# Report on the assessment of capacity building and training needs in ethics assessment

## Deliverable D2.3

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**July 2015**

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

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**Abstract**

The aim of the SATORI project is to build a common framework for ethics assessment of research and innovation in Europe. In report D1.1 of the project, the state of the art of ethics assessment was analysed by means of a large number of semi-structured interviews with formal assessors (members of ethics committees, ethicists, people involved in corporate social responsibility assessment and planning, etc.) and non-formal assessors (civil society organisations, interest groups, science journalists etc.). The interviews were also focused on the training and capacity building needs expressed by the interviewees, collecting their preferences and suggestions. In the current report, data obtained with by-hand coding of the interviews were analysed and integrated with a review of the existing literature on the theoretical basis of capacity building, with the aim to identify the most appropriate model for capacity building activities in ethics assessment. A three-level approach to capacity building tackling individual, organisational and societal/transnational weaknesses was identified as suitable for future training. An online systematic search of the existing training programs in ethics assessment was performed with the aim to identify useful tools (such as ethical matrices, case-history exercises and others) for the future involvement of all the stakeholders. Formal and informal ethics assessors were identified as possible targets for future capacity building activities and participatory processes.

## INTRODUCTION

The aim of the SATORI project is to build a common framework for ethics assessment of research and innovation in Europe. In report D1.1[1] of the project ethics assessment was defined as a key element of Responsible Research and Innovation, involving the identification and assessment of ethical issues in research and innovation. Ethics assessment is different from ethical guidance, which is the statement of ethical guidelines, principles, rules, codes, and recommendations to which scientific practices, innovation practices, developments in science and technology are expected or recommended to adhere. The term assessment implies an active approach toward the evaluation of the ethical issues in R&I and not only a theoretical knowledge of the contents and rules of laws and guidelines. In this report we use the term ethics assessment in the broader way, as a shortcut for ethics assessment and guidance, as we consider also people and institutions involved in producing guidelines and norms.

Ethics assessors are defined as agents (organisations or individuals) that engage in ethics assessment, usually on a professional basis. SATORI used this term more broadly, to include agents that engage in any type of ethics assessment, guidance, awareness raising or advisement, even informally. In this report we refer to this category as non-formal assessors. This definition does not imply that an ethics assessor has ethics assessment as its primary mission but it he repeatedly and systematically engages in activities that involves tools and knowledge that are proper to ethics assessment.

During the first phase of the project, the SATORI consortium conducted a large number of semi-structured interviews with people or representative of institutions formally involved in ethics assessment, as with a large number of non–formal assessors (representatives of institutions that evaluate the impact of research and innovation out of a formal framework, such as civil society organisations or investigative journalists, and other stakeholders).

One of the aim of the interviews was to assess their training needs (if any), their suggestions for participatory processes and capacity building activities that could facilitate the building of a common framework for ethics assessment.

The analysis of 230 interviews shows that ethical assessment of research and innovation lacks unity, recognised approaches, professional standards and proper recognition in some sectors of society. At the same time, as stated by the report D1.1, different actors - including universities and research institutes, corporations and government organisations - are investing in the field as they perceive the importance of ethics assessment. They are also developing different initiatives and mechanisms to address ethical issues. The rapid expansion of ethics assessment has not, however, been accompanied by significant efforts to harmonise approaches in different fields and organisations, to raise standards, and to introduce quality assurance. There is a need for improvement and coherence in the ethical assessment of R&I in Europe and this goal can be achieved also by fostering the opportunities of interaction among the different stakeholders with the aim to reach the goal using a capacity building approach and by promoting a common training in ethical assessment based on tools more then on contents or guidelines. This report analyses the existing training models in the field, the training needs as expressed by the different stakeholders and by experts and proposes a

[1] http://satoriproject.eu/deliverables/

model based on mobilisation and mutual learning (MML) and capacity building activities more than on a classic top-down, frontal training.

In Section 1 the report analyse some theoretical models for capacity building that can be useful for future activities within SATORI and beyond. The analysis is focused on the different organisational levels involved in capacity building activities, from the society to the single individual.

In Section 2 the report offers a brief overview of the existing training models and tools, and of good practices in training in ethics. The research was conducted by a systematic on line search using specific keywords.

Section 3 is based on the results of 64 interviews, selected among the 230 of the Satori database, in which the interviewees expressed their own needs and views about training in ethics assessment. We identified four major categories that could be interested in multidisciplinary training or participatory processes about ethics assessment: formal assessors (defined as institutional assessors such as members of research ethics committees in academies, governmental agencies, people involved in corporate social responsibility assessment and planning, etc.), non-formal assessors (mainly representatives on civil society organisations and interest groups), young researchers and scholars (as future actors in R&I and in ethics assessment) and science journalists (as non-formal assessors but also as key elements in raising the awareness of ethical issues within the society). Data were obtained with by-hand coding of the interviews and the suggestion and needs were summarised as practical key points for future training.

Section 4 offers a model for future training and capacity building in ethics assessment based on the interviews results and on the experience of experts in the field.

A table summarising the single interview results is added in appendix.

# 1 THEORETICAL MODELS OF CAPACITY BUILDING IN ETHICS ASSESSMENT

## 1.1 MEANINGS AND LEVELS OF CAPACITY BUILDING

"Capacity" is an ambiguous term, with many meanings. It will here be described as the ability of a person or an organisation to get things done[2]. The United Nations Development Program (UNDP 1997) describes capacity development as a "process by which individuals, organisations, institutions and societies develop abilities (individually and collectively) to perform functions, solve problems and set and achieve objectives". [3]

The UNDP document distinguishes between four levels of capacities:

- individual (skills, knowledge, values etc.)
- organisational (capacity to work effectively as part of a larger entity)
- interorganisational (ability to develop relationships and arrangements between organisations)
- environmental (ability to develop an enabling environment at state, civil society and private sector level).

In this perspective, capacity is a knowledge-bound capability.[4] Regards to ethics assessment, three levels of capacity building are central: individual, organisational and environmental (i.e. societal level). As SATORI project is working on the development of a common framework for ethics assessment and on the training opportunities to develop and share this framework among different stakeholders, two conceptual perspectives are particularly important:

- **organisational / management perspective**, focusing on some specific organisational areas needing reform, including the state organs or the legislative framework;
- **societal / transnational perspective**, in the sense of multidisciplinary involvement of the stakeholders, coupled with international and intergovernmental cooperation, requiring a broader and more integrated perspective.

Based on the conceptual framework, capacity building activities in the SATORI project on ethics assessment in research and innovation have to reflect these two fundamental reference points.

The review of the literature on capacity building shows that the term is used in a broad way, and some scholars argue that it became a "buzzword", meaning merely a euphemism for "little more than training". [5] [6] So it is crucial to remember that capacity building activities are context-dependent, especially when the key question is: what is the ethical capacity of an

[2] Wignaraja, Kanni (ed), D Balassanian (researcher), Institutional reform and change management: Managing change in public-sector organizations. A UNDP capacity development resource, 2006. http://www.asia-pacific.undp.org/content/rbap/en/home/library/kic/kic_pub3.html

[3] UNDP 1997. Capacity development. New York: UNDP report, Management Development and Governance Division.

[4] Smith J. *Context-bound knowledge production, capacity building and new product networks*. Journal of International Development 2005;17 (5): 647–659.

[5] Cornwall A. *Buzzwords and fuzzwords: deconstructing development discourse*. Development in Practice 2007; 17 (4-5); 471–484

[6] Although education and training are often used simultaneously, the term education is more appropriate because it refers to develop the mental, moral, or social capabilities; see http://www.thefreedictionary.com/educate

individual, an organisation or a society at large? Therefore, both the organisational or management perspective and the societal/transnational perspective are relevant.

### 1.1.1 Organisational or management perspective

In the organisational or management perspective, capacity building can be viewed as the development of "an ethics of support, an ethics of justice and ethics of critique. Together they can help to strengthen the individual and collective ethical knowledge and the sensitivity of the actors toward ethical issues". [7] Ethical capacity within an organisation can be enhanced when a large number of members, e.g. students in schools and universities or employees in industries[8], have acquired and embodied advanced ethical knowledge and efficacy.[9] One of the aim of SATORI (and others') trainings in ethics assessment could be to offer the participants some good models to enhance the "ethical awareness" among their own organisations.
A checklist of the components of systemic capacity building at the organisational level is provided by Potter & Brough.[10] They identify a pyramid of nine separate but interdependent components, with nine crucial questions to ask in the assessment of capacities in every field.

| |
|---|
| • ***Performance capacity:*** Are tools, money, equipment, consumables, etc. available to do the job? |
| • ***Personal capacity*****:** Are the staff sufficiently knowledgeable, skilled, confident to perform properly? |
| • ***Workload capacity*****:** Are there enough staff with broad enough skills to cope with the workload? |
| • ***Supervisory capacity*****:** Are there reporting and monitoring systems, lines of accountability in place? |
| • ***Facility capacity*****:** Are training centres big enough, with the right staff in sufficient numbers? |
| • ***Support service capacity*****:** Are there training institutions, services organisations, administrative staff? |
| • ***Systems capacity*****:** Do information, money flows and managerial decisions function effectively? |
| • ***Structural capacity*****:** Are there decision-making forums for inter-sectoral discussion, records kept? |
| • ***Role capacity*****:** Have individuals, teams, committees the responsibility/authority for decision-making? |

**Table 1 Nine components of systemic capacity [11]**

Potter & Brough argue that the systemic perspective could improve the diagnosis of sectoral weaknesses that can be strengthened by specific trainings. This approach could help to improve the design of capacity building projects in ethics, their monitoring and evaluation, and may lead to a more effective use of resources.

[7] UNDP 1997. Capacity development. New York: UNDP report, Management Development and Governance Division.
[8] Starratt R. J... *Building an Ethical School: A Theory for Practice in Educational Leadership*. Educational Administration Quarterly 1991; 27 (2); 185–202.
[9] Smith, D. *Fostering Collective Ethical Capacity within the Teaching Profession*. Journal of Academic Ethics 2014; 12 (4); 282
[10] Potter C., Brough R. *Systemic capacity building: a hierarchy of needs.* Health Policy and Planning 2004; 19 (5); 336–345.
[11] Ibid.

They also suggest a four-tier hierarchy of capacity building needs, involving different areas of intervention: structures, systems and roles; staff and facilities; skills and tools.

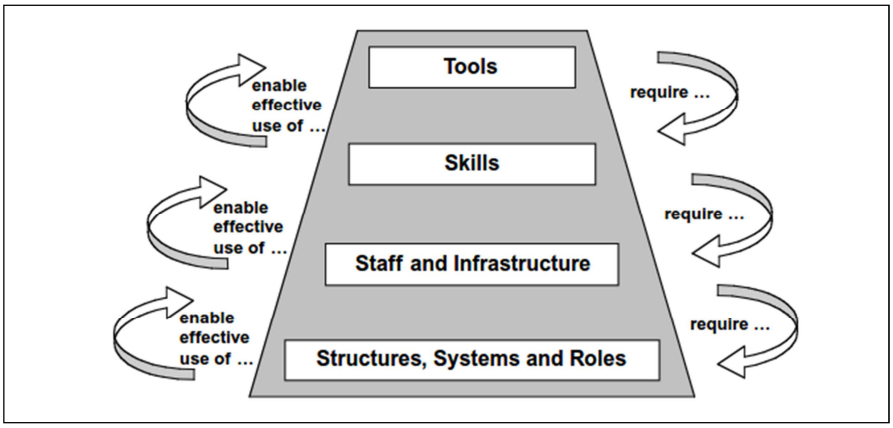


**Figure 1 Systemic capacity building**[12]

As SATORI project is evaluating capacity building needs in the field of ethics assessment in research and innovation, we also considered the model for capacity building in research (RCB) by Cooke et al that provides a framework for capacity building within a policy context. [13]

RCB can be greatly nurtured or restricted by the prevailing policy. This notion is particularly important for SATORI, as the project is developing a new and common ethical framework for the EU that could influence future policies and the very existence of supportive infrastructures. Cooke et al model states that research capacity building should improve the opportunities for individuals, teams, organisations and networks. Infrastructures, skills, practical tools, development of collaboration, sustainability and appropriate dissemination influence RCB as much as policies, in a mutual dialogue that is fostered by interdisciplinary and multilevel learning approach.

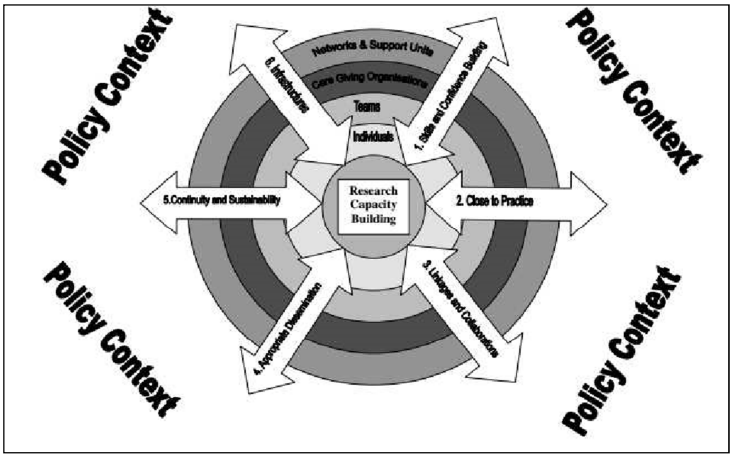


**Figure 2 Research Capacity Building**[14]

[12] Ibid.
[13] Cooke J. A framework to evaluate research capacity building in health care. BMC Family practice 2005; 6 (1); 44.
[14] Ibid.

### 1.1.2 Societal and transnational perspective

In the early 1990s, capacity building became a fundamental concept underlying interventions in the field of development. Anneli Milèn, advisor to the World Health Organization's department Health Service Provision argues that capacity building, as a societal process, can be linked to the ascendancy of three sociological perspectives in the 1970s and 1980s: the perspectives of agency, active citizenship and civil society. This means that active citizens, participating in the institutions of evolving civil societies, have the capacity to steer human endeavour in a direction that can produce self-determining, sustainable societies.[15]

The same concepts underlay the European Year on Citizens (EYC), an EU-funded initiative dedicated to the rights that come with EU citizenship that lasted from 2013 to 2014.[16] EYC encouraged dialogue between all levels of government, civil society and business at events and conferences around Europe to discuss notably the importance of both representative and participatory democracy in the European Union and inform on the existing tools to better participate in the European democratic process.

