Proposals for the institutional structure of ethics assessment in the EU and its constituent countries

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Annex 9

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 INTRODUCTION

This report offers proposals for the institutional structure of ethics assessment in the EU and its constituent countries. It aims to answer the question of what national and EU institutional structures and procedures are necessary to properly organize and harmonize the ethics assessment framework that is proposed in the SATORI report on subtask 4.3.1.

This question is addressed *at the EU level* for eight types of organisations that perform ethics assessment and/or ethics guidance, namely: universities, national science academies, research funding organisations, research ethics committees, national ethics committees, academic and professional organisations, civil society organisations, and companies. In addition, this question is addressed *at the national level* for EU countries, with special focus on countries that have less developed institutional structures of ethics assessment.

The recommendations given in this report are to a large extent based on the empirical research conducted for SATORI Deliverable 1.1: *Ethical Assessment of Research and Innovation: A Comparative Analysis*. This deliverable includes an analysis of ethics assessment and guidance in different types of organisations. It also includes a comparative analysis of ethics assessment structures in different countries, which is based on 11 in-depth country studies that are annexed to the main report – Austria, China, Denmark, France, Germany, the Netherlands, Poland, Serbia, Spain, United Kingdom and the United States of America.[1] As a part of the empirical research for Deliverable 1.1, a large number of interviews were conducted with representatives of different types of organisations involved in ethics assessment in the respective countries.

This report also builds on the findings of other reports in Work Package 4, including the reports on subtask 4.2.4 (*Models for Ethics Assessment and Guidance in Higher Education*), subtask 4.2.5 (*Models for Ethics Assessment and Guidance at CSOs*), subtask 4.2.6 (*Models for Ethics Assessment and Guidance in industry*), and subtask 4.2.7 (*Models for Ethics Assessment in Research Funding Organisations*).

In sections 2 through 9, we present recommendations regarding the institutional structure of ethics assessment for, respectively, universities (section 2), national science academies (section 3), research funding organisations (section 4), research ethics committees (section 5), national ethics committees (section 6), academic and professional organisations (section 7), civil society organisations (section 8), and industry (section 9). In section 10, finally, recommendations regarding institutionalisation are presented for the *national level* of EU countries in general, and, in particular, for a small number of countries that generally have a less developed institutional structure for ethics assessment.

[1] The reports are available at: http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/.

2 UNIVERSITIES

There are various means for advancing the consideration of ethical issues in research and innovation at universities. In terms of specific institutions, the main instruments are *scientific integrity boards* and *research ethics committees*. The recommendations in this section aim to address the challenges faced when relying on these institutions – challenges that have been identified and described in detail in previous SATORI reports.[2]

With regard to scientific integrity boards, our recommendations are aimed at ensuring that: (1) the operation of these bodies and decisions on misconduct are consistent across institutions; (2) real and apparent conflicts of interests are avoided; (3) the boards and investigators are afforded independence; (4) all cases of misconduct are addressed at a proper level; and (5) the rights of whistleblowers and of persons accused of misconduct are protected.

Similarly, with regard to research ethics committees the overarching goal of the recommendations is to ensure transparency and consistency across institutions and fields—while bearing in mind that due to the specific needs of some fields a one-size-fits-all approach may not be appropriate. Moreover, the recommendations are aimed at ensuring that the process of establishing common approach is inclusive and allows for change, and that the research ethics committees enjoy independence.

Scientific integrity boards

The following are our recommendations for improving the institutional structure of *scientific integrity boards* with regard to ethics assessment. For each general recommendation (indicated by a numeral), one or more actions (indicated by a letter) are listed that should be taken by specific actors.

1. There must be clarity in the legal framework in terms of which organisations are responsible for particular aspects of the inquiry and investigation processes.[3] This is important for transparency and consistency, as well as for avoiding potential litigation in response to irregularities in these processes.[4]
    a. The relevant body at the national level – which can be the national science academy, a university association, a governmental body or an official committee established with appointed representatives from those institutions – should establish clear guidelines on investigating scientific misconduct. These should include overarching principles as well as standard procedures that can be implemented at the level of individual institutions.
    b. Different entities should handle the investigation, adjudication/sanctions and appeal phases of an allegation of misconduct.[5]

[2] See forthcoming report on Models for Ethics Assessment and Guidance in Higher Education, Subtask 4.2.4 of the SATORI project.
[3] Boesz, Christine C., "Developing Research Integrity Structures: Nationally and Internationally", in *Promoting Research Integrity in a Global Environment*, edited by Tony Mayer and Nicholas Steneck, World Scientific Publishing, Singapore, 2012, pp. 7–16 [p. 11].
[4] Ibid.
[5] Boesz, 2012, p. 14.

c. The relevant body should decide upfront whether different organisations or bodies within or outside the research organisation are responsible for different categories of allegation of wrongdoing, to ensure that all are covered.[6] This division of labour could be based on the severity of the alleged wrongdoing; the wrongdoer (e.g., a student or an experienced researcher); or the type of alleged wrongdoing (e.g., personal misconduct, poor data practices, inappropriate research procedures or publication derelictions).[7]
d. The relevant body should write out sufficiently detailed procedures so that there is uniformity in inquiry and investigation processes across organisations.[8]
e. If there is an Ombudsman or similar body at the national level, there should be clear instructions provided to staff of research institutions about the Ombudsman's role and ability to provide counsel and advice.[9]
f. Investigators should maintain detailed, confidential records of all proceedings.[10]

2. The independence of those investigating alleged misconduct should be protected so that their investigation is fair and impartial. Such independence may be difficult to achieve for an institutional integrity board, but it is possible if the integrity board is separate from the research-performing sections of the institution. Conflicts of interest (real and apparent) must be avoided, and the integrity board should have the necessary resources to perform its work without having to rely on other sections of the institution.[11]
    a. The relevant body should ensure that integrity boards are independent. One way to do this is making the integrity body separate from the research-performing institution.
    b. The relevant body should have all investigators and staff make a "Conflict of Interest Declaration" both when hired and thereafter on a yearly basis.[12]
    c. The relevant body should write out explicit rules aimed at avoiding conflicts of interest.[13]
    d. Investigators of alleged scientific misconduct should not report to the research management under investigation.[14]
    e. Investigators should have an independent budget that is sufficient for thorough investigations and of which the source and amount is determined before investigations begin.[15]

