SATORI

Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries

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ABSTRACT

This deliverable offers a detailed picture of the *de facto* ethics assessment landscape in the European Union and other countries with regard to approaches, practices and institutions for ethics assessment across scientific fields, different kinds of organisations that carry out assessment, and different countries. The deliverable is based on in-depth study of ethics assessment in ten countries in the European Union, and the United States (US) and China, as well as studies of particular organisations in other EU countries. This main report summarises the results of work package 1 of the SATORI project and provides a comparative analysis of ethics assessment in the scientific fields, organisations and countries investigated. The annex to the report consists of detailed studies of ethics assessment in different scientific fields, types of organisations and countries, in addition to a number of reports on major principles, issues and approaches in ethics assessment.

Executive Summary

This report (along with 47 annexes), is a deliverable of the SATORI project, a forty-five month project on ethics assessment of research and innovation (R&I) that is supported by the European Commission through its FP7 funding scheme. The SATORI project aims to support mutual learning about ethics assessment and ethical guidance in different fields, organisations and countries, and strives to identify best practices, to support harmonisation and shared standards, and, to the extent that it is possible and desirable, develop common principles, protocols, procedures and methodologies for the ethical assessment of research and innovation in the European Union and beyond. The aim of this substantial research effort is to improve ethical assessment practices and strengthen respect for ethical principles in research and innovation.

The SATORI project is divided into three phases: a fact-finding phase, framework construction phase and elaboration and communication phase. This deliverable (D1.1) is the outcome of Work Package 1, which constitutes the largest element in the fact-finding phase. Its aim is to perform a mapping and comparative analysis the ethics assessment landscape for R&I in the EU, the US and China. The main report summarises the results of Work Package 1 and provides a comparative analysis of ethics assessment in the scientific fields, organisations and countries investigated. The 47 annexes consist of detailed studies of ethics assessment in different scientific fields, types of organisations and countries, in addition to reports on major principles, issues and approaches in ethics assessment.

Ethics assessment is a key element of Responsible Research and Innovation, involving the identification and assessment of ethical issues in research and innovation. However, ethical assessment of research and innovation (R&I) faces many challenges - it currently lacks unity, recognised approaches, professional standards and proper recognition in some sectors of society. At the same time, different actors - including universities and research institutes, corporations and government organisations - are flagging the importance of ethics assessment and 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 beyond. The SATORI project addresses this challenge.

Our deliverable is based on over 230 interviews with representatives of organisations that engage in ethics assessment and guidance, and experts in the field, in Europe, the US and China. It is also based on extensive desk research and literature surveys.

Our main report introduces basic terminology, discusses major traditions, approaches, principles and issues for ethics assessment, and provides comparative analyses of ethics assessment in different scientific fields, types of organisations, and countries. It also analyses ethics assessment and guidance policies and institutions at the EU and global level.

After an introduction (*chapter 1*), which introduces the goal of the study and the methods used, *chapter 2*, called *Ethics Assessment and Ethics Guidance*, introduces and defines basic terminology. It offers a description of what ethics assessment of R&I is, how it compares to other ethical and non-ethical studies and assessments of R&I, and provides a policy context for ethical assessment of R&I. *Ethics assessment*, or ethical assessment, is defined as referring

to any kind of institutionalised assessment, evaluation, review, appraisal or valuation of practices, products and uses of research and innovation that primarily makes use of 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, or new fields. There are many organisations engage in some form of ethics assessment of R&I.

Ethics assessment is furthermore distinguished 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, etc. are expected or recommended to adhere. Ethics assessment and ethical guidance can be directed at (1) R&I practices and products, (2) R&I policies, and (3) professional conduct in R&I, and each of these forms of assessment and guidance is different.

Ethics assessors are defined as agents (organisations or individuals) that engage in ethics assessment, usually on a professional basis. Sometimes, this term is used more broadly, to include agents that engage in any type of ethics assessment, guidance, awareness raising or advisement. This definition does not imply that an ethics assessor has ethics assessment as its primary mission, or even that it recognises itself to be doing ethics assessment. It merely means that the agent repeatedly and systematically engages in activities that can be analysed as involving ethics assessment.

