On the cost-effectiveness and risk-benefits of ethics assessment

A report from the SATORI stakeholder workshop
held in Copenhagen, May 2016

Compiled by:

Rasmus Øjvind Nielsen (The Danish Board of Technology Foundation)
Lea Amby Ottosen (The Danish Board of Technology Foundation)
Lise Bitsch (The Danish Board of Technology Foundation)

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

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SATORI

Contents

ABSTRACT

This report conveys recommendations from a co-design expert workshop about how the SATORI project may design a methodology for examining the cost-effectiveness of ethics assessment and for considering the risks and benefits involved in such assessment. The experts warned against the idea that the cost-effectiveness of ethics assessment can be generalised, stressing that only concrete cases with well-established operational goals can meaningfully be subjected to such examination. Instead, experts recommended producing tools to assist the implementation of the SATORI framework for ethics assessment in concrete organizational settings. One such tool could be a typology of relations between cost and effect. Another tool could be a reflective tool enabling considerations of qualitative relations between risk and benefit in the adaptation of the SATORI framework to a concrete setting. The report contains a number of suggestions for dimensions to be taken into account by such tools as well as suggestions for how they might be designed.

EXECUTIVE SUMMARY

This report conveys the main findings from an expert workshop concerning ways of examining the cost-effectiveness of ethics assessment of research and innovation along with the risks and benefits pertaining to such assessment.

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. The intention of the workshop was to find ways of supporting stakeholders wishing to adopt the SATORI ethics assessment framework by providing ways of demonstrating the cost-effectiveness and/or the positive relationships between risks and benefits of adopting such an approach to ethics assessment.

The participating experts raised three red flags regarding this intention. The experts made it clear that it is impossible – due to the variety of goals and mandates supporting ethics assessment in concrete settings – to make a direct cost-effectiveness comparison between different approaches to ethics assessment. Even seemingly similar approaches can only be subjected to such comparison if it can be established that they have very similar operational goals, which will rarely be the case. On this background, the experts warned against a narrow focus on monetary costs of ethical assessment in itself when the much greater issue has to do with the impacts – positive or negative – of ethical assessment on research and innovation.

The workshop participants suggested developing on the one hand a typology of relations between cost and effect and on the other hand a reflection tool for the consideration of the risks and benefits inherent in concrete choices about the objectives, methods and forms of organization taken in concrete cases of implementation. Beyond the ‘sales pitch’ situation, such contributions would help organizations wishing to adopt the SATORI assessment framework to make informed decisions about how best to adapt the framework in their concrete setting. A number of suggestions were made for dimensions to be included in these tools.

1 INTRODUCTION

1.1 CONTEXT: SUPPORTING ADOPTION OF THE SATORI FRAMEWORK

This report conveys the outcomes of an expert workshop concerning ways to examine the cost-effectiveness of ethics assessment practices as well as the relationship between the risks and benefits of such practices. The workshop was held in Copenhagen in May 2016 in order to contribute to the SATORI project.

The overarching goal of the SATORI project is to develop a common European framework of common 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 including scientists, regulators, industrial actors, public bodies, research ethics committees in the EU Member States as well as relevant international bodies.

Bearing in mind that research and innovation governance is already populated by a wide range of ethical and social practices regarding the assessment of research and innovation, the motivation of stakeholders to adopt the common framework developed in the SATORI project will be highly reliant on the ability of the project to position the proposed framework vis-à-vis competing approaches. One way of achieving this strategically necessary aim would be to document the cost-effectiveness relative to other assessment approaches of the ethical assessment practices proposed in the framework. A good compliment to this approach could be to provide a set of considerations regarding the broader, more qualitative issues of risks and benefits pertaining to ethics assessment practices. Providing ways of evidencing the cost-effectiveness of ethics assessment as well as ways of reflecting on the possible benefits of such assessment in relation to the risks involved would help organizational entrepreneurs interested in promoting the framework in their own organizations in making the case for adopting the SATORI framework. At the same time, adopting a cost-effectiveness perspective on the proposed framework while reflecting on the risk-benefit relations pertaining to it would provide a valuable feed-in to the framework development; by adopting this perspective the SATORI project would be better able to steer development efforts towards realistically applicable proposals by streamlining the cost-effectiveness of the proposed approaches beforehand.

However, evaluating ethical assessment practices from a cost-effectiveness perspective is not customary, and the specific nature of the contribution of ethics assessment to the governance of research and innovation means that off-the-shelf approaches to reflecting on the risks and benefits involved in ethics assessment practices are not likely to gel well with ethics assessors. To achieve the strategic aim of supporting stakeholders interested in adopting the SATORI framework, the project must therefore develop its own methodology for examining the cost-effectiveness of ethics assessment activities and for considering the risks and benefits involved, an approach that would make it possible to streamline the proposed approaches without compromising the ethics assessment quality.

Work package 5 has the purpose of developing such a methodology, i.e. a methodology for:

- examining the cost-effectiveness of the ethics assessment of research and innovation

- reflecting on the qualitative relations between the risks and benefit of ethics assessment of research and innovation
- maximizing the cost-effectiveness and benefit-to-risk ratios of ethics assessment of research and innovation without compromising their quality.

The expert workshop reported here (SATORI D5.3) is the first step in the direction of this methodology. Alongside conceptual considerations regarding the challenges of applying cost-effectiveness and risk-benefit approaches to ethics assessment (SATORI D5.1), the outcomes of the workshop will feed into a methodology for examining the cost-effectiveness of ethics assessment in research and innovation while also considering the risk-benefits relations (SATORI D5.2).

1.2 OBJECTIVES: IDENTIFYING ELEMENTS OF A CROSS-CUTTING METHODOLOGY

The purpose of the expert workshop, the outcomes of which are reported here, is to help guide the SATORI project towards a methodology that will take into account on the one hand the state-of-the-art of cost-effectiveness and risk-benefit analysis and on the other hand the specific areas of sensitivity which ethics assessment presents, areas that challenge generic approaches to cost-effectiveness and risk-benefit analysis.

