National Science Academy

The study presents the Joint Committee for the Handling of Security-relevant Research, established by the German National Academy of Sciences Leopoldina and the German Research Foundation (DFG) in 2015. Following up on the guidelines developed and published in 2014 by Leopoldina and DFG under the title *Scientific Freedom and Scientific Responsibility: Recommendations for Handling Security-Relevant Research*,[8] the Joint Committee was founded "to support research institutions in the sustainable implementation of the recommendations"[9] made in the document. This study is based on the materials available on the committee's website and an interview with a representative of the committee.

The development of the above-mentioned guidelines and the subsequent establishment of the Joint Committee took place in the aftermath of the public and governmental interest in research with apparent potential for misuse. This interest rose especially following the case of

[8] The document is based on "Guidelines and Rules of the Max Planck Society on a Responsible Approach to Freedom of Research and Research Risks" of March 19, 2010. The document is available at: http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf

[9] Leopoldina Nationale Akademie der Wissenschaften, "Joint Committee for the Handling of Security-Relevant Research", http://www.leopoldina.org/en/about-us/cooperations/joint-committee-dual-use/.

research carried out on the transmissibility of the avian influenza virus to humans, which was seen through the lens of its potential misuse as a bioweapon. The *Recommendations* present the risk analysis of potential use and misuse of research as an imperative for responsible research.[10] Decisions based on this analysis should be taken with regard to legal regulations but also to ethical principles.[11]

The Joint Committee is interesting for SATORI in several ways: a) as an attempt to develop an assessment framework combining risk and ethics assessments; b) with regard to the implementation of this kind of a framework, bearing in mind the different types and levels of organisations (science academy, funding organisation, research organisations; national vs. local level); c) from the point of view of cost-effectiveness of establishing national-level assessment procedures; and d) with regard to approaching the problems of risk-benefit assessment in research.

The Joint Committee was established to facilitate the implementation of the *Recommendations* by local ethics committees at individual research institutions. The Joint Committee has published a sample statute for these committees.[12] The committees at research institutions will make their decisions autonomously, with the Joint Committee operating "as a contact point for questions and a platform for the exchange of information".[13] The Joint Committee's website hosts a forum where local committees post contact information and optional further details on their work process, i.e. web links.[14] The Joint Committee will collect reports from the local committees and will prepare annual reports on the handled cases of the local committees starting in 2017.

The local committees will further elaborate the principles, procedures and institutional framework for risk and ethics assessment at their institutions, depending on their research field and institution type. In complicated cases where a decision cannot be reached on a local level, the German National Academy of Sciences Leopoldina can, in close collaboration with the Joint Committee, establish an ad-hoc working group that "can make a risk-benefit assessment of the research content under consideration".[15]

What is cost-effectiveness in this case?

While there has been no specific cost-effectiveness analysis applied to the work of the local committees so far, the Joint Committee has proposed guidelines (a sample statute) for the

[10] Deutsche Forschungsgemeinschaft/Leopoldina, *Scientific Freedom and Scientific Responsibility: Recommendations for Handling Security-Relevant Research*, http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf [p. 12].
[11] Ibid., p. 11.
[12] Deutsche Forschungsgemeinschaft/Leopoldina, Mustersatzung für Kommissionen für Ethik sicherheitsrelevanter Forschung, https://www.leopoldina.org/fileadmin/redaktion/Ueber_uns/Kooperationen/Mustersatzung_fu%CC%88r_KEFs_2016-03-18.pdf.
[13] Leopoldina Nationale Akademie der Wissenschaften, "Joint Committee for the Handling of Security-Relevant Research", http://www.leopoldina.org/en/about-us/cooperations/joint-committee-dual-use/.
[14] Leopoldina Nationale Akademie der Wissenschaften , "Contact persons and commissions in Germany responsible for ethics concerning security-relevant research", https://www.leopoldina.org/nc/en/about-us/cooperations/joint-committee-dual-use/list-of-committees/.
[15] Ibid.

composition, procedures and management of the committees, which individual institutions can adopt and adapt, considering their institutional structure. The Joint Committee will monitor the establishment, work and performance (e. g. number of cases analysed) of the local committees with the first report due for publication next year.

Use of cost-effectiveness

Some research institutions have now established specialised ethics committees for security-relevant research, while others have opted to widen the scope of already existing ethics committees at their institutions to include addressing security-relevant issues. The overall project is funded by Leopoldina and DFG, while the costs of local committees are covered by individual institutions. The sample statute for ethics committees proposes no fees for committee members.

The Joint Committee aims to raise awareness of security-relevant issues and related ethical principles, and believes the best way to establish effective assessment mechanisms nation-wide is to support networking between local committees who have the expertise to assess the risks and benefits of their own research, and to offer a platform for discussion among them.

What is risk-benefit in this case?

The *Recommendations* "advocate greater awareness of the problem of potential misuse of research findings and minimising associated risks without disproportionately restricting freedom of research and its further development for peaceful purposes and the well-being of society".[16] Risk analysis of the research itself is thus weighted against the risk of restricting the freedom of research but also of missing out on the benefits if certain kinds of research are abandoned: "failing to conduct research can also entail significant risks, such as when a vaccine needs to be found to avert an imminent epidemic".[17] In some cases, it is therefore difficult to weigh the risks against the benefits.

Research with potential dual-use aspects may pose "risks for human dignity, life, health, freedom and property, the protection of the environment and other values".[18] Ethical issues related to dual use are complicated, since they involve potential misuse by third parties. These uses of research are therefore out of the scope of influence of the research team, once the results are published.