The report goes on to relate ethics assessment to other forms of assessment, including quality assurance, social and environmental impact assessment, valorization, and compliance. Ethics assessment is distinct from these in its use of normative ethical criteria in assessment. The report also provides a policy context for ethics assessment, relating it to the overall objectives of R&I policy in the EU, and to decades of efforts at the EU and international level to ensure that ethical issues in R&I are adequately considered.

Chapter 3, *Issues, Principles and Approaches in Ethics Assessment*, introduces major traditions and approaches in ethics assessment, along with the ethical issues they consider and the ethical principles they refer to. It first offers a discussion of *research ethics*, which emerged as a distinct activity in the late 1940s, initially only for the medical sciences, but it has since come to cover other the other sciences as well. The chapter offers a discussion of the ways in which research ethics has become institutionalized, by means of research ethics committees, national ethics committees, regulations and policies, and other initiatives. Major issues and principles in research ethics are then examined, including those that concern the treatment of human subjects, the use of animals, scientific integrity, social responsibility, and others.

Next, the approaches of engineering ethics and ethics of technology and innovation are discussed. *Engineering ethics* is described as a tradition of professional ethics for engineers that has developed in response to health, safety and environmental hazards resulting from engineered products and systems. It is reflected in ethics codes, and contains principles like professional integrity, honesty, impartiality and responsibility for the safety, health, and welfare of the public. The *ethics of technology* is described as a field concerned with the analysis of ethical issues concerning the functioning of technology in society. It is concerned with the value-ladenness of technology and its impact on society, both regarding so-called hard impacts (health, safety and environmental) and soft impacts (regarding human rights, culture, identity and the social good). The *ethics of innovation* is considered as a scattered

series of initiatives, mostly in ethics of technology and business ethics, which consider ethical aspects of technological, social and organisational innovation processes.

Chapter 3 also considers the approach of *ethical impact assessment* and similar ethics assessment approaches that do not focus so much on research and innovation practices themselves as on their potential or actual impacts on society. Ethical impact assessment is an approach towards anticipating and ethically appraising the utilisation of science and technology in society before such utilisation takes place. It is described as an innovative approach to expand impact assessment to the realm of ethics that can help give content to the imperative of social responsibility in R&I.

Annex 1 contains eight in-depth studies of principles and approaches that are discussed in this chapter, each providing an analysis of the ways in which they are utilised in ethics assessment and how they are championed by different organisations. The annex contains reports on research integrity, social responsibility, human subjects' research, institutional integrity, the use of animals in research, dual-use in research, ethics and risk, and ethical impact assessment and conventional impact assessment.

Chapter 4, Comparative Analysis by Scientific Field is based on a systematised inventory of current practices and principles of ethics assessment in the five major areas of science: the medical and life sciences, natural sciences, engineering sciences, social sciences, and the humanities. The chapter compares and contrasts major traditions of ethics assessment that have developed within the five fields; the main ethical issues in the fields; national, EU and international legislation, standards, frameworks and protocols regarding ethical principles and issues that specifically concern or impact the fields; and an evaluation as to the state-of-the-art of ethics assessment in the fields, in addition to future developments in the area. The aim of the analysis is to determine differences and similarities between approaches to ethics assessment across the five fields, with a view to determining the feasibility of transferring ethics frameworks, principles and practices from fields with well-developed ethics assessment frameworks to other fields.

Our main findings are as follows. Ethics assessment exists to different degrees in the five fields. The most extensive institutions, policies and activities exist in the medical and life sciences, followed by the engineering sciences, and then the social sciences. EU and supranational organisations have an important role in giving guidance to ethics assessment in the medical sciences, in particular. The humanities have not really managed to establish their own tradition in ethics assessment. There is a growing institutionalisation of ethics assessment in nonmedical fields. Shared concerns of the five fields are research integrity, social responsibility, intellectual freedom, and professional attitudes like honesty, collegiality and impartiality. In addition, many fields have a concern for the protection of human subject and for the welfare of animals used in experimentation. There are, however, many ethical issues that appear to be specific to the fields, and this also seems to be true for many ethical principles, even though they may often be analysed as based on the same underlying values. Many approaches exist to doing ethics assessment within and across the different fields. Principlism is the main approach in biomedicine, and there have been attempts in other fields, the social sciences in particular, to transfer and take up this approach. This has been met with limited success, probably because of the different ethical issues that these fields are facing.