This purpose translates into the following objectives:

- Gather up to 10 experts that represent different categories of expertise (specifically expertise in cost-effectiveness analysis, risk-benefit analysis, and ethics assessment of research and innovation) as well as different stakeholder categories (research and innovation, industry, research and innovation governance, institutionalized ethics assessments).
- Facilitate a co-constructive process in which these experts, along with the SATORI team, develop recommendations regarding the methodology to be developed in WP5, specifically:
    - How best to examine the cost-effectiveness of ethics assessment of research and innovation in a way that makes ethics assessment comparable to competing assessment approaches while taking into account the specifically sensitive nature of ethics assessment
    - How to consider the risks and benefits pertinent to ethics assessment of research and innovation in a way that can help guide quality considerations of ethics assessment practices
    - How to take on board perspectives of cost-effectiveness and risk-benefit maximization in the development of the SATORI ethics assessment framework.
- Gather results in a format that may inform methodological development towards D5.2.

1.3 METHODOLOGY: CO-CONSTRUCTION WORKSHOP DESIGN

The objectives of the workshop present a number of methodological challenges that the workshop design must be able to address.

First among these challenges is that the end-goal of the co-productive process is not well defined. The methodology to be developed in WP5 must take into account the specific quality criteria of ethics assessment, but these criteria are not universal. As established in SATORI D1.3, the field of ethics assessment of research and innovation is organizationally diverse, makes use of a range of different principles and practices, and is carried out with a multiplicity of purposes in mind. It is therefore not at all clear beforehand what it means, for example, to adopt a cost-effectiveness perspective on ethics assessment while taking into account the specifically sensitive nature of such assessment.

A number of secondary challenges derive from this first point.

Because the quality criteria of ethics assessment are not clear, this makes it difficult both to compare ethics assessment with other forms of assessment of research and innovation (e.g. technology assessment) and to compare different ethics assessment practices. If different ethics assessment practices do indeed have different purposes and therefore different quality criteria, then the relative 'effectiveness' of each approach cannot be given a commensurate measure and cost cannot be isolated as a variable dependent on assessment practices.

Likewise, because the role that ethics assessment plays in the governance of research and innovation varies greatly between different organizational settings, considerations of the risks and benefits that pertain to such assessment must take into account a wide variety of actors' perspectives. In such considerations, what counts as a benefit for one actor may count as a risk or a cost for another. Such multi-perspective risk-benefit analysis does not lend itself easily to a process-optimization ambition, but rather helps to highlight the political nature of designing processes such as ethics assessment, in which different interests are more or less strongly represented. Such processes of negotiation between different interests may be presumed to have found a kind of settlement in already existing ethics assessment practices. As such, risk-benefit considerations may be meaningful in concrete cases. But with the SATORI ambition of developing a framework applicable across a number of different settings, this process of interest-negotiation will once again have to play out – a process that cannot be subsumed by expert opinion[1] (see e.g. Scrathe and Sheate 2002).

Finally, precisely because the ambition of the SATORI project is to develop a framework that is applicable to the situations of multiple categories of actors involved in research and innovation, the purpose and quality criteria to be met by the framework is difficult to narrow down. Consequently, the adoption of mechanisms for streamlining the cost-effectiveness of the proposed framework beforehand, while also taking into account considerations about the risks and benefits pertaining to the framework, is not a narrowly defined objective.

To address these challenges the workshop design sought to facilitate the identification of universally applicable methodological elements through the development and comparison of different case-based suggestions for how to apply cost-effectiveness analysis to ethics assessment and how to consider the risks and benefits pertaining to such assessment.

[1] See e.g. Scrase, J. Ivan, and William R. Sheate. "Integration and integrated approaches to assessment: what do they mean for the environment?." *Journal of environmental policy and planning* 4, no. 4 (2002): 275-294.

The workshop was designed around three methodological steps:

- Group discussions of cost-effectiveness, risk and benefits in relation to concrete cases
- Facilitated cross-pollination of groups
- Plenary discussions to identify cross-case methodological elements

Concretely, the workshop design grouped participants around ethics assessment in specific organizational settings. Taking as their starting point the case studies of such different settings developed in connection with SATORI D1.1, six groups were formed, each of which would focus on ethics assessment in: *research funding organizations, science academies, research ethics committees, national ethics committees, EU governmental level ethics reviews,* and *ethics assessment in industry*. The groups and cases were given to the participants in advance. At each table a member from WP5 were placed with the purpose of taking notes and gathering all the threads during the discussions.

The workshop was divided into two days based on the two basic themes:

- Day 1) Cost-effectiveness of Ethical Assessment
- Day 2) Risk-benefit of Ethical Assessment.

In the first sessions of each day the participants discussed the fundamental problems of adopting a cost-effectiveness perspective (day 1) and a risk-benefit perspective (day 2) on ethics assessment of research and innovation.

In the second session of each day, selected participants were moved from one group to another to facilitate cross-pollination between the reflections in each group. The cross-pollination method was used several times during the workshop. Only the members from WP5 were seated with the same case throughout the workshop.

Both workshop days ended with a plenary session – referred to as a cross-case conclusion session. This session was intended to extract elements of a cross-cutting methodology by collecting methodological ideas that, while having derived from a specific case, would nevertheless seem to be more generally applicable across the cases. On the second day, each group was asked to prepare a rough sketch of a methodological approach for examining the cost-effectiveness of ethics assessment in their particular case and for considering and taking into account the risks and benefits of such assessment. As a final part of the plenary session, experts were also asked to give individual feedback to the project as a whole.

Through this approach, the discussion of cost-effectiveness and risk-benefit perspectives on ethics assessment of research and innovation were bound to concrete cases while the identification of cross-case methodological elements were facilitated. The outcomes should thus serve the purpose well of guiding the development of a cost-effectiveness and risk-benefit methodology applicable to the SATORI framework as well as ethics assessment more broadly.

2 WORKSHOP FINDINGS

The following section is based on discussions and statements from the workshop. This is an attempt to compare the results that the participants reached during the workshop and to separate the parts that prove to be interesting in terms of developing a methodology.