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[6] European Science Foundation and ALL European Academies, "The European Code of Conduct for Research Integrity", 2011, pp. 8–9, 12. Available at: http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf.
[7] European Science Foundation and ALL European Academies, 2011, pp. 8-9, 12; Boesz, 2012 [p. 9].
[8] European Science Foundation and ALL European Academies, 2011, p. 15.
[9] European Science Foundation, "Good Scientific Practice in Research and Scholarship", 2000, p. 15. Available at: http://www.esf.org/fileadmin/Public_documents/Publications/ESPB10.pdf.
[10] European Science Foundation and ALL European Academies, 2011, p. 15.
[11] Boesz, 2012, p. 11–12.
[12] Hin, Lee Eng, "Research Integrity Challenges—A Singapore Perspective", in *Promoting Research Integrity in a Global Environment*, edited by Tony Mayer and Nicholas Steneck, World Scientific Publishing, Singapore, 2012, pp. 21–25 [p. 23].
[13] European Science Foundation, 2000, p. 14.
[14] Boesz, 2012, p. 11.

f. Investigators should be provided with clear, precise and easily understood standards so that they do not have to rely on researchers or other parties to explain the standards.[16]
g. Investigators should be experienced and qualified.[17]

3. In cases of severe fraud, it may be necessary to refer the case to integrity boards established outside the institution, e.g., at national science academies.
    a. The guidelines should specify criteria which should be considered in order to refer the case to the integrity board outside the institution, including the severity of fraud, the position occupied by the researcher who is suspected of misconduct.
    b. To ensure consistency, the integrity board to which cases of severe fraud will be reported should be predetermined, rather than decided on an ad hoc basis.
    c. The relevant body should predetermine if there are categories of cases that do not rise to the level of severe fraud but still warrant outside review. For these cases, the body should consider bringing in an outside mediator to the process.[18]

4. To encourage whistleblowers to report research misconduct when and if it occurs, institutions should put in place protections against retaliation against those who report misconduct.[19]
    a. The relevant body should make a "whistle-blowing policy" public and readily available to staff.[20]
    b. There should be a confidential mechanism through which whistleblowers can report allegations of wrongdoing or retaliation after having reported misconduct.[21]
    c. Where possible, the investigation as well as all communications with third parties and witnesses should be confidential to protect the identity of the whistleblower.[22]
    d. A whistleblower should not be penalized for making an allegation of research misconduct in good faith, even if it turns out to be incorrect.[23]

5. In the case of international research projects, the agreement that states the terms of the collaboration should clearly describe how allegations of research misconduct will be

[15] Boesz, 2012, p. 11–12.
[16] Boesz, 2012, p. 13.
[17] Boesz, 2012, p. 13.
[18] European Science Foundation, 2000, p. 11.
[19] Redman, Barbara, and Arthur Caplan, "No One Likes a Snitch", *Science and Engineering Ethics*, vol. 21, no. 4, June 2014, pp. 813–819 [p. 817].
[20] Hin, 2012, p. 23.
[21] Boesz, 2012, p. 13.
[22] Boesz, 2012, p. 14; European Science Foundation and ALL European Academies, p. 15.
[23] European Science Foundation and ALL European Academies, 2011, p. 16.

addressed. The text should include statements of what is considered research misconduct and the procedures through which such allegations will be investigated.[24]

a. The collaborators should explicitly decide on and write down a protocol to follow in cases of research misconduct before beginning research. The protocol should define, at a minimum, the authority structure, the scope and limits of an investigation, the rules for evidence and the source of resources.[25]
b. The collaborators should agree to report any potential deviation from the chosen protocol to designated persons.[26]
c. Before beginning research, all parties should agree on precise, written definitions of relevant terms (e.g. what constitutes "misconduct").[27]
d. Before beginning research, all parties should agree on the appropriate level of confidentiality for an inquiry into any allegation of misconduct.[28]

6. It is important to ensure that integrity boards have codified substantive protections for the parties involved in the case
    a. The relevant body should publish investigating procedures (including jurisdiction, rules of procedures, timeline and potential sanctions) in a clear, easy-to-understand and accessible manner for all staff.[29]
    b. The relevant body should ensure that the entire staff understands what constitutes misconduct.[30]
    c. The relevant body should provide the accused with complete details of the alleged wrongdoing.[31]
    d. The investigation process should allow sufficient time at each step of the process for the accused to fairly present his/her case.[32]
    e. Witnesses should be allowed to seek advice from and be accompanied by counsel.[33]
    f. All decisions should be subject to an appeal.[34]
    g. As much as possible, no penalty should be levied against an accused person before a verdict.[35]

Ethics assessment committees in higher education system

The following are our recommendations and action points for improving the institutional structure of ethics assessment committees in the higher education system:[36]

[24] OECD Global Science Forum, "Investigating Research Misconduct Allegations in International Collaborative Research Projects: A Practical Guide". http://www.oecd.org/sti/sci-tech/42770261.pdf.
[25] Boesz, 2012, p. 13; European Science Foundation and ALL European Academies, p. 9.
[26] European Science Foundation and ALL European Academies, 2011, p. 9.
[27] Boesz, 2012, p. 12.
[28] Boesz, 2012, p. 13.
[29] Ibid.
[30] European Science Foundation, 2000, p. 14.
[31] European Science Foundation and ALL European Academies, 2011, p. 15.
[32] European Science Foundation and ALL European Academies, 2011, p. 15.
[33] European Science Foundation and ALL European Academies, 2011, p. 15.
[34] European Science Foundation and ALL European Academies, 2011, p. 15.
[35] European Science Foundation and ALL European Academies, 2011, p. 16.

1. University associations and national academies of sciences should establish a joint framework that would set general standards at a national level regarding research ethics committees in higher education system, professional associations (e.g., associations of psychologists and sociologists) should be involved and consulted in the process, as well as play a leading role in establishing discipline specific standards.
    a. An official committee should be established with appointed representatives from universities, government, national academies, professional associations, the community and other potential stakeholders (e.g. lay persons, potential research subjects or patients) to determine this framework. A joint framework is unlikely to succeed if it does not receive comprehensive input.
    b. The committee, at the outset of the process, should decide on target completion dates for each step of the process.
    c. Before finalizing the standards, the committee should solicit public input to ensure that no opinions have been inadvertently left out of the discussion.
    d. Universities should commit to replacing their existing, independent standards with the national general standards created by this committee.[37]While striving for national general standards, the committee should keep in mind that research paradigms may differ between disciplines and a "one size fits all" policy might not be ideal. While the standards should be general across institutions, the committee should consider adapting the standards as needed across disciplines.[38]
    e. This should be an on-going process, since institutions will begin to develop individualized procedures (e.g. concerning modernizing electronic review).[39] Periodic meetings (e.g. yearly) will allow general standards to remain consistent and updated with best practices.

