Assessing the cost-effectiveness and risk-benefit of ethics assessment in relation to research and innovation: a decision-maker's guide

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 – Research Centre of the Slovenian Academy of Sciences and Arts), Julius Griessler (Secretariat of the Austrian Bioethics Commission), Lea Amby Ottosen (The Danish Board of Technology Foundation)***,** *Lise Bitsch (the Danish Board of Technology Foundation), Nina Bryndum (the Danish Board of Technology Foundation), Rok Benčin (ZRC SAZU - – Research Centre of the Slovenian Academy of Sciences and Arts), Rosella Cardone (Ericsson),*

Date of submission/publication

Deliverable D5.2

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

Contents

ABSTRACT

This report proposes **a methodology outlining when and where different approaches to cost-effectiveness assessment (CEA) and risk-benefit analysis (RBA) may meaningfully be applied to ethics assessment (EA) of research and innovation (R&I).** The aim of this methodology is two-fold. On the one hand the purpose is to guide decision-makers through the process of weighing costs and risks against effectiveness and benefits in relation to implementation of EA in organizations that are in one way or the other involved in R&I. On the other hand the purpose is also to prevent EA from being implemented in a manner where misplaced concerns about running costs and short-term risks undermine the efforts of the Ethical Assessment Unit (EAU) to guide research performing and funding organizations away from ethics breaches, staekeholder backlash, and negative impacts on society towards positive impacts and sustained levels of trust and legitimacy. To achieve this dual goal, the methodology presented herein identifies both appropriate pathways and blind alleys in the interface between CEA and RBA methodology and EA institutions and practices. More specifically, the methodology helps the decision-maker to stay clear of a largely ineffectual focus on tweaking the running costs of ethics assessment practices and to focus instead on achieving most effectively the goals that ethics assessment aims to attain while staying within a reasonable cost level.

EXECUTIVE SUMMARY

This report provides a guide by which decision-makers considering the implementation of ethical assessment in relation to R&I projects or programs may break down the questions of cost-effectiveness and risk-benefit of ethics assessment into manageable chunks. Following this guide, decision-makers may circumvent the pitfalls of an overly simplified application of cost-effectiveness and risk-benefit considerations to ethical assessment of R&I.

The report provides an overall framework of interlinked assumptions about the costs and risks, effects and benefits in relation to ethical assessment and ethical impact assessment of R&I. This framework helps to clarify that while operational costs of ethical assessment units are easily quantifiable and most of the other costs and benefits involved in ethical assessment of R&I are not, this should not trick decision-makers into treating operational costs as the only relevant variable.

The guide furthermore provides food for thought regarding the possible benefits of implementing ethical assessment as part of a broader ethics program; as part of a risk management strategy; and as a necessary compliment to external regulation.

The main risk that arises when applying ethical assessment to R&I is that research in 'grey areas' may not be approved. But this risk should be weighed against the possibility that ethical assessment, by shaping R&I plans, may help to point projects or programs towards new application areas or induce design improvements, which would otherwise have been overlooked. The risks arising from the application of ethics assessment should also be weighed against the risks stakeholder backlash and of human rights violations, both of which can go unchecked under ordinary quality and risk management approaches that do not specifically focus on ethical issues. From this risk management perspective, funding ethical

assessment may be seen as a wager on the potential for new opportunities to arise out of it and as an investment in quality, stakeholder management, and the protection of human rights.

All of this should not be seen as a sales pitch for ethical assessment. Rather, this guide provides concrete reflections relevant to the implementation of ethics assessment in R&I organizations or networks. For example, the guide discusses how to balance cost models against independence, reliability and accountability of the ethical assessment unit. These are the types of reflection necessary for the cost-effective implementation of ethical assessment, and the SATORI team hopes that the guide will help decision-makers through real world implementation considerations.

1 A PRACTICAL METHODOLOGY FOR ASSESSING COST-EFFECTIVENESS AND RISK-BENEFIT OF ETHICS ASSESSMENT

This report proposes **a methodology outlining when and where different approaches to cost-effectiveness assessment (CEA) and risk-benefit analysis (RBA) may meaningfully be applied to ethics assessment (EA) of research and innovation (R&I).** The aim of this methodology is two-fold. On the one hand the purpose is to allow decision-makers to weigh costs and risks against effectiveness and benefits in relation to implementation of EA in organizations that are in one way or the other involved in R&I. On the other hand the purpose is also to prevent EA from being implemented in a manner where misplaced concerns about cost and risk undermine the efforts of the Ethical Assessment Unit (EAU) and compromise the real and perceived quality of EA. To achieve this goal, the methodology presented herein identifies both appropriate pathways and blind alleys in the interface between CEA and RBA methodology and EA institutions and practices.

1.1 CONTEXT

The narrow context of this report is that it 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 organization involved in R&I. The approach to EA taken by the SATORI project seeks to expand the concept of EA beyond the scope of organizational-internal research integrity and ethical behaviour by also taking into account the ethical aspects of the downstream impacts of R&I (see SATORI D4.1)[i]. The project thus aims both to create a framework within which the practices of EAUs can be compared and to promote the extension of the scope of EA practices to include ethical assessment of the impacts of R&I on society and the environment.