A large group of institutions – international, governmental and nongovernmental – have increased their efforts on scientific or research capacity building issues, especially in developing countries. These organisations have included, most notably, the United Nations itself with its emphasis on the Millennium Development Goals (MDGs) and the Third World Academies of Sciences (TWAS), an umbrella organisation of national academies of science, which represent a "forum for building scientific capacity and leadership". Ethical assessment became part of their development programs.[17]

Some networks, such as the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)[18], the European Network of Research Ethics Committees (EUREC) and the Council for International Organisations of Medical Sciences (CIOMS) are focused on the transnational perspective in the field of ethics assessment.[19]

**Strategic Initiative for Developing Capacity in Ethical Review** (SIDCER) is a transnational initiative which works as a network of independently established regional fora for ethical review committees, health researchers and invited partner organisations. The primary objective of SIDCER is to contribute to human subject protections globally by developing local capacity for ethical review of research involving human subjects and for developing policies on the ethics of health research. SIDCER aims at "operating with mutual understanding and respect for cultural, regional and national differences".[20]

**European Network of Research Ethics Committees** (EUREC)[21] is a European network that brings together national Research Ethics Committees (REC) associations, networks or comparable initiatives on the European level. The aim is to interlink European RECs with other organisations or institutions in the field of research that involves human participants, like National Ethics Councils and the European Commission's ethical review system. Such a

[15] Kenny S, ClarkeM. Challenging capacity building: comparative perspectives. Palgrave Macmillan, 2010, p.3f.
[16] http://europa.eu/citizens-2013/en
[17] TWAS 2004. Building Scientific Capacity. See http://twas.org/sites/default/files/capbuildreport.pdf
[18] SIDCER. http://www.who.int/sidcer/en/
[19] CIOMS. http://www.cioms.ch/
[20] SIDCER. http://www.who.int/sidcer/en/
[21] EUREC. http://www.eurecnet.org/materials/index.html

network forms the infrastructural basis to promote awareness of specific working practices of RECs across Europe, to enhance the shared knowledge base of European RECs. Its function is to support coherent reviews and opinions and to meet new challenges and emerging ethical issues. [22]

The **Council for International Organisations of Medical Sciences** (CIOMS), is an international, non-governmental, non-profit organisation established jointly by WHO and UNESCO in 1949. In 2013, the membership of CIOMS included 49 international, national and associate member organisations, representing many of the biomedical disciplines, national academies of sciences and medical research councils. Its main objective is to facilitate and promote international activities in the field of biomedical sciences. Therefore it coordinates long-term programs on bioethics; health policy, ethics and human values; drug development and use; international nomenclature of diseases.

With the increase in the scientific capacities, international collaborations as well as the application of new technologies in different regions of the world, ethical issues rise at the same time. Because of this ethics assessment (mainly bioethics) has also become increasingly international. Anticipating this global trend, UNESCO launched in 2007 a database called the UNESCO Global Ethics Observatory system of databases in ethics of science and technology. The database offers a collection of legal instruments searchable by region, country, bioethical themes, legal categories and applicability to specific articles of the UNESCO Universal Declaration on Bioethics and Human Rights and International Declaration on Human Genetic Data. [23] As a transnational effort for capacity building in ethics, it serves many countries with a limited infrastructure in bioethics and a lack of expertise, educational programs, bioethics committees, policies, public debate and legal frameworks. The use of this tools presupposes of course that the countries have the capacities to use it. Due to the global nature of science and technology, the need for a global approach to ethics was triggered by the global investment in research, so any capacity building training in ethics assessment should be based on a transnational approach.

It is this societal perspective, with an emphasis on the science-policy-society nexus that matters. Jasanoff, a renowned researcher in Science and Technology Studies (STS) and an expert in scientific policy advice, argues that "we need the capacity – and will – to question our purposes deeply: to ask over and over how knowledge underpins institutions and policies that are sometimes serviceable but at other times perverse". [24]

What does this mean for capacity building in ethics assessment in research and innovation? Smith summarize the results of a year-long process to foster the ethical capacities and to build an ethical framework within the teaching profession: "Based on the lived ethical experiences of educators […]the main ethical resources are cases, narratives, ethical frameworks, digital stories, books and kits".[25] She concludes that the "building of ethical lenses" can foster the individual and collective ethical knowledge and sensitivity. [26]

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[22] Since 2011 EUREC provides Training and Resources in Research Ethics Evaluation (TRREE), as an online training course in seven languages. See http://elearning.trree.org/

[23] Ang TW et al. *UNESCO Global Ethics Observatory: database on ethics related legislation and guidelines*. Journal of Medical Ethics 2008: 34 (10); 738–741.

[24] Jasanoff S. *Watching the watchers: lessons from the science of science advice*, In: The Guardian, http://www.theguardian.com/science/political-science/2013/apr/08/lessons-science-advice; April 8, 2013

[25] Smith D.*Fostering Collective Ethical Capacity within the Teaching Profession*. Journal of Academic Ethics 2014; 12 (4): 271–286.

[26] Ibid.

## 1.2 ETHICS IN THE RESPONSIBLE RESEARCH AND INNOVATION FRAMEWORK

Why is capacity building in ethics assessment relevant to the concept of "responsible research and innovation" (RRI)? A working definition for responsible research and innovation is proposed by the European Commission DG Research and Innovation as

> a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society). [27]

Ethics is one of six key elements of the RRI framework, besides engagement, gender equality, science education, open access and governance. [28] Generally speaking the building of a common framework means that all societal actors - researchers, industry, policymakers and civil society – jointly participate in the research and innovation process, in accordance with the value of inclusiveness, as reflected in the Charter of Fundamental Rights of the European Union.

Societal challenges are framed on the basis of widely representative social, economic and ethical concerns and common principles. In addition, mutual learning and agreed practices shall be developed to evolve joint solutions to societal problems and opportunities, and to pre-empt possible public value failures of future innovation. [29] These should also be the basis of any capacity building program in ethics assessment if we want the ethical issues to be formulated explicitly, in order to adequately respond to societal challenges Beyond the mandatory legal aspects, the RRI framework states that ethics "should not be perceived as a constraint to research and innovation, but rather as a way of ensuring high quality results".[30]

### 1.2.1 The EU Commission's Ethical Indicators for RRI

In a recent report by an EU Commissions expert group[31], criteria for RRI indicators were reviewed and ethics was included among the eight criteria for monitoring R&D projects (see Table 1).

| | **Performance indicators** | |
|---|---|---|
| | *Process indicators* | *Outcome indicators* |
| **Ethics** | Documented ELSI/ELSA project | Documented change in R & I priorities (research |

[27] European Commission 2011. *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields*. European Commission DG for Research and Innovation. http://ec.europa.eu/research/science-society/document_library/pdf_06/mep-rapport-2011_en.pdf.
[28] European Commission 2007. *From the Ethics of Technology Towards an Ethics of Knowledge Policy and Knowledge Assessment*. *SSRN Electronic Journal*. http://www.ssrn.com/abstract=2436380
[29] European Commission 2011. *Responsible Research and Innovation - Europe's ability to respond to societal challenges*. European Commission DG for Research and Innovation. http://ec.europa.eu/research/science-society/document_library/pdf_06/responsible-research-and-innovation-leaflet_en.pdf.
[30] Ibid.
[31] EU Commission 2015. *Indicators for promoting and monitoring Responsible Research and Innovation*. EU Commission. http://ec.europa.eu/research/swafs/pdf/pub_rri/rri_indicators_final_version.pdf., p. 29ff.

| | | |
|---|---|---|
| | component and/or transdisciplinary component that addresses societal relevance and ethical acceptability (presence/frequency; qualitative descriptions; best practices) | or research funding) attributable to multi-stakeholder and/or transdisciplinary processes of appraisal of societal relevance and ethical acceptability. (presence/frequency; qualitative descriptions; best practices) |

**Table 2 Proposed indicators for ethics by EU Commission**[32]

The ethics assessment of the impact of research on its object (human beings, animals, environment etc.) is not the main current challenge as a criterion of RRI in the context of the EU. Rather, the expert group states that the main challenge is to prevent mandatory institutional ethics procedures from degenerating into perfunctory exercises.

Instead of futile attempts to train assessors at collecting data from below for a top down command-and-control system, the experts recommend that ethics indicator focus on bringing actors together to discuss the state of the art as a part of good governance. For RRI in general, and particular for the more overarching criteria such as ethics, indicators will and should be experimental in nature. The expert group provides a list (that can be a good basis for exercises on ethics assessment of research projects) that combines simple, quantitative suggestions with qualitative and more experimental ones, as shown below:

- documented change in R&I priorities (research or research funding) attributable to multi-stakeholder and/or transdisciplinary processes of appraisal of societal relevance and ethical acceptability (presence/frequency; qualitative descriptions; best practices);
- presence of multi-stakeholder and/or transdisciplinary processes of appraisal of societal relevance and ethical acceptability;
- in research projects, the existence of an ELSI/ELSA project component and/or transdisciplinary component that addresses societal relevance and ethical acceptability;
- public awareness and evaluation of mechanisms for multi-stakeholder and/or transdisciplinary processes of appraisal of societal relevance and ethical acceptability.

## 2 THE AIM AND CONTENT OF ETHICS ASSESSMENT IN RESEARCH AND INNOVATION

Many experts[33] have tried to summarize the aim of ethics assessment. Developed in the field of medicine and life sciences, ethics assessment is now required also in other fields where research and innovation can have an impact on the life of citizens. The Guidance document issued by the Directorate-General for Research and Innovation to promote ethics self-assessment for applicants for Horizon 2020 funding states:

> Consider that ethics issues arise in many areas of research. Apart from the obvious, the medical field, research protocols in social sciences, ethnography, psychology, environmental studies, security research, etc. might involve the voluntary participation of research subjects and the collection of data that might be considered as personal. You must protect your volunteers and also protect yourself (and your researcher colleagues).

[32] Ibid.
[33] Oliver P. The student's guide to research ethics. Open University Press (McGraw-Hill Education), Maidenhead, 2010.

The knowledge of the aim of ethics assessment is of course a prerequisite for the planning of any training program in the field. The following list of activities conducted by RECs can help people involved in training in ethics to identify the goals they want to reach with the training itself.

- Identify the aims of the research, its moral and social justification
- Identify the ethical issues related to the research project or to the introduction of an innovative tool or discovery
- Identify situations when/where research could be ethically undesirable
- Highlight the responsibility of the researchers involved in a project
- Verify the correspondence between the research design and the norms and laws governing research in the country where it will be conducted
- Analyze the procedures of recruiting (if human subjects or animals are involved), the principles of informed consent, the quality of the information provided to the subjects and to the public. Highlight possible risks for vulnerable groups of people
- Identify potential risks and benefits for the people involved in the research
- Analyze the quality of the research design
- Identify sensitive issues linked to religion and values differences among the population
- Verify the ethical of data recording, storage and analysis especially when dealing with sensitive materials
- Evaluate anonymity, confidentiality and privacy issues
- Verify the issues related to social sciences researches such as the quality and administration of questionnaires and interviews (including potential psychological effects on the respondents)
- Verify the availability of the research data to the participants
- Verify the frequency and quality of public information about the results
- Evaluate the possible social, political and environmental impact of the research or the introduction of innovations
- Verify the sponsorship and funding of a research, the possible conflicts of interest; issues of intellectual property and adherence to code of conducts of specific disciplines or professions
- Analyze the publication and dissemination of a research; the editorial procedures in academic journals; issues of plagiarism and self-plagiarism; the rules for authorship; the code of conduct of the reviewers; the representation of the research findings to non-researchers.

## 2.1 EXISTING TRAINING MODELS

The models for training in ethics assessment are not well established nor standardized. Many different experiences have been conducted in recent years, focused mainly on researchers, ethics assessors and ethics committees, mainly in the field of medical research and bioethics. Some tools and guidelines have been developed. The following list is not exhaustive but provides some examples of good practices or models for future training in ethics assessment, identified by a systematic search using the keyword "*training in ethics*", "*ethics assessment*", "*capacity building in training assessment*", "*stakeholders and ethics assessment*", "*ethics assessment course*", "*tools for ethics assessment*".

The **European Forum for Good Clinical Practices** (one of the most active bodies in research ethics in the European Union that aims to promote consistent, high quality ethical

review) held a workshop in 2011 with the aim to produce a syllabus[34] for training that could help identify needs and resources in different European Countries. The syllabus summarises standards and training for research ethics committees (RECs) issued from a discussion among representatives of 12 different European countries.

What was debated was not the need for training in RECs, but the best way to provide it, due to the lack of guidance. [35],[36] The syllabus is divided into four broad competencies: committee working, scientific method, ethical analysis, understanding of the regulatory framework. These categories reflect also the four major categories of training needs as expressed by the interviewees in the SATORI Project (see appendix 1).

Committee working capacities were divided into internal capacities (within the committee itself) and outside capacities (how to work with all the involved stakeholders such as public, patients, researchers and other regulators). Outside capacities involve:

- understanding the place of research in the field of interest, and how researchers plan, seek funding and conduct research;
- presenting and describing the authority, purposes and processes of REC to others;
- considering and promoting the public understanding of research.

In committee capacity involves to review proposals, debate an application and reach consensus. It is focused on how to:

- prepare for the committee meeting by reading documents; developing and using critical appraisal skills;
- have the skills and attitudes (empathy, humility, courage) to work together, present one's own views and accommodate those of others;
- debate issues in committees;
- be open to questioning and comments;
- be able to handle differences of views and opinions.

The training also foster the capacity to be committed to continuing training; to determine what the committee needs to know; to match training needs with possible resources.

Committees generally involve a wide range of professional expertise so trainings are an opportunity to share knowledge and expertise. The competencies in scientific method can be mutually learned in multidisciplinary groups (as the RECs themselves), especially when they involve representatives of CSO and other stakeholders with no specific scientific background. The basic need in this area, as expressed also by the interviewees in SATORI, is the capacity to review the scientific standing of a project, according to national and international guidance on gold standard for research in each scientific field. Ideally, each member of the committee should be able to:

- analyze research questions and appropriate methods to answer them;
- understand different research designs (quantitative and qualitative) and their

[34] Cairoli E et al. A syllabus for research ethics committees: training needs and resources in different European countries. J Med Ethics 2012; 38: 184-186.
[35] Davies H. How should we teach research ethics? Research Ethics Rev 2010; 6: 43-47.
[36] Centre for Professional Ethics at Keele University. European Textbook on Ethics in Research. http://ec.europa.eu/research/science-society/document_library/pdf_06/ textbook-on-ethics-report_en.pdf

appropriate application, including statistics that are relevant for REC;
- review the suitability of the applicant and the validity of the research;
- consider the researchers' role, constraints and motives;
- consider how the research team is assessed: CV, good practice training, resources, experience, skills etc.;
- consider and understand how conflicts of interest may arise and how they should be handled.

RECs members should also have competencies in regulatory framework in each specific field (i.e. the Declaration of Helsinki for biomedical research and other seminal documents in environmental or social sciences research). This implies also to have access to, and understanding, any relevant European directive, good practice guideline and national legislation; to understand the REC's and other bodies' role in protecting research subjects and facilitating research; understand and have access to the committees' governance and standard operating procedures and, last but not least, to understand the role of other regulators, how this links to the role of REC and how differences can be resolved.

Competencies in ethical analysis itself are only part of the duties of an ethics assessor. Training in this field should involve knowledge about research history, the benefits research has brought and its attendant risks. Assessors should also be able to:

- apply the common ethical models (e.g., duty based, rights based and consequentialism); [37] [38]
- analyse the ethical aspects of recruitment of participants and inclusion/exclusion criteria, consent (patient autonomy, principles of informed consent, information provided to participants);
- judge the burden of the study and its risks compared with its benefits;
- discuss payments to subjects, both volunteers and patients;
- evaluate confidentiality and data management, data and sample storage, publication policy and any issue relates to a research involving particular groups (children, elderly, mental health patients.

They should also have the capacity to make a judgment upon the ethical standing of a research project: understand how to reach judgments on research projects and reflect on one's own decisions and how they are reached.