The Joint Committee has held workshops dedicated to the questions of risks and benefits of research, although it has not yet established a specific risk-benefit assessment methodology, since the nature of research is unpredictable and the risks and benefits are hard to identify and depend on the specificities of the research in question. "Judging this kind of research is also difficult because future use chains are often unknown and estimating risks and consequences

[16] Deutsche Forschungsgemeinschaft/Leopoldina, *Scientific Freedom and Scientific Responsibility: Recommendations for Handling Security-Relevant Research*, http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf [p. 7]..
[17] Ibid., p. 9.
[18] Ibid., p. 11.

tricky."[19] In many cases, especially in basic research and emerging technologies, it is very difficult to assess the risks a research project can pose. Risk-benefit assessment of security-relevant research is therefore best performed on a case-by-case basis.

It is very important to raise awareness and implement mechanisms to assess and minimise risk, although individual research institutions should be allowed to adapt the procedures according to their own fields of research and assess risks and benefits according to their expertise. Ethics committees in this case are therefore based in individual research institutions, who must take the responsibility for their decisions. The role of these committees is primarily an advisory one:

> Each research institution should form a special research ethics committee to advise on issues arising from the implementation of ethics rules. This committee should provide researchers with support on issues of research ethics, mediate in differences of opinion between researchers on relevant matters, and issue recommendations on the implementation of research projects.[20]

The analysis of risk is based in expert deliberation: "The committee should be made up of persons with sufficient scientific expertise to handle each particular case in question."[21] The problem with including a wider spectre of stakeholders through participatory processes is that the risks identified by security-relevant researchers are related to the knowledge getting into the wrong hands. While research practices and assessment procedures should be as transparent as possible, it is not advisable to publically share details of the projects, while assessment is being done if it is precisely the publication of certain research results that might be risky.

Observations

Because of the unpredictable nature of research, risks and benefits are often hard to determine; hence the lack of widely used assessment methodologies in this field. Best practice of risk-benefit assessment in research may therefore be to deliberate on a case-to-case basis. Restricting research based on an ethical assessment bears the risk of missing out on potential benefits of research.

Regarding the cost-effectiveness of ethics committees, the case presents the practice of establishing local ethics committees, supported and monitored by a national academy of sciences and a national funding organisation. No specific cost-effectiveness models were applied in this case. As a best practice, this case suggest the networking and exchange of experiences between local committees, supported and guided by a national-level committee, rather than a top-down regulation, prescribing common procedures to individual research institutions.

4.1.3 Case study 3 – Ethics committee in an ICT research institution

This case study focuses on the ICT Ethics Committee at the University of Twente, The Netherlands, as an example of the ethics assessment of human subjects research in technology research context. The study is based on the interviews conducted with two members of the

[19] Ibid.,p. 9.
[20] Ibid.,p. 15
[21] Ibid.

ICT Ethics Committee. Further information was obtained through the University of Twente website and academic literature.

The past half-century of ethics assessment has focused on conduct of human research, mainly in the domain of medical, and more recently, social–psychological research.[22] Increasingly, research outside the medical domain, such as social sciences and anthropology, has been recognised to potentially cause risks to human subjects of experiments. The rapid expansion of information and communication technology (ICT) and the beginning of the modern Internet have created a range of new ethical concerns regarding human participants used in technology research context. Currently, a clear legal and institutional setup for overseeing human subjects in non-medical technology research does not exist. Nevertheless, some universities as a response to the new ethical concerns are establishing ethics committees to protect human subjects in non-medical research not technically covered by the Declaration of Helsinki.[23] These ethics committees share some features of the medical ethics committees, however they also have their specific characteristics. Human subjects used in technology research enjoy protection from the ICT ethics review; ideally in a manner comparable to the protections that exist in medical research. Furthermore, ICT ethics review helps to avoid legal liability and reputational damage in case of misconduct.

The ICT Ethics Committee was established five years ago as part of the CTIT of the University of Twente, one of the largest academic ICT research institutes in the Netherlands.[24] The Committee consists of eight members, of which five are ICT academics, two ethicists and one independent member (Secretary). CTIT has 21 research groups from four different departments and researchers engaged in a large number of research projects. Nevertheless, not all of these research groups and projects are subjected to ethics review. The Committee focuses on the assessment of the ethical permissibility of proposed research that include human subjects, therefore research that involves interaction with, or data gathered from human subjects.[25] This includes research in such fields as social engineering, security research, biomedical system. One example of the research project proposals is an assisting arm (robotics) for people with problems with moving after a stroke. The second example are experiments with children at school looking at how they interact with robots and computers as part of a playground. The Committee reviews two types of research project proposals: Master's students research proposals and senior researchers and PhD students research proposals.

The ICT Ethics Committee focuses primarily on risks and benefits or pure evaluation of ethical permissibility of research project proposals. Cost-effectiveness is not the main

[22] Koepsell, David, Willem-Paul Brinkman, and Sylvia Pont, "Human Participants in Engineering Research: Notes from a Fledgling Ethics Committee", *Science and Engineering Ethics*, Vol. 21, No. 4, August 2015), pp. 1033–1048.
[23] Ibid.
[24] CTIT University of Twente, https://www.utwente.nl/ctit/organisation/organigram/
[25] Faculty of Electrical Engineering, Mathematics and Computer Science, "Protocol for assessing the ethical permissibility of proposed research in the Faculty of Electrical Engineering, Mathematics and Computer Science at the University of Twente", Version of 28 February 2014, p. 5.

consideration of the committee. Assessments of scientific integrity (plagiarism, data fraud and alike) are also not the focus of the committee.[26]

What is cost-effectiveness in this case?