2. Accreditation committees, in the course of evaluating teaching programmes, should assess if research ethics are a part of the curricula.
    a. Accreditation committees should verify that the research ethics courses in the curricula are based on and reflective of the general standards adopted by the institution.
    b. The accreditation committee should not just check whether ethics are on the curricula but assess the quality of the research ethics program. This includes assessing how many hours students spend in ethics classes; determining the expertise of the ethics faculty; and learning from students whether they felt the ethics classes were a priority for the institution.[40] A recent study suggested that,

[36] These recommendations are derived from the SATORI report on subtask 4.2.4: Models for Ethics Assessment and Guidance in Higher Education.

[37] Subhan Eksioglu et al., "Ethics Committees in Turkish Universities," Procedia - Social and Behavioral Sciences 174, 2015, pp. 2882 – 2890 [p. 2889].

[38] Economic and Social Research Council, "ESRC Framework for Research Ethics," 2015, p. 15.
[39] Economic and Social Research Council, 2015, p.p 14–15.
[40] Pauls, Merril A., "Teaching and Evaluation of Ethics and Professionalism," Can Fem Physician 2012, 58, pp. 751–56 [pp. 753–54].

of European medical schools that have ethics curricula, for example, hours spent in classes ranged from 0 to 107 (with a mean of 44).[41]

3. Ethics assessment in higher education (in all fields beyond medicine, animal research and data protection where detailed legislation presently exists) should be placed within the institution responsible for the research performed.
    a. To ensure that the committee members are confident in their abilities to effectively review research and to promote institutional confidence in and respect for committee members, committee members should receive standardized training at the institution or department in which the committee is located.[42]
    b. The governing body should ensure that the committee, despite placement in the institution responsible for the research performed, has sufficient diversity in membership (see #4) and has no conflicts of interest.
    c. The governing body should periodically (at defined intervals) verify the continuing autonomy of the committee from the institution.

4. Ethics assessment in institutions of higher education should be organised into one or more research ethics committees. In order to address discipline-specific issues in project evaluation, the principle of interdisciplinarity and independence should be respected in committee membership.
    a. Each institution should decide, based on its size and volume of research, whether it should have multiple standing committees or one committee that has the authorisation to form sub-committees as needed.[43]
    b. Committees should consider appointing a chairperson who is not from the focus field for the committee or the institution, to ensure minimal bias.
    c. The committee should predetermine whether it will appoint "lead reviewers" for proposals and, if so, how this reviewer should be chosen.[44]

5. Members of research ethics committees should be appointed by the institutions' governing bodies.
    a. When appointing members, governing bodies should not solicit the opinion of current members of the committee, as this can lead to committees not adequately reflecting a diversity of opinions.
    b. The governing body should advertise broadly for committee members and approach community leaders for potential committee members.[45]
    c. Committee members must avoid conflicts of interests.
    d. It may be appropriate for the committee to seek advice from outside experts for certain research proposals or concerns. The governing body should

[41] Claudot, Frédérque et al, "Teaching Ethics in Europe," J. Med. Ethics, 2007, 22, pp. 491–95 [p. 492]
[42] British Psychological Society, "Code of Human Research Ethics," 2010, p. 29–30. Available at: http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf
[43] Economic and Social Research Council, 2015, p. 14.
[44] Economic and Social Research Council, 2015, p. 15.
[45] C.A. Schuppli and D. Fraser, "Factors Influencing the Effectiveness of Research Ethics Committees," J. Med. Ethics 2007, 33: pp. 294–201 [p. 297–98].

predetermine who will decide on experts and, if the governing body itself is not choosing the expert, should have to approve of the expert in order to make sure there is no conflict of interest.[46]

3 NATIONAL SCIENCE ACADEMIES

National Science Academies (NSAs) are 'associations of culturally, scientifically or politically influential people, founded as platforms for debate on socially important questions.'[47] As NSAs commonly have an influential position in scientific and public communities, they can have a considerable impact when setting standards for ethics assessment. Accordingly, the recommendations in this section focus on seizing the chance this potential impact entails. They are based on feedback received in interviews as well as the literature review conducted for the SATORI project, particularly Annex 3.d report concerning "Ethics assessment and guidance in different types of organisations: National Science Academies and Academic & Professional Organisations"[48].

The following are our recommendations (numerals) and action points (letters) for improving the institutional structure of *national science academies* in terms of ethics assessment:

1. In the majority of cases, there is no systematic monitoring of compliance with NSA recommendations. Therefore, monitoring and compliance programs should be incorporated into National Science Academies.
    a. National Science Associations should establish a compliance officer to monitor the number of mentions and citations of Academy results by policy, decision, and public actors.

2. Too often, the decision-makers do not accept/follow recommendations established by academic committees or see the need to conduct ethics assessment, and try to avoid difficult topics.
    a. NSAs should try to develop closer connections, while retaining their autonomy, to work in conjunction with policy and decision makers by establishing liaisons or programs to work alongside decision-makers.

3. Another pressing challenge is the lack of necessary resources (administrative staff, budget) that would facilitate the work of NSAs. Whether a public or private funded model is utilized, effectively gauging the necessary resources and needs should be presented.
    a. The EC should encourage the establishment of National Science Academies as a part of its requirements for countries to receive funding for research and innovations projects.

[46] Economic and Social Research Council, 2015, p. 14.
[47] SATORI Deliverable 1, Annex 3.d "Ethics assessment and guidance in different types of organisations National Science Academies and Academic & Professional Organisations", June 2015
[48] Ibid.

b. We recommend that governments (i.e., EU, UN, OECD and potentially other organizations) create a multi-stakeholder platform on a global level, in which the UN, OECD, and the EU could collaborate in pursuit of harmonized NSA objectives. This can build upon the existing work of associations that currently exist.

4 RESEARCH FUNDING ORGANISATIONS

Research funding organisations (RFOs) financially support research activities through funding programmes for research performing institutions. According to the SATORI report on ethics assessment in RFOs,[49] ethics assessment is perceived as a pertinent question in all analysed funding organisations and has become an integral part of the project selection process.

The majority of RFOs currently rely on external organisations for ethics assessment and hold the researcher submitting the proposal responsible for obtaining any necessary ethics approval. As argued in the forthcoming SATORI report on "Models for ethics assessment at research funding organisations",[50] such external ethics assessment is generally limited to criteria that are provided by law. It would be preferable, however, to have a broader set of ethical criteria for ethics assessment. After all, the ethics of new technologies are a moving target, meaning that legislation will always lag behind scientific developments. Ethics assessment of research projects and proposals can therefore best be provided through *in-house* ethics panels that are independent, multidisciplinary and pluralist. These in-house ethics panels would be more attuned to the specifics of, and current issues in, evaluating project proposals submitted to RFOs, and can have better lines of communication to other parts of the RFOs.