The **EST Frame Project** is an FP7 Science in Society collaborative project that ended in January 2015.[39] Its aim was to contribute to socially robust and ethically sound research and technology development by providing methodological development of appropriate tools for social impact assessment and technology evaluation. The project appraised current assessment methods for evaluating emerging science and technology with the objectives of mapping their strengths and weaknesses and determining their appropriate application domains. The project also identified to what extent - and in what contexts - a framework of a more integrated nature can be applied, and examined the appropriate position that such an

[37] Gillon R. What attributes should clinical ethics committees have? BMJ 2010;340: c2496.
[38] Larcher V, Slowther A, Watson AR, et al. Core competencies for clinical ethics committees. Clin Med 2010;10:30e3
[39] http://estframe.net/

integrated framework can operate in, within a context characterised by internationalisation, market politics, and new forms of public-private partnerships in technology governance. The project used four examples of emerging science and technologies - nanotechnology in food production, synthetic biology, biofuels and security in emerging ICTs - to determine how current frameworks are applied to assess social impacts. Some guidelines for training in ethics assessment tools were developed within the project.

*Ethical matrix tool* [40] [41] [42]

The ethical matrix is a conceptual tool designed to help decision-makers (as individuals or working in groups) reach judgments or decisions about the ethical acceptability and/or optimal regulatory controls for existing or prospective technologies in the field of food and agriculture. The ethical matrix applies a number of principles to a set of selected interest groups. The standard principles are: respect for wellbeing, autonomy and fairness, and together they form the columns of the ethical matrix. The rows consist of the 'interest groups' (i.e. affected parties) that are relevant to the issue in question. These might include different groups of people, such as consumers and food producers, but also non-humans, such as farm animals. The arrangement of principles and interest groups in a table, forming the ethical matrix, facilitates easy cross-referencing in deliberation and subsequent reflection on an issue. The ethical matrix was initially designed to facilitate ethical deliberation by those with particular knowledge and/or interest in novel biotechnologies, but who may have little or no formal training in academic ethical theory or have only limited experience in applying such theory to concrete issues. The aim of the ethical matrix is to help users identify ethical issues raised by the use of novel technologies and to arrive at intellectually defensible decisions. However, the ethical matrix does not prescribe any particular decisions, so it is particularly suitable as a tool for training in ethics assessment.

A number of organisations can apply the tool, including: governmental advisory committees and/or ad hoc working parties; ethics committees at various levels; non-governmental organisations; participants in exercises in public deliberation; commercial companies.

The ethical matrix has also been used by individuals to examine bioethical issues in academic publications. It can be used at a strategic level to review ethical dimensions or to review the specific ethical impacts of individual technologies (e.g. for a patent or license application). The use of the ethical matrix may be expected to result in one or more of the following outcomes: raise awareness of a wide range of ethical issues; encourage ethical reflection; provide a common basis for ethical decision-making; identify areas of agreement between individuals who might differ in their overall judgments; clarify the basis of disagreements; make explicit the reasoning that underpins any ethical decisions.

Workshops can be built using the Ethical Matrix tool applied to specific case histories.

*Ethical Delphi*[43]

[40] Kaiser, M. & E-M. Forsberg, 'Assessing fisheries - Using an ethical matrix in a participatory process', Journal of Agricultural and Environmental Ethics (2001) 14, 192-200.
[41] Mepham, B., 'The ethical matrix as a framework for teaching ethics to sciencestudents'. In: M. Marie et al. (eds.), Animal bioethics. Wageningen Academic Publishers, Wageningen 2005, 313-27.
[42] Schroeder, D. & C. Palmer, "Technology assessment and the 'ethical matrix'". Poiesis Praxis (2003) 1, 295-307.

An ethical Delphi is an iterative participatory process between experts for exchanging views and arguments on ethical issues. The method is structured around the notion of a virtual committee where the exchange of ideas is conducted remotely through a series of opinion exchanges. Anonymity of the participants is central to the process. This feature aims to eliminate external power relations and personal influences that may interfere in the discussion of ethical dimensions within a committee environment. The Delphi method, first developed by the RAND Corporation in 1950s, was designed to combine the knowledge and abilities of a diverse group of experts to the task of quantifying variables that are either intangible or shrouded in uncertainty. A series of questionnaires are sent either by post or e-mail to a pre-selected group of experts. Increasingly questionnaires are being made available as web-based surveys. The questionnaires are designed to elicit and develop individual responses to the problems posed and to enable the experts to refine their views as the group's work progresses in accordance with the assigned task. The technique has been used for a variety of applications such as technology assessment, Environmental Impact Assessment (EIA), public health.

This method can be used by a number of groups to explore ethical issues raised by the use of a defined technology. An ethical Delphi can also be used in preparation for ethical training workshop to avoid the preliminary study of a case and to highlight the procedures and sources used by the participant to identify ethical issues and reach an agreement on how to manage it.

*Corporate Moral Responsibility kit (CoMoRe kit)*[44]

The CoMoRe-kit was built by the EST Frame Project to facilitate ethics assessment in the field of food production. It is based on the idea that food chain value communication consists of three different dimensions that are usually intertwined with each other. The three dimensions of food chain value communication are:

- clarifying corporate values: what concerns, ethical values and identity does the corporation itself have, and how can these values and concerns be morally discussed in a profound manner;
- clarifying stakeholder values: what concerns and ethical values does a corporation ascribe to its stakeholders;
- stakeholder dialogue: how can the moral values of the corporation and its stakeholders be communicated and debated, and how can actions and initiatives that comply with these values be assigned and taken up.

The CoMoRe-kit can help a corporation to be better aware of its own integrity and, hence, to improve it if necessary. It helps the corporation to achieve a clear and well-founded view of its own responsibilities and the responsibilities of its stakeholders with respect to new technologies.

CoMoRe is a good example of tool that can be taught and used in training on ethics assessment when corporations are invited to share the training and to bring their own issues

[43] Linstone, H.A. & M. Turoff (eds.), The Delphi method. Techniques and applications. http://www.is.njit.edu/pubs/delphibook/index.html

[44] Kaptein, M., Ethics management. Auditing and developing the ethical content of organisations. Kluwer Academic Publishers, Dordrecht/Boston/London 1998.

and competencies.

The **World Health Organization** published two important training guides for ethics assessors in biomedicine. The "*Operational Guidelines for Ethical Committees that Review Medical Resea*rch"[45] are intended to facilitate and support ethical review in all countries around the world. They are based on a close examination of the requirements for ethical review as established in international guidelines, as well as on an evaluation of existing practices of ethical review in countries around the world. They do not, however, purport to replace the need for national and local guidelines for the ethical review of biomedical research, nor do they intend to supersede national laws and regulations. In 2009 the WHO published "*Basic concepts for capacity building for research ethics committees*". The aim of the document, designed for ethics committees in developing countries involved in the evaluation of biomedical research, is to give a general overview of the glossary used in ethics and in science, to help in the selection of the members of the committee and basic suggestion for the organisation of training sessions based both on lecture and on case-studies. A common vocabulary and an expertise in the selections of the members of ethics committees are two key needs expressed also by SATORI interviewees.

The **European Network of Research Ethics Committees** took part into the development of the TRREE Program (Training and Resources in Research Ethics Evaluation)[46]. It aims to provide basic training, while building capacities, on the ethics of health research involving humans. TRREE achieved this goal primarily by developing a training program with local collaborators. In its initial stages TRREE focused primarily, but not exclusively, on the needs of African countries.

TRREE provided free-of-charge access to e-Learning (a distance learning program and certification on research ethics evaluation) and e-Resources (a participatory web-site with international, regional and national regulatory and policy resources).

This program promoted co-learning, collaboration and capacity-building amongst partners and has three general objectives: to increase knowledge as well as practical skills of those involved in the management and conduct of ethics evaluation and research partnerships; to create a participatory process that will foster partnerships with and amongst low and middle income partners; to create a resource that will facilitate the dissemination of knowledge in North-South partnership.

The aim of the project is to strengthen the research ethics evaluation capacities in African, European and other participating countries. The training material is designed for all those involved in collaborative research involving humans including physician-investigators and other researchers, students, research ethics committees and regulatory agencies.

The use of on line tools and repositories of documents relevant for ethical assessment were asked also by many SATORI interviewees, with the aim to offer a long lasting improvement of the training opportunities and to reach as many people as possible.

The **National Institutes of Health Department of Bioethics** (USA) offers an online course

[45] http://www.who.int/tdr/publications/training-guideline-publications/operational-guidelines-ethics-biomedical-research/en/
[46] http://elearning.trree.org/

on Ethical and Regulatory Aspects of Clinical Research. [47] The goals of the course is to enable participants to use a systematic framework for evaluating the ethics of a clinical research protocol; apply appropriate codes, regulations and other documents governing the ethical conduct of human subject research to their own research; discuss controversial issues relating to human subject research; identify the critical elements of informed consent and strategies for implementing informed consent for clinical research; describe the purpose, function, and challenges of their research project and appreciate the experience of human subjects who have participated in research protocols. Lectures podcasts and pdf are available online free of charge but no interaction with the teachers is provided. The course is based on frontal lectures, case descriptions and basic knowledge of the history of human research, ethics codes development and regulations. Case-history based training was suggested also by some stakeholders interviewed by SATORI.

The **UKRIO (UK Research Integrity Office)** training tools are devoted to the field of scientific integrity. UKRIO has provided independent, expert and confidential support across all disciplines of research, from the arts and humanities to the life sciences. They help all professionals involved in research: researchers, research organisations and members of the public, including patients and research participants. The aim of their publication is to provide guidance that are not mandatory but reflects and reinforces best practice. They promote common approaches to common situations and provide subject-specific expertise whenever necessary. They act as advisory board in case of bad practices and misconduct. They offer an online check list [48] on misconduct for researchers, a practice guide to investigate misconduct and scientific frauds. They also provide, when requested, formal frontal trainings both for researchers and for official investigating allegations of misconduct. They provide an online guideline for retractions [49] to help the researchers in dealing with these issues in an ethical way.

The availability of check lists and guidelines for the management of the most common issues an ethics assessor has to deal with is perceived as a plus also by some SATORI interviewees and could simplify the spread of common approaches and tools, one of the aim of the development of a common ethical framework by the SATORI project.

### 2.1.1 Considerations on the existing programs

Our research on online resources for training or capacity building in ethics assessment demonstrate that there are few standardized training programs available for ethics assessors, mainly in the field of biomedicine and medicine.

The targets of the online trainings are often ethics assessors in developing or low and middle income countries, while few initiatives are available in Europe and USA. No specific training is available for lay persons that are involved in ethics assessment.

Capacity building programs for non-profit organisations, civil society organisations and other stakeholders were designed mainly for developing countries and to improve personal skills more than organisational ones.

Few specific training programs are available for the assessment of new technologies that are

[47] http://www.bioethics.nih.gov/courses/ethical-regulatory-aspects.shtml
[48] http://ukrio.org/publications/checklist-for-researchers/
[49] http://ukrio.org/publications/guidance-on-retractions/

not related to medicine, for the analysis of the environmental impact of research or industrial productions. Some EU projects on environmental issues developed general tools that can be used to evaluate the ethical impact of research or innovation in other fields.

Social sciences and humanities seams not to be considered as a topic that deserve specific training programs or repositories of documents and guidelines.

# 3 CAPACITY BUILDING AND TRAINING IN ETHICS ASSESSMENT IN THE SATORI SAMPLE

In the SATORI Project, data was collected on different stakeholders involved in ethics assessment or with potential interests in the field of research and innovation. We conducted a large number of semi-structured interviews. We selected the interviews where the interviewee expressed needs and/or concerns about training or capacity building opportunities in ethics assessment. The selected interviews were coded by hand (see appendix 1).

We identified four major categories of organisations or people involved, formally or informally, into ethics assessment that could be the target of future trainings (formal institutional assessors, CSOs, young scholars and researchers and science journalists). Each category expressed its own view on the role and interest in ethics assessment that will be used to build future capacity building activities within SATORI but can be also useful for other actors, both institutional and academic. Other information about the training needs of the identified categories was deduced by a review of the literature.

## 3.1 FORMAL ETHICS ASSESSORS NEEDS

The SATORI project identified as ethics assessors a large number of stakeholder in R&I (see Table 3), not only members of RECs. The reason for this broad inclusion is in what we intend as ethics assessment:[50]

> We define ethics assessment (ethical assessment, ethics review, ethical review) to refer to any institutionalized kind of assessment, evaluation, review, appraisal or valuation of practices, products and uses of research and innovation that makes use of primarily ethical principles or criteria. The objects of research or innovation that are assessed may be research or innovation goals, new directions, projects, practices, products, protocols, new fields, etc. Ethics assessment is the prototypical task of research ethics committees that assess plans and protocols for research. Ethical assessment can be distinguished from other types of assessment and from other activities within ethics by the fact that it involves some kind of moral judgment or opinion concerning research and/or innovation, that is, an opinion that certain practices, projects, developments, etc. are morally (im)permissible, (un)controversial, (ir)responsible, or are in violation of or in conformity with specific moral values, principles or norms.

Under this umbrella we can define as ethics assessment also many of the activities and evaluations conducted by CSOs, patient organisations and representatives of interest groups.

[50] SATORI Deliverable D1.1 Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries. June 2015, p. 19.

| | |
|---|---|
| National ethics committees | Standardisation organisations |
| Research ethics committees | Accreditation and certification organisations |
| Associations and networks of research ethics committees | Governmental Organisations and Councils |
| Universities and research institutes | Companies |
| Associations of universities and research institutes | Business and industry associations |
| Science academies and associations of science academies | Academic and professional organisations in R&I |
| Research funding organisations | Civil society organisations |
| Academic and professional organisations in science and engineering | |

**Table 3: Organisations that engage in ethics assessment and ethical guidance for R&I**

Analysing the interviews of this category of stakeholders, we identified three major subgroups:

1. Members of RECs, professional ethicists, academic representatives
2. Business and industry representatives.
3. Representatives of CSOs, non-profit organisations, interest groups.

The needs in training and capacity building in ethics assessment as expressed by the three groups are clearly different, notably between the first two groups that are engaged in a more formal ethics assessment and the third. In this section we will focus on formal institutional assessors, as CSO representatives expressed different needs and suggestions for future trainings and participatory processes, so we considered them as a separate category.

Members of RECs, professional ethicists and academic representatives seems to be reluctant in being involved in training or capacity building projects. They perceive themselves as trainers more than trainees and ask for a training involving the people they have to deal with and to evaluate (researchers, young scholars, representatives of H2020 national antennas etc). Their idea of training is linked to the acquisition of knowledge (about science, scientific methods, norms and laws regulating R&I). They ask for online courses and lectures on the principles of ethics assessment and on line databases of documents that can be used as sources for deliberation and repository of cases that can be used as precedents, applying to ethics assessment the same methodology used by Common Law.

Representatives of industry are reluctant in identifying their activity in the field of corporate social responsibility as a form of ethics assessment. They perceive their role as an instrument of corporate strategies more than an independent evaluation of R&I in the name of the society at large. [51] They don't feel they need any kind of external training because many training

[51] Friedman M. The Social Responsibility of Business is to increase its profits. In: Zimmerli WC et al. Corporate ethics and corporate governance. Springer 2007, p. 173-178.

programs in CSR are available within the academic curricula in economy or marketing. Courses on CSR principles and evaluation tools are also available as continuing professional education.[52] The involvement of industry representatives in capacity building activities will be a major challenge for the future success of a common European framework in ethics assessment.

CSO representatives' suggestions will be analysed in a separate paragraph as they often conduct formal ethics assessment but expressed different needs and a different approaches to the implementation of a common framework.

The needs and suggestions expressed by formal ethics assessors were highlighted in the interviews with by-hand coding and summarised in a list of key points that merge similar opinions in a more general practical advice about the contents and tools that each future workshop should offer.