2.1 LIST OF ACRONYMS

EAU: Ethical Assessment Unit
CEA: Cost-effectiveness Analysis
RBA: Risk Benefit Analysis
EA: Ethical Assessment
CE: Cost-effectiveness
RB: Risk Benefit
R&I: Research and innovation

2.2 CROSS-CUTTING FINDINGS I: RED FLAGS

At various points during the workshop, the participating experts generally agreed on the following 'red flags' regarding the assumptions and ambitions underlying SATORI Work Package 5. Some of these reiterate the reflections underlying the workshop design (see 1.3 above) while others were new to the SATORI consortium and therefore highly valuable to the WP5 process going forward. These red flags serve as reservations to be taken into account when making use of the cross-cutting methodological recommendations below.

Red flags include:

- *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 also to 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.*

2.3 CROSS-CUTTING FINDINGS II: METHODOLOGICAL RECOMMENDATIONS

Based on the data gathered at the workshop, the following cross-cutting recommendations regarding a methodology for examining costs-effectiveness of ethics assessment and considering the risks and benefits of such assessments may be deduced. These cross-cutting recommendations as they are formulated here are the result of the SATORI group's readings of the diverse recommendations made by the different workshop groups on the basis of their individual cases. While these recommendations directly reflect the suggestions made by workshop participants, they have not been consolidated as 'cross-cutting' by the participants.

In this regard they reflect the understanding of the SATORI group of the discussions at the workshop.

Recommendation 1: Create a typology of relations between costs and effects of ethics assessment to establish comparability between approaches with similar objectives

As flagged above, it is impossible to make direct comparisons of the cost-effectiveness of different approaches to ethics assessment in general because of their different goals, mandates and desired impacts/effects. To establish comparability, it is therefore necessary to create a typology of relations between costs and desired effects to allow stakeholders to compare different ways of achieving precisely the same desired effect.

Such a typology should not only be a tool for examining the cost-effectiveness of different approaches to ethics assessment. Rather, it should allow for the examination of the cost-effectiveness of different ways of achieving certain desired effects, whether these ways include ethics assessment or not. Such a tool would help to open up the 'black box' of ethics assessment and place it in direct competition with other governance tools and ideas while at the same time clarifying the unique contributions of ethics assessment.

Such a typology will include 'primary' and 'secondary' effects of ethics assessment as well as different categories of cost. The cost-effectiveness perspective seems most fruitful when it comes to the relationship between secondary effects and costs, as we shall explain.

Primary effects of ethics assessment include the identification of potential ethical breaches built in to the activities being assessed. Whether such assessment achieves the primary desired effect of identifying ethical problems is reliant on the elusive 'quality' of the assessment, i.e. the reliability of the assessment in terms of subsequent decision-making. More likely than not, it will prove impossible to establish a direct relationship between cost and quality. Rather, quality and reliability would likely have to be treated as matters of risk and benefit. For instance, the reliability of an ethics assessment is generally understood to be more trustworthy the more independence is granted to the assessor, but at the same time greater independence comes with the risk of lack of insight in the subject matter of the phenomenon to be assessed. Different forms of organization thus imply different risks and benefits that pertain uniquely to ethics assessment, which cannot be meaningfully captured in a simple cost-effectiveness calculus.

Secondary effects may include:

- *implementation/enforcement* of ethically motivated action recommendations
- *changing of social perceptions* regarding the ethical acceptability of research and innovation
- *raising of ethical awareness* in general
- *social shaping of research and innovation* beyond the concrete project assessed.

Cost categories may include:

- Operational costs (personnel and overhead) of the ethics assessor(s)

- Implementation costs incurred by research and innovation actors when complying to action recommendations
- Monitoring costs incurred either by research and innovation actors or by external governance actors
- Losses from missed opportunities in research and innovation

A typology of relations between such secondary effects and costs would ideally be established empirically. However, the notes from the workshop and the expertise gathered in the SATORI consortium ought to be enough to establish a set of *a priori* assumptions about such relationships. Providing such a typology would help greatly in structuring the 'sales pitch' of actors attempting to adopt and adapt the SATORI framework for ethics assessment in a concrete context.

Recommendation 2: Create a reflection tool to help adopters take into account risk and benefits of different objectives, methods, and modes of organization of ethics assessment

The SATORI ambition of developing a common European framework for ethics assessment implies a level of generality, which will leave much work to be done to adapt the framework to concrete organizational settings. For this reason and others the SATORI project cannot meaningfully attempt to balance out risks and benefits in the construction of the framework itself. Rather, Work Package 5 should provide some tool to help adopters consider the risks and benefits of pursuing different objectives as well as making use of different methods and modes of organization when adopting and adapting the SATORI framework for ethics assessment in a concrete context.

Dimensions of risk and benefit to be taken into account by such a reflection tool may include:

- OBJECTIVES
    - Is the objective to establish precaution or ex-post accountability?
        - Precaution promises to prevent damage, but risks hindering useful innovation.
        - Ex-post accountability promises to allow free exploration, while it risks creating a litigious culture.
    - Is the objective to guide or to control researchers and innovators?
        - Guidance promises to allow flexible and efficient self-governance, while it risks non-implementation of action recommendations.
        - Control promises securing implementation, but risks stifling creativity.
    - Is the objective to achieve social steering of research and innovation (strong ambition) or to raise awareness of ethical issues in research and innovation (soft ambition)?
        - A strong ambition promises to deliver ethically acceptable research results, but risks creating opposition to ethics assessment from researchers and innovators.

        - A soft ambition promises to facilitate a more open debate on ethical issues in research and innovation, but risks letting unethical research and innovation off the hook.

- METHODS

    - Is the assessment of a reflexively adapted or universal 'check-box' kind?
        - Reflexive adaptation of methods promises to result in more reliable identification of ethical problems, but risks the assessment becoming unreproducible by other assessors.
        - Check-box assessments promise to deliver reproducible and comparable results, but risks missing novel ethical dimensions specific to new forms of research and innovation.

    - Is the assessment performed by an expert group, a group of lay people, or the group of researches/innovators themselves?
        - Expert assessment promises a high degree of reliability and sophistication in the identification of ethical problems related to research and innovation, but risks on the one hand missing the depth of the research and innovation phenomena in question and on the other hand may introduce elite biases regarding, for instance, social distributions of the risks and benefits of the research and innovation.
        - Assessment by lay people promises to gauge citizens' perceptions of 'red lines' that research and innovation should not cross and to do so more dependably than expert assessments, but it risks missing the nuances of ethical reflection that expert assessors are trained to discern.
        - Self-assessment by researchers and innovators promises to deliver ethical assessments that are informed by the deepest possible understanding of the content of the research and innovation to be performed, but risks being biased towards a positive outcome due to the conflict of interest inherent in self-assessment.