The broader context in which the SATORI project has its place is one in which society's reliance on R&I as a means of addressing societal challenges continues to grow while trust in the integrity and usefulness of R&I is itself challenged[ii].Against this background, comparative analysis has shown that ethical assessment is currently spreading in geographical, disciplinary as well as sectoral terms: from core Europe to new member states; from medical research to all scientific disciplines; and from national institutions to local governments, funding agencies and industry (see SATORI D1.1). The spread of EA practices and EAU institutionalization is indicative of a broadly shared perception that ethical reflection may serve as a necessary safeguard against breaches of trust in the relationship between R&I organizations and the public. Building on this perception, Commissioner Moedas in 2015 called for a European initiative on research integrity[iii].

1.2 OBJECTIVES

Within this context this report presents the outcome of work package 5 (WP5) of the SATORI project, which has explored the relevance and possible application of methods of CEA and RBA to EA practices. The ambition of this work package is to support considerations by decision-makers regarding how to design and implement EA so as to get the most value-for-money from EA with regard to improving the ethical standards of R&I practices and

outcomes. In this regard the work package has sought to understand when and where CEA and RBA can provide reliable answers regarding the cost-effectiveness of EA practices and the balance between risks and benefits pertinent to such practices.

The objective of this report is to present the findings of the work package in a systematic, but hands-on manner, so as to provide useful assistance for decision-makers and their staff in the process of gathering decision-supporting evidence useful for the design and implementation of EA.

To this end the report will:

- Outline known means of maximizing cost-effectiveness in EAUs and EA practice;
- Show how EA may be adopted alongside other ethics interventions as elements of organizational quality control to support a 'culture of ethics';
- Indicate how EA may be integrated with risk management in the relationship between organizations and their environment;
- Evidence the necessity of organization-internal means of supporting ethical behaviour in contrast to external legislation;
- Explain why certain conceivable applications cost-effectiveness analysis to EA, which are likely to provide only pseudo-evidence, represent blind alleys to be avoided by decision-makers.

1.3 EVIDENCE BASE

The work package upon which this report is based has explored in various ways the problem of how to apply methods of cost-effectiveness and risk-benefit analysis to EA in a useful and relevant manner. After an initial phase of explorative desktop studies and interactive cases studies, the work package held an expert and stakeholder workshop exploring dos and don'ts in the application of cost-effectiveness and risk-benefit analysis to EA in relation to different types of EAUs. The outcomes of this workshop (see SATORI D5.3) helped to shape a second, more systematic literature review and to put the outputs of six case studies in the proper context. The resulting overview of conceptual and practical issues related to the application of cost-effectiveness and risk-benefit analysis to EA practice was reported separately (see SATORI D5.1). In addition to the work carried out in WP5 this report also draws on results gathered in work package 4 (WP4), which has explored ways of maximizing the effectiveness of ethical assessment units on the basis of practitioners' interviews and literature studies (see SATORI D4.1). Readers interested in exploring the underpinnings of this report are invited to download these reports at http://satoriproject.eu.

2 OVERALL APPROACH

EA may be said to entail two major categories of costs. The first category is the operational costs of the R&I practitioners and the EAU involved in assessing the planned conduct of R&I projects and possibly (as proposed in SATORI D4.2) the ethical dimensions of the foreseeable impacts of R&I projects and processes. This first cost category ultimately boils down to salaries/stipends and ordinary office overheads. The second major category is the costs incurred by R&I practitioners and organizations in order to achieve compliance with the recommendations of the EAU. This second cost category is much broader and cannot be defined beforehand. Such costs range from the costs of improved data security infrastructures to the costs of providing animals subjected to laboratory research with an artificial environment that mimics their natural one. Any organization involved in R&I practice must ultimately calculate such compliance costs as an element of the cost of doing business.

The costs entailed by EA must, however, be weighed against the costs of non-compliance. Such costs include the costs of civil suits, the costs of retracted research results or products, the costs of lowered productivity due to moral distress among workers, and the costs of lost funding and business opportunities due to reputational damage and/or missed identification of opportunities inherent in ethical R&I design.

This latter point is central both to the spread of EA and to SATORI's suggestion to expand EA practice to include the assessment of the ethical dimension of the impacts of R&I. Not only can EA contribute to the avoidance of costs incurred in the case of ethical breaches and negative impacts from R&I on the economic, social and physical environment; EA may also improve R&I processes by directing them towards societally acceptable versions of the research results and/or products they wish to produce.

EA should thus not only be seen as a safeguard against crossing red lines, such as human rights, it can also serve as an important element in the quality control and risk management of organizations involved in R&I.

That being said, the existing evidence on the effectiveness of different approaches to EA is all but non-existent. While smaller organizations may be reluctant to develop in-house EA capacities due to costs, and while cost may be mobilized as an argument against publically funded EA units, in large public or private organizations the operational costs of EAU is generally dwarfed not only by the budgets of R&I projects but also by the costs necessary to train R&I practitioners and monitor their behaviour as well as the open category of ethical compliance costs. For this reason, existing research on the effectiveness of ethics interventions center on ethical guidance and training. Based on currently available evidence considerations about the cost-effectiveness of EAUs therefore remain qualitative and learning-oriented. From a purely scientific point of view, this would seem to indicate a need for improved monitoring. However, from a practical point of view at least the operational costs of EAUs may be considered too low to merit elaborate – and hence costly - monitoring schemes.

Ultimately, the question of the operational costs of EAUs is not so much one of quantity, but one of who pays, which influence the payer has over the outcomes of the EAs, and how the EAU works to achieve trustworthy identification of and solution to ethical issues in R&I.