Since ethics assessment rules, procedures and legislation will always lag behind scientific developments, RFOs would be wise to organise a permanent structured exchange with their international counterparts to discuss these rules, procedures and legislation in relation to new and emerging technologies.[51] RFOs might then be quicker to recognise and pick up one another's good practices in response to these new technologies.

It has been reported that some RFOs try to encourage researchers to include considerations with regard to thinking widely about ethical issues at an early stage.[52] In general, RFOs could do more to raise awareness of ethics and ethical issues among researchers who submit project proposals. This would likely improve the ethical aspects of, and increase the overall quality of, the research proposals when they are first submitted. RFOs could reach out to research

[49] Wolfslehner, Doris, "Ethics assessment in different types of organisations: Research Funding Organisations", SATORI D1.1 report, June 2015.
[50] Annex "Models for ethics assessment at research funding organisations" to the forthcoming SATORI D4.2 report *Standards, tools and best practices for policy-oriented assessment and guidance of new developments and practices in research and innovation*.
[51] Ibid.
[52] Wolfslehner, op. cit., 2015.

institutions through presentations on the ethical implications of research, as well as through easy to understand information provided on their websites.

Based on the above, the following are our recommendations (numerals) and action points (letters) for improving the institutional structure of *research funding organisations* in terms of ethics assessment:

1. Large RFOs (spending more than 100 million Euros a year) should themselves be responsible for conducting ethics assessments of research proposals submitted to them. Smaller RFOs (usually privately funded NGOs) can continue to rely on external ethics assessment.
    a. Large RFOs should institute in-house ethics panels for conducting full ethics review of all project proposals that have been flagged as ethically problematic during a pre-screening phase. This pre-screening phase would be conducted by staff members of the RFO who are involved in project selection and who have received prior training in the field of ethics.

2. RFOs should organise a permanent structured exchange with their international counterparts to discuss (good practices in) ethics assessment in response to new and emerging technologies.

3. RFOs should do more to raise awareness of ethics and ethical issues among researchers who submit project proposals.
    a. RFOs should institute a program in which they reach out to research institutions through presentations on the ethical implications of research, and through information provided on their websites.

5 RESEARCH ETHICS COMMITTEES

Research ethics committees conduct ethics assessment on research projects with the aim of preventing harm to research subjects and the environment.[53] The scope of RECs is broad, depending upon whether the REC is national, regional, local, or embedded within an institution. As their institutions or levels differ, it is important to clarify the legal conditions RECs are operating under. The recommendations found here are developed based upon feedback received in interviews as well as literature review discoveries for SATORI project, particularly Annex 3.a report concerning "Research Ethics Committees"[54].

The following are our recommendations (numerals) and action points (letters) for improving the institutional structure of *research ethics committees* in terms of ethics assessment:

1. It should be clear in a legal sense when RECs are to be included in the ethics assessment practice.

[53] SATORI Deliverable 1, Annex 3.a "Research Ethics Committees", June 2015
[54] Ibid.

   a. Local and national governments should make the necessary legal provisions at the appropriate level - whether institutional, local, regional, or national - for when RECs are to be included in the ethics assessment practice.

2. For the sufficient funding of the REC, including any necessary secretariat or administrative staff, means of accommodations should be established They can be either directly funded by the government or a respective institution, or incorporated into the research project proposals.

3. RECs should have representatives that participate in forums directed at the discussion and guidance of emerging ethical issues and guidelines. This is to ensure harmony with international trends, but also to provide input in their developments.

   a. RECs in a particular country should consider establishing a platform for discussion and cooperation if the country in question does not have such a platform. These networks can complement the top-down coordination by providing bottom-up solutions based on experience from day-to-day practices of committees.

6 NATIONAL ETHICS COMMITTEES

National ethics committees (NECs) are government-instituted, independent bodies whose aim is to formulate recommendations and foster debate, education and public awareness of, and engagement in, bioethics. All existing NECs have a strong focus on bioethics, often including the fields of medicine and health, biology and life sciences. Some NECs have a slightly broader focus, which may include issues such as social welfare and the environment. Given that these are not the only scientific fields in which ethics guidance at a national level may be relevant, it might be good for NECs to make their focus broader so as to encompass all scientific fields.

Since NECs usually have an advisory or consultative role for national governments, it might also be helpful if they have organisational structures that allow for the consultation of citizens, civil society organisations, external experts and possibly other external groups. Some SATORI WP1 interviewees indicate this is not always the case and they stress the importance of consultation of these groups in ethics guidance by NECs. Their inclusion may lead to a broader range of perspectives being considered on particular ethical issues, which is generally beneficial in ethical decision-making and may enhance the legitimacy of NECs' decisions and recommendations.

It is also stated or implied by some WP1 interviewees that there is insufficient monitoring for compliance with ethics guidance by NECs. Naturally, it would be helpful to NECs to have a general sense of what are the effects of their ethics guidance, especially with regard to members of RECs and other ethics assessors.

Most NECs refer to their work as ethics guidance for national governments and professionals, the latter category being composed of those who ethically assess research and innovation

projects. NECs are therefore well placed to offer training programs for REC members and other ethics assessors, which can contribute to the quality of the assessments of these groups. Such training programs would also be an important factor in any successful implementation of SATORI's ethical impact assessment framework.

Based on the above, the following are our recommendations (numerals) and action points (letters) for improving the institutional structure of *national ethics committees* in terms of ethics assessment:

1. NECs should broaden their focus to encompass all other scientific fields besides the medical and life sciences.
    a. NECs should institute special sub-committees for different disciplines—including the natural sciences, engineering sciences, social sciences and the humanities fields—perhaps in collaboration with professional associations.

2. NECs should create an organisational structure that allows for the consultation of citizens, civil society organisations, external experts and possibly other external groups.
    a. Individual NECs should institute a temporary sub-committee to investigate how they could best include citizens, civil society organisations, external experts and possibly other groups in their ethical decision-making process.

3. NECs should monitor for compliance with the ethical guidance they offer to ethics assessors.
    a. Individual NECs should set up a special committee that evaluates, in general terms, the compliance to their ethical guidance.

4. NECs should be more actively involved ensuring the quality of the ethics assessments made by REC members and other ethics assessors.
    a. NECs should offer training programs for REC members and other ethics assessors.