Annex 2 contains five in-depth studies of ethics assessment in the major scientific fields that are discussed in this chapter: medical and life sciences, natural sciences, engineering sciences,

social sciences and humanities. It also contains twelve studies of ethics assessment in disciplines and subfields within these fields: eight in the medical and life sciences, two in the social sciences, and two in engineering.

Chapter 5, *Comparative Analysis by Type of Organisation*, provides a comparative analysis of ethics assessment and guidance by a variety of organisations - or "assessor types" – that are active in this area. The report distinguishes fifteen types of organisations that routinely or professionally engage in ethics assessment or guidance: research ethics committees (RECs), Associations and Networks of Research Ethics Committees, national ethics committees (NECs), governmental organisations and councils, universities and research institutes, associations of universities and research institutes, research funding organisations, science academies and associations of science academies, academic and professional organisations in R&I, companies, business and industry associations, civil society organisations (CSOs), standards organisations, certification and accreditation organisations, and academic ethics centres and departments.

Each type of organisation is studied in detail with regard to the aims and institutional structure of the organisation; the extent to which the organisation type carries out ethics assessment, including aims, beneficiaries, objects and motivations for assessment; the institutional set-up for ethics assessment; procedures for ethics assessment; principles and issues in ethics assessment; and the main strengths and weaknesses in the area of ethics assessment for the organisation. The aim of the comparative analysis is to understand the ways in which principles and practices of ethics assessment vary for different actors who engage in ethics assessment (both explicitly and implicitly) and to determine the extent to which similarities and differences exist in the use of frameworks and procedures.

Our main findings are as follows. We observe that of the fifteen types of ethics assessors we have examined, each performs a significant but different role in ethics assessment. Sometimes the role is well-established (RECs, NECs), in other cases it is less well established (e.g. companies and CSOs). The objects of assessment or guidance are numerous, and include research and innovation agendas, technological innovations, scientific conduct of professionals, research grant applications, principles of research ethics, draft laws, the conduct of companies, professional conduct, societal impacts of R&I, and others. The beneficiaries of assessment are similarly diverse, and there is also great diversity in the institutional setup and procedures for ethics assessment and the ethical principles and guidelines that are used. For certain types of organisations, ethics assessment or guidance is an optional activity. For example, not all companies or industry associations see a role for themselves in setting or following ethical or CSR standards. Not all universities or research funding organisations pay serious attention to ethics assessment; indeed, whether they do may depend on the presence of hard and soft law, incentives, and the individual choices made by these organisations. Many organisations see problems in the way that ethics assessment and guidance are practiced, including a lack of clear procedures and guidelines, lack of time and resources, lack of training, lack of awareness of ethical issues in the organisation and ways of approaching them, and an insufficient ability to recognise and incorporate new issues and challenges.

Annex 3 contains nine in-depth reports on organisations that engage in ethics assessment or guidance, with some reports analysing more than one type of organisation. The reports are on research ethics committees, national ethics committees, research funding organisations, national science academies and national and academic & professional organisations, civil

society organisations, industry, universities, government and government-funded organisations, and standards, certification and accreditation organisations.

Chapter 6, *Comparative Analysis by Country*, comprises an analysis of ethics assessment structures and agents in both the public and private sectors in ten countries, namely seven European Union countries and one candidate for membership (Serbia), the United States and China. Each country is studied in detail with regard to the organisational structures, laws, policies and procedures that have been established for ethical assessment; the ways in which publicly funded and private research and innovation systems address ethical issues in research and innovation; and the role ethical assessment plays in the activities of professional groups and associations for research and innovation and civil society organisations. The country studies also include basic information about the country's research and development landscape, in addition to the historical development of ethics assessment institutions in the country. The aim of the analysis is to make an international comparison of the ethics assessment infrastructure in the respective countries, with a focus on understanding those structures and agents that comprise the ethics assessment landscape, in addition to their funding and scope.