**Key points**

***What formal ethics assessors estimate should be the contents of training in ethics assessment***

- Training should be directed to non-formal assessors, young scholars and representatives of H2020 national antennas (as a measure of prevention for malpractice or unethical research proposals)
- Basic knowledge of laws and norms regulating ethics assessment in the different fields
- Basic training in science and scientific method
- Databases of sources of norms and laws, repository of previous deliberations in ethics in the different European countries
- Tools to identify ethical issues
- Training should be based on real cases analysis

## 3.2 CIVIL SOCIETY ORGANISATION (CSO), NON-GOVERNMENTAL ORGANISATION (NGO) AND INTEREST GROUPS TRAINING NEEDS.

As stated in previous paragraph, CSOs can act very differently toward ethics assessment. Some of them act as formal assessors (sometimes as part of institutional committees), some are conducting "informal" ethics assessment within their own activities (i.e. consumers associations that provide information about the working condition in industries to enhance the consumers responsibility toward human and legal rights of the workers all over the world) and some others are interested in the topic even if they don't do any kind of assessment. Although they have very different approaches to the issue, their needs and suggestions for future trainings seem very similar so we decided to consider them a single category, even if each CSO can have a different level of knowledge and capacity in ethics assessment.

According to the European Commission's Communication of September 2012

[52] http://www.academiccourses.com/Courses/Corporate-Social-Responsibility-%28CSR%29/

> the EU considers CSOs to include non-State, not-for-profit structures, non-partisan and non-violent, through which people organize to pursue shared objectives and ideals, whether political, cultural, social or economic.[53]

According to the SATORI Basic Concepts document, CSOs are "non-governmental, non-industry organisations that represent the interest and will of citizens". [54] Although CSOs activities are rarely defined as ethics assessment, many CSOs perform informal ethics assessment or guidance in the course of their activities.

As attested by the SATORI Assessors Reports on Civil Society Organisations[55]

> assessment by CSOs range from the conduct of scientists, professionals, or companies, to the involvement of particular groups in research and innovation and the impacts of particular technologies. In order to influence policy making on a larger scale CSO offer guidance in the course of setting research agendas. The CSOs that conduct research make sure that it adheres to ethical standards".

Analyzing the interviews conducted by SATORI, we noticed that representatives of CSOs and interest groups suffer of a lack of awareness of the role they play in informal ethics assessment (i.e. in assessing corporate social responsibility of industry when they want to protect consumer rights or the environment). They seem to be interested in capacity building activities because many of them want to contribute in building the common European framework for ethics assessment even if they fear that such a framework could threaten the values they represent and the norms that reflects the different approaches and values toward ethical issues in the different European countries. They ask for tools to identify the ethical issues and to evaluate them, as for exercises to improve their skills in arguing and defending their own position when they have to deal with experts in RECs or other institutions were they do formal assessments.

The needs and suggestions expressed by CSOs and stakeholders organisations representatives were highlighted in the interviews with by-hand coding and summarised in a list of key points that merge similar opinions in more general practical advices about the contents and tools that future workshops should offer.

**Key points**

***What informal ethics assessors would appreciate in future trainings***

- Opportunities for multidisciplinary discussions and participatory processes on the future framework for ethics assessment
- Capacity building activities based on mutual learning involving both experts and lay people
- Training based on the learning by doing approach and on case histories
- Some basic knowledge of the basis of ethics assessment (values, norms, laws…)
- Tools to identify ethical issues

[53] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2012) 492 final, Brussels, 12.9.2012, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0492:FIN:EN:PDF
[54] SATORI, Basic Concepts v. 2, p. 6
[55] SATORI Assessors Reports on Civil Society Organisations, p. 21

- Tools to evaluate research design
- Techniques and skills to defend their opinion in a formal context

## 3.3 RESEARCHERS AND YOUNG SCHOLARS

Researchers and young scholars were not directly interviewed by SATORI as an independent group but were included mostly as representatives of the disciplines they are involved in. Nonetheless formal ethics assessors clearly stated that any kind of training and capacity building program should involve them as a category per se.

In an article published on the blog that the peer reviewed journal *Science* devotes to career resources, Benderly[56] reports the results of a session on ethics training for young researchers at the Euroscience Open Forum in 2012:

> Difficult ethical issues can present significant challenges to graduate students and early-career scientists, but few receive adequate training and guidance in dealing with these problems […]. Formal training in ethics was unknown in science before 1990, when it became a requirement in the United States, said Nicholas Steneck of the University of Michigan, who is a consultant to the Federal Office of Research Integrity. In recent years, he continued, interest has increased in other countries as well. Concepts of ethics and responsible research vary among countries and disciplines, however, the speakers agreed, and there is no uniformity in the content of training even within countries. And, although various initiatives are underway in a variety of nations, nowhere is training sufficient to the needs of young researchers, the panelists said.

Ethics training for young researcher should cover topics as malpractice and fraud in science, authorship, retractions and plagiarism, but also the role of science and research in the European society. In the same ESOF session, experts stated that the most common trainings in ethics available for young researchers are online course created by their own academy or research institution and focused on norms and guidelines to comply with all the administrative and formal requests of RECs. This is not enough to build a real awareness of the role of ethics in research and to be an effective tool of deterrence for frauds and malpractices.[57]

As SATORI didn't include young scholars and researchers as a specific category for interviews, we collected with by-hand coding all the suggestions expressed by the other interviewees that refer to them. Some formal assessors in academic institutions and national ethics committees expressed strong concerns about the lack of awareness and knowledge of the basic principles underlying ethics assessment - and especially self-assessment - in this category. Their suggestions were merged in a key point list including some topics that should be, in their opinion, covered by future training and capacity building projects.

**Key points**

***What young scholars and researchers would appreciate in a training program***

[56] http://blogs.sciencemag.org/sciencecareers/2012/07/difficult-ethic.html
[57] De Vries R et la. Normal Misbehavior: Scientists Talk about the Ethics of Research. J of Empirical Research on Human Research Ethics 2006; 1 (1): 43-50.

- Opportunities for multidisciplinary discussions and participatory processes on the role of science in society
- Knowledge of the basis of ethics assessment (values, norms, laws…)
- Tools to identify ethical issues
- Tools to evaluate their own research design

### 3.4 SCIENCE JOURNALISTS

In an editorial published by Nature in 2009, the main scientific peer-reviewed science journals stated:

> Some [scientists] will see science journalism as an ally, useful for shaping the public's understanding of science-related issues such as nuclear proliferation, stem cells or genetically modified crops — and, not incidentally, for making the case for a thriving research enterprise to public and politicians alike. And a minority, moving beyond perceived self-interest, will point to the deeper value of journalism, which is to cast a fair but sceptical eye over everything in the public sphere — science included. This kind of scrutiny is easy for researchers to applaud when a news report questions dodgy statistics, say, or dubious claims about uncertainties in evolution. It is not so easy when the story takes a critical look at sloppy animal-research practices, overblown claims about climate change or scientists' conflicts of interest. But such examinations are to the benefit of the enterprise as a whole: society needs to see science scrutinized as well as regurgitated if it is to give science its trust, and journalists are an essential part of that process[58].

Science journalists, as stated by the interviews conducted by SATORI, perceive themselves as informal ethics assessors, especially when they investigate on issues as science misconduct and frauds (such as in the autism-MMR study that was dismanteled by the investigation by the science journalist Brian Deer)[59] and retractions (as in the case of RetractionWatch, a repository of all the papers retracted by peer-reviewed journals that greatly contributed to the debate on this issue)[60].

They also perceive themselves (and are identified by scientists and stakeholders) as facilitators and "translators" of difficult or controversial information that are produced by science and research but have an impact on the society:

One of the interviewees by SATORI, in an article on the social and ethical role of science journalism in health reporting published in 2013, stated:

> While the general assignment reporters focus mostly on the facts in front of them – like the physician facing an individual patient – the specialised journalists try to evaluate the same facts in the wider context of evidence-based medicine and public health" stated the "In doing so, science journalists are constantly reminded that journalism is different from science, because most readers (ie: ordinary people) will always interpret very subjectively the meaning of words like «evidence», «risk» and «benefit», not to mention expressions like «statistically significant» as opposed to «clinically significant» or just significant. Citizens need «simply significant» news, and one of the most difficult challenges science journalists

[58] Cheerleader or watchdog? Nature 2009; 459: 1033.
[59] Deer B. How the case against the MMR vaccine was fixed. BMJ 2011; 342: c5347.
[60] http://retractionwatch.com

> face is finding a way to make newsworthy what they think is more significant for them and their audience. In simple words.Which is not a simple task. [61]

In the field of neuroethics (that involves all the ethical issues raised by the development of neuroscientific research, such as brain devices, diagnostic tools and brain diseases classification that can have a huge impact on individual and society), science journalists trained in ethics assessment are still perceived as necessary for the involvement of all the stakeholder by a large group of scientists and ethicists.[62]

Both European science journalists' associations (EUSJA and EFSJ) interviewed by SATORI appreciated the offer of a training or capacity building workshop on ethics assessment but EFSJ expressed some concerns on the content of the training, as they feel they need to improve the skills of science journalists in independent evaluation and investigation.

They also expressed some concerns about the independence of journalism, but they think that journalists could offer a plus in a multidisciplinary capacity building activity because they have an expertise in evaluating the strength of the evidences and the trustability of the sources in controversial cases. They also highlight the important role of science journalists as promoters of ethics assessment among the journalists with no specific background in science when they have to deal with scientific news.

SciDev.net, a web site considered to be a reliable and authoritative source of news and analysis on information about science and technology for global development, asked for a training involving also representative of all the stakeholders from developing countries, as research is more and more a global enterprise with ethical issues that involve also non-European countries.

The needs and suggestions expressed by representatives of the science journalism in Europe were highlighted in the interviews with by-hand coding and summarised in a list of key points that merge similar opinions in a more general practical advice about the contents and tools that future workshops should offer, in terms of formal training but also in terms of opportunities to enhance the perception and self-perception of the role of this category in fostering the public debate about ethical issues.

**Key points**

***What science journalists' association representatives would appreciate in a training and capacity building programme***

- Opportunities to train the journalists within the European national association to strengthen their awareness on the role of science journalism as informal ethics assessor.
- Training involving also stakeholders from on European countries, especially from developing countries, to discuss ethics assessment in a global perspective
- Training based on case-histories and tools for assessment more than on a top-down, frontal lectures approach.

[61] Turone F. The Number Needed to Inform: what we talk about when we talk of science journalism. Epidemiology, Biostatistic and Public Health 2013; 10: e8816.
[62] Illes J, Moser MA et al. NeuroTalk: improving the communication of neuroscience. Nat Rev Neuroscience 2010; 11(1): 61.

- Opportunities to highlight the role of science journalism as a watchdog of science and scientist among the other stakeholders and formal assessors.
- Case histories on scientific malpractice and frauds, science communication impact on citizens' perception of new technologies, ethical background of research and innovation, environmental and social impact of innovation.
- Opportunities to develop their own ethical framework with some values shared with journalism and some values shared with science, and to discuss it with other stakeholders.
- On-line courses, massive open on-line courses (MOOC) on ethics assessment and repositories of documents and sources on ethics assessment.

## 3.5 TRAINING NEEDS IN DIFFERENT CATEGORIES

Even if each category expressed specific needs for future trainings, there are some commonalities and some issues that should be highlighted. The categories that expressed less interest in general training and toward a common framework in ethics assessment are industry representatives and formal assessors' members of institutions and research ethics committees. Industry and companies representatives seem to be concerned by internal norms and constraints: they perceive themselves as stakeholders of their firm values more than independent assessors. Their participation in multi-stakeholders workshops could be useful to share with the representatives of the civil society the values that companies, industries and private research and innovation institutions should be inspired by.

Formal assessors could be involved in participatory processes and mutual learning activities to share their knowledge of the basic principles, norms and tools for ethics assessment but also to learn from civil society representatives the expectations of lay people in terms of a more ethical way to do research.

CSO representatives have very different levels of knowledge in the field, but most of them lack of awareness of the role they could play in ethics assessment and in inspiring the future framework. Participatory processes and capacity building programs could foster their role, as the role of science journalists as a key element in the transmission of values and norms that should inspire research and innovation, as in evaluating critically the activity of the other categories. Science journalists could also be used as facilitators in MML activities and workshops, as they are used to translate technical language into simple concepts.

Young scholars and researchers should be involved in workshops because all the other categories identified them as a key element for the development of a more ethical way to do research and to plan innovation. They should also be trained in the evaluation of a research design from the ethical point of view in more conscious way and not only in applying a check list of requests dictated by the local norms and law.

All the categories expressed a preference toward multidisciplinary discussions and participatory processes, while basic knowledge about norms and guidelines should be reserved to background materials, on line trainings or courses that could be a good tool to share the future common framework. CSOs and science journalists expressed also a preference for practical training, based on case histories and on tools for the identification of the ethical issues related to specific cases that could be useful also for their daily activities.
Representatives of non-European countries should be involved in workshops as research and innovation is perceived as a global activity.

# 4 PROPOSAL FOR FUTURE TRAININGS IN ETHICS ASSESSMENT

From a European perspective, it is important to realize that any training or capacity building activity to improve the level of ethics assessment has to take care of the "different value sets and attitudes are confronted with each other, leading to different capacities for responsible research and sustainable development, often competing for priority[63]".

A top-down approach to training (or any classic academic training) is not suitable to reach this goal: only capacity building activities based on mobilisation and mutual learning (MML) and participatory processes (MLP) can achieve the goal to enable both experts and stakeholders to evaluate ethical issues in research and innovation and to reach common solutions in a democratic manner and under a common framework.

Defining priorities is important in this context because participatory approaches can also be carried out on specific science and technology-related issues and could be focused on formulating and elaborating policy and research agendas[64].

## 4.1 EXPERTS SUGGESTIONS FOR TRAINING AND CAPACITY BUILDING IN ETHICS ASSESSMENT

In order to learn from previous experiences, SATORI interviewed two experts in training in ethics: Elmar Doppelfeld, Chair of the board of the European Network of Research Ethics Committees (EUREC)[65], and Giovanni Boniolo, director of the research program Foundations of the life sciences, ethics and epistemology at IFOM-IEO Campus in Italy, and Dean of an innovative PhD program for future ethicists coupling lab research with a classic training and education in ethics[66]. Doppelfeld has an expertise in training at the organisational and transnational level, while Boniolo built his training program on the development of individual professional skills.

Doppefeld described the duties and roles of RECs in Europe as following: [67]

- providing legal basis and legal competence for ethics assessment;
- handling conflicts of interest and malpractice in science and research;
- assuring the liability of RECs and of its members (by selecting the members);
- establishing ethics assessment institutions;
- acting as a system of appeal;
- interacting with the authorities;
- acting as a link among different research institutions in multicentric trials;
- evaluating the appropriateness of financial supporting.

[63] Kroesen, J. Otto, Darson, Rudi & Ndegwah, David J. 2015. *Capacities, Development and Responsible Innovation. In B.-J. Koops u. a. Responsible Innovation*. Springer International Publishing, p.201–222. http://link.springer.com/10.1007/978-3-319-17308-5_11.

[64] Sciencewise-Expert Resource Centre, *The Government's Approach to Public Dialogue on Science and Technology*, Department for Business Innovation and Skills, September 2013, http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Project-files/Sciencewise-ERC-Guiding-Principles.pdf

[65] Trescher, D 2015. SATORI-Interview with Elmar Doppelfeld on Research Ethics Committees in Europe.

[66] Ovadia, D 2014. SATORI Interview with Giovanni Boniolo on the contents of the training in ethics.

[67] Doppelfeld, Elmar 2014. European Network of Research Ethics Committees – EUREC. SATORI Kick-Off Presentation 15.01.2014

In his view, any capacity building project should help the experts in coping with this list of duties.

