Standards, tools and best practices for policy-oriented assessment and guidance of new developments and practices in research and innovation

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Annex 2

A reasoned proposal for a set of shared ethical values, principles and approaches for ethics assessment in the European context

Deliverable 4.1

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1 STANDARDS, TOOLS AND BEST PRACTICES FOR POLICY-ORIENTED ASSESSMENT AND GUIDANCE OF NEW DEVELOPMENTS AND PRACTICES IN RESEARCH AND INNOVATION

1.1 INTRODUCTION

When considering the best practices for policy-oriented assessment and guidance, this report follows in the findings of SATORI *Deliverable 1* for its conceptualization between what constitutes ethics guidance versus ethics assessment. It has identified 3 major categories of ethics assessment units (EAUs) that typically engage in policy-oriented assessment and guidance: Governmental organizations, National Ethics Committees, and Civil Society Organizations. The introductions and recommendations presented here are built upon previous SATORI deliverables, incorporating the empirical work of *Deliverables 1, 2 and 3* plus the analysis in SATORI *Deliverable 4.1*. The recommendations are presented in accordance with the principles of SATORI *Deliverable 4.1*. Each of the three organizational types are considered in their own right. For each, we propose best practices *Standards for policy oriented guidance, Standards for policy-oriented assessment, Expertise for policy-oriented assessment and guidance, and Procedures for policy-oriented assessment and guidance.*

1.2 POLICY-ORIENTED ASSESSMENT AND GUIDANCE

The following section is a reproduction of from SATORI Deliverable 1 *Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries.*

Policy-oriented assessment is understood here as the ethics assessment of (new) scientific fields, methods, techniques, technologies, devices or innovation areas. This kind of assessment is performed by National Ethics Committees, government entities, CSOs (often informally), and other agents who are active in the policy arena.

> Example of moral judgment: “Human cloning is morally wrong, and should be banned.”

There are substantial differences between these types of assessment. Project- and practice-oriented assessment is the most typical type of ethics assessment, and focuses on practices and associated phenomena like aims, proposals, collaborative structures, and tools of scientists and innovators. Policy-oriented assessment does not focus on these practices, but rather considers ethical issues associated with science and technology from a general, societal point of view. Here the question is rather: what kinds of ethical issues associated with science and technology should society worry about, and how should it deal with these issues? Such assessments naturally give rise to policy advice. This policy advice may affect research and innovation practice, but it may also affect the dissemination and use of the products of research and innovation.

 Policy-oriented ethical guidance: Ethical guidance for broader developments in science and technology and related policies (i.e., a framework for assessing such

developments, not the actual assessments themselves). This is, in a sense, guidance for society as a whole, as opposed to guidance for particular actors.

Example: the precautionary principle, principles of distributive justice and the rights of future generations.

Extended example: An ethical framework for assessing research, production and use of energy from the European Group on Ethics in Science and Technology.

It should be observed that the distinction between ethical guidance for projects and practices and policy-oriented guidance is sometimes blurred, because policy-oriented assessments sometimes focus strongly on particular research and innovation practices, and may for that

Ethical guidance has two major applications: (1) Guidance decisions, behaviors and practices in R&I, and (2) Ethics assessment of R&I

Regarding the first use, ethical guidance can be used to directly guide individual and collective decisions, behaviors and practices in R&I. For example, ethics codes for engineers may contain the principle "Be truthful". Engineers who learn the code could be inspired to shape their actions so that they adhere to this principle. Ethical guidance is also used to guide ethics assessment. This occurs when its principles are used as a framework for making moral judgments in ethics assessment. For example, a principle of informed consent for ethical guidelines for medical practice may be used to assess whether or not a research proposal or practice properly incorporates informed consent in the research design.

Ethical guidance is, by definition, advisory, not mandatory. However, ethical guidance is sometimes turned into mandatory regulation akin to law, and ethical guidelines are sometimes encoded in law. It should be observed, finally, that the distinction between ethics assessment and ethical guidance is not always sharp, because statements and reports may contain both ethical guidelines and ethical assessments. Usually, however, either ethical guidance or ethics assessment constitutes the primary aim of the document.