7 ACADEMIC AND PROFESSIONAL ORGANISATIONS

Academic organisations are 'voluntary and non-profit organisations, open to researchers working in a specific discipline'[55], with the aim to promote a certain discipline. Professional organisations additionally focus on the professional interests and working conditions of their members, and are mostly connected to other professional organisations. Academic and professional organisations often work in tandem with national science academies, and thus there is a high degree of correspondence between recommendations between national science academies and academic and professional organisations. The recommendations given in this chapter are based on feedback received in interviews as well as the literature review conducted for the SATORI project, particularly Annex 3.d report concerning "Ethics

[55] SATORI Deliverable 1, Annex 3.d "Ethics assessment and guidance in different types of organisations National Science Academies and Academic & Professional Organisations", June 2015

assessment and guidance in different types of organisations National Science Academies and Academic & Professional Organisations"[56]..

1. There is in the majority of cases no systematic monitoring of compliance with academic and professional organisation activities, therefore monitoring and compliance programs should be incorporated into the institutional setup of academic and professional organisations.
    a. Academic and professional organisations should establish a compliance officer to monitor the number of mentions and citations of Academy results by policy, decision, and public actors.

2. Too often, the decision-makers do not accept/follow recommendations established by academic committees or see the need to conduct ethics assessment, and try to avoid difficult topics. As such, academic and professional organisations should try to develop closer connections, while retaining their autonomy, to work in conjunction with policy and decision makers by establishing liaisons or programs to work alongside decision-makers.
    a. The EC should recognise the participation of academic and organisations as stakeholder contributions.

3. Another pressing challenge is the lack of necessary resources (administrative staff, budget) that would facilitate the work of academic and professional organisations. The institutional setup of each should account for the objectives or the organisation and how to best achieve those goals, with an emphasis placed upon the ethical activities of the membership groups.
    a. We recommend that governments create a multi-stakeholder platform on a global level, in which the UN, OECD, and the EU could collaborate in pursuit of a harmonized academic and professional organization objectives, such as the forums created for the discussion of guidelines within specific disciplines as exemplified by groups like CIOMS for biomedicine. This can build upon the existing work of associations that currently exist.

4. Academic and professional organizations should create forums for the consolidations of developments in ethics assessment, which produced unambiguous results that can be implemented and monitored by memberships groups.

5. Academic and professional organisations should utilise their positions as membership-granted organisations to train members to instil responsible research and practices through the development of partnerships with universities and other research conducting organisations that account for its membership group.
    a. The EC should recognise academic and professional organisations as potential conduit points for the implementation of training programmes for responsible research.

[56] Ibid.

8 CIVIL SOCIETY ORGANISATIONS

There are different ways in which *civil society organisations* (CSOs) can become involved in the process of ethical assessment of research and innovation. On the one hand, CSO representatives can be members of the existing research ethics committees and other bodies assessing research; on the other hand, CSOs can cooperate with each other in order to establish their own structures and organisations focusing on ethics assessment. The rationale behind the following recommendations is to make both of these models of engagement more effective. Moreover, the cooperation of different CSOs across borders could alleviate the existing disparities as regards the level of civil society involvement in ethics assessment of research and innovation that exist between different countries.

The following are our recommendations for improving the institutional structure of *civil society organisations* (CSOs) in terms of ethics assessment:[57]

1. CSO representatives should make efforts to be involved in research ethics committees as representatives of a specific vulnerable group (e.g., consumers or patients) or spokespeople for a specific interest (e.g., the animal welfare).
    a. CSOs should draft a comprehensive list of potential vulnerable groups or specific interests to ensure no group is being unintentionally omitted.[58]
    b. CSOs should coordinate (e.g., through a network as described in #2) to ensure that multiple groups are not inadvertently representing the same vulnerable groups or specific interests while leaving others underrepresented.
    c. CSOs should consider potential conflicts of interest between the interests of different vulnerable groups and how to navigate those conflicts.
    d. When deciding which group to represent, CSOs should consider their relative expertise and knowledge about specific groups.
    e. If the CSO is representing specific individuals within a vulnerable group, it must make sure to obtain informed consent from the people themselves or, if they are unable to give it, those legally capable of providing consent on their behalf.[59]
    f. Internally, before making efforts to join a committee, CSOs should articulate their desired role on a committee and what they would contribute to a research ethics committee.[60]
    g. When attempting to become involved with a research ethics committee, CSOs should frame their presence as allowing for a more holistic, informed and cooperative approach to an ethics issue.
    h. Especially if facing resistance to gaining membership, CSOs also may emphasise that CSO members on the committees will gain insight into the

[57] These recommendations are derived from the SATORI report on subtask 4.2.5: Models for ethics assessment and guidance at CSOs.
[58] British Psychological Society, "Code of Human Research Ethics," 2010, p. 31. Available at: http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf.
[59] British Psychological Society, 2010, pp. 30–31.
[60] See World Economic Forum, "The Future Role of Civil Society," January 2013, p. 34. Available at: http://www3.weforum.org/docs/WEF_FutureRoleCivilSociety_Report_2013.pdf.

dilemmas facing other stakeholders, who might have the impression that CSOs focus only on "risk issues" without needing to provide solutions.[61]

2. There should be support at the EU level for the development of ethics assessment related CSO networks. These networks could vary in terms of structure, level of interdependence, aims etc. The purpose of networking would be to exchange information (knowledge and experience) and learn from each other (through sharing best practices, coordinating activities, obtaining common funding, organising advocacy campaigns, influencing the adoption of new regulative acts, etc.).
    a. To gain support for EU-level CSO networks for ethics, CSOs should emphasise the EU's acknowledgement of the importance of CSOs in the globalising world[62] as well as the importance of research ethics and of hearing different opinions in research ethics discussions.[63]
    b. When advocating for or forming a network, CSOs should explicitly articulate the network's purpose.
    c. CSOs should also decide the target membership, both in terms of size and scope (i.e. whether the network is attempting to connect CSOs across a particular field, e.g., medical ethics, or across a particular role, e.g. watchdog CSOs).[64]
    d. To save resources, CSOs should consider whether ethics assessment related CSO networks could be formed within existing networks (e.g., CSO-Net[65] or Euclid network[66]).
    e. If petitioning for a new EU-level CSO network, CSOs should be prepared to explain why a new network is necessary and preferable to working through an existing network.
    f. Developing CSO networks should study and reflect best practices from existing CSO networks (e.g. emphasising financial management, forming collective leadership and forming networks between groups with historic ties and trust).[67]

3. Due to a disparity between different states as regards the level of civil society involvement in ethics assessment of research and innovation (re. for example the existence of dedicated organisations, or the level of involvement of the public in debates about the societal aspects of research and innovation), there is a need to exchange best practices between organisations and groups from different states. This