Our main findings are as follows. All countries that were studied are currently expanding their ethics assessment and guidance infrastructure, including the expansion of (non-medical) RECs, and greater efforts to address ethical issues by governments, universities, research funding organisations, CSOs and industry. The expansion of ethics assessment in non-medical areas is especially noteworthy. There are also significant differences in the extent to which ethics of R&I is institutionalised, ranging from limited (Serbia, Poland, China) to extensive (Netherlands, Germany, Austria) institutionalisation. We also observed interesting national differences in the kinds of ethical principles and issues that receive attention. We also found the role of government in ethics assessment and guidance to be different, ranging from strong (China) to little (US) regulation and intervention, with EU countries located at different points in between. We also observed that governments stimulate CSR for industry to different degrees and with different means, and CSOs engage in informal ethics assessment and guidance in public discussion, and have a role in ethics assessment procedures by other organisations in some countries.

Annex 4 contains eleven in-depth reports on the structures and agents for ethics assessment and guidance in different countries. There are reports on Austria, China, Denmark, France, Germany, the Netherlands, Poland, Serbia, Spain, United Kingdom and the United States. The report on Denmark only focuses on major national organisations and has not been included in the comparative analysis in chapter 6.

Chapter 7, *EU and Global Ethics Assessment and Guidance*, provides a summary of the ethics assessment landscape at both EU and global levels, specifically with regard to the relation between EU and global counterparts in particular areas including organisational structures, laws, policies and procedures for ethical assessment and guidance; the role of publicly funded and private research and innovation systems in addressing ethical issues in research and innovation; and the manner in which ethical assessment plays a role in the activities of professional groups and associations for research and innovation.

Ethics assessment and guidance of research and innovation takes place across both private and public research and innovation systems in the EU. Ethics review is well organised at European Commission level and is supported and enhanced by European research funding

organisations. In addition, there are a variety of organisations at both the European Commission and European Parliament that carry out ethics assessment/guidance as part of their mandate, or encounter ethical issues in other kinds of assessment activities. Specific laws and policy mechanisms set a solid base for ethics assessment of R&I. The incorporation of the European Charter of Fundamental Rights into the Lisbon Treaty has generally enhanced the consideration of ethics and human rights at EU level and the work of advisory bodies such as the EGE, in particular. The importance of international guidelines and frameworks at EU level is clear, particularly in the ethics review of research proposals and projects. The global ethics landscape reflects the increasing interconnectivity between regional actors.

Annex 5 contains two in-depth reports on ethics assessment and guidance at the EU and global levels, respectively.

Chapter 8, *General discussion and conclusions,* offers a discussion and conclusion of the findings, in addition to a forward look to the next stage of the project. The main findings of the comparative analyses are as follows:

- There is reason to doubt the feasibility of transferring ethics frameworks, principles and practices from fields with well-developed ethics assessment frameworks to other fields. While there are certainly specific aspects that can be usefully transferred, some areas such as the social sciences and humanities are faced with the challenge of dealing with familiar issues, such as informed consent and data protection, in novel, and largely unknown, contexts.

- Various challenges have been identified in the practice and implementation of ethics assessment and guidance ranging from a lack of clear procedures and guidelines to insufficient capacity to incorporate new issues and challenges. Thus, it appears that the baseline from which organisations develop and practice ethics assessment and guidance varies.

- All of the countries studied here are currently expanding their ethics assessment and guidance infrastructures.

- As regards ethics assessment at EU and global levels, one sees increasing coordination and cooperation across regional levels.

This public report, and its 47 annexed in-depth reports, can function as a major repository of information on the state of the art in ethical analysis, assessment and guidance of research and innovation, in particular in the EU, the US and China and at the supranational, global level. For the SATORI project, it is, in addition, an important means by which we will take our next step: the identification of best practices, the development of proposals for harmonisation and shared standards, and, to the extent possible, the proposal of common principles, protocols, procedures and methodologies for the ethical assessment of research and innovation in the European Union and beyond.

1 INTRODUCTION

1.1 CONTEXT AND GOALS OF THE STUDY

Research and innovation are central components in the European Union's blueprint for smart, sustainable and inclusive growth and jobs, and in its ambition to tackle societal challenges.[1] The need to better align research and innovation with societal challenges is a key part of this blueprint and is reflected in high-level policy, strategy and programming documents including the Europe 2020 strategy (2010), the Horizon 2020 framework programme, and in the notion of "Responsible Research and Innovation" (RRI), a concept that is increasingly used in policy circles.[2]