1.3 GOVERNMENTAL ORGANISATIONS

This section will focus on standards, tools and best practices for policy-oriented assessment and guidance of new developments and practices in R&I by governmental organisations; broadly understood as organisations dealing with R&I that answer directly to national or regional governments or are directly funded by those governments. Most of the discussion will be based on the SATORI *Deliverable 1, Annex 3.f* report on Government and Government-funded organisations, *Annex 3.c* of the same deliverable on Research Funding Organisations and the SATORI *Deliverable 4.1* report; specifically the section on shared ethics assessment procedures. Additionally, specific literature on governance of R&I will be consulted.

In order to identify *best practices* with regards to ethics guidance and assessment of government-related entities, we will take in account the concept of "good governance" that plays a key role in deciding which policies are adequate for addressing a public issue. According to Munshi, Abraham and Chaudhuri (2014), this

includes "public sector management as well as the formation of rules and institutions"[1]. They argue that good governance should adhere to the principles of effectiveness, honesty, equality, transparency and accountability. According to the United Nations, good governance is necessary for fostering human rights[2] and it is defined as the "exercises of authority through political and institutional processes that are transparent and accountable, and encourage participation"[3].

In the next sections, we firstly discuss the standards for guidance of ethics in R&I, followed by its assessment, the role of expertise and recommended procedures. Special attention will also be paid to possible impacts of differences in value-systems and ethics assessment practices in the context of globalisation, as based on SATORI *Deliverable 3.2* and *Deliverable 3.3*.

1.3.1 Standards for policy-oriented guidance

First, we deal with the question *how* policy-oriented guidance could best be exercised, mostly based on earlier findings in the SATORI project. With "guidance" we can understand soft-law recommendation type policies that for instance recommend how ethics committees could be set up or how certain ethical guidelines could be taken into account in an organisation's management structure. Based on the findings in the SATORI *Annex 3.f* and *Annex 3.c* reports of *Deliverable 1,* we identified a number or ways in which guidance is currently organised. Some tools for guidance are very implicit, for instance by involving an ethical expert in the review of an R&I project. Some tools are directed at the political level, being advices for policy reforms, and some tools are directly focused on steering R&I by providing specific methods or guidelines for dealing with ethics in the project or using funding mechanisms to incentivise ethical R&I. Moreover, there are different ways in which the people who are providing guidance to the ethical aspects in R&I are selected. Sometimes, committees exist solely of governance officials, sometimes they include appointed experts and sometimes they include a broad range of stakeholders.

How guidance is organised

- Implicit tools for ethics guidance in R&I
  - General ethical codes of conduct at the governmental level
  - Involving an ethical expert in technical reviews of R&I projects
  - Gather advice from specialised CSOs
- Tools directed at the political level
  - Develop national plans for long-term development
  - Policy guidance for legislators by expert groups
- Direct guidance of ethics in R&I
  - Providing grants for establishing ethics committees, developing training programs, or chairing programs
  - Preparing opinions, guidance and proposals regarding ethical principles
  - Develop integrated ethics approaches
  - Encouraging subsidies based on ethical qualities of a project

[1] Munshi, S., B.P. Abraham, & S. Chaudhuri. *The intelligent person's guide to good governance*. Los Angeles: SAGE Publications. 2014. http://doi.org/10.1007/s13398-014-0173-7.2
[2] OFFICE OF THE UNITED NATIONS HIGH COMMISSIONER FOR HUMAN RIGHTS. *Good governance practices for the protection of human rights*. New York. 2007.
[3] Ibid. p.2.

Composition of bodies providing guidance

- Committee of government officials
- Committee of experts
- Ethics committee based on rule-governed broad representation

Recommendations for best practices

As a development in the area of ethics guidance by government organisations, the SATORI project mentions the good practice of transparent evaluation of the ethics guidance practices themselves[4]. This implies that the organisations providing for the ethics guidance should conduct internal evaluations at regular times in order to check on their accountability and transparency. Also, it mentions the good practice of including lay people in the guidance process as well, to have a fair representation of society that is affected by R&I and to increase the visibility of the R&I practices for the public in order to increase the transparency and accountability of the process. Wessner suggests an additional practice for guidance (for innovation initiatives, but also applicable to ethics guidance), namely to involve CSOs in the guidance process[5] to include a diversity of voices. Finally, in accordance with *Deliverable 3.2*, we recommend that special attention is paid to the correspondence of ethics guidance practices to the value system in which they are deployed; especially whence the R&I project they apply to includes researchers from different cultures or countries[6].