Giovanni Boniolo identified a practical approach to capacity building in ethics assessment. In his view, any program in this field should address the following issues:

- correct identification of the ethical issues related to a specific topic and of the stakeholders that can be interested/affected by them;
- ability to predict the impact of a new technology or a research based on the knowledge of previous similar cases;
- knowledge of the basic norms and principles of ethics assessment also in a historical perspective;
- ability to debate an issue and to defend a position in a multidisciplinary context;
- ability to avoid direct conflict, to solve conflicts among other stakeholders acting as facilitator/mediator and to reach a compromise;
- knowledge of practical tools that can help all the stakeholders to reach the above goals.

Boniolo's training program is based on real cases (case-history approach) and he invites his students to apply specific tools (such as ethical matrixes) to identify the ethical issues and MML tools to discuss with all the stakeholders and reach a common decision. His training is based on the principle of democratic deliberation.[68] In his view, a possible result of capacity building activities could be the development of a platform for online democratic and participatory ethics assessment deliberation.[69]

A list of MML tools and approaches used in previous EU projects that can be adapted to capacity building and training activities in ethics assessment is available in the *Report (handbook) of participatory processes* produced by SATORI. [70] Capacity building should involve mobilisation of stakeholders, participation and mutual learning. As stated by our analysis,

> the notion of 'mutual learning' (with an emphasis on 'mutual') is very idealistic, implying a level of consensus. The notion of 'mobilisation" also implies a sort of common awareness of a certain issue. Mutual learning involves a genuine exchange between stakeholders and scientists and the creation of new knowledge. Mutual learning is about bringing experts with different backgrounds together. Mobilisation is about getting many people involved, including people from universities that did not have engagement previously. Learning derives from the fact that people work alongside people with very different levels of experience […]. In addition, very established institutions and newly established grassroots organisations work together, as well as partners of different ages and with different agendas.

Following the three-level model of capacity building described in the first section of this report, we can identify some examples of measures for ethical capacity building involving individuals, organisations and stakeholders. These measures are summarised in Table 4.

[68] Boniolo G, Schiavone G. Deliberation and democracy. In: James D. Wright (editor-in-chief), International Encyclopedia of the Social & Behavioral Sciences, 2nd edition, Vol 6. Oxford: Elsevier. pp. 61–67.
[69] Schiavone G et al. Epistocracy for online deliberative bioethics. Cambridge Quarterly of Healthcare Ethics (2015), 24, 1–9.
[70] http://satoriproject.eu/work_packages/dialogue-and-participation/

| Level | Examples of measures for ethical capacity building |
|---|---|
| **Individual** | • education of members of RCEs (experts and lays) and acquisition of skills<br>• organisation of summer schools, workshops on research, conferences<br>• acquisition of appropriate tools to correctly identify ethical issues, e.g. ethical matrix |
| **Organisational** | • knowledge of legal and normative basis of ethics<br>• implementation of independent audits and publicly shared systematic reviews<br>• availability of funds and investments for RECs (fees) |
| **Societal/ transnational** | • implementation of the WHO recommendations for capacity building [71]<br>• fostering true collaborations in research (co-authorship)<br>• understanding context specificity of ethics assessment and of the development of capacities in the field<br>• examining capacities in context of systems<br>• having a long-term commitment of partners in RECs<br>• exercising process thinking (process-oriented mindset) in all phases of ethics assessment<br>• setting objectives: planning strategies, taking actions, evaluating results |

**Table 4: Suggestions for practical measures for ethical capacity building using the three-levels model**

Based on the literature review and the interviews in the SATORI project, important needs for a good quality of ethics assessment are:

- basic legal and normative knowledge to guarantee independency of the members of research ethics committees;
- a multidisciplinary composition of the committees, based on competencies;
- organisational infrastructure and a solid financial basis.

Not all these aspects can be improved by capacity building activities, but some of them, as a basic knowledge of the legal grounds of ethics assessment and the capacity to select the members of RECs can be.

# 5 CONCLUSIONS

Putting together the opinion expressed by different stakeholders interviewed by SATORI, experts opinion, online searching for existing programs and a review of the literature on the topic it is clear that no classic training will be able to help the building of a common framework in ethics assessment. Nonetheless, some stakeholders like members of RECs and some representatives of CSO expressed also the need for a better knowledge of the basic principles and tools underlying ethics assessment.

A mixed approach (some frontal lectures coupled with participatory activities and MML tools) seems to be suitable to cover a wide range of needs, some of them in contrast with the others.

[71] WHO 2009. *Research ethics committees: Basic concepts for capacity-building*. World Health sationOrganisation. http://apps.who.int/iris/bitstream/10665/44108/1/9789241598002_eng.pdf?ua=1 .

The first challenge any capacity building program will have will be to overcome is the lack of interest in training from experts and the lack of awareness of their role in ethics assessment for lay people and representatives of CSO. The second general challenge will be to involve representatives of industries, as corporate social responsibility evaluation and planning are often perceived as different from ethics assessment and more related to the marketing strategies of the firm than to the social role of industry in research and innovation.

The report D 1.1 on ethics assessment published by SATORI[72] analysed the situation of ethics assessment all over Europe and beyond, and also in specific disciplines that are not commonly involved in this kind of activity. Although some countries (i.e. Germany and UK) have a longstanding experience in ethics assessment and developed a strong infrastructure to help the development of RRI, other countries (mainly Eastern Europe countries) are still developing the needed infrastructure. The need for a new infrastructure (and sometimes also for the development of guidelines that take into account the values expressed both by the experts and by the civil society) is common also in some disciplines that only recently are starting to express concerns about the ethical framework of their investigations and to develop a corpus of norms and values. This is the case of the humanities and social sciences that are still developing specific approaches (as are the engineering sciences and natural sciences). Some organisations (e.g., universities, research funding organisations, governmental organisations and companies) currently seem to be increasing their role in ethics assessment. As stated by report D 1.1, these are experts-in-the-making and may have an interest in a specific training in ethics assessment and in the development of a common framework.

Many interviewees asked for a "learning by doing" approach to training that can be achieved by teaching some practical tools for a better identification of the issues related to different cases: this will allow members of RECs and lay people to be able to deal with many different problems, in many different fields, separating the skills in assessing the issues for the expertise in the field.

Young scholars and researchers were identified by the experts as preferential targets for any kind of training and capacity building activity: the awareness of the ethical aspects of their future job and of the impact their research can have on the society they are part of has to be fostered since the youngest age.

Online repositories of documents on basic ethical principles, laws and norms could help all the stakeholders in understanding what are the common values and interests they have to protect and preserve. This kind of repository is easily available in bioethics but is lacking in other fields such as environmental sciences, social sciences and humanities.

Lay people members of RECs and CSO representative also asked to be trained in the capacity to identify strong arguments and to defend their own position in a multidisciplinary context.

The SATORI project will include a wide range of stakeholders in the challenge of developing a common ethics assessment framework for research and innovation in Europe. This framework should be supported and shared by all the main actors involved in the design and application of research ethics standards and principles, including scientists, regulators, civil society, industrial actors, public bodies, research ethics committees in the Member States,

[72] http://satoriproject.eu/deliverables/

relevant international bodies and other stakeholders in society, including science journalists and the public.

The SATORI consortium will try to stimulate collective reflection among stakeholders involved in the design and application of research ethics standards and principles in order to tackle ethical challenges in ways that match up with the values, interests and needs of a wide range of stakeholders in European society.

## APPENDIX 1: STAKEHOLDER OPINIONS ON CAPACITY BUILDING AND TRAINING NEEDS: THE RESULTS FROM THE SATORI INTERVIEWS

*Legend:*
CSO: civil society organisations
A: assessors (organisations that engage in ethics assessment)
NA: non-assessors (organisations that do not engage in ethics assessment)
n.a.: not applicable

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
|---|---|---|---|---|---|---|
| 1 | All European Academies (ALLEA) - Europe | Academies' association - Ethical guidance, NA ALLEA was founded in 1994 and currently brings together 58 Academies in more than 40 countries from the Council of Europe region. Member Academies operate as learned societies, think tanks and research performing organisations. They are self- governing communities of leaders of scholarly enquiry across all fields of the natural sciences, the social sciences and the humanities. | Representing European academies of sciences and humanities and imparting their positions to the relevant European authorities, ALLEA works on science policy to contribute to the improvement of the framework conditions under which science and scholarship can flourish in Europe and beyond. | One of the most important ways to prevent misconduct or trespasses of scientific norms is the individual responsibility of the researcher. No matter the amount of regulations, codes, sanctions or punishments, it is the individual conscience of the scientist or the researcher that is of the final importance. The scientific/moral conscience should be developed within students and younger researchers, and can be done by training, by education, by discussing things, by making ethics and integrity a part of the regular methodological courses in universities. And, it should also be done by setting an example: if you work in a research group, then the leader, by her own behavior, should act as the mentor and | See capacity building needs | n.a. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
|---|---|---|---|---|---|---|
| | | | | lead on dealing with ethical issues. | | |
| 2 | Amnesty International/EU level (UK) | CSO, NA<br>Amnesty International (AI) is a global movement of more than 3m supporters, members and activists in over 150 countries and territories who campaign to end grave abuses of human rights. | AI work is based primarily on research not so much on innovation. They try to be as much factual as it is possible, so they document human rights abuse cases. Having their own research ensures their independence. It is fair to say that their research is not the same as in scientific filed but rather directed towards campaigns and advocacy for the right of individuals. | Interviewee thinks that gaps might be addressed through capacity building and training activities and AI performs lot of capacity building and training activities. But, when it comes to the difficulties and constrains in that process, they are sometime connected with lack of recourses for trainings and capacity building. Even though, they are trying to do it as much as it is possible, because they believe in participatory approach. | Does not directly engage in ethics assessment | Sometimes it would be even better to have more active participation of people involved in a research, particularly when they document human rights abuse. However, this is not always possible. |
| 3 | Appeal Bioethics Committee - Poland | Research Ethics Committees (REC), A | Appeal Bioethics Committee handles appeals to decisions issued by local Bioethics | There is a need to educate new people for the functions of national consultants. | They have their own training programs. | n.a. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
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| | | | Committees that concern research involving human beings. | | | |
| 4 | Association for Research Ethics (AfRE, formerly AREC) (GB) | CSO, A<br>The Association for Research Ethics seeks to promote excellence in ethical research in human beings; the protection and maintenance of the health and safety of the community by promoting proper standards of research involving human participants and by fostering high standards of ethical review; to provide information, support and training to its membership, to establish national, European and regional networks for the discussion of topics of mutual interests and to encourage co-operation amongst its membership to enable the collection and collation of information and opinions from them; to work in partnership with external agencies in order to better promote sound ethical | AfRE is interested in the use of ethics guidance by other organisations and its impact on research and innovation practice<br>- in promoting excellence in the ethics of research with humans through training and education<br>- in promoting research ethics as a subject in its own right | -functioned as a representative body for those RECs.<br>- they need some kind of capacity building project for the researchers as there has been an expansion in the number of postgraduate projects requiring ethics review and more and more academic teaching involves an element of research. The challenge involves meeting the demands of expansion in the areas covered and in the number of projects to be reviewed. Universities will have on average around 2,000 projects a year which require some kind of review. | They have their own training programs. | AfRE recently introduced an electronic system for research ethics review that could be used as an example. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
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| | | standards | | | | |
| 5 | Bioethics Committee of Children's Memorial Health Institute (Poland) | Research ethics committee, A | The Committee assesses drug trials, genetic research and new therapeutic methods. | In the assessment process the involvement of non-professionals is very important due to the fact that they provide for an outside point of view. | n.a. | n.a. |
| 6 | Bioethics Society of Serbia (Serbia) | CSO, NA<br>BSS gathers citizens who are interested in ethical issues in the fields of medicine, healthcare, population politics, animal welfare, food production etc. Main goal of BSS is to stimulate, help and develop bioethics, bioethical education and research. Its mission is promoting of bioethical research and education and bioethics of life in general as well as sensitisation of general public for ethical issues. | BSS are organisation whose members are scientist they are highly interested in research and innovation and its ethics implications. | They don't feel they need any help in capacity building as they are experts in the field of bioethics. | Does not directly engage in ethics assessment, so they don’t feel they need a specific training. | BSS is not satisfied on how the ethical issues in research and innovation are addressed. They think that it is necessary to have separate courses about ethical issues and dilemmas already in elementary school, not just as a part of courses like philosophy. This is the only way to build ethical awareness in a society where moral thinking |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
|---|---|---|---|---|---|---|
| | | | | | | has been neglected in the past 25 years |
| 7 | Center for Bioethics at Harvard Medical School (USA) | University, A | The Center is designed as a platform for integrating ethics and scientific discovery, and for generating collaboration. The purpose is for each discipline to collaboratively bring their disciplinary perspectives to bear on ethical challenges posed by present and future biomedical advances. | In many medical research organisations ethics is outsourced, so when an answer comes back clinicians expect the problem to be solved. It is hard to resist 'efficiency' in decision-making and moral decision-making is not easily efficient except if you do not challenge conventional thinking. The Bioethics Center is addressing the problem through capacity building in ethics courses at the medical school. | The interviewee did not express any specific needs. They have some internal training both as courses and online. | n.a. |
| 8 | Center for Engineering, Ethics, and Society (CEES) - USA | National academies, A Education | CEES activities address ethically significant issues that arise in engineering and scientific research, education, and practice. | CEES seeks to improve the awareness of ethics in relation to science and research. A major project is here The Online Resource Center. A website which previously focused on educational activities within engineering and research ethics, by providing e.g. case studies. CEES has | The interviewee did not express any specific needs. | n.a. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
|---|---|---|---|---|---|---|
| | | | | however received funding from the National Science Foundation to expand the website to include educational material on ethics for all the sciences under the National Science Foundation. | | |
| 9 | Center for the Study of Bioethics (Serbia) | CSO, A<br>The Center for the Study of Bioethics (CSB) is a recently founded organisation closely related to University of Belgrade and it is situated within the Institute for social sciences. The purpose of the CSB is the stimulation of scientific debate on a variety of issues bioethics deals with. CSB envisions to be regional in scope, but with a number of outstanding associate members from outside the region. It is not supposed to promote specific standpoints, but to stimulate a free exchange of ideas. | CSB is interested in bioethical issues of R&I. The research program is interdisciplinary. Members are scientists from different fields, especially social and medical sciences. The CSB conducts research on ethical and social dimensions of issues arising in the domain of bio-medicine. | n.a. | There is no training and education for members of ethics committees and many of them are not ready and not competent for such task and decision-making, so any help in training would be welcomed. CSB has only advisory role and doesn't make any ethical decisions. | It is necessary to adopt clearly defined criteria for ethical assessment, which currently do not exist. |
| 10 | Centrale Commissie Mensgebonden Onderzoek (CCMO) (The Netherlands) | CSO, A<br>The Central Committee on Research Involving Human Subjects (CCMO) protects subjects taking part in medical research by reviewing the research on the | Before research with human subjects can commence in the Netherlands the research file must first be approved | They act as "capacity builders" as in its task as administrative body the CCMO plays a key role as (inter)national provider of information on medical research with human subjects which is (also) carried out in the Netherlands. The public and press members are ever | n.a. | The interviewees do not have an official CCMO viewpoint on the SATORI ethics assessment |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
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| | | basis of the statutory provisions laid down for them and taking into account the interests of medical progress.<br>The organisation and operation of the CCMO is laid down in her rules and regulations. These regulations, including the complaints procedure have been approved by the Minister of Health, Welfare and Sport (VWS). | by an independent committee of experts. This is laid down in the Medical Research Involving Human Subjects Act (WMO). | more aware of this role and how to reach the organisation. The aim of their activity is to empower the patients/participants in researches involving human subjects. | | framework. The desirability of a shared European ethics assessment framework might be negative. It might even be scary. Europe is culturally diverse, so they are not sure that the aim of a training should be to »teach« the common framework issues by the activity of the project. |
| 11 | Citizens of Academia - Poland | CSO, NA | One of the main goals of CA is to ensure high quality of research. | CA is preparing their own "Charter of Good Practices", which will cover issues regarding ethics of work place, work relations, non-discrimination, as well as ways scientists should function in the society and what their role should be. | The problem is the fact that ethic is not included in the university curricula (except few disciplines, where researchers deal directly with human subjects, such as psychology or | n.a. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
|---|---|---|---|---|---|---|
| | | | | | medicine). | |
| 12 | Commission for Accreditation and Quality Assurance (Serbia) | Governmental, A Accreditation organisation for universities/academy/ Besides the implementation of the accreditation procedure and issue of licenses the Commission is proposing the following standards and procedures determined by the National council: standards and procedure of accreditation of higher education institutions; accreditation of study programs; self-assessment and quality evaluation of the higher education institutions. The Mission of the Commission is to contribute to the maintenance and enhancement of the quality of Serbian HE, to comply with internationally accepted quality standards. and to act as a main driving force for the development of quality assurance in HE of WB countries by fostering cooperation between agencies in the region. | Check of scientific verification of PhD theses. | They have their own internal standards, but they could be interested in multidisciplinary dialogue about them. | The Commission doesn't have separate unit that deals with ethical issues, but they have their own procedures to create a pool of trained reviewers for process of accreditation and external quality control. | n.a. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
|---|---|---|---|---|---|---|
| | | | | | | |
| 13 | Committee of Bioethics at the Presidium of the Polish Academy of Sciences (Poland) | National Ethics Committee, A | The Committee identifies and analyses ethical problem resulting from the development of the sciences, especially the biomedical sciences, and their impact on the social, political and legal spheres. It also focuses on ethical implications of technological progress in medicine and biology. | The Committee issued statements concerning (awareness raising?):<br>- the ethical problems of reproductive medicine and the genetics, and the need to introduce necessary laws concerning these issues;<br>- pre-implantation genetic diagnosis;<br>- direct-to-consumer genetic tests;<br>- the “conscience clause”. | There is a need for trainings in research ethics and for mechanisms of transmitting values into practice. | Scientists should aware of and use codes of conduct that are established. |
| 14 | Committee of Ethics in Science (Poland) | Academy of Sciences | The main task of CES is the diagnosis of ethical consciousness of Polish scientific community and recommendations for its improvements. | n.a. | There is a general problem that the representatives of the science express opinions on topics beyond their field of expertise and in doing so, they frequently violate ethical and | CES appealed to all scientists for precision and integrity when referring to scientific data in the media. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
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| | | | | | methodological standards. It can be therefore assumed, that the researchers might need training on research integrity. | |
| 15 | Conference of European Churches – CEC (EU, Belgium) | CSO, religious organisation, NA | CEC is an ecumenical organisation for churches in European countries (but also beyond). It groups about 120 churches. Because of its ecumenical and religious character, they consider ethics to be at the core of their mission and entrenched in all their activities. There are however some units dealing with fields directly related to R+I, such as bioethics, environmental | They address ethics focusing not only in research practices, but on the general wellbeing of the community. While acknowledging the freedom of research, they consider it to be inextricably linked to their consequences and how those are handled. So social, environmental and ethical consequences of research are consider of utmost importance (i.e. conflicts between growth and sustainability, inequality, dignity of the human being…) and a great emphasis is thus placed in the dialogue and ethical deliberation between politics, science, ethics and religion. They would appreciate multidisciplinary discussions on ethical issues and mutual learning opportunities. | Training in ethical assessment should be focused on case-histories and problem solving tools, on techniques to better identify the ethical issues and to be able to discuss their own values and point of view. | Logic, rhetoric and philosophical basis of ethics should be part of the training. Training should be focused on tools and not on contents. Any common framework should be the result of a discussion and not a top-down process. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
|---|---|---|---|---|---|---|
| | | | issues and economic and human rights. | | | |
| 16 | Court of Honor of Serbian Chamber of Engineers (Serbia) | Industry national organisation/, NA<br>The Chamber was established to improve the conditions for performance of the professional work in the field of the spatial and city planning, design and construction, and in other fields of relevance for planning and construction; protect the general and individual interests in these fields; organize rendering of services in these fields, and also to achieve other objectives set by the Chamber Statute. | Research and development in Serbian industry practically do not exist. They use European standards and technology, since there is no money for scientific research and innovations | n.a. | Does not directly engage in ethics assessment. There are no ethics bodies in the industry. The decisions are made *ad hoc*. They don't feel they need a specific training, they don't appreciate to be trained in a common framework that is perceived as a top-down approach. | n.a. |
| 17 | Electric Power Industry of Serbia (Serbia) | Industry, NA<br>The prevailing activity of EPIS is electricity supply whereas electricity generation, electricity distribution and distribution system management, production, processing and transport of coal, generation | When it comes to environmental protection, EPIS invests a lot in research and innovations. There are a number of projects in cooperation with | They are more interested in training the people on environmental issues related to energy consumption than in ethical assessment itself. | They are not engaged directly in ethics assessment, so they don't feel they need a training in this field. | Permanent education of citizens, using practical examples, is necessary in order to change their attitude |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
|---|---|---|---|---|---|---|
| | | of steam and hot water in combined processed are performed in subsidiaries. | scientific institutes and faculties. | | | towards the environment. They were planning to organize a course on environmental protection in schools but it was not accepted. |
| 18 | Ethics Commission, Faculty of Psychology, Warsaw University (Poland) | University, A | The role of the Ethics Commission is to ensure that research conducted at the Faculty of Psychology is ethical. To achieve this goal, the Commission gives opinions on research projects as well as prepares and promotes ethical standards concerning psychological research. | n.a. | One of the important problems (however rather abroad than in Poland) is data fabrication. The possible solution is to educate students in research ethics. | It would be desirable for universities to have a policy regarding research ethics. University's role should also be to ensure that all research done on human beings is ethically assessed. |