The European Commission recognises 'ethics' as one of the thematic elements of RRI,[3] and sees "ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence" for all activities funded by the European Union.[4] Such activities must comply with ethical principles and relevant national, EU and international legislation, for example the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights. A significant element of the RRI endeavour is the identification and assessment of ethical issues in research and innovation. Ethics assessment in research is crucial to anticipating potential benefits and harms of research, identifying specific ethical issues in particular areas of research (e.g. stem cell research) and in ensuring the ethical conduct of researchers in their research activities. Ethics assessment of innovation enables the characterisation of the ethical dimensions of new technologies and applications which, in turn, allows us to make informed decisions about which technologies to promote, which to discourage and how to develop and distribute them in just and ecologically sensitive ways.[5] The SATORI ethics assessment framework (that will be developed in work package 4) will not only help strengthen shared understandings among actors involved in the design and implementation of research ethics, but also support the achievement of the vision for more responsible research and innovation in the EU.

However, ethical assessment of research and innovation (R&I) faces many challenges - it currently lacks unity, recognised approaches, professional standards and proper recognition in some sectors of society. This has clearly become visible in our study of the literature and in the more than two hundred interviews that we have undertaken with representatives from organisations that undertake ethics assessments. The lack of shared vocabularies, standards, approaches, and methodologies is striking. Many organisations active in ethics assessment cannot point to a clear methodology or framework for doing it, and quality assurance and accreditation procedures are often lacking. There is a lack of unity between approaches and vocabularies in different types of organisations, different countries, and different scientific fields. In cases where a clearly defined approach exists, such as in the medical sciences, other problems exist. Medical research ethics is dominated by a single approach, principlism, which is based on the four ethical principles of autonomy, beneficence, non-maleficence and justice. However, this approach does not have a developed method for balancing the principles

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[1] European Commission, "What is Horizon 2020?". https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020

[2] Jacob, K., J. van den Hoven, et al. *Options for Strengthening Responsible Research and Innovation: Report of the Expert Group on the State of the Art in Europe on Responsible Research and Innovation,* European Commission, Brussels, 2013.

[3] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation

[4] https://ec.europa.eu/programmes/horizon2020/node/767

[5] Sandler, R. (ed.), *Ethics and Emerging Technologies*, Palgrave Macmillan, 2014, pp. 5.

against each other, and since it was originally developed for the treatment of human subjects in clinical trials, the approach cannot easily accommodate other ethical issues.

This comes at a time in which there is a rapid expansion of ethics assessment in different sectors of society. An increasing number of universities and research institutes are instituting research ethics committees across the university, in addition to research integrity offices. Corporations are increasingly paying attention to issues of corporate responsibility. Moreover, government organisations, such as the European Commission, are emphasising ethics and responsible conduct of research and innovation in their policies. This rapid expansion has not yet, however, been accompanied by significant efforts to harmonise approaches in different fields and organisations, to raise standards, and to develop quality assurance.

In addition to the fact that the current lack of unity and standards hampers mutual learning and progress in ethics assessment practice, there are other developments that need to be addressed. Ethics assessment co-exists with current legislation, and is enabled and constrained by it. Thus, the rapid growth of legislation and regulation at European level will have consequences for ethics assessment, which will need to be incorporated. [6] Furthermore, the progressive globalisation of research and innovation activities presents challenges for ethics assessment, as illustrated by the practice of "ethics dumping" to developing countries or the exporting of research practices that would not be accepted in Europe on ethical grounds. Finally, ethical principles and laws frequently lag behind the rapid pace of technology development and innovation, necessitating adaptation to the evolution of technologies and societal concern. Taken together, these items demonstrate the need for improvement and coherence in the ethical assessment of R&I in Europe and beyond - SATORI addresses this challenge.

The SATORI project aims to support mutual learning about ethics assessment in different fields, organisations and countries, and strives to identify best practices, to support harmonisation and shared standards, and, to the extent that it is possible and desirable, develop common principles, protocols, procedures and methodologies for the ethical assessment of research and innovation in the European Union and beyond. The aim of this substantial research effort is to improve ethical assessment practices and strengthen respect for ethical principles in research and innovation. In so doing, SATORI will contribute to better and more inclusive practices of governance for the European system of research and innovation and its member states.