- ORGANIZATION

    - Is the assessment performed inside or outside the organization where recommendations for actions are to be implemented?
        - In-house assessment promises to deliver highly relevant assessments, but risks introducing positive bias.
        - Outside assessments promises to deliver higher reliability in the individual assessment, but risks stripping the organization of ethical awareness and competencies for navigating ethical issues

    - Is the assessment group organized on a permanent basis or in a more ad-hoc, network based manner?
        - Permanent organizational membership promises to build up expertise and efficiency, but risks giving rise to group-think and organizational goal-seeking.

- An ad-hoc network-based organization promises to deliver flexibility and adaptability, but risks being unable to muster the necessary resources and to be influenced by powerful actors.

These are only some of the possible interconnections between risk and benefit that a tool for reflection might take on board. Further issues are mentioned in the notes from the workshop (see annex 3 and 4) where suggestions are also made for how to structure them in some form of reflexive tool (e.g. annex 4, group 1 and 2).

Recommendation 3: Take organizational and territorial embeddedness seriously when considering costs, risks, effects and benefits of ethics assessment

While the ambition to create a common European framework for ethics assessment of research and innovation was generally viewed as commendable by participants, the idea that any one framework could be universally applicable to all manners of cases was generally rejected. Whatever form the SATORI framework will take, its application in concrete organizations will be subject to organizational strategies, goals and mandates as well as territorially specific legislative frameworks and regulations.

Against this background, the above recommendations should be viewed not only as a 'sales tool' to assist organizational entrepreneurs interested in adopting the SATORI framework, but also more seriously as a tool to help design meaningful strategies for implementation of the SATORI framework in a concrete context. Helping adopters to reflect on the risks and benefits inherent in different choices made in the course of implementation could guide the process of adapting the framework to an organizationally and territorially specific situation.

As regards the self-application of these considerations by the SATORI project on the framework, the implied warning seems to be one that is in line with the considerations that went before the workshop, namely that SATORI should not attempt to preempt the processes of negotiation that arise between different interests over how to implement ethics assessment. Instead, SATORI should remain neutral between different approaches as appropriate in individual settings.

3 CONCLUSIONS

This report has conveyed the main findings of the expert workshop on the cost-effectiveness of ethics assessment of research and innovation and the risks and benefits involved in such assessment.

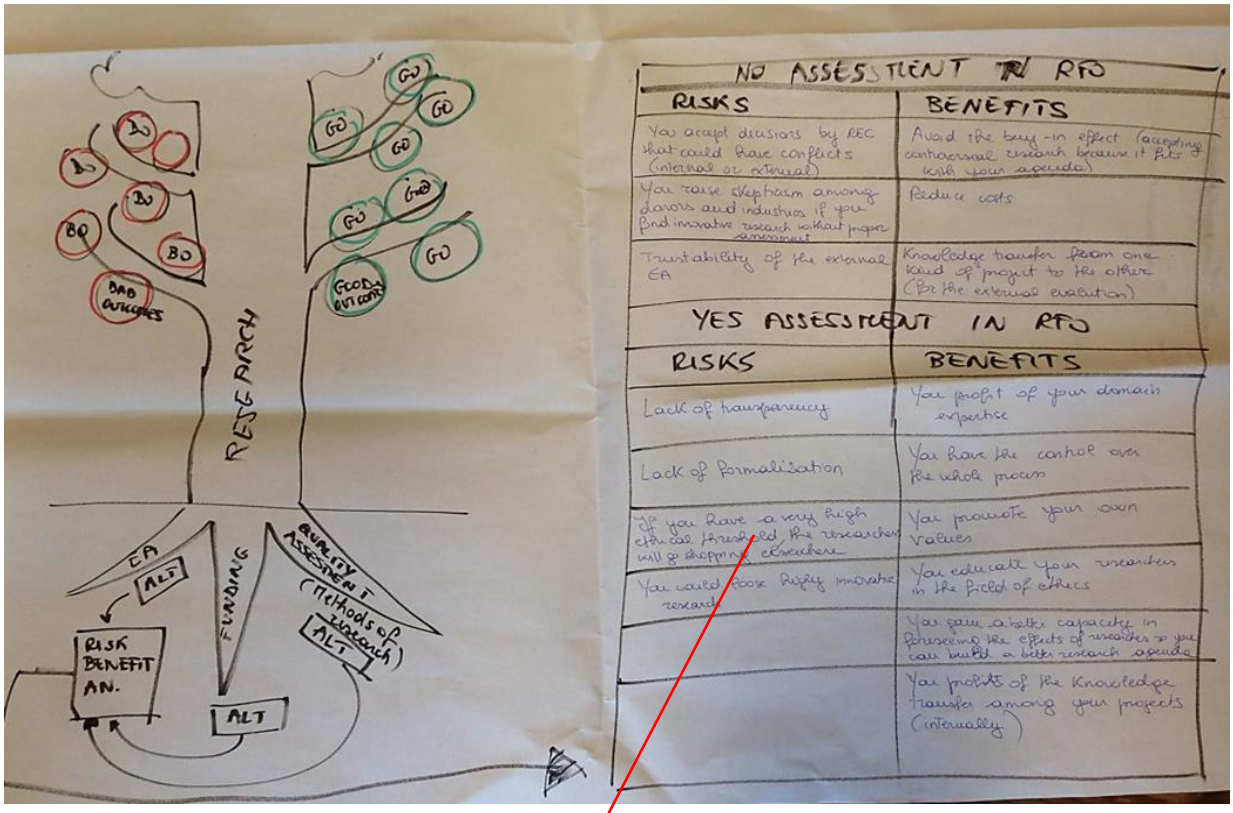
The main conclusions to take forward on the basis of these findings are:

- It is not possible to compare the cost-effectiveness of different approaches to ethics assessment of research and innovation at a general level. Only when concrete objectives have been established in a concrete setting can such comparisons be developed, and here ethics assessment will be in competition with other approaches as well.
- It should be possible, however, to establish a typology of relations between multiple dimensions of cost and effect associated with ethics assessment on the basis of already existing practices. The report has highlighted some of the contributions from the workshop towards such a typology.
- It should likewise be possible to create a tool useful for reflection concerning the balancing of risks and benefits that go with the choices made in the implementation of SATORI framework in a concrete context.
- Both of these suggested tools would help SATORI adopters become efficient SATORI adapters and would thus help establish the relevance and longevity of the efforts made in the SATORI project.