- Directly involve CSOs in the ethics guidance process
- Regularly evaluate the ethics guidance procedures
- Include community members and lay persons in the ethics guidance processes
- Create greater public visibility of ethics guidance
- Ethical guidance must rest on ethical values and principles that are in line with society.

1.3.2 Standards for policy-oriented assessment

Secondly, we deal with the question of *how* policy-oriented assessment could best be exercised, mostly based on earlier findings in the SATORI project. With "assessment" we understand here policy-oriented tools that either enable the assessment or directly assess R&I projects according to established criteria. Governmental organisations have relatively little to do with ethics assessment, while research funding organisations do. Some tools for ethics assessment are aimed at *creating* policies that define practices for ethics assessment, directly at the political level. Other tools are either supervision tools that allow for direct policy-oriented influence on and R&I project or tools for granting or denying funding for an R&I project. According to *Annex 3.c* and *3.f* of SATORI *Deliverable 1*, the following tools for ethics assessment are currently used in R&I:

[4] Ibsen-jensen, J., & Lygum, A. K. (2015). Ethics assessment and guidance in different types of organisations Government and Government-Funded Organisations (No. D.1 Annex 3.f). p.16.
[5] Wessner, C. W. Best practice in state and regional innovation Initiatives. National Research Council of the National Academies. Washington D.C. 2014. http://doi.org/10.1007/s13398-014-0173-7.2

[6] Brey, P. (2015). International differences in ethical standards and in the interpretation of legal frameworks (No. Deliverable 3.2).

How assessment is organised

- At the political level
  - Drafting national regulations
  - Transposing EU directives
- Direct influence on R&I projects
  - Ethical tests by independent experts of different countries
  - Supervision
- Funding control of R&I projects
  - Obligatory ethics clearance
  - Evaluation of R&I funding proposals

Composition of bodies doing the assessment

- Supervision committee with scientists and administrative experts
- Appointed selection committee of experts
- Reviewers voted by community of experts

Recommendations for best practices

Some best practices have been identified with regards to how ethics assessment of R&I by governmental organisations can be improved. First of all, one of the issues that are identified in the *Annex 3.c* report of *Deliverable 1* is that in committees doing the ethics also non-ethicists should be included in order to assure a plurality of voices and to create understanding amongst researchers as to why ethics assessment is done. Another best practice that has been identified is to make sure that when laws and regulations are aligned, for example when EU laws are transposed to the national level, this process is made transparent and accessible to all stakeholders involved. Moreover, we recommend that diversity be taken into account in the composition of the bodies doing the ethics assessment, focusing on e.g. representation from different countries and a gender balance. Finally, in line with Haggerty we recommend that attention should be paid to the bureaucratic burden of ethics assessment procedures, in order to not transform the means of an ethics assessment process into a bureaucratic end in itself.[7]

- Include non-ethicists in ethics assessment committees
- Transparently align different law regimes
- Diversify the ethics assessors according to country, gender etc.
- Prevent an “ethics creep” from happening; minimise bureaucracy

1.3.3 Expertise for policy-oriented guidance and assessment

Thirdly, we shortly discuss the way expertise plays a role in the process of policy-oriented ethics guidance and assessment of R&I. “Expertise” refers to a quality that the people doing the ethics guidance and assessment ought to possess, although the definition of this quality is largely dependent on the context and value system in which the process takes place. Currently, as can be derived from the abovementioned overviews, technical, professional and scientific expertise play a highly dominant role

[7] Haggerty, K. D. Ethics Creep: Governing Social Science Research in the Name of Ethics. Qualitative Sociology, 27(4), 35–37. 2004. http://doi.org/10.1023/B

in the guidance and assessment processes. Most committees involved in these processes are appointed members of the community of bureaucrats, scientists or ethicists that enjoy high respect from their peers.