Cost-effectiveness may be perceived as both cost-effectiveness of ethics review of research ethics proposals and cost-effectiveness of a research project proposal.

Regarding the costs of activity of ICT Ethics Committee and ethics assessment of research ethics proposals, the members participate in the Committee on a voluntary basis, mostly as "ethics enthusiasts", and therefore they are not paid. The work for the committee is mainly a side activity to their main academic work at the University. The cost may be perceived as time spent on the review of proposals. Nevertheless, the committee does not have a structural approach to calculate hours spent on the review. The time spent depends on the type and size of the project (Master's student research proposal, PhDs student research proposal or professor's research proposal), the topic and complexity of the project. Nevertheless, to improve efficiency of the assessment, the committee has implemented a two-steps assessment process. The first step is a pre-assessment by the ethics advisor and secretary who prepare the initial assessment, including the quality check and focus on the main ethical considerations. This initial step intends to remove some of the burden and limit the time spent by the committee on assessing bad quality proposals. The second step is the assessment by the whole committee. The interviewees perceive this two-step approach as a good practice in terms of cost-effectiveness.

The focus is on costs for the University rather than on costs for broader society. The cost of having an ethically assessed research project proposal is rather non-quantifiable. It is rather "a feeling". These non-quantifiable costs include bad PR and reputational damage for the University, research institute or a group, but also unhappiness of individual employees. The only case where the cost could be calculated, is when a PhD student does not finish her PhD, due to a negative decision based on ethical considerations. The University receives money for each finished PhD. Only in this case the cost could be calculated.

The committee is also concerned with the potential costs for individual researchers to prepare an ethically permissible proposal. This may be perceived as imposing an additional bureaucratic burden on them. In addition to the ICT Ethics Committee, the CTIT has created the position of the ethics advisor to help researchers within CTIT in making decisions about values that go beyond their technical expertise.[27] The advisor's role is not to decide arbitrarily on the ethical permissibility of the research, but rather to work "alongside researchers to help them identify and describe the values promoted in their work, and to ensure that the outcome of their research accurately reflects the values of the researchers themselves and of their sponsors."[28] Researchers can approach the ethics advisor when preparing their research project proposal. This institution was intended to improve the quality of proposals in terms of ethical permissibility. However, the interviewees could not say whether having the ethics

[26] Faculty of Electrical Engineering, Mathematics and Computer Science, "Protocol for assessing the ethical permissibility of proposed research in the Faculty of Electrical Engineering, Mathematics and Computer Science at the University of Twente", Version of 28 February 2014, p. 3.
[27] CTIT, "Ethical Advisor". https://www.utwente.nl/ctit/research/ethical_advisor/.
[28] Ibid.

assessor helps in reducing costs of ethics assessment (e.g. time spent on the assessment by the committee).

In terms of effectiveness, one of the roles of the committee is raising awareness of ethical considerations among researchers. This is particularly important for students and young scientists, who are at an early stage of their career. The committee finds its educative role especially when revising Master's students' research project proposals. Raising ethical reflection in ICT research is perceived by the interviewees as an advantage of ethics assessment.

In terms of costs, one of the interviewees raised the point that the position of the committee's members is an additional task to their regular obligations, which may threated assessment quality due to time pressure. Therefore, they have limited time. In the opinion of the interviewee, if the members of the Committee would be paid for extra the quality of the recommendations might improve.

Both of the interviewees emphasised that the ICT Ethics Committee is relatively a new body and is still in a development stage. The committee has a strong support from the University, nevertheless as a new body it needs to work on gaining the visibility, recognition and trust among researchers.

Use of cost-effectiveness evaluation

The assessment of cost-effectiveness of the project proposals is not explicitly used by the ICT Ethics Committee. It is because the ethics committee is an advisory body providing recommendations and not binding decisions on the ethical permissibility of project proposals. The recommendations are provided to the dean, who makes the final decision whether to accept or reject a research proposal. Therefore, it is mainly the dean who uses cost-effectiveness. The dean, in addition to ethical considerations, also takes into account the broader context of a research proposal, including a business case. Nevertheless, the committee also takes into consideration a broader context of the research, cost-effectiveness of the research project proposal. For instance, the committee may discuss whether benefits for society from a long-term perspective can justify the ethical costs in the short term.

The evaluation of cost-effectiveness of research project proposals is also a bureaucratic stage, where a proposal is checked in terms of financial resources for realisation of the project. The ICT Ethics Committee is not engaged in this evaluation: the administration of the University performs this task.

Risks in this case

The ICT Ethics Committee focuses on research project proposals including human subjects. Therefore, in this context risk can be understood as a harm to people directly involved in the study. Risks include concerns about exploring people and misusing data. In a broader sense, risks include potential harms to society, implications for people applying technology.

The risk involved in carrying out a research project that was not ethically assessed can include bad publicity, reputational risks and legal liability of the University. Furthermore, the ICT

Ethics Committee takes very seriously the happiness of the University's employees. Many research projects engage employees as a target group, e.g. security research projects targeting employees as targets of security attacks on their computers. The committee takes into consideration the amount of projects with experiments on employees and tries to limit the interruptions. Moreover, the risks of ethics can be perceived as risks on individual level for the members of the ICT Ethics Committee. The members are also researchers and work in various research groups. They revise research project proposals, make judgements, and therefore their independency may be questioned. The recommendations of the committee also have financial consequences. The dean takes into consideration the recommendation and decides, whether to fund the project or not. The risks for the members of the committee include stigmatisation (social status as "This is this ethics person that judges us"), separation from the research group, and division between us and them—"the enemy".