2.1 ASSUMPTIONS ABOUT EA IN CONTEXT

In a nutshell, the approach presented in this report, as illustrated below, assumes the following connections between costs, risks, effects, and benefits.

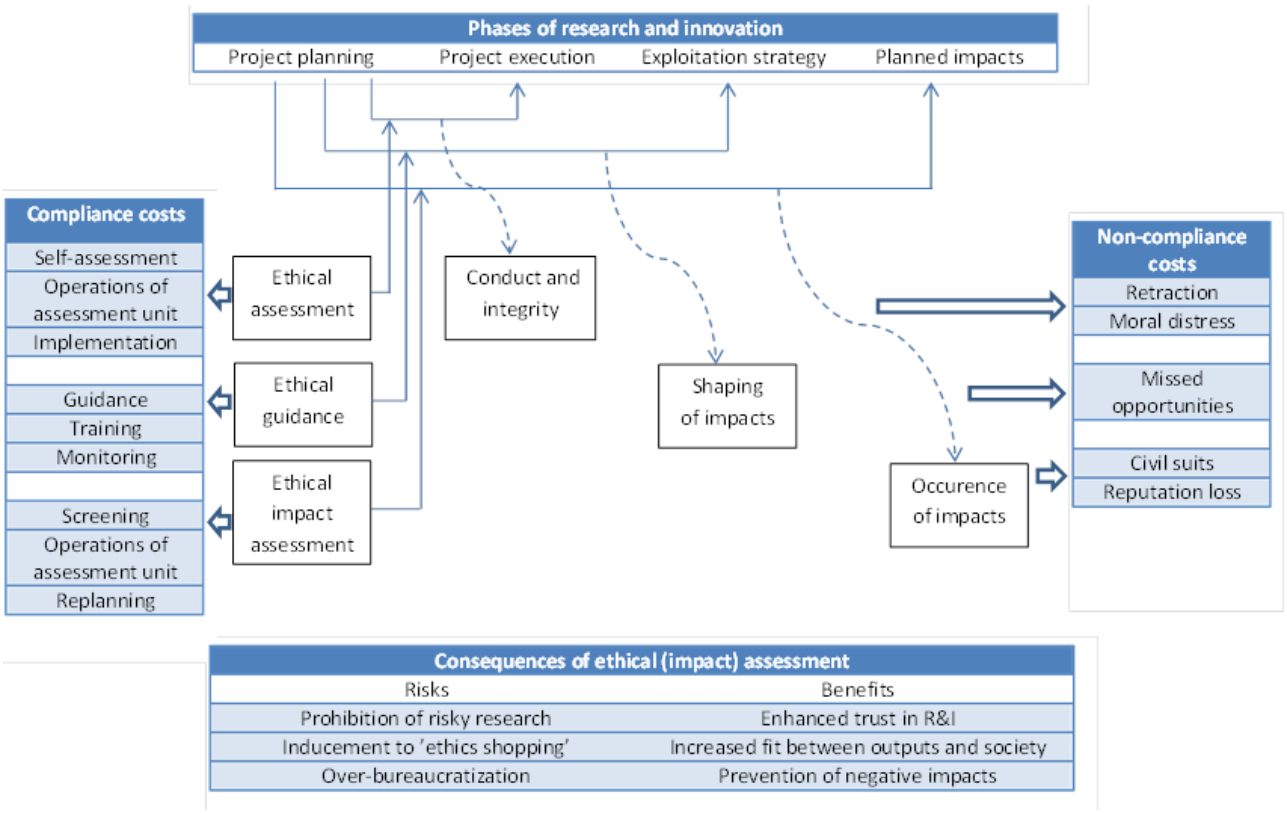

Figure 1: Connections between costs, risks, effects and benefits pertaining to the implementation of EA in relation to R&I.

Ethical assessment as it is currently implemented (see SATORI D1.1) pertains first and foremost to the conduct and integrity of people and organizations involved in the project. To assess planned projects entails operational costs of ethical assessment units and/or practitioner self-assessment as well as the costs of implementing recommendations. If recommendations are well implemented, however, ethical breaches at individual and/or organizational level may be avoided, which may in turn lead to the avoidance of non-compliance costs such as retraction of research and products and productivity costs due to moral distress. Ethical assessment bears the risk that seemingly risky research or innovation may be prohibited and may induce teams and organizations to engage in 'ethics shopping', i.e. to seek funding and a license to operate in less restrictive countries or regions. But if ethical assessments are allowed to influence project planning and execution it may help to enhance trust between R&I practitioners and organizations on the one hand and R&I stakeholders on the other

Ethical guidance throughout project execution and results exploitation is not treated specifically in the SATORI project, but represents major compliance costs such as guidance by leadership, ethics training, and monitoring of conduct. Ongoing ethics guidance, however,

may conversely help to shape the impacts of R&I by guiding the R&I process towards opportunities inherent in ethical design

Finally, **ethical impact assessment** represents a means of upstream ethical guidance where exploitation strategies and the planned and unplanned impacts it is likely to produce are assessed from an ethical perspective. Ethical impact assessment in its full form may expand the cost of ethical assessment significantly, but precisely for this reason the SATORI project proposes a step-wise threshold analysis to avoid over-bureaucratization and unnecessary delays (see SATORI D4.2 and D7.1). The potential benefit of ethical impact assessment is to avoid already before the commitment of significant R&I resources the costs of civil suits and loss of reputation, which may be incurred in case of negative impacts occurring.