However, we also found that the diversity of stakeholders and the processes by which they are appointed do not strictly confirm with the principles of good governance, of transparency and accountability. The SATORI *Deliverable 3.2* showed that although the role of government is perceived differently across cultures, democracy is a shared value across cultures[8]. For that reason, we recommend that democratic principles as principles of accountability be taken into account in the composition of the groups of people that perform the guidance and assessment processes. Good practices of implementing democratic values are the voting of committee members in a community of peers, or the allotment of lay people to include them as representatives in the ethics guidance and assessment bodies.

Best practices for making sure that the bodies performing guidance and assessment are accountable are, as we have seen above, the following of strict rules of representation (for instance, always including people from certain stakeholder groups) or guaranteeing a certain level of diversity, for instance by establishing rules concerning gender balance. Finally, *Deliverable 3.2* showed that the public is often distrustful of developments in science in technology though it trusts scientists in general. Therefore, we recommend to promote the engagement of experts in bodies that do guidance and assessment of R&I in public debates.

Recommendations for best practices

- Taking into account the value of democracy in the composition of ethics guidance and assessment bodies
    - Voting of committee members amongst peers
    - Allotment of lay people as representatives[9]
- Taking into account the accountability of expert bodies
    - Following strict rules of representation in appointing committees
    - Guarantee diversity in committees
- Experts should engage in public debates

1.3.4 Procedures for policy-oriented guidance and assessment

Fourthly, we shortly discuss best practices for procedures for policy-oriented guidance and assessment. Since for governmental organisations most procedures have to do with ethics guidance practices, they are often not very explicit. For research funding organisations, however, some procedures are very strict; for instance with regards to decisions concerning the granting or rejection of funding for an R&I project. What can be said is that some procedures have an informal character, such as consultation procedures during which governmental bodies consult a CSO or a group of experts. Formal procedures include for instance specifications of requirements for receiving ethics clearance for an R&I project, a formal decisions made by an ethics

[8] Brey, P. International differences in ethical standards and in the interpretation of legal frameworks (No. Deliverable 3.2). 2015.

[9] See also Seyfang, G., & A. Smith. Grassroots innovations for sustainable development: Towards a new research and policy agenda. *Environmental Politics*, *16*(4), 584–603. 2007. http://doi.org/10.1080/09644010701419121

assessment body to interfere in a R&I project or to grant or decline funding and the official presentation or publication of the ethics assessment process.

How procedures are organised

- Informal procedures
  - Consultation
- Formal procedures
  - Specification of requirements
  - Formal decision on interference
  - Formal decision on funding
  - Presentation of findings/decisions

Recommendations for best practices

With regards to the best practices for procedures of ethics guidance and assessment, two suggestions can be derived from the SATORI project. First, emphasis should be placed on the monitoring of the proper implementation of procedures for ethics assessment. Secondly, based on *Deliverable 3.2,* we recommend that the formality of procedures should be enforced carefully, for the pervasiveness of formal procedures has to be understood in the context of the value systems in which they are embedded.

- Monitoring of the implementation of procedures
- Sensitivity for intercultural differences

1.4 NATIONAL ETHICS COMMITTEES

1.4.1 Standards for policy-oriented guidance

Standards for policy oriented guidance of National Ethics Committees relate on the one hand to regulatory frameworks which are applicable to biomedical research and innovation at international level and on the other hand to the practice of National Ethics Committees.[10]

Several regulatory frameworks are applicable to biomedical research and innovation at international level, such as the Nuremberg Code of 1947,[11] the World Medical Association's Declaration of Helsinki 1964 in its latest revision,[12] several UNESCO Declarations[13] and the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 1997 (Convention on Human Rights and Biomedicine).[14] The only instrument which is legally binding in this context is the Convention on Human

[10] See: http://satoriproject.eu/media/3.b-National-ethics-committees.pdf
[11] See: http://www.cirp.org/library/ethics/nuremberg/ or http://www.who.int/bulletin/volumes/85/8/07-045443/en/
[12] See: http://www.wma.net/en/30publications/10policies/b3/
[13] See for instance:
- http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/
- http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genetic-data/
- http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/