Benefits in this case

The benefits of having ethically revised research project proposal can be understood in various ways depending on who benefits from it.

The main benefit of the ethics review of research project proposals is creating useful technology and preventing this technology from causing harm to the users. Value-sensitive-design arguably promotes design that avoids future harms[29].

The ethics review protects the University by stopping potentially controversial research going without reflecting on its ethical aspects. The benefits in this case include avoiding bad PR, reputational damage, legal and financial consequences. In some cases, ethics assessment can help a project. For instance, the UT's *Living Smart Campus* project received good publicity from the media, thanks to including privacy considerations. The ethically assessed research projects including human subjects may also run smoother because potential risks were addressed in advance. Ethical guidelines improve the transparency of the research and acceptability from participants. If participants are satisfied with the way the research was performed, they will be willing to participate in other research.

The benefit of having the ICT Ethics Committee consist of people who are also researchers, is that the other researchers know them, they are familiar with their research, and therefore may be more willing to cooperate with them than with outsiders. One incentive and benefit is also an opportunity to publish papers together with the committee's members.

One of the interviewees also pointed out that ethical review and including ethical considerations in research project proposals also helps people to be better researchers.

Methods used for assessing risks and benefits

The committee addresses potential risks relying on the experience of the members. Because definitions and opinions may vary, the committee poses the question "what the worst is likely to happen?"

[29] For example, Friedman, B., Kahn Jr, P. H., Borning, A., & Kahn, P. H., *Value Sensitive Design and information systems. Human-Computer Interaction and Management Information Systems: Foundations*. ME Sharpe, New York, 2006, [p. 348–372].

The committee does not provide a "yes/no" decision. The committee addresses a number of potential consequences and gives recommendations on how the proposal could be improved.

Who assesses of risks and benefits?

The assessment of risks and benefits is internal within the committee. Nevertheless, as was mentioned in the previous section on cost-effectiveness, the committee does not ethically approve research project proposals, but provides recommendations to the dean who makes the final decision. It acts as an advisory body.

The committee does not engage external stakeholders in the assessment process.

The committee may consult external experts in case the members of the committee do not have an extensive knowledge in a particular research. The interviewees noted that until now external experts were consulted only informally.

Observations

The cost-effectiveness and risk benefit in the case of the ICT Ethics Committee can be understood in different ways. This depends on the perspective: whose costs, risks and benefits do we look at?

In the case of the ICT Ethics Committee that functions at a public institution (a university), the costs, risks and benefits of the ethics assessment of research ethics projects including human subject are mainly non-quantifiable. There are two reasons for this:

1. The ICT Ethics Committee functions on a voluntary base, the position of the Committee's members is in general unpaid.

2. Costs, effectiveness, risks and benefits are difficult to calculate in a strictly economic way, e.g. good or bad PR and reputational damage of the University; happiness of employees (including the members of the Committee and researchers); happiness and satisfaction of participants of experiments; the costs and benefits of creating of an ethically assessed technology in comparison to non-ethically assessed one.

4.1.4 Case Study 4 - Ethical Impact Assessment in an Industrial Organisation

In 2010, the UN recognised the human right to water. A few years later, Ericsson began a project with the aim of improving water availability in line with its Technology for Good Program.

Through Atlanta-based personal contacts, Ericsson had the opportunity to drive an innovation project in coordination with the Chattahoochee Riverkeeper and the Waterkeeper Alliance to find more efficient ways to leverage Ericsson's expertise in wireless technology in support of clean water objectives.

The problem with the Chattahoochee, Atlanta's local river system, is linked to the process for measuring and managing water for cleanliness that is expensive, time consuming, and

inefficient. Inevitably, this poses some challenges on the Riverkeeper's clean water stewardship. This issue was not limited to the Chattahoochee. Governmental and nonprofit organisations globally are struggling to find resources, funding and adequate technology solutions to monitor water quality.

The connected water field trials will utilise a design prototype based on the winning idea from a recent Ericsson-sponsored Technology for Good innovation challenge with university students. Telecommunications provide AT&T will provide all wireless connectivity for the Internet of Things (IoT) devices.

At Ericsson, effectiveness in relation to ethical procedures is understood as integrating the analysis of ethical impacts in every phase of their projects. It is an integrated part of their corporate strategy and it is not considered as an additional task. Therefore, good practice is to fully incorporate throughout the process the analysis of ethical aspects and to prevent any risk.

In this context, both risks and benefits are a contextual construction in relation to ethical procedures. Indeed, intangible risks such as those linked to the Sustainability and Corporate Responsibility are taken into consideration.

What is cost-effectiveness in this case?

As mentioned above, risks and benefits were part of the decision making across all the steps of the project in a systematic way. In particular, when taking the decision of starting the project, potential impacts on society (people, environment, business, and other stakeholders) both positive and negative were highlighted and analysed. Analysis is qualitative and quantitative, supported by Risk Mapping, SWOT Analysis and other supporting tools.

Since from these analyses no harm on society resulted (among the others requirements to satisfy) then the key stakeholders part of the Steering Group of the project decided to proceed with it. Moreover, in the risk and benefits assessment, the cost-efficiency itself, enabled by the expected results of the project, was one of the key benefits supporting the green light.