2.2 On the calculability of cost-effectiveness and risk-benefit ratios

The calculability of cost-effectiveness and risk-benefit ratios pertaining to EA is highly dependent on uncertainties pertaining to the realization of the potential benefits of the R&I project in question. The closer to basic research the R&I project is, the greater the uncertainty of the benefits from the project. On the other hand, the closer to serial production of innovative products, the easier it will be to quantify and possibly monetize costs and benefits to different actors beforehand. But even for high-probability innovation projects, the more competition in the market place between the solution produced by the project and other comparable solutions, the more uncertainty is introduced with regard to the realization of the benefits of the project. These uncertainties originating in the R&I project itself directly and negatively affect the possibility of calculating quantitative cost-benefit ratios of investments in EA/EIA implementation.

Furthermore, the organizational goals for which EA and EIA will typically be implemented – avoidance of non-compliance costs and the realization of benefits – are only ever realized as the result of a multiplicity of factors, which include the excellence of the researchers involved, the quality of management and coordination, market factors, political factors, and many others[iv]. For this reason, attributing the benefits of the R&I project to the EA/EIA implementation is all but impossible, even in cases where the implementation will have been experienced as making a significant difference. This further complicates the matter of calculating quantitative cost-benefit ratios for the investment.

Finally, the intrinsic and absolute value of protection human rights means that monetizing the willingness of research subjects to accept violations of those rights is inappropriate *a priori* for any public body or private organization funding research and innovation in polities that are constitutionally obliged to defending human rights. This means that even if an when the long-term impacts of R&I would become calculable, the running costs of ethics assessment would remain tied to an area of non-negotiable (moral) value.

Since the ambition here is not to make calculable the overall cost-benefits of R&I projects, but rather to make possible specific considerations of the cost and effects, risks and benefits pertaining to EA, the approach suggested here recommends a retreat from any grand calculus of EA costs and benefit and suggests instead to address specific, more manageable areas of the question. Suggested approaches to these specific areas follow in the remainder of the report.

2.3 On the appropriateness of Willingness-To-Accept (WTA) Indicators

The retreat from a grand calculus of EA costs and benefits recommended above in turn eliminates the appropriateness of a range of conceivable Willingness-To-Accept (WTA) and Willingness-To-Pay (WTP) indicators.

Funding organizations that implement EA procedures for research and innovation project proposals incur running costs for administrative staff and in some cases for internal ethics experts. If one were to take a short-term perspective, these costs could be weighed against the willingness of the funding organization to pay to avoid ethical breaches in the projects they fund. This willingness would most likely be linked to perceived middle-term costs of stakeholder backlash and long-term costs of missing out on societal benefits generated by the R&I project due to backlash and demands for retraction. However, it is the first step that makes this calculus impossible. Even beginning to assess the funding organizations' willingness to pay to avoid human rights violations (along with other absolute policy priorities) implies that on the other side of the table is a human being or a population willing to accept certain levels of rights violation or subjection to negative effects from R&I for a certain degree of compensation. This implication, however, is highly problematic; in fact inappropriate. The European Convention of Human Rights and its many implementations in European law do not allow for the willing alienation of human rights against compensation. This is in contrast to the contact-based US system of negotiated rights. So it would be inappropriate to consider the willingness of human subjects to accept rights violations as part of a cost-effectiveness calculus aimed at EA practice.

Mandated EA procedures impose administrative burdens on the organizations that present project proposals. These costs may be calculated using the EU's Standard Cost Model. In a short-term perspective, these costs could be weighed against the willingness of the organization making the proposal to pay for a chance at gaining funding for its project. This willingness to pay could then be added to the willingness of the same organization to pay for the prevention of a stakeholder backlash. However, applying an 'administrative burdens' perspective on ethics assessment runs into the same problem as mentioned above, namely the absolute value and the unquestionable obligation to protect human rights. A calculus carried out according to the Standard Cost Model would therefore risk crossing lines of appropriateness and should thus be avoided in relation to ethics assessment.

2.4 Recommended: A proportionality approach to cost-effectiveness of EA

Based on the above considerations, we recommend adopting a conscious de-coupling between the running costs of ethics assessment units and the effects that ethics assessment has in the short, middle and long terms.

Instead, we recommend adopting a proportionality approach to managing the costs of ethics assessment. Adopting a proportionality approach to the cost management of ethics assessment means to take into account the orders of magnitude that separate running costs of ethics assessment units from the costs of research and innovation, the costs of potential positive or negative effects on society, and the absolute value of human rights protection. At the same time, this approach will relegate the question of effectiveness of ethics assessment to the

ongoing dialogue between different groups of ethics assessors and between ethics assessors and other stakeholders involved in the ethics assessment process. This approach follows current trends in related fields such as corporate social responsibility, where appraisal costs are also seen as a necessary and relatively small investment, which helps organizations to steer clear of much larger risks[v]. This approach also takes into account economic modelling, which indicates that the cost of gathering the data that would be necessary for a 'hard' evaluation of cost-effectiveness of ethics interventions is disproportionate to the potential gains from this knowledge[vi]; a research strand which also ends up ultimately recommending an approach that relies on negotiation over professional standards and norms.