[14] See: http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164

Rights and Biomedicine. All the other texts are non-binding commitments of the Member States, which result in a common understanding of the issues concerned.[15]
National Ethics Committees do not stick to fixed ethics principles and ethical issues in their deliberations and their reports. National Ethics Committees choose their ethics framework according to the topic. National Ethics Committees are usually alluding to the following ethics principles: justice / fairness, human dignity (including individual vs. collective interests), equality / non-discrimination, autonomy / freedom, privacy, solidarity / altruism, and the right to information.[16] They however add principles if needed.
The work of National Ethics Committees aims at the assessment of scientific and technological developments, at the formulation of recommendations and at fostering debate, education and public awareness of, and engagement in, bioethics.
National Ethics Committees are usually established by law. Their term of office varies between a fixed period of about four years or their term of office is tied to the term of office of the appointing authority. As regards the institutional set-up, they usually consist of about 15 or more non-remunerated members based in different fields of scientific research. Appointment procedures, tasks, composition, convocation of meetings, procedures, and the establishment of secretariats are usually provided for by law.[17]

Recommendation:

- National Ethics Committees should respect the international regulatory frameworks as applicable to biomedical research and innovation as laid down in Nuremberg Code of 1947, the World Medical Association's Declaration of Helsinki 1964 in its latest revision, several UNESCO Declarations and the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 1997.

- In addition National Ethics Committees should develop reference principles according to the topic under scrutiny and should be transparent about the ethics framework applied.

- National Ethics Committees should aim at providing recommendations for the political level and at fostering debate, education and public awareness of, and engagement in, bioethics.

- National Ethics Committees should be established by law.

- The work of National Ethics Committees should be supported by a permanent secretariat.

[15] See: http://www.google.at/url?sa=t&rct=j&q=&esrc=s&source=web&cd=6&ved=0ahUKEwiUna2CorPKAhXM0xoKHTbmC4MQFgg7MAU&url=http%3A%2F%2Fnerri.eu%2Fdownload.ashx%3Furl%3D%2Fmedia%2F10910%2Fcec-bookonline.pdf&usg=AFQjCNEGv72V_QezPcGNvbgc4DCjUERzCg&bvm=bv.112064104,d.d24
[16] See: http://satoriproject.eu/media/3.b-National-ethics-committees.pdf
[17] See: http://satoriproject.eu/media/3.b-National-ethics-committees.pdf

1.4.2 Standards for policy-oriented assessment

Does not apply, as NECs provide guidance.

1.4.3 Expertise for policy-oriented guidance and assessment

The establishment of Ethics Committees is advocated for by the Universal Declaration on Bioethics and Human Rights. Article 19 of the Universal Declaration on Bioethics stipulates that "Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level […]"[18], which also relates to the establishment of National Ethics Committees.
As previous research has shown,[19] a "golden standard" for which disciplines should be represented in National Ethics Committees does not exist, as the needed expertise also relates to the specific mandate which can vary among committees. It can however be witnessed that Ethics Committees respect the principle of multidisciplinary, as the following examples illustrate:

- The *Austrian Bioethics Commission* consists of experts representing the fields of medicine (especially reproduction medicine, gynaecology, psychiatry, oncology, and pathology), molecular biology and genetics, law, sociology, philosophy and theology. The legal basis also provides for an equal gender distribution of the members.

- The scientific The *Danish Council of Ethics* disciplines of include law, humanistic information studies, multimedia, science of public health and philosophy. The Law also provides for an equal gender distribution of the members.

- The *Finish National Advisory Board* is a multi-professional and multi-disciplinary board. There are university professors in health care, social care and ethics, doctors and nurses, social workers, members representing people with mental retardation and other types of disabled people, mental health, elderly care, communities and primary and specialist health care.

- The *German Ethics Council* is composed of twenty-six members specializing in scientific, medical, theological, philosophical, ethical, social, economic and legal concerns.

- The *Health Council of the Netherlands* consists of eight standing committees who are advised by 170 experts. The *Health Council of the Netherlands* does not meet on a plenary basis, but rather works on a case-by-case basis. The established permanent Committees are responsible for providing advice on frequently returning topics.

- The current membership of the *Slovenian National Ethics Committee* also includes a psychologist, an expert in law, a philosopher, a moral theologian, and a layperson.

The principle of independence relates to the fact that members of Ethics Committees are not bound by instructions of sending institutions. They participate in deliberations in their personal capacity as experts in a particular field of competence.

[18] See: http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/
[19] See: http://satoriproject.eu/media/3.b-National-ethics-committees.pdf

The principle of pluralism is usually interpreted as a call for the appointment of members representing different values as represented in society.