| No | Stakeholder name & country | Stakeholder type (A-assessor/NA – non assessor) and objectives | Interest in R&I | Capacity building needs | Training needs in ethical assessment | Suggestions for future trainings |
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| 19 | Ethics Committee of Military Medical Academy (Serbia) | Education, A<br>The Military Medical Academy (MMA) is a medical, educational and scientific-research institution with an internationally acknowledged reputation. MMA has 27 clinics and 17 institutes, the Specialist Outpatient Clinic, the Poison Control Center, the Emergency Department and the Solid Organ Transplantation Center performing more than 5000 diverse diagnostic and therapeutic procedures. The MMA operates as a part of the Ministry of Defense. | Institute of Medical Research is a part of MMA. The scientific-research work in the field of biomedicine represents the Institute's principal activity aimed at resolving actual issues of concern to the Serbian Armed Forces Medical Services. The Institute carries out diagnostic and consulting activity concerning immunology, molecular medicine and neurobiochemistry issues. Four departments operate within its framework: Department of Clinical and Experimental | n.a. | Training in ethical assessment is necessary and would be desirable. | There is no self-evaluations practice and procedure in ECMMA and no clear procedure (standards, protocols, guidelines) how to perform ethics assessment.<br>These are main thing that should be change in the future. |

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| | | | Physiopathology, Department of Clinical and Experimental Immunology, Molecule Medicine Department and Department of Laboratory and Experimental Care and Use of Animals. | | | |
| 20 | Ethics Committee of Clinical Center Nis (Serbia) | Research Ethics Committee, A.<br>ECCC deals with issues related to drugs clinical trials tested on humans, and gives approvals to protocols. Ethics Committee also decides about issues on biomedical assisted fertilisation, organ transplantations etc. Furthermore, they make assessments of medical devices and provide results for sponsors, patients and the Agency for Medicines and Medical Devices. | ECCC is specially interested in clinical trials and R&I in the fields of biomedical assisted fertilisation and organ transplantation. | They are not interested in general capacity building of stakeholders as they are focused on very technical issues. | There is no training for members, but it would be desirable. | In their opinion, every clinical researcher should be trained and should pass an exam on good research practice. The trainings should be carried out by experts from International researchers' association. |
| 21 | Ethics Council | Ethical committee, A | They are interested | They are not interested directly in | Training is | Education and |

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| | for the Protection of Experimental Animal's Welfare (Serbia) | ECPEAW is a special working group established by the Minister with the regulations governing the civil service, in order to discuss professional issues, providing expert opinions and participating in the implementation of terms of reference in the field of animal welfare. This Council has only an advisory role and no binding power. | in any research using animals. | capacity building activities as they are focus on technical issues. | considered to be desirable for researchers especially if focused on the legal framework of animal research. | training of people who conduct research have been done, but not enough; existing training programs need to be improved, but the biggest problem is that researchers don't know and don't follow the law on animal research. |
| 22 | Ethics in Science Commission at Polish Academy of Sciences - Poland | National academy of sciences, A | The Ethics in Science Commission at Polish Academy of Sciences plays a supervisory role with regard to standards of research integrity.<br><br>It deals with cases of alleged infringements of the rules of scientific integrity. | The Ethics in Science Commission promotes the high standards of research integrity and have drawn up the Ethical Code of a Researcher. | n.a. | n.a. |

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| 23 | Euclid Network, (Europe) | CSO, NA<br>Euclid Network was founded in 2007 and has a strong track record of networking, peer learning and policy impact in the civil society and social enterprise arenas. EN has delivered a range of European programs in the fields of civil society capacity-building, social entrepreneurship, social innovation and responsible research & innovation.<br>- ethics assessment is not a topic they are specifically engaged in. | - to empower civil society and social entrepreneurship to drive positive social change.<br>- involved in Responsible Research and Innovation (RRI) projects: Consider and Responsible Industry projects.<br>- to share and produce knowledge and know-how regarding professional development in social entrepreneurship | - the respondent felt that, common ethics assessment does not seem to be a part of the European Research Area (ERA).<br>- Euclid Network has just recently developed a set of four brief values but they are not particularly 'ethical' - they include innovation and entrepreneurship for societal impact, openness to collaboration across borders etc. on which they could envisage capacity building activities | Does not directly engage in ethics assessment but Euclid's role is to bridge the gap between the research community and civil society community. | The respondent felt that it would be more desirable to have a more general activity on ethics assessment rather than a common European framework for ethics assessment. The EU could share best practices on ethics as a first step before talking about a common ethics assessment framework. Mutual recognition could be a second step - Part of this second step could also be the coordination of policies at least |

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| | | | | | | at national ethics committee level. However, there cannot be real harmonisation in the future - the first step is developing and sharing best practices. |
| 24 | European Association for Neuroscience and Law (EANL) (Europe, Italy) | CSO, scientific association, NA | - Evaluation of the impact of neuroscientific research on law<br>- Policy making and norms involving new neurotechnologies | - The aim of the association is to improve the awareness of the impact and limits of neuroscientific discoveries in the community of jurists, so they would like to have more opportunities for mutual discussions and learning between scientists and jurists<br><br>-They identify the media community as central in shaping the public trust in new neuroscientific discoveries when they are brought to courts as evidences. They ask for a better knowledge of the ethical and social impact of neuroscience among the journalists | -EANL does not directly engage in ethics assessment, even if many members are involved in ethical assessment because of their specific expertise. They think that their field of interest is peculiar and needs a specific training both in law and in neuroscience. They are planning to open their own training course in neuroscience and law at University of | Avoid frontal teaching and top-down approach; they would appreciate multistakeholder workshops designed to foster the capacity to identify ethical dilemmas and issues. |

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| | | | | | Pavia (Italy). | |
| 25 | European Consumer Organisation – Italian Chapter (BEUC-Altroconsumo) (EU, Italy) | CSO, consumers association, A | - investigates EU decisions and developments likely to affect consumers, with a special focus on Financial Services, Food, Digital Rights, Consumer Rights, Sustainability, Safety, Health and Energy.<br>- works to ensure that consumer policy at EU level is sustainable for all (that means respect and protection of the environment, including climate change, but also reduction of negative social and economic impacts of innovation). | They focus their activity in publishing reports and magazines for the consumers, because they believe in information as a tool for empowering the consumer and helping him to do a better choice, so they are interested in mutual learning from other stakeholders. They elaborate their own internal guidelines so they are interested in tools to identify issues related to the issues they are involved in. | They feel they could benefit from a training by science journalists on the tools used in investigative journalism as there try to have a journalistic approach to their evaluations. Training in legal framework for industrial production and in consumers rights would also be appreciate. | They need a training that can be extended to their representatives in the different countries so they suggest online interactive course and tools or, at least, a dedicated web site. |
| 26 | European consumer voice | CSO, NA | Standards are bearers of | ANEC defends consumers' interests in the development of standards. It has | They have their own standards so | n.a. |

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| | in standardisation (ANEC) (The Netherlands) | | knowledge and share knowledge as widely as possible. This is a base for innovation. Through conforming at certain standards innovations can prove its safety e.g. | principles according to which they operate. It could be interested in capacity building activities that enhance the public awareness about the role of standardisation as an instrument for public control and security | they don't think that a specific training could be useful. | |
| 27 | European Federation for Science Journalism (EFSJ) (EU, Belgium) | CSO, NA<br>Media and journalism | The EFSJ is the newly born umbrella association for science journalism in Europe. They are planning to evaluate the ethical aspects of science journalism, its impact on the society and on R&I. They highlight the role of science journalism as a watchdog of science and | They feel they play a key role in capacity building process of the other stakeholder. They also play an important role in fostering the capacities in ethics assessment among the other, non-specialized journalists. They feel they need to develop their own ethical framework with some values shared with journalism and some values shared with science. They feel this is an uncomfortable position so they would like to strengthen their position among the scientific and the media community through multistakeholder discussion and opportunities for sharing opinions. | Training should be focused more on tools than on contents: any tool that can help to identify ethical issues is welcomed. | Multidisciplinary workshops and discussion are welcome but also any online tools and an online repository of tools and background materials on ethics assessment. |

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| | | | scientist. They are interested in scientific malpractice and frauds, science communication impact, ethical background of research and innovation, environmental and social impact of innovation. | | | |
| 28 | EURORDIS (European Organisation for Rare Diseases) (Europe, France) | CSO, NA<br>EURORDIS seeks to improve the quality of life of people living with rare diseases in Europe through advocacy at the European level, support for research and medicines development, facilitating networking amongst patient groups, raising awareness, and many other actions designed to reduce the impact of rare diseases on the lives of patients and family. | Main activity of EURORDIS is to identify research projects with different opportunities for their stakeholders and to build capacity among patient so that they can understand the importance of science, especially lab work, in the field of rare diseases. They are trying to foster | Capacity building and training activities can be helpful in overcoming gaps but, according to the interviewee, the best thing is learning by doing. Past experience has shown that patients in different countries understand risks and benefits from clinical trials in a completely different way. Now they know that and they are trying to apply this knowledge when they communicate with patients. | EURORDIS doesn't have special unit within organisation that deals with ethical issues, but they could be interested in a general training on ethics in biomedicine. | One of the most important assignments of EURORDIS is to build trust, to learn how to work together. In their opinion the work of Ethics committees has to be more transparent: they would focus any kind of training on transparency: they want to |