As most of the existing technologies used to monitor the quality of water in real time are not cost-efficient, Ericsson, in partnership with other stakeholders, aimed to find a cost efficient way to carry out such monitoring and transfer it to other parts in the world.

Use of cost-effectiveness

Key ethical issues analysis has been applied at the beginning of the project and reviewed at every step of the process from planning to the delivery phase with no issues identified. This systematic process of reviewing risks and benefits allowed for potential negative impacts to be identified before reaching a stage where recovering from such impacts implies social costs, financial costs and potential brand impacts.

No extra costs were imposed to perform such analysis since it was an intrinsic part of the project itself. Indeed, the final goal of the project had positive impacts on most of the ethical aspects discussed in the assessment and no impacts on the others. Moreover, the solution

proposed by Ericsson led to an improvement of sustainability, as checking on possible water contamination means no environmental pollution, which enhances the lives of citizens.

Cost-effectiveness in this context is both a tool used to assess the effects of the project and one of its aims: the identification of a cost-effective method to monitor water quality transferable to other countries. The cost-effectiveness of the project has been evaluated by the main internal Ericsson stakeholders.

The advantages of using cost-effectiveness are that it is an easy and straightforward assessment, and that in this case, it is useful both to assess costs and effects and as a driver of the project itself.

The pitfall of cost-effectiveness is that it is not a detailed and standardised model for assessing ethical issues, like those provided by external formal requirements (e.g. ISO).

When it comes to ethical aspects, the Ericsson approach was more enabled by very structured processes and Corporate Responsibility Directives rather than by the utilisation of recognised official models by external bodies.

Even though the cost-effectiveness of the project was a relevant part of it, its role was mainly linked to the impacts of the project, and not as a way of evaluating its feasibility from an economic point of view. In this regard, Ericsson implemented a cost-benefit analysis. This latter consists in the quantification of all the costs related to the projects and of its benefits in terms of branding, visibility, positioning in the market, etc.

The suggestion for best practice is to adopt an integrated approach into the project management and decision making. Consideration must always be given to ethical issues in every step of the process, from planning to delivery. This should be done even when the project itself does not seem to provide problems.

What is risk-benefit in this case?

From an industry point of view, the benefits of carrying out an EIA at the Research & Innovation phase are linked to the identification at a very early stage of potential barriers, trends and enablers of the new product and/or solution being investigated. Indeed, for industry is very important to be aware of this since the objective is to exploit the positive impacts and to mitigate or prevent with ad hoc actions, the negative ones.

When this procedure is not followed, the risk is to find out too late (e.g. during deployment in the market once that all institution and consumers are aware):

- the presence of positive impacts linked to the new product and/or solution investigated not being considered, which represents a lost opportunity;
- the presence of negative impacts which, in the worst case scenario, deeply affect the brand, the positioning and the credibility of the industry.

Such an analysis applies to all sectors, and therefore was carried out in this case study as well as part of the cost-benefit analysis which represents the most common method to assess risks and benefits.

Within Ericsson, this assessment is done by following a constructivist mind set that entails the continuous and adjustable identification of risks and benefits. The assessment of risks and benefits was carried out by a Steering Group that is part of the company's internal governance and takes the decision. In this case, the group was composed by the principal sponsor of the project and by other key stakeholders such as those with responsibility for implementing sustainability and innovation strategies in the company. Each one assessed the risks and benefits against the specific field. The steering group of the project also deliberates on risks and benefits.

Risks are assessed against two aspects: the probability that the risk will happen and its potential impact. Ericsson's objective is to reduce all risks. Misuse of technology may cause potential risks to the right to privacy, use of information, international relations and other human rights. Conducting business responsibly is a key aspect of Ericsson's strategy and this entails that actions must be taken to address any potential risk, including ethical ones.
The Chattahoochee River Project did not pose any risk on society and environment, and therefore perfectly fitted Ericsson's strategy of delivering positive change with reduced risks.

In addition to the risks, the benefits of the project have been assessed. This assessment involves the analysis of revenues, branding opportunities and visibility. An important role is also given to the relationships with stakeholders as well as to the possibility of building up new skills and of positioning in the market.

As mentioned above, the main strategy of Ericsson is to deliver positive change with reduced risks. This implies the fact that high attention must be given to ethical aspects. Indeed, Ericsson's stated goals for sustainability and corporate responsibility requires a total respect of ethical aspects which if not considered will have a negative impact on both the branding and visibility of the company.

Observations

Introducing a well-structured EIA at the very early stage of R&I provides an immediate identification of risks and benefits, reduces costs and improves the customers' perception of the company.

Ericsson carried out the ethical impact assessment without having an external standardised method to do it. They learned that it would have been extremely useful to have the possibility of relying on such model since it would have given them the certainty that the most appropriate framework to assess ethical impacts was being used. This latter would have benefited both the company and the stakeholders.

4.2 CROSS-CASE CONCLUSIONS

The following table gathers the central observations of the four case studies with regard to how costs, risks, effects and benefits are conceptualised and operationalised in each case.