Recommendations:

- National Ethics Committees should be established as independent, multidisciplinary and pluralist ethics bodies.
- The legal base of a National Ethics Committees should also provide for an equal gender distribution of members.

1.4.4 Procedures for policy-oriented guidance and assessment

Procedures for deliberations in National Ethics Committees can be divided into three phases.[20]

- The initial phase is characterized by the selection of the relevant topics. The discussion of a particular topic can either be requested by the authorities under which National Ethics Committees are operating or National Ethics Committees select a topic which they deem important by themselves.
- The deliberation phase is characterized by the organisation of the discussion among the members of the Committee. Most National Ethics Committees establish working groups, which interact with the plenary on a permanent basis. If need be, external experts are consulted during the discussion phase in the working groups or the plenary. In case of dissenting opinions National Ethics Committees usually aim at also examining and communicating the arguments of those members who have a dissenting opinion to the majority vote.
- Strategies of National Ethics Committees after the publication of an opinion relate on the one hand to informing the responsible authorities about their views and discussing their recommendations with them; and on the other hand in disseminating the opinion to the public.

In order to contribute to the international ethics debate, most National Ethics Committees translate their opinions into English.[21]

Recommendations:

- National Ethics Committees should work on topics which are assigned to them by the authorities under which they are operating. They should however also be able to select topics which they deem necessary in order to contribute to a relevant national or international debate.
- As regard working methods National Ethics Committees should organise plenary discussions which can be prepared by working groups or rapporteurs. Room should also be given for the discussion of dissenting opinions.

[20] See: http://satoriproject.eu/media/3.b-National-ethics-committees.pdf
[21] See: http://satoriproject.eu/media/3.b-National-ethics-committees.pdf

- National Ethics Committees should after the publication of an opinion inform the responsible authority about their views and should actively disseminate their opinion to the public. Dissenting opinions should be published in the same document as the majority opinion.

- In order to foster international debate National Ethics Committees should try to also provide their opinions in a language understood by the international community.

1.4.5 Recommendations for National Ethics Committees– summary

- National Ethics Committees should respect the international regulatory frameworks as applicable to biomedical research and innovation as laid down in Nuremberg Code of 1947, the World Medical Association's Declaration of Helsinki 1964 in its latest revision, several UNESCO Declarations and the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 1997.

- In addition, National Ethic Committees should develop reference principles according to the topic under scrutiny and should be transparent about the ethics framework applied.

- National Ethics Committees should aim at providing recommendations for the political level and at fostering debate, education and public awareness of, and engagement in, bioethics.

- National Ethics Committees should be established by law.

- The work of National Ethics Committees should be supported by a permanent secretariat.

- National Ethics Committees should be established as independent, multidisciplinary and pluralist ethics bodies.

- The legal base of a National Ethics Committees should also provide for an equal gender distribution of members.

- National Ethics Committees should work on topics which are assigned to them by the authorities under which they are operating. They should however also be able to select topics which they deem necessary in order to contribute to a relevant national or international debate.

- As regard working methods National Ethics Committees should organise plenary discussions which can be prepared by working groups or rapporteurs. Room should also be given for the discussion of dissenting opinions.

- National Ethics Committees should after the publication of an opinion inform the responsible authority about their views and should actively disseminate their opinion to the public. Dissenting opinions should be published in the same document as the majority opinion.

- In order to foster international debate National Ethics Committees should try to also provide their opinions in a language understood by the international community.

1.5 CIVIL SOCIETY ORGANIZATIONS

The following sections on Civil Society Organizations (CSOs) are reproduced in full from SATORI Deliverable 4.2.5 **Models for ethics assessment and guidance at CSOs,**[22] except the section on 1.5.2 on Expertise. Civil Society organizations operate their own unique role within the ethics assessment and guidance framework but are largely are involved in policy oriented guidance, hence their inclusion in this report.

1.5.1 Standards for policy-oriented guidance and policy-oriented assessment

Criteria that good ethics guidance or assessment should meet in order to serve the interests (goals) of the CSOs can be divided into two groups: general and specific. General criteria are not different from those proposed in Satori Deliverable 4.1.3, based on John Rawls conception of morality[23]. Example of a set of minimum moral requirements for ethic assessment could be based on following principles: (i) general, (ii) universal, (iii) public (for the sake of transparency), (iv) include conditions for ranking/weighing, and (v) override other concerns."