4 ANNEXES

4.1 SUGGESTIONS FOR METHODOLOGICAL MODELS

GROUP 1 – RESEARCH FUNDING ORGANISATIONS



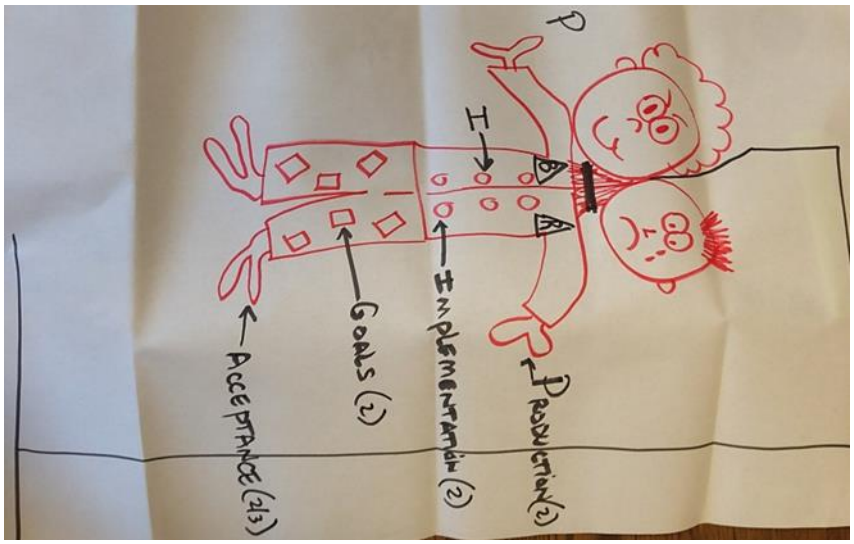
No assessment in RFO

Risk	Benefits
You accept decisions by organizations that could have in organization conflicts	Avoid the buy in effect (accept controversial research because if fits with their agenda)
Scepticism from the donors and industry if they fund very innovative research without assessment	Reduce costs
Trustworthiness of the external ethics assessment	Knowledge transfer from one king of project to the other (for the external evaluator)

Assessment in RFO

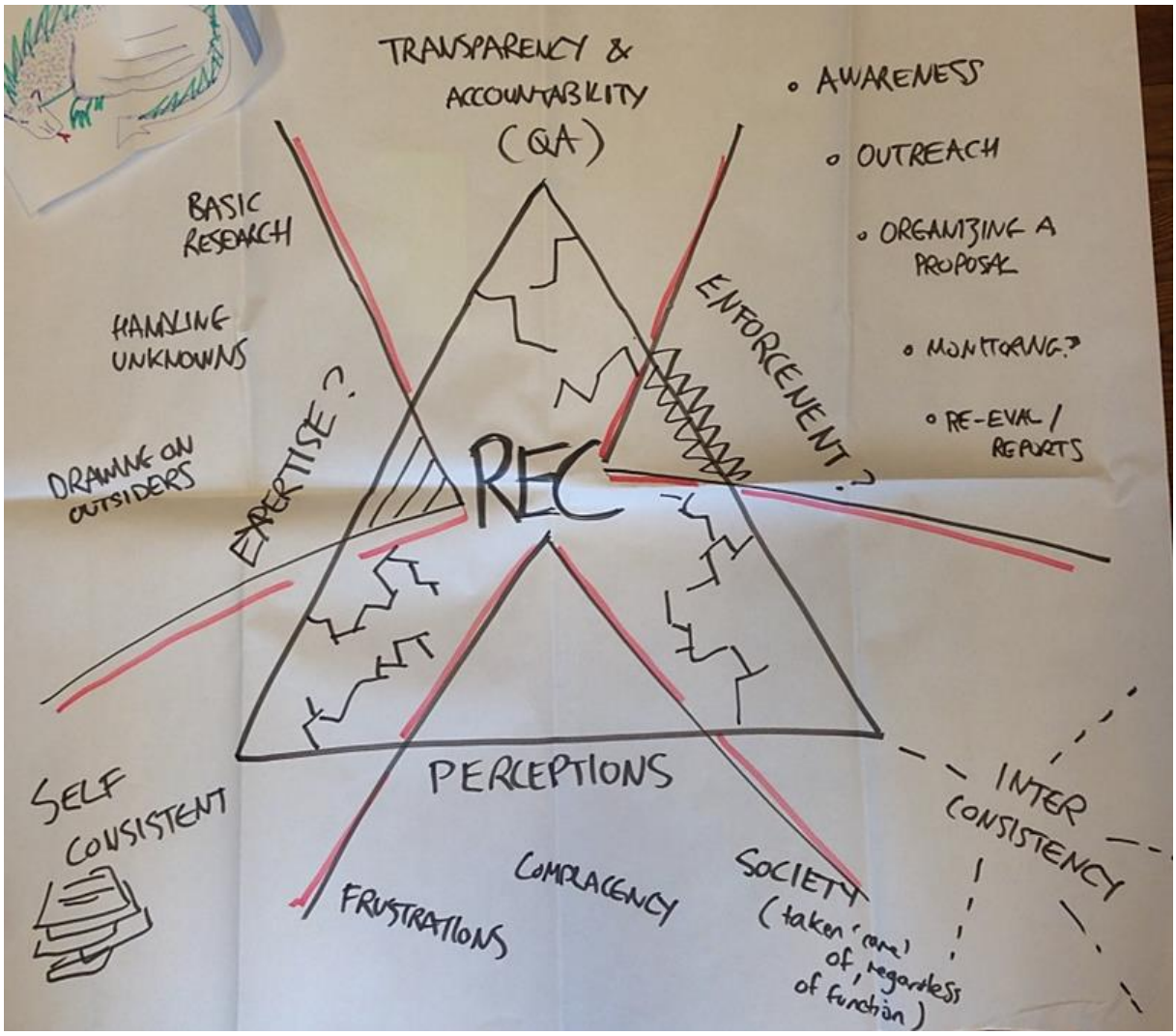
Risk	Benefits
Lack of transparency	Domain expertise
Lack of formalization	Control
If you have a high threshold, the researchers will go shopping in other funding organization	Promotion of your own values
You could lose highly innovative research	Education of researchers
	Better capacity to set the research agenda for the future
	Knowledge transfer among your projects if you do it internally