Precisely what will be deemed 'proportionate' will necessarily be a matter of debate for each organization implementing ethics assessment procedures as part of their research and innovation management structure. The overall logic, however, is that the running costs of self-assessment and assessment of research proposals and innovation projects by professional ethics assessors should be weighed not only against the short-term overall costs of preparing proposals and projects, but also against those medium-term costs which are of an entirely different magnitude – the total investment in each project and the potential costs of stakeholder backlash – long-term costs – potential benefits and potential negative impacts, and absolute values – the protection of human rights. This approach dictates that ethics assessment is a necessary part of any management structure around research and innovation while the costs must remain 'proportionate' – as evaluated by stakeholders in a qualitative dialogue – to the level of investments, the magnitude of potential benefits, and the risks involved.

As a rule-of-thumb total quality appraisal costs in a successful company will be as high as 15-20 pct. of total revenue[vii]. Ethics assessment seems to make up only a fraction of those costs. In the case studied that were done in preparation of this guide, none of the persons interviewed were able to provide a concrete estimate of the costs of their ethics assessment practice as a percentage of total running costs. Nevertheless, they all maintained that ethics assessment was worth the cost. Taking this assessment seriously, we maintain that a dialogical assessment of proportionality in each case is the best and most appropriate approach to managing the cost of ethics assessment in research and innovation.

A pragmatic solution to reaching a proportional cost level is to carry out a threshold analysis as a first step in any given set of procedures for ethics assessment. With a threshold analysis it is possible to assure that each research and innovation project or proposal only accrues a level of ethics assessment costs, which is proportionate to the risks involved in the project or proposal. This approach is adopted in the SATORI framework[viii] and is already implemented to a greater or lesser degree in many ethics assessment procedures; one notable example being the self-assessment embedded in the H2020 proposal template.

3 MAXIMIZING COST-EFFECTIVENESS OF ETHICAL ASSESSMENT UNITS

The ethical assessment unit (EAU) and the effectiveness of its procedures are crucial to organizations that aim to reap the benefits of not only ethics assessment but also of a culture of ethics more broadly. Even if these benefits are difficult to quantify, it is intuitively evident that the functions provided by an ethical assessment unit is a key element in the construction of a reliable organizational strategy for achieving a culture of ethics.

To be sure, the functions assigned to EAUs are multiple and vary across different contexts. To begin with, the concept of the 'ethical assessment unit' is a generic one adopted by the SATORI project to refer to a multitude of different types of organizations or sub-organizations that perform ethical assessment of R&I either as a primary or secondary service. Such units include: **scientific integrity boards** internal to universities and **research ethics committees** (RECs) that support research institutions from the outside; **national science academies** (NSAs); **research funding organizations** (RFOs); **national ethics committees** (NECs); academic and professional **associations**; **civil society organizations** (CSOs); and units dedicated to **corporate social responsibility** (CSR) in industry.

While these EAU types work with different mandates, functional commonalities do exist (See SATORI D1.1). All ethical assessment thus ideally provide **a point in the flow of decision-making** where the desirability of an R&I project or program is considered from the point of view of **the general interests and values of society** rather than that of the **special interests of those who perform, fund, govern or benefit directly** from the project or program.

The underlying mechanisms through which each EUA performs this function also vary from one context to the other. However, any EAUs must be able to establish and maintain:

- *Independence* from the strategic considerations of the actors involved
- *Reliability* in the identification of ethical issues
- *Accountability* to the ethical profession, democratic institutions, and the public.

When considering the cost-effectiveness of EAUs, the factors to be taken into account are on the one hand the operational costs of the work of the unit and on the other hand the degree to which the prerequisites for the unit to perform its functions effectively are fulfilled. For example, organizations considering the adaptation of ethics assessment might consider foregoing the establishment of an EAU altogether, opting instead for self-assessment on the part of R&I leaders and managers. But while this would lower the costs of assessment considerably it would also violate the independence criterion for the performance of the function of an EAU. The example illustrates that there are limits to the flexibility of the EAU role beyond which cost considerations could lead to the wholesale dismantling of the function.

On the other hand, the flexibility of the EAU role also means that there is much that practitioners and organizational stakeholders may learn from each other across different organizational settings. In the following, we present qualitative considerations on how to maximize cost-effectiveness in EAUs as expressed by practitioners and organizational stakeholders. See also SATORI D4.1 and D4.2 for further detail.

3.1 CHOOSING AN EAU COST MODEL

Decision-makers considering the implementation or improvement of an EAU may want to consider different cost models.

The two main variables that determine the cost models of different EAUs are the status of the EAU and the type of remuneration that ethics assessors receive when working in it. The EAU may either have independent status or be in-house. Ethics assessors may receive fixed salaries (rarely full-time), per-assessment fees, or no remuneration at all in the case of voluntary participation and/or participation as part of a broader job description. Each of the six resulting logical possibilities may be recognized among existing EAUs.

	Salaries	**Fees**	**No specific cost**
In-house EAU	Dedicated in-house unit	Ongoing in-house assessment program	Distributed in-house assessment practice
Independent EAU	Permanent independent body	Network-based assessment capacity	EA integrated in other services

Table 1. Cost model typology for EAUs

For some types of EAUs there is a strong correspondence with a specific cost model. For example, national ethics committees will most likely have independent status with members receiving fixed (although not necessarily full-time) salaries. For other types there is greater diversity with regard to cost models. Scientific integrity boards may, for instance, be placed either in-house in a specific faculty or shared between faculties while its staff may participate voluntarily or for a per-assessment fee.