When it comes to specific criteria they could stem from CSOs area of work and interests, i.e. their missions and visions. In line with that we have identified two groups of criteria for good guidance or ethics assessment.

In some cases, CSOs ethics guidance are created for assessing broader developments in science and technology and related policies. This guidance considers ethical issues associated with science and technology from a general, societal point of view and can be seen as *guidance for society as a whole*, as opposed to *guidance for particular actors*. In line with that, one of the most important questions is: what are the ethical issues associated with scientific research and innovation that society should worry about, and how should it deal with these issues? Accordingly, the first group of criteria for good guidance or ethics assessment should fit this question and can be labelled - *concern for the society* (i.e. social responsibility, sustainability, preservation of cultural monuments serving public interests, transparency, solidarity...)

On the other hand, some CSOs represent interests of particular groups of people, such are rear disease patients, professionals in different fields, consumers, etc. For them one of the most important questions is: what are the ethical issues associated with scientific research and innovation that CSOs members and "clients" should worry about, and how should they deal with these issues? In line with that, the second group of criteria for good guidance or ethics assessment should fit this question and can be

[22] SATORI Deliverable 4.2.5 **Models for ethics assessment and guidance at CSOs**
[23] John Rawls, *A theoryofjustice*, rev.ed, Oxford: Oxford Univ. Press, 1999 (1971), p. 112ff.

labelled - *concern for the individual* (i.e. professional and scientific integrity, privacy, safety, informed consent, confidentiality, non-malfeasance)

1.5.2 Expertise for policy-oriented guidance and assessment

A common issue for CSOs is the lack of expertise to engage in ethics assessment process. This may stem from a lack of experience, knowledge, or subject area competency.[24] Therefore the recommendations are to

- engage experts in the procedures of ethical assessment;
- establish expert groups and forums for expert discussions;
- perform in the role of the "public" in ethical guidance and assessment
- engage in *ethics capacity building and training*, with other CSO or individuals to enhance their capacity to perform ethics assessment or guidance

in line with the specific goals of the particular CSO.

1.5.3 Procedures for policy-oriented guidance and assessment

CSOs can take an important role in the phase prior to ethics assessment. According to Satori Deliverable 4.1.3 procedures prior to assessment run from the formulation and dissemination of policies for ethics assessment, to the actual submission of proposals to the ethics assessment unit as well as the procedures necessary for preparing the proposals for ethics review. Based on the summary of the relevant procedures taking place prior to ethics assessment, the most common procedures identified are (i) procedures related to the selection of relevant topics or questions that are in need of further assessment, and (ii) procedures related to the submission of R&I proposals for ethics assessment, or the ethics assessment / ethics audit of R&I activities. In many cases the selection is initiated due to a pressing need to explore the ethical impact of R&I, especially regarding the development and use of new technologies, recent biomedical or biological advances or new or controversial research methods.

In view of the fact that one of the aims of ethics assessment is to increase the awareness about ethical impact of research, policies and procedures CSOs can play an important role before ethic assessment begins. The procedures prior to ethics assessment that could be performed by CSOs are:

1. ethics pre-screening – analysing the potential ethical issues i.e. identification of relevant topics or questions that should be further analysed from ethics point of view;
2. raising awareness about ethics – disseminating knowledge of and promoting ethics in R&I; organising public debates (tribunes, round tables, discussions)

[24] [24]http://satoriproject.eu/media/3.g-Civil-society-organisations__.pdf

on ethical and moral dilemmas; promoting ethical behaviour among researchers;
3. providing education and training regarding ethical issues and assessment;
4. supporting civic (political) activism - lobbying, influencing policy making and makers, giving advices, providing advocacy;
5. creating guidance or codes of conducts;
6. engaging external ethics experts or audits.

1.5.4 The role of CSOs during assessment

CSOs rarely formally engage in the ethic assessment process and if they are involved their role is often informal. As we already mentioned, ethics assessment performed by CSOs is primarily related to analysing data that has been gathered, and the writing of reports, guidelines and recommendations. That is why it is very important to make room for participation of CSOs in institutionalised forms of ethics assessment or guidance and formal advisory panels.