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| | | | patient organisation curiosity and trust on basic research and to inform patient organisations on what kind of research is available for their diseases. EURORDIS is also helping patient organisations interested in research projects that will lead to the development of the new drugs by creating a *Charter for clinical trials*. They also set up the *Community advisory board* as a facilitator between participants in clinical trials, the investigators and | | | know and understand how and why Ethics committees took their decisions and how they exchange information. EURORDIS has the capacity to organize trainings, because they have experience in organising summer school. They launched their Summer School in 2008 to empower patients' representatives in the area of clinical trials and EU regulatory affairs. From 2015, this school will combine |

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| | | | the sponsor, public or private. They discuss all the aspects of the development of a new drug in the different stages, they decide on outcome measures of the trials or design. Among all, they also follow up the whole development of the clinical trials and contribute to the ethical discussion; they also advice the sponsors on the development of the trial and on how to communicate unexpected events in the trial. | | | training of expert patients and researchers on drug development. |
| 29 | European Union of Science Journalist's | CSO, NA | EUSJA is interested in questions posed | They need to train the journalists within the European national association to strengthen their | Any kind of training would be welcomed. They | n.a. |

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| | Associations (EUSJA) (EU, France) | | by emerging science, and it believes that seasoned, critical and specialized journalists are needed to assess that. In their view, science journalists play an important role s independent and critical outsiders acting as knowledge brokers between scientists and the public, but also as ethics checkers, as they are attentive to misconduct and other ethical issues in research and have the advantage of being independent. | awareness on the role of science journalism as informal ethics assessor. | would appreciate a training based on case-histories and tools for assessment more than a top-down, frontal lecture approach. | |
| 30 | Federation of Patients and Consumers Organisations | CSO, NA<br>Was founded in 1992 to bring together patient and consumer organisations in the | They look after the quality of (innovative) health care | NCPF would like to include more and more the patients' perspective in research grant proposals. They give the patients the right to assess the grant | They don't do training directly. The select as reviewers only | n.a. |

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| | (NPCF) (the Netherlands) | Netherlands to speak as one voice on areas of common interests, such as patients' rights and access to care. It was realized in the late 1980's that it was important for patients groups to work together in order to have a stronger voice and become a significant national player. | They define the interest of the patients and consumers in innovations such as eHealth and health information accessibility, exchange and privacy<br>They make the information on best practice available to patients<br>They foster solidarity in health care, including access to innovations | proposals acting as reviewers, working in groups of three patients for each new proposal. Capacity building activities could be interesting to increase the numbers of patients willing to act as reviewers | patients with a high level of education because grant applications are often complex and in English. They don't express specific needs in this field, as they support the role of the patients in assessment based on a »learning by doing« approach. | |
| 31 | Food Ethics Council (United Kingdom) | CSO, NA<br>Food Ethics Council brings people together to find ways through contentious ethical issues in food and farming to make more considered decisions. | They are open to exploring the potential and the risks of any technologies that relate to food and farming including nanotechnologies, synthetic biology, food irradiation, | The Food Ethics Council has strong links historically with bioethicists and ethicists - the organisation has ethicists and philosophers on its advisory council and will be recruiting additional members in the near future.<br>- There is a need to mainstream ethics and get people involved in all walks of life – not only people in research and innovation – and encouraging them to | Does not do ethics assessment as such, rather the organisation tries to encourage decision-makers who work within food and farming to take ethics into account and to explicitly | The respondent feels that, intuitively, a common approach would make common sense. There are too many separate |

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| | | | GM food, in vitro meat, etc. | make fairer and more considered decisions in their daily lives.<br>- The Food Ethics Council finds it is important to engage people early on and they believe in “fair play, fair say and fair share”.<br>- Moreover, very few of these processes are carried out using a trained ethical framework approach. It would be helpful if people started to adopt ethical tools and applied them and used them. | justify a course of action (this is how the Food Ethics Council defines ‘ethics’).<br>While the respondent feels that his organisation has a long way to go in this regard, they are trying to make ethics more accessible.<br>- The bigger question is perhaps how ethics assessment is perceived and the value that people place on it and therefore whether there is a demand for ethics assessment. | initiatives.<br>- Food Ethics Council creates a space and provide tools with which to think about ethics and the impact of decisions. One example is their Ethical matrix tool to enable people to make more ethical and considered decisions. The tool offers a way of thinking about or assessing the ethical impacts of different technologies and has been used by individual businesses and more widely in various business schools and |

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| | | | | | | universities. |
| 32 | Forschungswende (Germany) | CSO, NA | FW's main focus is the research and innovation agenda setting process. | n.a. | Research agendas are very technical and too narrow in their focus. Research is not only about technology, but also about the social change and the change for society (lifestyle, consumer patterns, way of living). | It would be helpful to have an independent organisation that would focus on research and innovation and cooperate with other specialized CSOs in developing agendas and strategies of their own. Governments or big foundations could support this core organisation. |
| 33 | Foundation for Polish Science (Poland) | Funding organisation, NA | The Foundation grants funds for research. | In Europe there is general problem regarding scientific integrity. Due to the fact that a lot of emphasis is put on the results, researchers may feel pressured to manipulate data, in order to get the funding. The issue of scientific integrity has been touched upon in the Foundation's Code of Ethics. | They would appreciate a capacity building training in ethics assessment for researchers and young scholars that will apply for their grants. | n.a. |

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| 34 | German Academy of Sciences Leopoldina (Germany) | Scientific Academy, NA | The Committee assesses current situation, usually in Germany, concerning issues related to science and their ethical background. | One of the key missions of Leopoldina is providing scientifically informed policy advice, which may lead to amending the existing provisions or establishing new laws. | One of the goals of Leopoldina is to teach scientists how to follow ethical rules, for a considerable number of basic researchers is not aware of the ethical aspects of their work. They don't feel they need capacity building training for themselves but for the researchers they advise. | Researchers should be made aware of the ethical problems regarding their work. |
| 35 | German Ethics Council (Germany) | National ethics committee, A | The Council pursues the questions of ethics, society, science, medicine and law and the probable consequences for individual and society that result in connection with research and development. Particular | In some cases it is difficult to predict what impact scientific developments will bring (this is the case of, for example, the dual–use research). In other cases new developments can considerably influence everyday life of people who are not prepared to handle the consequences (for example the direct-to-consumer genetic tests).<br><br>The opinions of the Council will not solve the problems but they help in dealing with them. | n.a. | n.a. |

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| | | | attention is paid to the field of life sciences and their application. | | | |
| 36 | Health funding institution [The interviewee wished that both his name and the organisation was to remain anonymous] (USA) | Funding institution, A Evaluation of research projects. | The institution reviews a great number of research grant applications each year. | The interviewee did not express any specific needs. | The interviewee did not express any specific needs. They have their own training programs. | The public can be engaged in the assessment of grant applications through an online suggestion website. The public might become more engaged in the future, e.g. by assessing the value of certain areas of science. The interviewee would like to have meetings with the public in the future to strengthen this feedback. |
| 37 | INformation, KOordination, TAgungen- | CSO, NA INKOTA aims to invigorate the political landscape in | In general INKOTA does not directly | CSOs need to be made more aware of how the process of introducing technological innovations is organized. | INKOTA does not directly engage in ethics assessment. | It would be advisable for |

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| | INKOTA (Germany) | Germany and to raise public awareness for the darker sides of globalisation and the importance of human rights. They campaign for dignified employment, overcoming the problem of hunger and for fair financial and trade relationships in the world's economy. | concentrate on research and innovation issues, it becomes interested in those topics when they concern fields that it focuses on in its everyday work (e.g. work conditions, food and agriculture policies). | They perceive themselves as capacity builders and they don't feel they need a specific training. | | CSOs to become more involved and more active in the process of technological development. |
| 38 | Information Commissioner's Office (ICO) (UK) | Impact Assessment Organisation, NA<br><br>ICO provides guidance for organisations to perform privacy impact assessment (PIA).<br>The PIA helps organisations identify the most effective way to comply with their data protection obligations, identifies and minimizes privacy risks of new projects or policies. | ICO co-operates with European and international partners, e.g. European Commission and other data protection authorities on sharing information and good practice; helping with complaints, investigation and enforcement; and working together to improve | They recognize the usefulness of having an assessment category called ethical impact assessment, next to social and environmental impact assessment concept, especially for instance in the case of big data. They would appreciate a capacity building training focus on this issue for people involved in data management. | They would like to be sure that assessors have the right skills, training and abilities. Potentially this could be enabled at University level. | n.a. |

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| | | | understanding of data protection law, and produce common positions and guidance where appropriate and necessary. Providing practical advice to organisations about how they can make improvements to comply with the Data Protection Act by either conducting an audit, arranging an advisory visit, a self-assessment questionnaire or a data protection workshop | | | |
| 39 | Interacademy Council (IAC)/ Interacademy Partnership (IAP), UK | Academies of Science, International Organisations, NA<br><br>- provide clarity and advice in forging an international consensus on responsible | The IAC/IAP look at ethical issues as policy and practice issues for the community, as global scientific topics. Some of | There is a need to look at emerging challenges and see how polices, practices and standards can be upgraded as part of a diffused global process. There are reports on Responsible Conduct and how to enhance the Capacity of African | There is also a need for mentoring and education about good practices. | It would be desirable to have something [framework] for the world and certainly for the |

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| | | conduct in the global research enterprise.<br>- an educational guide will be released early next year focusing on the issues of scientific responsibility and integrity targeted at younger researchers and graduate audiences | the reports do not specifically focus on ethical assessment per se though scientific integrity and scientific responsibility are key issues. Ethics is related, however, to good science**.** | Science Academies.<br><br>- Technological growth and globalisation have opened up new areas for people doing things both wrong and right. Part of the challenge is to assist, especially, the organisations in countries that do not have much in place to address issues and challenges.<br><br>The US NAS has organized workshops focused on research integrity in places such as Aqaba, Jordan, and other places. The approach is described in the report Developing Capacities for Teaching Responsible Science (http://dels.nas.edu/Report/Developing-Capacities-Teaching-Responsible-Science/18356). | | EU. It would be a hard thing to achieve, but worth the effort.<br><br>- There could be common procedures and values for shared collaborative basis that could seep back into the national level too. |
| 40 | International Women's Forum (Europe) | CSO, NA<br>The IWF mission is to strengthen the women's role in the economy and promoting entrepreneurship by creating positive models of a businesswoman, initiating the research and studies on female entrepreneurship, organising regular discursive meetings, | IWF in the past was not primarily oriented on research and innovation but, at the moment they are one of the partners in a project about gender innovation and sustainable | They provide capacity building activities in the field of gender equalities, so they are interested in this specific topic. | Does not directly engage in ethics assessment, even if they have an » informal ethical assessment approach« in gender equality when they deal with innovation or research, | If SATORI manages to bring experts from different field and, stakeholders to discuss together and agree about the most important ethical issues in |

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| | | as well as conferences and training. | development in the Baltic sea region. IWF also research academic equality in gender terms and perform other studies. | | | R&I issues it will be a huge success. But first of all they suggest to organize discussions with all the stakeholders, people from different fields including people interested in gender issues. Trainings are not the best choice. The better way is to encourage sharing thoughts and ideas between different experts, creating some knowledge networks composed of people on the same level of expertise (mutual |

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| | | | | | | learning and participatory processes on ethics more than training workshops). |
| 41 | Israel Medical Association World Fellowship (IMA-WF) | CSO, religious association, A Established in 1912, it regroups Jewish doctors and medical professionals that are not resident in Israel. The objectives of the IMA-WF are to create and enhance mutual bonds between Israeli health professionals (including physicians, residents, fellows, medical students and allied health professionals) and their counterparts in other countries. Actually IMA-WF has 15 national chapters. | They are interested in medical research and bioethics. | The main motivation for ethics assessment in IMA-WF is the possible applications of Jewish norms, values and laws in the context of a multi-religious and modern society. They would appreciate any opportunity to debate about their area of interest with other stakeholders, but they don't feel they need a training or capacity building workshop because they organize their own internal trainings. | They are not interested in formal training if the aim is to present a common European framework for ethics assessment because they feel that every country and every stakeholder should be allowed to find its own gold standard based on its own values. | There are many training programs for people involved in ethical bioethics committees that should be taken as a basis for future initiatives. |
| 42 | ISO - CEN and national member bodies such as NEN, DS or BSI | Standardisation organisations, NA | ISO, CEN and all its member bodies facilitate the making of standards. The standardisation organisations | Any intervention that enhances the common perception of the importance of standardisation would be welcomed. | Does not directly engage in ethics assessment (with exceptions of some member bodies) | n.a. |

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| | | | themselves play a neutral role. The standards, made up by consensus according to standardized international rules, could facilitate the uptake of innovation and research results. | | | |
| 43 | Jednake mogučnosti (Equal opportunities) – (Serbia) | CSO, equality development, NA<br>NGO "Equal Opportunities" is an organisation established with the goal to facilitate equal access for both women and men in using modern information and communication technologies. | New technology motivates the organisation to make it accessible to those that would ordinarily have less chance of making use of it. EO is especially interested in social implications of innovation: who has access to it, what stereotypes are linked with it, for what purposes is it used by different groups, etc. | EO organizes its own capacity building events for its target audience to encourage the use of ICT in empowering women and their daily lives. | Ethical training for CSOs would be most welcome. This kind of training would address the need to articulate the activities of CSOs in ethical terms, regarding both, the ethical impacts of their projects and the activists/researchers professional work. | Training should inform about ethical guidelines and present good practices. |

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| 44 | Ministry of Education, Science and Technological Development (Serbia) | National funding organisation, NA<br>Carries out public administration activities related to: the system, development and promotion of scientific and research activities for the purposes of scientific, technological and economic development; defining and implementing the policies and strategies of scientific and technological development; defining and implementing the programs of scientific, technological and development research; training scientific research staff; defining and implementing innovation policies; fostering techno-entrepreneurship and the transfer of know-how to the economy; developing and improving the innovation system in the Republic of Serbia; developing the scientific and research information system and scientific and IT infrastructure; defining the | MESTD has huge interest in research and innovation. It is practically the only government body that funds research and innovation in Serbia in such a great scale. | Interviewee considers training and building capacities to be very useful and that Center for the Promotion of Science will have crucial role in this process. It is important to raise awareness, but also to educate. | There is no special body in Ministry of Education, Science and Technological Development that deals with ethical evaluation of research and innovation. | n.a. |

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| | | policies and strategy for building the information society; preparing laws, other regulations, standards and measures in the field of e-business; investigating the application of IT and the internet; providing IT services; developing and improving the academic computer network; coordinating the preparation of strategic and development documents at the national level; research in the field of nuclear energy; ensuring the safety of nuclear facilities; producing and disposing of radioactive materials, except in nuclear power plants, as well as other activities stipulated by the law. | | | | |
| 45 | National Centre for Research and Development (Poland) | Funding organisation, A | NCRD funds research. | n.a. | There is a lack of trainings among the researchers - officials do not become acquainted with the ethical codes established for researchers. | n.a. |
| 46 | National | Ethical committee, A | NCB is primarily | n.a. | Respondent | One of the |