GROUP 2 – SCIENCE ACADEMIES

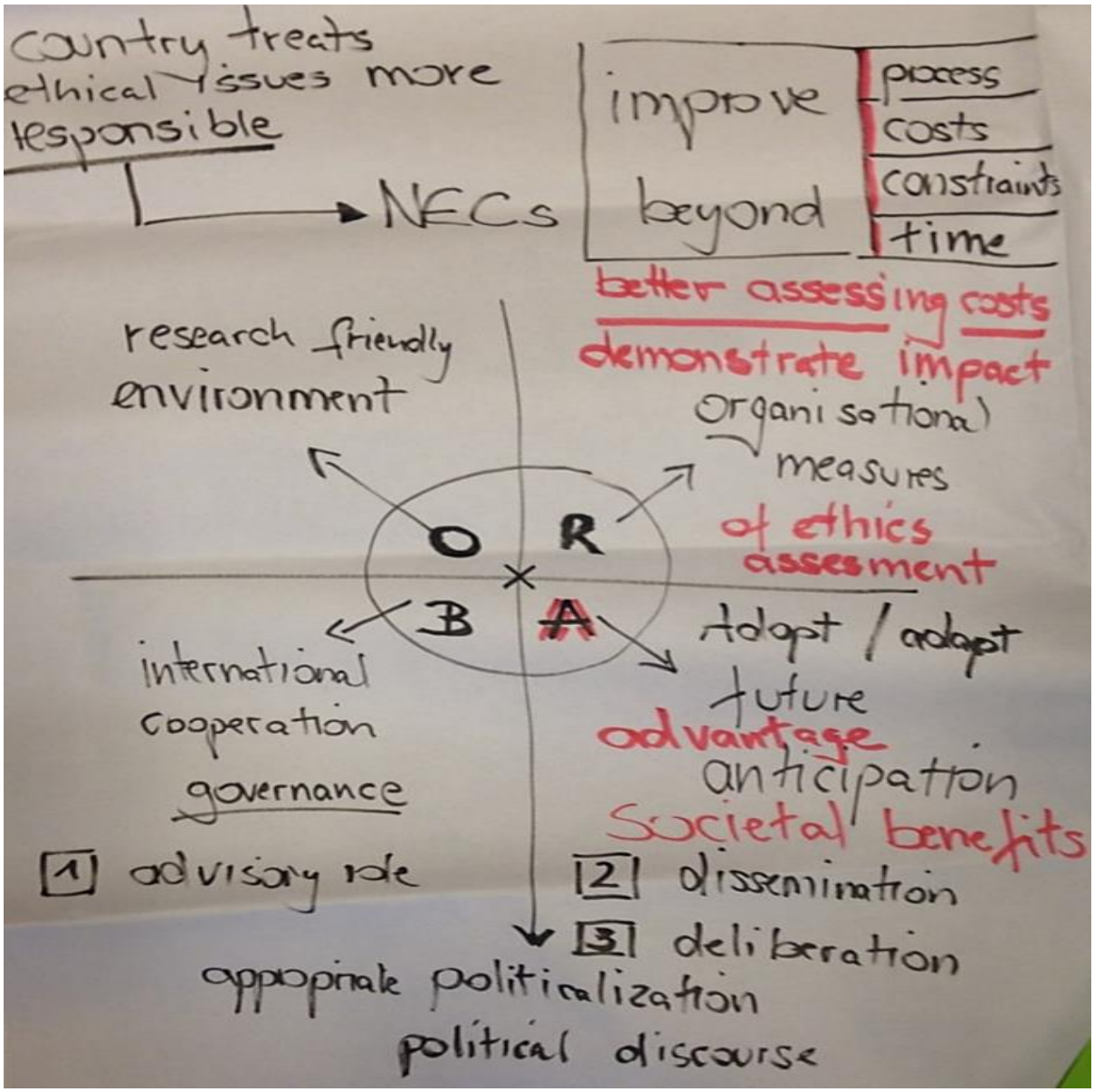


	Production	Implementation	Goals	Acceptance
Risk	Blind spots Out touch with realities Too general	Not implemented Fit for purpose	Not achieved Restricting innovative research	Trust in research Innovation not used
Benefits	Expertise Representative position, common voice	Increased awareness of ethical principles and issues	Ethical research Efficiency research Avoiding illegal conflicts	Initiate discussion (educational awareness – Participatory processes) Increased trust in science More funding