Choosing between different cost models is a decision that will be made in the intersection between one the one hand existing organizational and employment regulation, norms and practices and on the other hand quality considerations. The former will be different in each case. Some of the latter considerations are outlined below.

3.2 SECURING INDEPENDENCE

An EAU should be *composed* so as to ensure independence between each ethics assessors and project/program stakeholders, i.e. the R&I practitioners involved in projects, the funders who decide strategic investments and governors who promote R&I. The EAU as a unit should furthermore be *established* at arm's length from project/program stakeholders so as to prevent the practices of the unit being shaped by strategic considerations.

When attempting to construct an EAU with a proper degree of independence, each cost model outlined above has different trade-offs. At one end of the scale it is obvious that in-house ethics assessment carried out by voluntary participants as part of their general job description bears the risk that ethics assessor may be unable to prioritize ethics assessment properly due to time resource constraints or that peer pressure from colleagues may test the integrity of each assessor. At the other end of the scale fully independent EAUs with public funding and a legal mandate to intervene in the formation and funding of R&I projects/programs is more

likely to develop a culture of independent assessment, but may at the same time attract opposition from outside stakeholders such as lobbyists and institutional competitors who may challenge the mandate of the EAU politically.

In each case, the challenge of implementing and EAU in a manner that balances considerations of costs against considerations of independence is to secure that appropriate safeguards are put in place to defend independence when it is challenged. In the case of the in-house voluntary cost model, *peer supervision* among ethics assessors may thus help each assessor to prioritize their time resources and to articulate effective responses to peer pressure. Likewise, in the case of independent assessment boards, *institutional oversight* from a dedicated parliamentary committee or a cross-ministerial board of governors may help shift political pressure away from the EAU and to maintain a broad base of legitimacy.

3.3 SECURING RELIABILITY

An EAU should be *composed* so that it is able to reliably identify ethical issues with regard to both conduct and impacts of R&I projects/program. EAUs should further have *access* to all information regarding R&I projects/programs necessary to anchor ethical assessments in the specifics of the project or program. Naturally, it should also be *organized* so as to deliver output at a reliable pace and cost.

Composition, access privileges and organization should ensure that the EAU is:

- **Competent as regards ethical analysis**
  The title of 'ethicist' is not a protected title and should not be. Many aspects of ethical analysis have to do with intuition and experience and are not necessarily standardisable. Still any EAU should have as part of its group composition people who are well versed in ethical principles, the history of ethical assessment development, and methods and practices in ethical assessment.

- **Able to assess and question the technical aspects of science**
  Ethical assessment is not a scientific method assessment. However, when it comes to the identification of ethical issues, both in terms of conduct and impact, the devil is often in the detail. EAUs must therefore be able to follow the intricacies of the technical planning of R&I projects and programs in order to identify specific risks of ethical transgression in a specific and practical manner. EAU group composition should therefore include people with the necessary expertise to follow technical aspects of R&I method and planning. EAU groups should furthermore have access to the necessary information to make these assessments; preferably with the possibility to make further inquiries in direct dialogue with the R&I practitioners in question. The standardized SATORI approach (see SATORI D6.2) may provide overall guidance to ethics assessors, but cannot substitute for professional training and learning.

- **Experienced in providing practical solutions to ethical issues**
  While academic ethical expertise is a necessary as part of group composition, experience in creating practical solutions to ethical problems in R&I is equally

necessary to ensure that the EAU is able to make reliable recommendations about how to solve ethical problems.

- **Diverse in terms of professional and social backgrounds**
  Understanding R&I in societal and environmental context is an essentially transdisciplinary undertaking. While no EAU can include expertise on all relevant aspects of R&I in context, group composition and assessment practice should ensure that the EAU has the possibility to reflect on not only technical and narrowly defined 'ethical' issues, but also economic, legal, social, historical, environmental and/or other 'fringe' aspects of R&I. Achieving such diversity of perspectives also demands compositional diversity in terms of gender, age, and ethnicity.

- **Representative of the communities affected by the R&I it assesses**
  EAUs should work actively to deconstruct possible group think, elite bias and/or agenda capture by involving non-expert representatives of the communities affected by R&I – either directly in the R&I activities or indirectly from the impacts of R&I. Some ways of achieving such representation include the involvement of non-expert citizens as members of the EAU – in temporary positions to avoid 'expertification' – or the addition of citizens' panels – also with temporary memberships. Individual EAUs may wish to experiment with more advanced forms of citizens' participation[ix]. As an aside it should be noted that in this context citizen representation is preferable to quantifiable examinations of citizens' views, such as Willingness-To-Pay and Willingness-To-Accept indicators. Such indicators in most cases risk serving as an extension and consolidation of group biases and thus do not reap the benefits of the outsider point of view provided by various citizens' participation methods.

3.4 SECURING ACCOUNTABILITY

EAUs must be accountable for the assessments and recommendations, but mechanisms for securing accountability must be constructed so as to avoid pressures on the EAU to conform to the strategic outlooks of the special interests involved. Already mentioned is the ability to **separate institutional oversight over EAUs from the strategic decision-making through which R&I is promoted**. At the same time, it is necessary that the work of the EAU is made open to **scrutiny by international peers** in the ethics profession and that ethical assessors have the opportunity to receive **peer supervision**. This **openness should extend to the public in general**, which must be able to scrutinize the work of the EAU.