	Ethics committee in a research funding organisation	Responsibility committee in a national science academy	Ethics committee in an ICT research institution	Ethical impact assessment in an industrial organisation
Intervention type	Ethics committee providing ethics assessments of research proposals flagged by applicants as containing ethical issues	Risk and ethical assessment of research with potential for dual use (i.e. military "misuse")	Committee to assess permissibility of research involving human subjects	Upstream and downstream procedures for assessing impacts of internal R&I projects before and during implementation
Assessment procedures	Interdisciplinary assessment through committee dialogue	Guidelines for responsible research implemented through local committees	Two-stage assessment (screening; assessment)	Qualitative and quantitative impact analysis integrated into management procedures
Types of costs	Remuneration to committee members	Remuneration to committee members	Ordinary salaries (participation part of ordinary work)	Appraisal costs
Size of costs	€20.000+ per year	Varies between different research institutions	Not isolated (part of salaries)	Not specified (part of management costs)
Intended effects	Ensure that only ethically acceptable research projects and projects with proper ethics management are funded.	Responsible handling of security-relevant research in and between research performing institutions	Ethical awareness raising	Identify potential positive and negative effects of R&I projects on
Risks of non-assessment	Public scandals in regard to state-funded research projects, inability to fund R&I in ethical 'grey areas'	Misuse of research results through appropriation for military purposes	Moral distress; reputational damage; non-completion of PhD projects	Social and/or environmental costs to the community, shut-down and/or lost opportunities, negative brand impacts to the organisation
Risks of assessment	Loss of research opportunities (if ethics is assessed too black-and-white)	Loss of research opportunities (when risks of misuse are identified)	Ruling out beneficial research	-

Perceived benefits	Enhanced license-to-operate for the RFO.	Enhanced freedom of research under responsibility criteria	Prevention of (future) harm	Enhanced risk management in relation to R&I projects
Cost-effectiveness evaluation	Not formalized; based on ongoing practical experience	Ongoing performance evaluation	Part of top management procedures	Experience-based
Cost-effectiveness perceptions	"Well worth it"	Unknown (first evaluation still due)	It is mostly "a feeling"	"Positive impacts"

The following cross-case observations are of specific importance for the purpose of designing a common framework for evaluating the cost-effectiveness of ethics assessment and guidance interventions and for reflecting on the risks and benefits involved:

- None of the organisations studied participate in any kind of systematic sector-wide evaluation procedure regarding the cost-effectiveness of ethics interventions.
- Only the industry case has a systematic approach to cost-effectiveness evaluation of ethics interventions. In this case, cost-effectiveness evaluation of the ethics intervention is a part of the general quality management of the organisation.
- The industry case is also the only one where ethics assessment is seen as part of a broader program of ethics interventions throughout the lifecycle of projects and production.
- In the three cases that deal with public organisations, perceptions regarding the cost effectiveness of the ethics interventions implemented in each case are largely experience-based.
- None of the organisations have chosen to explicitly risk-benefit analyse the ethics intervention itself. Instead, the ethics intervention is seen as part of a risk assessment and risk management approach.
- Nevertheless, perceptions of risk rotate around an axis that spans from risks in relation to the external social and environmental environment (damage done, reputation lost) to the risks of losing out on opportunities.
- Perceived benefits of ethics assessment range from securing the organisations' license-to-operate to enhancing its risk-management capability – concerns that are arguably two sides of the same coin.

All in all these observations corroborate the literature-based conclusions that reliable and comparable data regarding the effectiveness of ethics assessment is neither being used nor produced in a systematic fashion. Instead, ethics interventions are most often implemented on the basis of more general considerations regarding the risks that stem from non-assessment and the benefits of organisational license-to-operate to be gained from its implementation. The cases indicate that where such practices are implemented, they are perceived – on the basis of experience – as worthwhile. This indication, however, may be the direct result of selection bias (the cases being selected as best practice examples) and as such have only minimal general significance.

5 COMPARISON WITH OTHER FORMS OF R&I ASSESSMENT

When considering whether to implement ethics assessment in an organisation, it may be useful to consider the knowledge produced by such assessments in comparison with competing analytical approaches. Relevant to such considerations, the EST Frame project[30] performed a comparative study of 98 assessments of emergence science and technology from five different assessment 'domains': economic assessment, risk assessment, impact assessment, technology assessment, and ethics assessment. Among the observations criteria used in the analysis was a registration of the degree of explication of ethical issues in the assessment (rated on a Likert scale from 1-5) as well as whether or not the assessments took social and environmental impacts of the R&I under assessment into account.

These results tell us something about the comparable virtues of ethics assessment vis-à-vis other assessment types. As shown in the table below, ethics assessment – perhaps unsurprisingly – far outperform the four other assessment types when it comes to explicating ethical issues. This would indicate that the *a priori* assumption that ethics assessment excels in the identification of ethical issues vis-à-vis competing assessment practices is also observable *a posteriori*. When it comes to the identification of social impacts, ethics assessment is also scores top marks. The degree of consideration given to social impacts in the selected assessment is thus equal to that of the group of assessments from the impact assessment domain and slightly outperforms the assessments form the technology assessment domain. However, with regard to the consideration of environmental impacts, ethical assessments are outperformed significantly by assessments produced in the impact assessment and technology assessment domains.

	Economic assessment	Risk assessment	Impact assessment	Technology assessment	Ethics assessment
Ethics analysis (1-5)	1,6	1,8	3,6	2,1	4,5
Social impacts	50*	45%**	100%	80%	100%
Environmental impacts	50%	50%	80%	100%	66%

Table 4: EST Frame comparison of R&I assessments

** Social impacts are separated from economic impacts in this analysis. If the two are conflated the mean for economic assessments is 1,0 and the mean for other assessment domains is also higher.*

*** Social impacts are separated from health impacts in this analysis. If the two are conflated the mean for the selected assessment is 0,7.*

These findings would seem to corroborate the assumption that ethical assessment is an effective intervention for organisations seeking to identify ethical and social issues upfront, but that ethical issues need not be taken as proxy for longer-term environmental impacts for which other assessment domains would seem better suited.