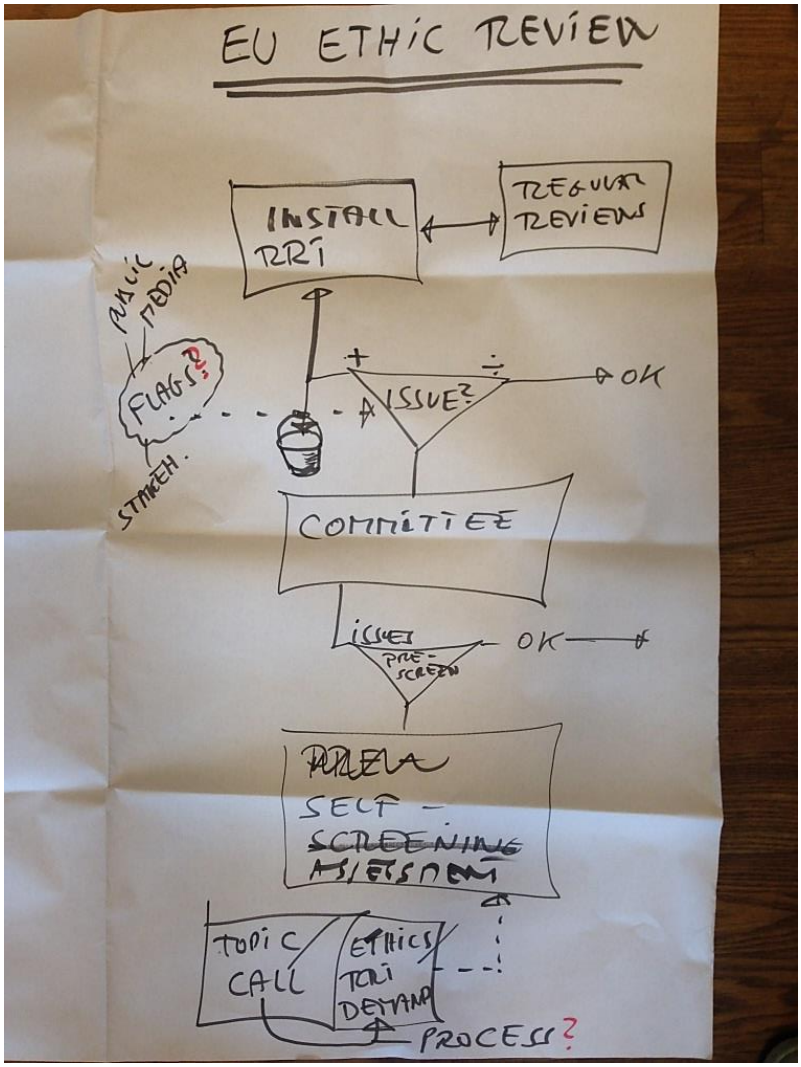
GROUP 3 - RESEARCH ETHICS COMMITTEES



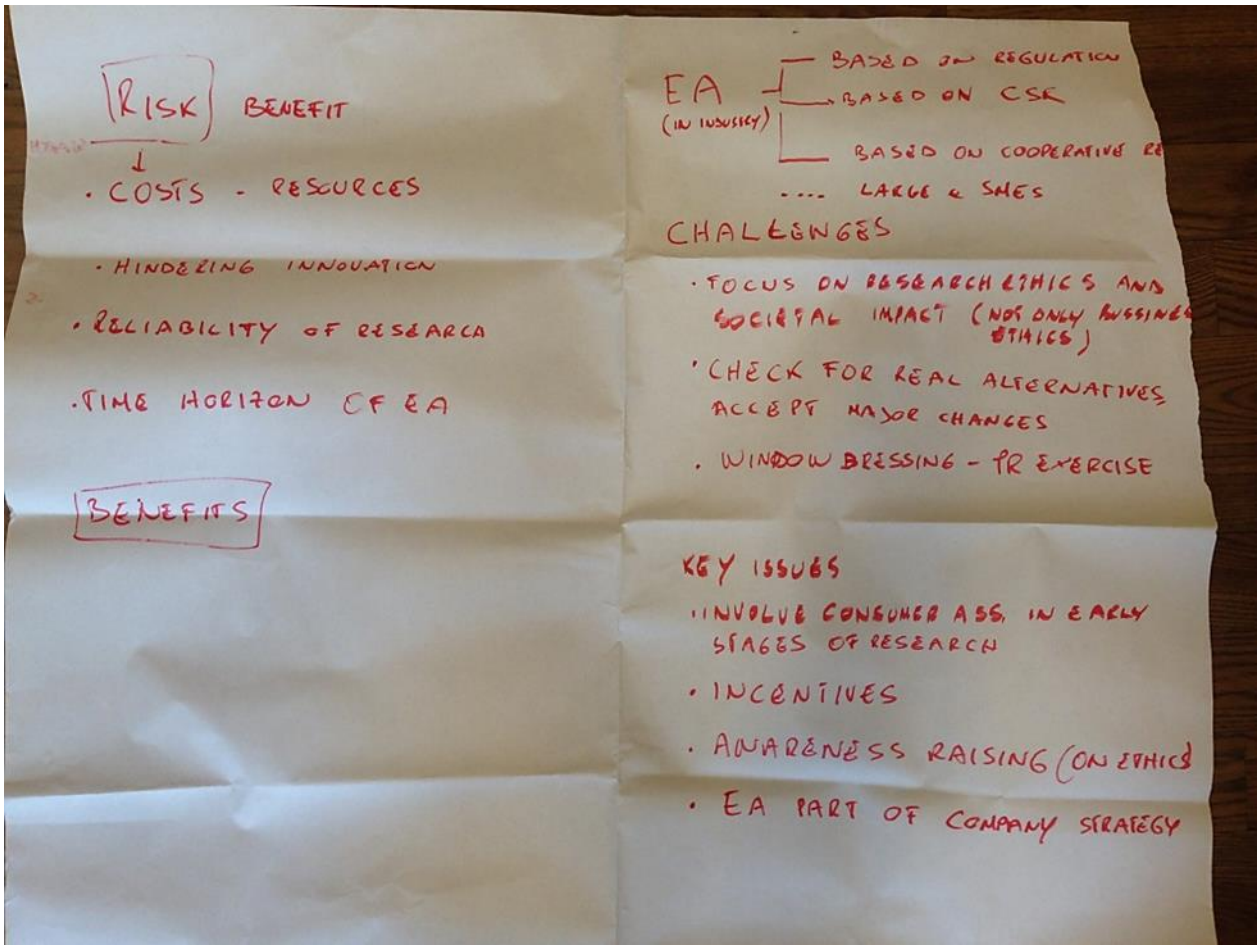
GROUP 4 - NATIONAL ETHICS COMMITTEES



GROUP 5 - EU GOVERNMENTAL LEVEL ETHICS REVIEW



GROUP 6 – INDUSTRY



Risk Costs and resources Hindering innovation Reliability of research Time horizon of EA Benefit	EA in industry Based on regulation Based on CSR Based on cooperative research ….in large and SMEs. Challenges: Focus on research ethics and societal impact (not only business ethics) Check for real alternatives; accept major challenges Window dressing, PR exercise Key issues: Involve consumer in early stages of research Incentives Awareness raising on ethics EA part of company strategy

4.2 WORKSHOP PARTICIPANTS

The names marked with blue is the experts
The names marked with orange is members from the SATORI consortium