4 THE EAU AS AN ELEMENT OF A BROADER ETHICS PROGRAM

If implemented properly, an EAU in an organization or a network of organizations is a highly effective means of providing a point in the decision-making process where R&I projects or programs are assessed from the point of view of the general interests of society. However, even the most effective EAU can, if treated as a 'silver bullet' solution to the question of ethics in and between R&I organizations, only provide moderate results in terms of changed behaviour and outcomes.

An EAU that alone bears the responsibility for securing ethical conduct and outcomes of R&I in a specific organization or network will very likely end up the defender of ethical considerations as opposed to strategic concerns. Recent research thus shows that even a well-functioning EAU if implemented alone can only hope to make slight changes to organizational culture[x].

To reap the full potential of implementing an EAU, decision-makers must view the EAU as an element of an arsenal of possible 'ethics interventions', which may be implemented as part of a broader effort to align the overall strategy and quality assurance approaches of the organization or network with ethical considerations[xi].

We do not yet have strong empirical data on how to influence the ethical aspects of behaviour and outcomes in R&I-specific. But data from a broad selection of organization have identified the following **nine ethics intervention types** as being **cumulatively effective** in preventing unethical behaviour, which means that the more of these interventions are implemented in a specific organization or network in parallel, the greater the influence on behaviour.

Below these nine intervention types are listed in order of priority, i.e. if decision-makers have to choose they should start from the top and implement as many interventions as possible[xii]:

Codes of ethics
Training and communication
Accountability policies
Monitoring and auditing
Investigation and corrective policies
Ethics office(r)
Ethics report line
Incentive policies
Pre-employment screening

The cumulative effectiveness of ethics interventions makes sense if one considers ethics as an element of overall quality assurance and strategic implementation. Quality and strategic alignment are both complex endeavours which organizational leadership must pursue via multi-pronged strategies ranging from recruitment policies to meeting culture adjustment to user involved and on and on. Achieving a culture of ethics in an organization is no different in so far as ethics only becomes a part of the culture if it becomes inescapable to leaders and employees alike. Mutually reinforcing, the different elements of an ethics program mean that high and low-level decision-makers are met with ethical demands at every turn, which leads over time to the routinization and entrenchment of ethics as an element of organizational culture. As an aside, such routinization is likely to raise the cost-effectiveness ratio of ethics over time since start-up costs are eliminated once ethical considerations become institutionalized in informal exchanges within the organization[xiii].

5 ETHICS ASSESSMENT AS AN ELEMENT OF RISK MANAGEMENT

Ethics assessment produces the risk that R&I projects may be stopped, but also enables risk management of both internal and external risks. Ethics assessment is therefore viewed – especially in industry – as an element of risk management. This perspective may meaningfully be adopted by decision-makers in R&I considering the risk and benefits involved in embarking on the implementation of an ethics assessment as part of an ethics strategy for an organization or network.

Internal risks specific to ethical aspects of R&I have to do with **staff morale**. Moral distress, i.e. the experience that the tasks set out by management violate the values held by staff, has been shown to affect productivity in some non-R&I organizations[xiv], and there is no immediately appealing reason to expect different results from R&I organizations and networks. Ethical assessment may help to raise red flags before such effects occur.

External risks specific to the ethical aspects of R&I have to do not only with **libel risks**, but also with the broader process of **judgment in the eye of the public**. Such risks may be incurred by individuals, organizations, networks or institutions involved in R&I decision-making both in relation to R&I conduct and outcomes. Risks include lawsuits, 'earning surprises', reputation damage, and damage to the relationships between R&I actors and their stakeholders broadly speaking.

Case studies conducted for SATORI D5.1 furthermore shows that organizations that implement ethics programs as an element of risk management may also improve their ability to identify opportunities, i.e. potential benefits of R&I projects and programs that might otherwise have been overlooked. This is due to the fact that the multifaceted analyses and reflections that go into an ethics assessment may induce R&I practitioners to consider otherwise overlooked dimensions of the impacts their projects.

	Ethics committee in a research funding organization	**Responsibility committee in a national science academy**	**Ethics committee in a research institution**	**Ethical impact assessment in an industrial organization**
Risks of non-assessment	Public scandals, inability to fund R&I in ethical 'grey areas'	Misuse of research results through appropriation for military purposes	Moral distress; reputational damage.	Costs to the community, shut-down and/or lost opportunities,
Risks of assessment	Loss of research opportunities	Loss of research opportunities	Ruling out beneficial research	-
Perceived benefits	Enhanced license-to-operate for the organization.	Enhanced freedom of research under responsibility criteria	Prevention of (future) harm	Enhanced risk management in relation to R&I projects

Table 2. Risks in relation to ethics assessment implementation. Source: SATORI D5.1

6 ETHICS REGULATION VS INTERNAL ETHICS PROGRAMS

Many public sector decision-makers in Europe believe that public regulation is among the most effective intervention when it comes to securing ethical conduct[xv]. However, while no specific data exist about the effects of external regulation on the ethics of conduct and outcomes of R&I projects, research indicates that the effectiveness of regulation may be overrated.

If ethics regulation is not supported by ethics interventions in the organizations or networks subject to the regulation the external regulation may have **only limited effects** on the perceptions of leaders and staff as to what counts as 'ethical' or 'unethical' behaviour[xvi].

Consequently, if ethics regulation is unsupported by ethics interventions in the organization, then to achieve the intended effects of the regulation, compliance monitoring must also be demanded. Compared to the costs of implementing a culture of ethics through organizational ethics programs, however, modelling research indicates that **mandatory compliance monitoring is much less cost-effective**[xvii].