[30] http://estframe.net/

6 CONCLUSIONS

This report has drawn together a number of different data sources in order to arrive at a better understanding of how best to evaluate the costs, risks, effects and benefits of ethics assessment and ethics guidance in R&I in ways that take into account the quality of such ethics interventions in an appropriate manner. On the basis of the analyses presented in the report, we may draw the following conclusions about the conceptualization and implementation of such evaluation.

Conceptualization

- Ethics interventions such as ethics assessment and guidance are best understood as **elements of ethics programs** that also include leadership commitment, ethics training, ethics hotlines, and other similar organisational interventions.
- The operational costs of ethics assessment and ethics guidance can meaningfully be categorized together as '**proactive prevention cost**s' and should be weighed against the 'reactive non-compliance costs' and the risks they represent
- Ethics programs should thus be seen as **an element of risk and quality management**.

Documented effectiveness

- Ethics assessment, perhaps unsurprisingly, stands out against a background of other types of assessment as **best able to identify ethical problems**.
- On their own, individual interventions such as ethics assessment or guidance may at best be **moderately effective** in preventing ethical lapses
- When implemented as part of organisation-wide ethics programs, even interventions that have no measurable effect on their own contribute to the **cumulative effectiveness** of the program as a whole towards the creation of a 'culture of ethics' with **high significance for the prevention of ethical lapses**.
- External regulation has **very limited effects** on organisational culture.

Risks connected with ethics assessment

- Ethics assessment is generally held to **lower the risk of undesirable social consequences** from R&I, while also entailing a risk of **missed opportunities.**

Current evaluation practice

- Industrial organisations seem to be **leading the development of organisation-wide program approaches to ethics interventions** – although this is only indicative.
- Monitoring of ethics intervention effectiveness is almost only found in the field of ethics training, and even here it **is not done systematically.**

Implications for SATORI D5.2

- The costs, risks, effects and benefits of ethics assessment and ethics guidance should be evaluated as part of a program approach.
- European R&I spans across many different organisation types, which will bear different costs and risks while enjoying different benefits from ethics interventions. This should be taken into account in an evaluation framework.
- Systematic evaluation of ethics interventions could be part of the framework.

7 ARTICLES CITED IN LITERATURE STUDY

Article no.	Search terms	Source	Title
01	Effectiveness of ethic*	WoS	Maier M, Kälin S. Ethik-Cafés in der geriatrischen Langzeitpflege: halten sie, was sie versprechen?. Ethik in der Medizin. 2016 Mar 1;28(1):43-55.
02	Effectiveness of ethic*	WoS	Steele LM, Mulhearn TJ, Medeiros KE, Watts LL, Connelly S, Mumford MD. How do we know what works? A review and critique of current practices in ethics training evaluation. Accountability in research. 2016 May 9(just-accepted)
03	Effectiveness of ethic*	WoS	Kaptein M. The effectiveness of ethics programs: The role of scope, composition, and sequence. Journal of Business Ethics. 2015 Dec 1;132(2):415-31.
04	Effectiveness of ethic*	WoS	Vynckier T, Gastmans C, Cannaerts N, de Casterlé BD. Effectiveness of ethics education as perceived by nursing students Development and testing of a novel assessment instrument. Nursing ethics. 2014 Aug 4:0969733014538888.
05	Effectiveness of ethic*	WoS	May DR, Luth MT. The effectiveness of ethics education: A quasi-experimental field study. Science and engineering ethics. 2013 Jun 1;19(2):545-68.
06	Effectiveness of ethic*	WoS	He L, Ho SJ. Monitoring costs, managerial ethics and corporate governance: A modeling approach. Journal of Business Ethics. 2011 Apr 1;99(4):623-35.
07	Effectiveness of ethic*	WoS	Schiff E, Ben-Arye E, Shilo M, Levy M, Schachter L, Weitchner NA, Golan O, Stone J. Touching ethics: Assessing the applicability of ethical rules for safe touch in CAM—Outcomes of a CAM (Complementary and Alternative Medicine) practitioner survey in Israel. Complementary therapies in medicine. 2011 Feb 28;19(1):12-8.
08	Effectiveness of ethic*	WoS	Thirunavukarasu P, Brewster LP, Pecora SM, Hall DE. Educational intervention is effective in improving knowledge and confidence in surgical ethics—a prospective study. The American Journal of Surgery. 2010 Nov 30;200(5):665-9.
09	Effectiveness of ethic*	WoS	Malloy DC, Sevigny P, Hadjistavropoulos T, Jeyaraj M, McCarthy EF, Murakami M, Paholpak S, Lee Y, Park I. Perceptions of the effectiveness of ethical guidelines: an international study of physicians. Medicine, Health Care and Philosophy. 2009 Nov 1;12(4):373-83.
10	Effectiveness of ethic*	WoS	Schmaling KB, Blume AW. Ethics instruction increases graduate students' responsible conduct of research knowledge but not moral reasoning.