[61] René von Schomberg (editor), "Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields," European Commission, 2011, p. 11. Available at: http://ec.europa.eu/research/science-society/document_library/pdf_06/mep-rapport-2011_en.pdf.
[62] For example, Marchetti, Raffaele, "The Role of Civil Society in Global Governance: Report on the joint seminar organised by the EUISS, the European Commission/DG Research, and UNU-CRIS," 1 October 2010, p. 2. Available at: http://www.iss.europa.eu/uploads/media/Civil-Society_Report.pdf
[63] European Commission, "European Textbook on Ethics in Research," 2010, p. 7; European Commission, "Ethics for Researchers," 2013.
[64] See World Economic Forum, January 2013, p. 9.
[65] CSO-Net, ECOSOC Civil Society Network. Available at: http://esango.un.org/irene/index.html.
[66] Euclid Network: third sector leaders. Available at: http://www.euclidnetwork.eu/.
[67] NGO Connect, "NGO Tips: CSO Networking for Democratic Social Change," Capable Partners Program, 2011, p. 2.

could be done at the EU level, for example by means of establishing dedicated working groups in the existing CSO networks (e.g., the Euclid network).

a. CSOs should form a working list of all existing CSO networks at the EU level to determine which, if any, would be best fitted to the exchange of research ethics best practices.
b. CSOs should examine existing EU-level groups that engage in the exchange of best practices in other fields to determine which have been most successful, and why.[68]
c. If possible, CSOs should reach out to these existing groups to determine how they decided to affiliate with EU-level groups and the process through which they went to do so.
d. CSOs should consider whether these exchanges of information would be more successful if they included either non-EU nations or only a subset of EU nations.[69]
e. If the exchange networks are set up at the EU level, the CSOs should determine the degree of autonomy the exchange needs from the governing EU structure. They should also consider how the exchange network would be funded.[70]

9 INDUSTRY

This section focuses on institutional setup for industry. The main question that is addressed in this report is: what national and international (EU level and global level) institutional structures are necessary to properly organize and harmonize the ethics assessment framework with regard to industry that is proposed in task 4.3.1. The report is based on the analysis of the relevant interviews from SATORI work packages 2 and 3 as well as previous SATORI reports (work packages 1, 3 and 4 reports). As the result, this report provides the recommendations that arise from them.

This report firstly focuses on challenges in the institutional structures of ethics assessment of R&I in industry. These challenges are addressed in terms of the external institutional structures (outside a company). The internal institutional setup (within a company) is covered in subreport 4.2.6. Secondly, for each challenge we provide general recommendations. Each general recommendation is supplemented with the proposals of specific actions by various actors. The general recommendations and actions are proposed by SATORI on the basis of desktop research and our analysis of the aforementioned interviews and reports.

Note: In case of industry, the ethics assessment of R&I is strongly related to corporate responsibility (CR).[71]

[68] For example, the Community of Practice on Partnership (http://partnership.esflive.eu/) and surgery practices (Dutch Transplant Foundation et al, "Exchange of best practices within the European Union: surgery standardization of abdominal organ retrieval,: 2014).
[69] For example, "Civil Society Dialogue" operates between EU nations and Turkey. Available at: http://civilsocietydialogue.org/us/.
[70] OECD, "Civil Society Empowerment", April 2013 (draft), p. 7.
[71] Note: in this report we use a broad understanding of corporate responsibility (CR) instead of corporate social responsibility (CSR). Further explanation and discussion can be found in previous SATORI reports on industry.

9.1 Challenges in the institutional structures of ethics assessment of R&I in industry

This subsection describes the challenges in the institutional structures of ethics assessment of R&I in industry. In turn, we will discuss the governance models for institutional setup of CR that encourage responsible approach to R&I by industry; the variety of CR initiatives and networks; the voluntary character of CR tools and lack of transparency; and the variety of types of companies, industries and their organisations that make up "industry". On the basis of these challenges, recommendations are offered in subsection 9.2.

1. *Governance models for institutional setup of CR that encourage responsible approach to R&I by industry*

There are two dominant models structuring corporate responsibility (CR):

- the government-dominant model, and
- the industry-initiated model.

In the first case, the government would establish the standards and expect companies to fulfil them. Companies do not take part in the process of setting the standards. They are only the recipients and subjects of the regulation. If a company did not comply with the standards, the government would take appropriate action. In the second model, industries regulate themselves on a voluntary base (self-regulation) going behind basic regulations set by governments.

Nevertheless, the effectiveness of these two approaches is highly discussed by lawyers, academics and civil society organisations. The effectiveness of governance models highly depends on the creation process of the initiative. Therefore, the bargaining process, actors who are engaged in the discussions, the leading forces, advocacy level, timing and politics surrounding. In this regard, we highly recommend that any institutional model for ethics assessment of R&I in industry should engage a variety of stakeholders and should be based on cooperation, dialogue, and mutual-learning.

2. *Variety of CR initiatives and networks*

A variety of initiatives and networks is a great advantage of CR that enables dialogue, sharing experiences and learning from each other. Furthermore, the participation in specific CR organisations, networks and initiatives helps in the recognition of a company as responsible and sustainable (beneficial for both a company and consumers). Having this said, the interviewees emphasize major drawbacks of having variety of standards – confusion which standard is the leading one and additional costs both direct (e.g. ISO standards) as well as indirect (additional bureaucracy, internal audits).

These weaknesses are also valid from the institutional point of view: the confusion of structures and (legal) regimes, the hierarchy and importance of various networks and initiatives, and additional costs of participation. Industry (and other stakeholders) prefer harmonization of these different frameworks. Our respondents strongly emphasize that we do not need new CR tools, we need to start integrating currently existing CR tools in order to

avoid an overlap and provide a clear, fully compatible and flexible CR framework. This framework should consider integrating ethics assessment of R&I institutions into already existing CR institutional structures.

3. *Voluntary character of CR tools and lack of transparency*

Despite the growing awareness and the number of companies declaring their commitment to CR standards, the actual adherence to CR principles and guidelines remain unclear.