To be sure, evidence about the costs and effectiveness of external regulation vs. internal ethics programs is scarce, and the indications above should be taken as just that. Most likely, external regulation could and should be seen as yet another factor that may improve the effectiveness of ethics programs without being overrated as a 'silver bullet' solution to the challenge of achieve ethical conduct and outcomes of R&I.

7 AVOIDING MISTAKEN APPLICATIONS OF COST-EFFECTIVENESS TO EA

Based on inputs from experts and the research that went into this framework, the SATORI project wishes to warn against three common misconceptions that decision-makers should avoid when considering the implementation of ethics assessment:

- *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.*

8 CONCLUSIONS

This report has provided a guide by which decision-makers considering the implementation of ethical assessment in relation to R&I projects or programs may break down the questions of cost-effectiveness and risk-benefit of ethics assessment into manageable chunks.

The report has provided an overall framework of interlinked assumptions about the costs and risks, effects and benefits in relation to ethical assessment and ethical impact assessment of R&I. This framework helps to clarify that while operational costs of ethical assessment units are easily quantifiable and most of the other costs and benefits involved in ethical assessment of R&I are not, this should not trick decision-makers into treating operational costs as the only relevant variable.

When placed in a broader framework of the costs and possible benefits that pertain not only to the ethical assessment itself, but to the R&I projects and programs under assessment, the operational costs of EAUs are in many cases dwarfed by other costs as well as possible gains. In terms of the implementation costs, operational costs of EAUs will often be insignificant in comparison with the ancillary costs of ethics training of staff and other ethics programs costs, not to mention the costs of R&I projects. In terms of possible gains from ethical assessment, there is also in each case the potential that the gains from successful R&I-based products or processes may entirely overshadow the costs of ethical assessment just. The same goes for the losses which ethical assessment may help to prevent in terms of retraction costs, libel costs, losses from damaged reputation and other consequences of R&I projects and products suffering the ethical judgment of society.

The main risk that arises when applying ethical assessment to R&I is that research in 'grey areas' may not be approved. But this risk should be weighed against the possibility that ethical assessment, by shaping R&I plans, may help to point projects or programs towards new application areas or induce design improvements, which would otherwise have been overlooked. From this risk management perspective, funding ethical assessment may be seen as a wager on the potential for new opportunities to arise out of it.

All of this should not be seen as a sales pitch for ethical assessment. Rather, the guide has attempted firstly to provide a more realistic and therefore more complicated picture of what decision-makers need to take into account when considering the implementation of ethical assessment in one form or the other. Secondly, the guide has attempted to break down this more complicated outlook into smaller bits.

The guide has thus provided concrete reflections about costs models of ethical assessment units and how the choice of cost model can be moderated by quality considerations regarding the independence, reliability and accountability of the unit.

The guide has further provided food for thought regarding the possible benefits of implementing ethical assessment as part of a broader ethics program; as part of a risk management strategy; and as a necessary compliment to external regulation. The guide has thus provided a pathway of reflection by which decision-makers may circumvent the pitfalls of an overly simplified application of cost-effectiveness and risk-benefit considerations to ethical assessment of R&I.

9 REFERENCES

[i] This documents references deliverables from the SATORI project as, for example, SATORI D1.1. meaning the first deliverable of the first work package of the SATORI project. All deliverables are available for download at the SATORI project website (http://satoriproject.eu) under 'Results'.

[ii] Saltelli, A., Ravetz, J. and Funtowicz, S.: 'Who will solve the crisis in science?' in: Benessia, A., Funtowicz, S., Giampietro, M., Guimarães Pereira, Â., Ravetz, J. Saltelli, A., Strand, R., and van der Sluijs, J. P.: *The Rightful Place of Science: Science on the Verge*, Tempe, AZ, Consortium for Science, Policy and Outcomes, 2016

[iii] Moedas, C.: Open Innovation, Open Science, Open to the World. Speech given on 22 June 2015, SPEECH/15/5243. Available at: http://europa.eu/rapid/press-release_SPEECH-15-5243_en.htm

[iv] See for example Fuller, S. *The governance of science*, Buckingham: Open University Press, 2000.

[v] See e.g. Asgary, N. and G. Li: 'Corporate Social Responsibility: Its Economic Impact and Link to the Bullwhip Effect', Journal of Business Ethics, 2016 June, 135(4): 665-681

[vi] 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.

[vii] Duffy, G. L.: *The ASQ Quality Improvement Pocket Guide: Basic History, Concepts, Tools and Relationships*, ASQ Quality Press, 2013

[viii] See http://satoriproject.eu/framework/section-5-ethical-impact-assessment/

[ix] See e.g. the Engage 2020 Action Tool which allows EAUs and others to choose appropriate participation methods for their specific purposes. http://engage2020.eu/news/action-catalogue-an-online-method-tool-that-lets-you-find-the-exact-method-you-are-searching-for/

[x] 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.

[xi] 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. See also footnote iv above.

[xii] See footnote iv above.

[xiii] See footnote vi above.

[xiv] Atabay G, Çangarli BG, Penbek Ş. Impact of ethical climate on moral distress revisited Multidimensional view. Nursing ethics. 2014 Aug 7:0969733014542674.

[xv] 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.

[xvi] 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.

[xvii] See foot note xi above.