			Accountability in Research. 2009 Sep 24;16(5):268-83.
11	Effectiveness of ethic*	WoS	Antes AL, Murphy ST, Waples EP, Mumford MD, Brown RP, Connelly S, Devenport LD. A meta-analysis of ethics instruction effectiveness in the sciences. Ethics & Behavior. 2009 Sep 17;19(5):379-402.
12	Effectiveness of ethic*	WoS	Kemp KR, Thompson JC, Jefferson T, Ong B, Sharkey CD, Jeffries J, Nuñez L. Ethics training for military medical trainees: The Brooke army medical center experience. Military medicine. 2008 Oct;173(10):968-74.
13	Effectiveness of ethic*	WoS	Chen YY, Chen YC. Evaluating ethics consultation: randomised controlled trial is not the right tool. Journal of Medical Ethics. 2008 Aug 1;34(8):594-7.
14	Effectiveness of ethic*	WoS	Kligyte V, Marcy RT, Sevier ST, Godfrey ES, Mumford MD. A qualitative approach to responsible conduct of research (RCR) training development: Identification of metacognitive strategies. Science and Engineering Ethics. 2008 Mar 1;14(1):3-1.
15	Effectiveness of ethic*	WoS	Olivier S. Ethics review of research projects involving human subjects. Quest. 2002 Aug 1;54(3):196-204.
16	Effectiveness of ethic*	WoS	Nolan PW, Markert D. Ethical reasoning observed: a longitudinal study of nursing students. Nursing Ethics. 2002 May 1;9(3):243-58.
17	Effectiveness of ethic*	WoS	Green S, Weber J. Influencing ethical development: Exposing students to the AICPA code of conduct. Journal of Business Ethics. 1997 Jun 1;16(8):777-90.
18	Effectiveness of ethic*	WoS	Fischer GS, Arnold RM. Measuring the effectiveness of ethics education. Journal of general internal medicine. 1994 Nov 1;9(11):655-6.
19	Effectiveness of ethics	GS	Garcia-Sanchez IM, Rodriguez-Dominguez L, Gallego-Alvarez I. Effectiveness of ethics codes in the public sphere: Are they useful in controlling corruption?. International Journal of Public Administration. 2011 Feb 14;34(3):190-5.
20	Effectiveness of ethics	GS	Demmke C, Moilanen T. Effectiveness of good governance and ethics in central administration: evaluating reform outcomes in the context of the financial crisis. European Institute of Public Administration [cited 8 September 2014]. Available from Internet: https://www. oeffentlicherdienst. gv. at. 2011 Dec.
21	Effectiveness of ethics	GS	Fletcher-Brown D, Buono AF, Frederick R, Hall G, Sultan J. A Longitudinal Study of the Effectiveness of Business Ethics Education: Establishing the Baseline. Journal of Academic Ethics. 2012 Mar 1;10(1):45-56.
22	Effectiveness	GS	Bradbury MD. Toward a cost-effectiveness assessment

	of ethics		of state ethics commissions: An analysis of enforcement outputs. Public Integrity. 2007 Sep 1;9(4):333-47.
23	Effectiveness of ethics	GS	Murphy PR, Boatright JR. Assessing the effectiveness of instruction in business ethics: A longitudinal analysis. Journal of Education for Business. 1994 Aug 1;69(6):326-32.
24	Effectiveness of ethics	GS	Maesschalck J, De Schrijver A. Researching and improving the effectiveness of ethics training. Lawton, A. van der Wal, Z. & Huberts, L.(Eds.). Ethics in Public Policy and Management: A global research companion. New York: Routledge. 2015:198-212.
25	Effectiveness of ethics	GS	Smith G. Assessing the effectiveness of ethics legislation in influencing parliamentary attitudes toward corruption: a cross national comparison between the UK and Ireland. Journal of Public Affairs. 2011 May 1;11(2):100-10.
26	Effectiveness of ethical	GS	De Waegeneer E, Van De Sompele J, Willem A. Ethical Codes in Sports Organisations: Classification Framework, Content Analysis, and the Influence of Content on Code Effectiveness. Journal of Business Ethics. 2015:1-2.
27	Effectiveness of ethical	GS	De Waegeneer E, Devisch I, Willem A. Ethical Codes in Sports Organisations: An Empirical Study on Determinants of Effectiveness. Ethics & Behavior. 2016 May 9:1-22.
28	Effectiveness of ethical	GS	Chinniah A. A Conceptual Study on an Effectiveness of Ethical Standards for Preparers of Financial Statements and Fraud Risk Management. CLEAR International Journal of Research in Management, Sciences & Technology. 2015 Jul 1;5(10).
29	Benefits of ethic*	WoS	Robertson C, Geiger S. Moral philosophy and managerial perceptions of ethics codes: Evidence from Peru and the United States. Cross Cultural Management: An International Journal. 2011 Aug 2;18(3):351-65.
30	Benefits of ethic*	WoS	Gilley KM, Robertson CJ, Mazur TC. The bottom-line benefits of ethics code commitment. Business Horizons. 2010 Feb 28;53(1):31-7.
31	Benefits of ethic*	WoS	Francis R, Armstrong A. Ethics as a risk management strategy: The Australian experience. Journal of Business Ethics. 2003 Jul 1;45(4):375-85.
32	Benefits of ethic*	WoS	Van Zyl E, Lazenby K. Ethical behaviour in the South African organisational context: Essential and workable. Journal of Business Ethics. 1999 Aug 1;21(1):15-22.
33	Benefits of ethics	GS	Gagne ML, Gavin JH, Tully GJ. Assessing the costs and benefits of ethics: Exploring a framework.

			Business and society review. 2005 Jun 1;110(2):181-90.
34	Negative impact of ethic*	WoS	Atabay G, Çangarli BG, Penbek Ş. Impact of ethical climate on moral distress revisited Multidimensional view. Nursing ethics. 2014 Aug 7:0969733014542674.