Erich Griessler Institute for Advanced Studies	**Signe Annette Bøgh** Danish Standards
Rachel Douglas-Jones IT University of Copenhagen	**Dubravka Vejnovic** Center for the Promotion of Science
Johannes Rath University of Vienna	**Andrea Porcari** Italian Association for Industrial Research
Aleksandar Antovic Bio Save Group	**Anna Leinonen** VTT Technical Research Centre of Finland
Finn Arler Aalborg University	**Sudeep Rangi** UNESCO
Frede Hvelplund Aalborg University	**Agata M. Gurzawska** University of Twente
Erin Kenneally Homeland Security Advanced Research Projects Agency	**Rok Benčin** Research Centre of the Slovenian Academy of Sciences and Arts
Lars Klüver Danish Board of Technology Foundation	**Lise Bitsch** Danish Board of Technology Foundation
David Wright Trilateral Research	**Rasmus Øjvind Nielsen** Danish Board of Technology Foundation
Tilimbe Jiya De Montfort University	**Marlou Bijlsma** NEN
Gregor Strle Slovenian Academy of Sciences and Arts	**Philip Brey** University of Twente
Daniela Ovadia European Union of Science Journalists Association	**Dino Trescher** European Union of Science Journalists Association
Thamar Zijlstra NEN	**Zuzanna Warso** Helsinki Foundation for Human Rights
Raija Koivisto VTT Technical Research Centre of Finland	**Lea Amby Ottosen** Danish Board of Technology Foundation

4.3 WORKSHOP PROGRAMME

DAY 1

Day 1 – Introduction to the workshop and SATORI			
11.00 - 11.30	• Welcome and introduction to the workshop • Introduction to SATORI – main achievements so far	Plenary	Lise Bitsch, DBT Signe Bøgh, DS Philip Brey, UT
11.30-12.00	• Introduction to Cost effectiveness and risk-benefit in relation to ethics assessment – developing a methodology • Introduction to the measurement of impact of ethics assessment	Plenary	Lise Bitsch, DBT Raija Koivisto, VTT
12.00 -12.15	• General introductions	Plenary	Everyone
Co-designing analyses of the cost-effectiveness of ethics assessment procedures			
12.15-12.45	Cost effectiveness analysis of ethics assessment procedures across 6 case studies. • What is the main desired effect (ex. health maximisation) for ethics assessment in various "cases" (ex. EU ethics review or science academies)?	Groups	Group 1: National Research Ethics Committees Group 2: Science Academies Group 3: Research Ethics Committees Group 4: National Ethics Committees Group 5: EU governmental level ethics review Group 6: Industry
12.45-13.00	Short discussion of initial promises and challenges	Plenary	Groups choose a representative to present in the plenary
13.00-14.00	Lunch		
14.00-14.45	Identifying methods for maximization of desired effect of ethics assessment • What about ethics assessment procedures in your case, what are their costs and contributions to the 'main desired effect'?	Groups	Group 1: National Research Ethics Committees Group 2: Science Academies Group 3: Research Ethics Committees Group 4: National Ethics Committees Group 5: EU governmental level ethics review Group 6: Industry
14.45-15.15	Cross-pollination for further development of methodology for CEA	Groups	Mixing of groups for diversification of ideas
15.15-15.45	Cross-pollination for further development of methodology for CEA	Groups	Mixing of groups for diversification of ideas
15.45-16.15	Coffee break		
16.15-	Elements of a cross-case analysis design	Plenary	Groups choose a representative to

17.15			present in the plenary
17.15-18.00	'Fishbowl' session – advice from external participants to SATORI about how to assess the cost-effectiveness of ethics assessment procedures in general	Plenary (5 min each)	Eric Griessler, University of Vienna Erin Kenneally, Homeland Security Rachel Douglas-Jones, University of Copenhagen Lars Klüver, Danish Board of Technology Foundation Johannes Rath, University of Vienna Aleksander Antovic, Bio Save Group Finn Arler, Aalborg University Frede Hvelplund, Aalborg University
18.00	End of day 1		

DAY 2

Day 2 – How to add value by using of risk-benefit analysis *in* ethics assessment procedures			
9.00 – 9.15	• Introduction to the day	Plenary	Lise Bitsch, DBT Raija Koivisto, VTT
9.15 – 9.30	• Introduction to risk-benefit in relation to ethics assessment – developing a methodology	Plenary	Dino Trescher, EUSJA
9.30-10.15	• TBC	Plenary	Erin Kenneally, Homeland Security Advanced Research Projects Agency
Co-designing hybrid ethics assessment procedures by adding elements of risk-benefit analysis			
10.15 -11.00	Risk Benefit analysis of ethics assessment procedures across 6 case studies. • What is done at present? • How is it done (promising methods?) • What are challenges?	Groups	Group 1: National Research Ethics Committees Group 2: Science Academies Group 3: Research Ethics Committees Group 4: National Ethics Committees Group 5: EU governmental level ethics review Group 6: Industry
11.00 -11.15	Short discussion of initial promises and challenges	Plenary	Groups choose a representative to present in the plenary
11.15 -11.45	Coffee break		
11.45-12.30	Improving ethics assessment through inclusion of risk-benefit analysis. • How could risk-benefit analysis be beneficial in ethics assessment?	Groups	Group 1: National Research Ethics Committees Group 2: Science Academies Group 3: Research Ethics Committees Group 4: National Ethics Committees

	• How can challenges be overcome?		Group 5: EU governmental level ethics review Group 6: Industry
12.30 - 13.00	Cross-pollination for further development of methodology for RBA	Groups	Mixing of groups for diversification of ideas
13.00-14.00	Lunch		
14.00-14.30	Cross-pollination for further development of methodology for RBA	Groups	Mixing of groups for diversification of ideas
14.30 -15.15	Cross-case conclusions: Added value from risk-benefit analysis in ethics assessment	Plenary	Groups choose a representative to present in the plenary
15.15-16.00	Coffee, Joint construction of a (draft) methodology	Plenary	Chair: Lise Bitsch, DBT
16.00-18.00	End of CEA and RBA part – start of SATORI Roadmap Session		Chair: Raija Koivisto, VTT Everyone is invited to participate. Please see separate program for details.