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| | Committee for Bioethics (Serbia) | NCB aims to promote the position towards ethical and legal matters resulting from research in life science, their implementation, as well as stimulates the exchange of ideas and information, primarily through h education; takes positions, passes decisions and provide opinions on ethical-moral issues related to life itself, at all its levels an d development stages; studies, evaluates and holds its position with respect to human activity within classical medical ethics, but also other scientific areas, such as biology, philosophy, law, economics, politics, that involve the question of life and death, health and illness; takes position and provides opinion on ethical issues significant for securing good scientific practice and preservation of main principles and obligations of scientific workers and researchers; supports the | dealing with the issues of moral-ethical behavior within the sphere of natural sciences and research. It pertains primarily to biological and medical sciences, their interrelations through biomedicine, as well as behavior of scientists and physicians at work performed within their institutions. | | highlights that training for ethics committees' members is one of the biggest challenges. First round of these trainings is aimed at medical committees. Training programs will be accredited and realized by School of Medicine at University of Belgrade and *National Committee for Bioethics*. The trainings may also be organized by non-governmental organisations. It is planed that participants receive a certificate after training completion. It is also planned to include training obligation in the | problems is related to the structure of ethics committee members on institutional level. In Serbia only medical doctors are ethics committee members while in other countries nurses and medical technicians are members too. Also in Serbia there are only two external members – to include people with different backgrounds in process of ethics assessment. |

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| | | activities in order to raise the general level of public awareness, with specialized and sensitive groups and decisions of general and private type related to bioethics;<br>NCB has advisory role so their decisions are not binding. | | | Law, since it is not the case at the moment. The principle aim is to harmonize the work of Ethics Committees and their procedures. One time training was performed. The main problems are financial, e.g. fees for medical doctors. | |
| 47 | National Science Centre (Poland) | Funding organisation | NSC funds research | There is a lack of ethical awareness among the researchers. | It is important to educate young researchers, that they are ethically responsible for their studies. | Young researchers should be made aware, that concentrating only on legal regulations is not enough to establish whether theirs actions are right or wrong. |
| 48 | Netherlands Enterprise Agency (RVO) Rijksdienst voor Ondernemend | Governmental, NA | The Netherlands Enterprise Agency focuses its attention on four areas: | RVO provides some ethical guidance through encouraging subsidies when certain criteria are met, including e.g. sustainability. | RVO gives advice on how to apply for funding at the Dutch government. They do not need | n.a. |

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| | Nederland (RVO) (the Netherlands) | | *Sustainable enterprise* supports Dutch and international entrepreneurs and researchers in developing sustainable projects related to energy and climate and the environment in line with the 2020 and 2050 objectives for sustainable energy and reduced CO2 emissions.<br><br>*Agrarian enterprise*: The European Common Agricultural Policy (CAP) was developed to balance European agriculture. The CAP encourages farmers to make | | any training from SATORI | |

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| | | | their businesses more sustainable and innovative. The Netherlands Enterprise Agency is responsible for realising this policy in The Netherlands.<br><br>*Innovative enterprise*: The Netherlands Enterprise Agency supports and promotes international business, cooperation and development efforts, both private and public, and encourages knowledge institutes in knowledge valorisation.<br><br>*International business enterprise*: The | | | |

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| | | | Netherlands Enterprise Agency supports and promotes international business, cooperation and development efforts, both private and public, and encourages knowledge institutes in knowledge valorisation. | | | |
| 49 | Netherlands Research Council (NWO) (the Netherlands) | CSO, NA | NWO funds scientific research at Dutch universities and research institutes. NWO does this through a range of 150 funding instruments linked to its ambitions.<br>. | NWO's scientific integrity policy is aimed at preventing and detecting scientific misconduct and is in line with the policy of the universities, the Association of Universities in the Netherlands (VSNU) and the Netherlands Academy of Arts and Sciences (KNAW).<br>The NWO policy applies to both the application phase and the phase after research proposals have been awarded funding, and concerns:<br>• Awareness: Netherlands Code of Conduct for Scientific Practice | Any training that enhances the knowledge of what is considered a scientific misconduct is welcomed. | n.a. |

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| | | | | • The possibility to report violations via the Scientific Integrity Desk<br>• Possible measures from NWO after a violation of integrity has been established<br><br>They indirectly enhance the capacities of the scientist in ethics as they ask them to be familiar with the Code of Conducts and that they are complying with it. Also after an application has been awarded funding, NWO requires researchers to state in the progress reports that they are adhering to the code. | | |
| 50 | Nuffield Council on Bioethics (UK) | Ethics committee, A<br><br>- to identify ethical issues that are likely to arise in the context of new developments in biological and medical research. | - try to identify developments in research, understand the social and ethical implications of them and then try to find an ethical approach that helps them to offer solutions or policy approaches. | The Council does carry out consultation with stakeholders and the public but this is difficult to achieve in practice. They have formal and informal networks.<br>- There is a need to facilitate a much wider mechanism for public discussion to discover people's concerns and values. | It is part of the Council's job to take the process of ethical decision-making that people do in their daily lives and see how that relates to decision-making within policy environments. The next step is to make | While the interviewee felt that there is some value in continually engaging in discourse whereby people challenge each other and try to work together |

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| | | | | | the connection so that people can be exposed to the kind of thinking that goes on and can realize that they can be involved in this on a wider basis. | through these problems, he felt the idea of common and settled solutions is probably unrealistic. Overall, the respondent felt that it is only possible to agree on things at a pretty abstract level. The respondent felt that best practices, guidelines and recommendations may be the best way to go. Moreover, he stressed the importance of discourse in finding common ground. |

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| 51 | OECD - Science, Technology and Innovation section - Global Science Forum; (International) | Governmental organisation, NA | The Global Science Forum (GSF) provides a venue for consultations among senior science policy officials of OECD member countries. It produces findings and action recommendations on high-priority science policy issues requiring international consultations/co-operation, and identifies opportunities for collaboration on major scientific undertakings. | -There are gaps about the whole issue of public engagement: how to do it, why it is important? Sometimes, people are working on issues without being aware that there are public ethical concerns about them. Science needs to engage. In some fields, e.g. life sciences, maybe there should be training on the philosophy of science. Scientists themselves are in the best position to think about these issues, especially as many of them are not about fundamental ethics, but predominantly about practical, applied ethics. | An important aspect is research integrity, what good scientific practice is and what isn't. In some countries, there is a need for building a structure and culture around ethics. In terms of the capacity building per se, there is currently a lot of effort now on building research ethics committees in Africa. | The issues is not just about training, it is important to involve public. If public does not trust science, it cannot work. And there are many brilliant scientists who can engage with public and present scientific issues. |
| 52 | Panoptykon Foundation (Poland) | CSO, NA | In the Foundation's scope of interest are different types of surveillance, in which technological | The Foundation is involved in educational activities – the aim is to make people realize what the dangers of certain technologies are, and what they can do to avoid them – including by means of technical solutions, such as encryption. | n.a. | n.a. |

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| | | | innovation plays a significant part (e.g. medical databases, mobile phones and tracking techniques, CCTV cameras, Internet applications, GPS etc.). | One of the problems related to the issue of surveillance state is that the politicians pay no attention to the negative effects of some technologies on social relations - for example how cameras impact mutual trust among the society. | | |
| 53 | Polish Ethics Society (Poland) | National ethics association, A | - assessment of research ethics<br>- the Society deals with the issue of animal experimentation | With regard to ethical issues, the Society provides advice, draft opinions and lobby in the course of the legislative process. In addition, members of the Society visit schools and provide educational activities for students. | Members of the local ethics committees are not trained in ethics and there are no requirements for them to participate in such trainings. | Researchers should be educated in bioethics, for questions about the subjectivity of animals are not posed in the course of studies in medicine or biology. |
| 54 | Professional Ethics Committee, University of Belgrade (Serbia) | Academy, A<br>PEC makes sure that the Code of Ethics is being honored by teachers, associates and students of the University; Maintaining the dignity of the University of Belgrade and further developing moral values of | Interested in research and innovation activities performed by universities. | n.a. | Classic training in ethical assessment would be desirable for researchers and young scholars. | n.a. |

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| | | the academic community. | | | | |
| 55 | Regional Environmental Centre for Central and Eastern Europe/EU-level (Hungary) | CSO, NA<br>International organisation with a mission to assist in addressing environmental issues. The REC fulfills this mission by promoting cooperation among governments, non-governmental organisations, businesses and other environmental stakeholders, and by supporting the free exchange of information and public participation in environmental decision making. | Although REC supports research project it is not a research organisation. | There is a big room for improvement. There are some open issues and problems that could be resolved through capacity building and training activities. REC is interested both in participating and co-organising such trainings. | Does not directly engage in ethics assessment | One set of lectures should be aimed at raising awareness about the importance of basic ethical values. For the most of people, both ordinary and experts, still is not clear where ethics ends and law, or some other domain, starts and vice versa. So, these are the question that should be answered during the trainings. |
| 56 | Royal academy of art and sciences (KNAW) *Koninklijke Nederlandse Akademie voor* | Scientific Academy, A | The Academy regularly issues advisory reports on a wide variety of subjects. In some cases, it is asked to do so by | n.a. | They would appreciate a training on ethics assessment and rules for researchers and young scholars. | n.a. |

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| | *Wetenschappen* (The Netherland) | | the authorities or universities; in other cases, it does so on its own initiative. | | | |
| 57 | Royal Dutch Society of Engineers (KIVI) Koninklijk Instituut van Ingenieurs (KIVI) (the Netherlands) | Professional organisation, NA | As the network body for engineers and other highly educated technical professionals in the Netherlands, KIVI's primary objective is to promote the importance of technology in our society. | As a network of engineers, KIVI facilitates the debate on ethics for engineers. Its members can explore the issues, but KIVI does not have an ambition in this issue itself | Some representatives of the Society could be interested in training on a personal basis, but they don't feel to have a real need as this is not their main function. | n.a. |
| 58 | SciDev.Net (UK) | CSO, development, journalism, NA<br>SciDev.Net is the world's leading source of reliable and authoritative news, views and analysis on information about science and technology for global development.<br>Its mission is to help individuals and organisations apply evidence and insights from science and technology to decision-making in order | Research and innovation is considered by SciDev.net from the point of view of uptake, usage and impact. In selecting and reporting scientific news they have a strong focus on ethical concerns about the | SciDev.net is in itself an experiment of capacity building through information. Good journalistic practice supports research. SciDev.Net is trying to lead by example and is also active in the scientific journalism community by promoting professional high standards (issues of gender representation in science journalism, censorship) and capacity building. They publish practical guides, not only to help journalists but also to help researchers in science communication. Workshops | They would participate into training programs on ethical assessment practical tools. | n.a. |

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| | | to have a positive impact on equitable and sustainable development and poverty reduction. | practice of research (principles of sustainability and equity), the implications of research (for development) and the communication of research (by researchers themselves and by science journalists). | and trainings are also organised by SciDev that address this, so they have their own capacity building program even if it is not specifically devoted to ethical assessment. | | |
| 59 | Serbian Environmental Protection Agency (Serbia) | National organisation responsible for environmental impact assessment, A<br><br>The development, coordination and management of the national information system for environmental protection (monitoring the status of the environmental factors through environmental indicators, the registry of pollutants, etc.); | Not directly involved in scientific research and innovation | Representative thinks that capacity building should be the next step, but unfortunately there is no money for that | - Does not directly engage in ethics assessment | Some gaps can be addressed through capacity building and training activities but that is far from enough if government doesn't take more active role. Until government has not put environmental protection in |

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| | | Conducting (performing) monitoring on national level of air and water quality Manage National Laboratory Collection and compilation of environmental data, processing and preparation of reports on the state of the environment and implementation of environmental policy; Development of procedures for processing environmental data and their evaluation; Keeping data on best available techniques and practices and their implementation in the field of environmental protection; Cooperation with the European Environment Agency (EEA) and the European Network for Information and Observation Network (EIONET), as well as other duties prescribed by law. | | | | their agenda there would not be any improvements in that filed. |
| 60 | The Office of Technology | Technology assessment organisation, A | TAB advises the German | There are capacity building needs in the field of interdisciplinary. While | There is a need to improve the | NGOs should put |

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| | Assessment at the German Bundestag (TAB) (Germany) | | Bundestag on matters concerning research and technology. | engineers do not have to be experts in ethics, they still do need to be able to speak to non-engineers about ethical problems. They should be aware of the ethical issues involved in their work in the lab.<br><br>With regard to civil society and NGOs - there is a need for capacity building and empowering that would allow those groups to engage in discussions with scientists. | communication skills of both scientists and other people involved in the process of assessment. NGOs should put more effort on communication with researchers. | more effort on communication with researchers. |
| 61 | Shell | Industry, A | In their declaration they say: "our commitment to technology and innovation continues to be at the core of our strategy. As energy projects become more complex and more technically demanding, we believe our engineering expertise will be a deciding factor in the growth of our | They are not allowed to participate into multi-stakeholders initiatives but they have their own CSR activities on capacity building for the population of the countries where they work. | They have their own internal rules and they don't feel they need external training. | n.a. |

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| | | | businesses.<br>Our key strengths include the development and application of technology, the financial and project-management skills that allow us to deliver large field development projects, and the management of integrated value chains." | | | |
| 62 | Technalia (Spain) | CSO, NA | TECNALIA is participating in the European research project Responsible-Industry, whose aim is – among others – to answer the question of how ethical practices in industry R&D best be improved. | Capacity building and training activities in ethics assessment would not, in their view, be the most effective solution. Resources would need to be assigned and strategic importance given to this topic for it to develop further. | In particular, it would be interesting to have a shared approach to what responsible research means for European RTOs. | There should be a unified approach to ethics and assessment of research & innovation. It is possible to have a general common framework, with a series of general |

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| | | | | | | principles developed for particular types of activities (e.g. an EU financed R&D project), and adapted to different types of organisations (RTO, large corporation, SME, university etc.)<br><br>- A shared approach should comprise how to ensure ethical principles in RTO management<br>RTO governance: role of partners in a public private partnership<br>Good practices in stakeholder |

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| | | | | | | management for RTOs.<br>Simple standard and tools for assessment of ethical practices in research. |
| 63 | The Convent of Disciplinary Officers (Poland) | Advisory body overseeing cases of scientific misconduct, A | The Convent form opinions on projects setting out the principles of good scientific practices in science and academic work.<br><br>It oversees also research ethics in the sense of scientific integrity and reliability and intervenes in cases of scientific misconduct | One of the roles of the Convent is to increase the level of awareness about issues related to scientific integrity. | n.a. | N/A |
| 64 | United Kingdom Research Integrity Office (UKRIO) (UK) | Independent ethics advisory body, A<br>They give advice on research ethics, publication ethics and good research practice. | UKRIO covers all research sectors: higher education, the NHS, private sector organisations and | - There is a lot of shared good practice out there, however, one challenge stems from having only a small number of people working on these issues within institutions, so any training should involve as many people as | UKRIO provides training in three ways. One, they help behind the scenes and provide advice on content | The respondent felt that ethics assessment on a EU level is going to be challenging because you need |

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| | | | charities – wherever the research affects the public good. | possible, using also online tools.<br>- Since UKRIO was set up in 2006 the proportion of organisations coming to them for advice has grown considerably over the years.<br>- Their survey on impact (2011) with 75 surveyed universities about the use of their two key guidance publications. Over 50 had adopted them outright or were using them as the basis for the creation or the whole scale revision of one of their codes of practice. The documents are designed as benchmarks - they are reference tools that institutions can use when setting up or revising their own particular codes of practice. | for training courses, e.g. they recently provided input into a Medical Research Council online training course for its grant holding researchers. Two, they deliver training as part of programs of research and development for staff or students. Third, they offer standalone lectures or workshops - this is partly training and partly awareness raising for the latter. | something that covers every kind of research done within the EU - the best one can come up with is a set of broad principles. |