The opinions about the "hard" and "soft" character of CR tools are divided. The interviews conducted for SATORI seem to share this dichotomy. On the one hand civil society organisations and human rights institutes observe that soft-law instruments have some impact on consciousness, awareness within a company, on developing policies and processes, but in practice the profit motive will always win. On the other hand, some businesses think that innovation requires research based on freedom. Therefore, additional constraints such as additional ethical standards could limit the creativeness of firms. The other opinions make a step forward, emphasizing that the crucial point is that legislation should be enforced. Many of the challenges related to business activity such as employee's rights, wages, non-discrimination are tackled in legislation, however, the legislation is not enforced. The issue that was highlighted is "the need to have a balance between appropriate legislation combined with effective enforcement."[72]

The CR tools provide the verification procedures of the fulfilment with their requirements. The supervisory institutions oblige companies to submit reports, which however are internal reports not available for the general public. Individual reports on the actual performance are hardly accessible. Therefore, although CR tools promote transparency, it is up to a company to decide what information and in which way should be communicated to the public. Furthermore, the participation/certification should not be granted indefinitely. The adherence to the CR tool's requirements should be verified regularly by the CR organisation/network.

4. *"Industry" consists of variety of types of companies, industries and their organisations*

There is a variety of types of companies, branches of industry and their organisations. Companies vary depending on their size, branch of industry, and scope of activity. Large multi- and transnational corporations have different expectations, interests, challenges and opportunities than small and medium-sized enterprises (SMEs) or start-ups. Membership and participation in CR institutions should be multi-layered, providing general principles and requirements applicable to all types of actors as well as specific provisions suitable for different types and categories of actors (e.g. branches of industry, different sizes or scope of activity). For instance, it is extremely difficult to know which CR standards or frameworks are relevant. Interviewees representing both larger corporations and SMEs, observe that there is a variety of global, European and national frameworks. However, they need to address their actual goal, which is to support capacity within smaller businesses and the most effective means of doing that. Clarity at the international level is crucial.

[72] Jo Webb, Sedex, Case study: Responsible Supply Chain Governance, Deliverable 3.3

9.2 Recommendations

1. A broad institutional structure of corporate responsibility including R&I should be formed as a cross-sectoral approach based on collaboration.[73]
2. The institutional structures should enable engagement with stakeholders to evaluate and review impacts and actions. Adopt multi-stakeholder approaches.
3. CR (including R&I activities) should be based on appropriate mix of bottom-up and top-down approaches to promote CSR, also taking into account local context and values.

Proposed actions for recommendations 1, 2 and 3:

a. Actions by business/companies/business networks and associations
   - Stakeholders engagement in various phases of the R&I processes and assessment

b. Actions by EU
   - The EC should encourage public-private partnerships (PPPs) in the R&I area. This could be done through grant opportunities. One of the requirements of a proposal should be the ethics assessment check; another requirement to include a work package focus on ethical aspect of the project.
   - The EC could put more attention on consumer awareness and capacity building in regard to ethical values and ethical impact assessment. This could be done through organizing multi-stakeholder meetings and forums with CSOs participation. In this regard, the EC should develop a methodology to better align CSOs proposals in final policies (avoid check-list approach).

c. Actions by EU, UN, OECD and potentially other organisations
   - We recommend that governments create a multi-stakeholder platform on a global level, in which the UN, OECD, and the EU could collaborate in pursuit of a harmonized ethics assessment framework for ethical supply chains. The EU could have a leading role.

4. The institutional structures for ethics assessment of R&I for industry should be incorporated with already existing general CR institutional structures.

Proposed actions for recommendation 4:

a. Actions by business/companies/business networks and associations
   - The need for awareness of R&I as part of companies' CR activity
   - Include responsible R&I as a part of CR business platforms (e.g. CSR Europe, Sedex, B-Corp)

b. Actions by SATORI consortium

[73] STM Electronics (WP1 interview): "Compare and share experiences with other (external) organizations is generally useful and interesting at company level; (…) There is a need of an appropriate mix of bottom-up and top-down approaches to promote CSR, also taking into account local context and values.

- when developing R&I ethics assessment framework, SATORI partners should refer to already existing institutional structure in the field of human rights, corporate responsibility and business ethics (e.g. The OECD Guidelines for Multinational Enterprises – OECD National Contact Points)
- Advocating within EU (and other actors such as UN, OECD, for integration of R&I into general corporate responsibility framework (including EU policy on CR). Participate in EU forums on CR, organise workshops, propose future EU funding projects.
- Encourage the academic community and business to better align responsible R&I and corporate activity. This could be done through participation in R&I conferences as well as business forums, publishing joint papers with SATORI industry partners.

c. Actions by EU

- Include ethics assessment of R&I into the EU's CR agenda and its structures (including the activity of the OECD National Action Points)

d. Actions by UN

- Include responsible R&I as a part of CR business forums (e.g. UN Annual Forum on Business and Human Rights)

5. For the benefits of stakeholders, the institutional structures for ethics assessment of R&I should promote recognition of the companies as their members.

Proposed actions for recommendation 5:

a. Actions by EU

- The EU can motivate companies not only by adopting the "naming and shaming" approach, but also by creating incentives for responsible companies: certification, awards for responsible and sustainable innovation/design
- The EU should include SATORI R&I ethics assessment framework/toolkit into all R&I granting programs as an obligatory requirement (take an example from the EUROSTARS Program). This refers to both R&I granting proposals for actors located in EU, as well as beyond.

6. Appropriate legislation should be combined with effective enforcement.

Proposed action for recommendation 6:

a. Actions by EU and EU Member States

- Ensure the enforcement of currently exciting legislation

7. The membership of a company in the institutional structures should not be granted indefinitely. The adherence to the ethical requirements should be verified regularly.

Proposed action for recommendation 7:

a. Actions by ethics assessment institutions/bodies

- If ethics assessment institution/body is a membership or certification organisation, ensure various levels of membership depending on the progress of a company in improving its engagement in responsible R&I, and verify regularly the adherence to ethical requirements by a company (in relation to Recommendation 5)

8. The institutions for the ethics assessment of R&I in industry should respond to the needs of different types of businesses.

Proposed actions for recommendation 8:

a. Actions of business/companies/business networks and associations

- Business initiatives should engage both large enterprises as well as SMEs giving an opportunity to cooperate.
- Individual companies should join CR platforms and forums. These platforms and forums should encourage particularly SMEs (lower participation fee, if any, detailed guidance).
- Small and micro-enterprises might face difficulties to individually engage in responsible R&I activities. For this reason, business is exploring alternative approaches for smaller actors, such as a cluster approach – a group of SMEs. For example, the GRI is exploring a cluster approach to sustainability reporting through collaborating either to report as a group or receiving training as a group of SMEs of the same sector and location. SME should explore creating clusters in order to strengthen responsible approach to R&I in their region or field.

b. Actions by EU and EU Member States

- EU and EU Member States in their CR and R&I strategies should create particular incentives for SMEs, including funding for projects and initiatives on responsible and sustainable innovation/designs and awards for responsible and sustainable innovators/designers. This should give opportunities also for businesses outside EU.

c. Actions by SATORI Consortium

- The institutional structure for ethics assessment framework developed by SATORI should be multi-layered, providing general principles applicable to all types of actors as well as specific provisions suitable for different types and categories of actors (e.g. branches of industry).
- The institutional setup could provide different levels of participation in ethics assessment of R&I structures depending on the engagement (e.g. UN Global Compact). This approach could motivate companies that are at the beginning process of developing their corporate responsibility strategies. Avoiding the approach “all or nothing”.