In addition, CSO should make use of the available forms of their engagement, e.g. participate ad research ethics committees

When it comes to phases and objects of ethic assessment defined by Satori Deliverable 4.1.3 the CSOs can have important role in protecting stakeholders from undue risk and harm (e.g. individuals participating in research) as well as in increasing the awareness of the ethical impact of R&I. For example a Patient CSO can be formally involved in assessing research grant applications for medicines to bring in the experience and perspective of patients or CSO representatives could be members of ethics committees.

Furthermore, CSOs can take part in creating “policies, guidelines, tools and principles for ethics assessment of R&I” as well as in monitoring “behavioural compliance with legislation, ethics standards, polices and declarations”

1.5.5 The CSOs role after ethics assessment

CSO can also have important role after ethic assessment take place. Many of CSOs already have experience and developed procedures and techniques for monitoring compliance and disseminating results and recommendations, which are the most important procedures after ethic assessment is performed:

1. monitoring procedure – CSOs have in general extensive and well-functioning procedures regarding monitoring compliance. The purpose for looking at the phase after the assessment is to see monitor compliance and to inform and to make the reports, policies, codes and guidelines that are the result of the EAUs assessment public. If non-compliance has been identified during the assessment/audit process it will be further monitored by the auditing body. The progress of the follow-up actions of the enterprise will be tracked. A final report will be written. In some cases, the final report are made public.

Monitoring is also an important tool for making researchers aware of the importance of ethics review of R&I. If there are no monitoring procedures or no measures taken when individuals or organisations do not comply, there is a risk that the trust towards ethics assessment organisations will be undermined.

2. dissemination procedure – CSO can have important role in disseminating ethical assessment results bearing in mind that main aspects of their work is related to communication with public. Thus, CSO can use their channels and networks to communicate results of ethic assessment to stakeholder and society in general. Steps in dissemination procedure could include:
    - identification of stakeholders and target groups to communicate with
    - preparing press releases and other materials (newsletters, flyers, posters) for the media
    - using website, social media, e-mail for dissemination of materials and communication
    - publishing documents – Policy papers, Reports, Scientific journal articles, conference presentations, education and training books and manuals
    - organising conferences, workshops, round tables, seminars, education and trainings

1.5.6 Recommendations for CSOs – summary

The process of establishing a framework should be a participatory effort. Moreover, the framework itself, in terms of its scope, should also be inclusive, meaning that in the process of ethics assessment interests of different groups should be taken into consideration. The framework should be, to a largest possible extent, "a living instrument". It should adopt a human rights based approach and should account for the existing discrepancies, for example between states.

There is a need for implementing different models of engagement, depending on the extent to which CSOs (bearing in mind the available resources) may become involved in the ethics assessment/guidance. For example, CSOs whose activities are related in some way to R&I, but who do not plan to have a dedicated unit or an officer who would perform ethics assessment or guidance, should be offered trainings in order to increase the awareness of ethical issues, as well as tools such as checklists and general guidelines that can be easily used on an on-going basis in different types of projects. They should be able to consult with organizations who specialize in performing ethics assessment or guidance (networking should be supported).

In the case of organizations that wish to have a dedicated structure for ethics assessment/guidance, there is a need to ensure financing. Moreover, it would be advisable to support the development of independent CSO that would focus on research and innovation and cooperate with other CSOs in developing agendas and strategies of their own.

In order to increase the impact of CSOs there is a need to:

- ensure the participation of CSOs in research projects;
- strengthen the CSOs mandate to have representatives in research ethics committees; encourage CSO to participate in RECs;
- ensure the participation of CSOs in institutionalised forms of ethics assessment or guidance and formal advisory panels; it would allow CSOs to develop expertise in the area of assessment and guidance. At the same time, it is necessary to make sure the functioning of any mechanisms is transparent and remains open to interested parties.
- strengthen the CSOs right to participate in decision-making - CSOs should be able to comment on policies, plans, programmes and proposals for R&I projects affecting the society; they should receive feedback;
- engage CSOs in ethics capacity building and training to enhance their capacity to perform ethics assessment or guidance
- encourage CSOs networking and creating working groups devoted to ethics assessment and guidance