10 NATIONAL INSTITUTIONAL STRUCTURES FOR ETHICS ASSESSMENT

In this section, we offer recommendations for the institutional structure of ethics assessment *at the national level*. We discuss national level coordination, networking between RECs, ethical guidance and training, ethics assessment in non-medical fields and institutional problems.

The comparative analysis by country, conducted by SATORI, observed that the level of institutionalisation of ethics assessment in different countries varies greatly, although all studied countries are currently expanding their efforts in the area. While regulation and institutional structures are highly developed in countries such as the Netherlands, Germany and Austria, countries such as Serbia still have a long way to go. There are also significant differences in the level of centralisation or decentralisation of ethics assessment. In some countries, the role of governmental institutions and national-level regulation is very strong, while in others, ethics assessment is carried out according to regional regulation and by local committees with a high degree of autonomy.

Considering the differences between governmental systems, political traditions and cultures in various countries, the following recommendations do not intend to propose a uniform national institutional structure to fit any country. Instead, they are a based on specific problems and good practices identified in individual country studies. A comparative view allows solving country-specific problems by locating and adopting as well as adapting good practices in other countries.

10.1 National-level coordination

For ethical assessment of medical and life science research, most countries we analysed have a system of regional or local research ethics committees (RECs), established by law. The level of national regulation and coordination of these RECs in terms of procedures and guidelines varies greatly. In some countries (e.g., Denmark) national ethics committees (NECs) have a strong role in coordinating individual RECs. In some smaller countries (e.g., Slovenia) the NEC is itself responsible for ethical assessment of all medical projects in the country. In many countries, however, procedures for ethics assessment are more dispersed, mostly due to higher levels of regional and institutional autonomy. In some countries, even the most developed ones in terms of ethics assessment (e.g., Germany), a NEC does not exist.

Many interview respondents from countries with a low degree of national-level coordination (e.g., France, Serbia) or with a non-existent national ethics committee have stressed the problems of the lack of uniform procedures and monitoring of the work being done by individual RECs and called for a greater level of harmonisation between individual committees.

Recommendation:

- We therefore recommend that a national ethics committee be established with the aim of coordinating individual RECs. Its tasks should include the development of ethical guidance and assessment procedures to be implemented by RECs, as well as developing procedures for monitoring RECs activities. The national ethics committee

can also function as a court of appeal, in cases when RECs decisions are being disputed.

Proposed action:

- National governments should establish a national ethics committee, carefully considering its composition and tasks.

10.2 Networking between RECs

In many countries, RECs have established networks as platforms for discussion, exchange of experience and best practices. Examples include: Permanent Working Party of Research Ethics Committees in Germany, the Spanish National Association of Research Ethics Committees (ANCEI), the European Network of Research Ethics Committees (EUREC), etc.

Recommendation:

- While a national ethics committee can provide top-down coordination, REC networks can complement it by providing bottom-up solutions based on experience from day-to-day practices of committees.

Proposed action:

- RECs should consider establishing a platform for discussion and cooperation.

10.3 Ethical guidance and training

Ethics assessment procedures are based on ethical guidance, i.e. ethical principles, rules, codes and recommendations to which research practices are expected or recommended to adhere. Institutions that develop these guidelines are also well placed to provide advice to RECs regarding complicated cases and emerging ethical issues. Many interview respondents from different countries complained over the lack of trainings for REC members.

Recommendation:

- Ethical guidance and training, coordinated at the national level, is an important part of ethics assessment, providing the grounds for awareness of ethical principles and issues among researchers and research institutions as well as common guidelines for ethics assessment procedures.

Proposed action:

- Institutions with the knowledge, experience and authority to provide ethical guidance are national ethics committees and REC networks as well as national academies and professional associations in specific fields and disciplines. These institutions, especially NECs, are also well placed to provide training programs.

10.4 Ethics assessment in non-medical fields

While ethics assessment in medicine and related fields is well established in most countries and can rely on widely accepted international standards, ethics assessment in other fields of research, such as social sciences and humanities, is only recently gaining ground. In most countries, ethics assessment in these fields is not yet developed or takes place only at the local level of individual research institutions.

The Norwegian network of national ethics committees can be considered as a case of good practice. Norway has independent national ethics committees for research ethics in social sciences and humanities as well as for natural science and technology. In most countries, however, national professional associations have an important role in ethical guidance in specific fields, e.g. Social Research Association in the UK. International associations are also important in this regard, e.g. the European Federation of Psychologists' Associations.

Recommendation:

- We believe that ethics assessment in non-medical fields would benefit from field or discipline-specific national-level guidance.

Proposed actions:

- In non-medical fields, professional associations have proven to be best placed to provide common ethical guidance and platforms for discussion of ethical principles and issues.
- We recommend that national ethics committees expand to include special sub-committees for different fields and disciplines, perhaps in cooperation with professional associations, which can provide insight into field-specific research practices and their ethical issues.

10.5 Institutional problems

Interview respondents have reported a number of issues regarding ethics assessment practices in their countries (e.g., Serbia), such as lack of funding and infrastructural support for NECs or RECs, lack of comparable standards and procedures at national level, lack of ethical awareness, lack of trainings for REC members, non-implementation of laws and regulations (e.g., China), etc.

Recommendation:

- National institutional structures cannot function if the administrative requirements and conditions of their work are not guaranteed. It is also important to encourage the implementation of their guidelines and the compliance with their directives at the local level.

Proposed actions:

- We recommend that governments take actions towards a functioning national system of ethics assessment, providing the necessary funding and impetus to national-level institutions as well as to take measures to implement national regulations.

11 CONCLUSION

This report aimed at giving a proposal for the institutional structures of ethics assessment in the EU and its constituent countries. Most recommendations aim at the ethics assessors' independence and interdisciplinary set-up, to avoid biases and conflicts of interest. For this purpose, stakeholders should be included in the ethics assessment process. It was also highlighted that ethics assessors should know the legal status of their guidelines and work results. Furthermore, ethics assessors can benefit from each other, which is why organizations should encourage an exchange of knowledge and best practices.