SATORI is divided into three phases: a fact-finding phase, framework construction phase and elaboration and communication phase. Work Package 1 - of which this deliverable is the product - is a key element in the fact-finding phase. Our report aims to contribute to this phase by developing a detailed picture of the *de facto* ethics assessment landscape in the EU and other countries with regard to approaches, practices and institutions for ethics assessment across scientific fields, different kinds of organisations that carry out assessment, and countries in the European Union, the United States (US) and China. This main report summarises the results of Work Package 1 and provides a comparative analysis of ethics assessment in the studied scientific fields, organisations and countries investigated. The annex to the report consists of detailed studies of ethics assessment in different scientific

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[6] Major legal initiatives such as the new Clinical Trials Regulation (applicable after May 2016) and the proposed Data Protection Regulation also impact the way ethics assessment is organised and implemented in the Member States.

fields, types of organisations and countries, in addition to a number of reports on major principles, issues and approaches in ethics assessment.

1.2   APPROACH TO THIS STUDY

Deliverable D1.1 is the product of the consolidation of research tasks aimed at mapping and analysing the ethics assessment landscape in EU, the US and China. This deliverable is structured along all of the work package 1 tasks which, taken together, enable an up-to-date comparative analysis of EU and international practices related to ethics assessment in scientific research and related innovation activities. The following provides a chapter outline of the main report that includes an exposition of our approach in each chapter.

Chapter 2 introduces basic concepts and tools for the SATORI project. It provides definitions of key concepts, including the concepts of "ethics assessment", "ethics guidance" and "research and innovation." It then identifies different kinds of ethics assessment, actors that engage in ethics assessment, and objects of assessment. It also compares and contrasts ethics assessment with other types of assessment of R&I, such as quality assurance, compliance and impact assessment. This chapter concludes with a description of the policy context for ethics assessment in Europe.

Chapter 3 describes major approaches, methods and issues in ethics assessment. It describes the major traditions in ethics assessment: research ethics, engineering ethics, ethics of traditions, and recurring principles and issues that these traditions are concerned with, such as the protection of human subjects, animal welfare, scientific integrity, social responsibility, and others. There is a special focus on ethical approaches that are concerned with impacts of R&I, next to approaches that focus more on the ethical issues internal to research or innovation practices.

Chapter 4 offers a comparative analysis of ethics assessment by scientific field. The comparative analysis is based on a systematised inventory of current practices and principles of ethics assessment in five different fields, including the medical and life sciences, natural sciences, engineering sciences, social sciences, and the humanities. In-depth case studies of the five fields offer an overview of the major traditions of ethics assessment that have developed within the field; the main ethical issues in the field; national, EU and international legislation, standards, frameworks and protocols regarding ethical principles and issues that specifically concern or impact the field; and an evaluation as to the state-of-the-art of ethics assessment in the field, in addition to future developments in the area. The aim of the analysis is to determine differences and similarities between approaches to ethics assessment across the five fields, with a view to determining the feasibility of transferring ethics frameworks, principles and practices from fields with well-developed ethics assessment frameworks to other fields.

Chapter 5 offers a comparative analysis of ethics assessment by a variety of organisations - or "assessor types" – that are variously involved in the area of ethics assessment. The comparative analysis is based on in-depth case studies of organisations including research ethics committees, national ethics committees, research funding organisations, national science academies and national and international academic organisations, civil society organisations, industry actors, universities and STI policy (government) organisations. Each type of organisation is studied in detail with regard to the aims and institutional structure of the organisation; the extent to which the organisation type carries out ethics assessment,

including aims, beneficiaries, objects and motivations for assessment; the institutional set-up for ethics assessment; procedures for ethics assessment; principles and issues in ethics assessment; and the main strengths and weaknesses in the area of ethics assessment for the organisation. The aim of the comparative analysis is to understand the ways in which principles and practices of ethics assessment vary for different actors who engage in ethics assessment (both explicitly and implicitly) and to determine the extent to which similarities and differences exist in the use of frameworks and procedures.

Chapter 6 offers a comparative analysis of ethics assessment structures and agents in both the public and private sectors in ten countries, namely seven European Union countries and one candidate for membership (Serbia), the United States (US) and China. Each country is studied in detail with regard to the organisational structures, laws, policies and procedures that have been established for ethical assessment; the ways in which publicly funded and private research and innovation systems address ethical issues in research and innovation; and the role ethical assessment plays in the activities of professional groups and associations for research and innovation and civil society organisations. The country studies also include basic information about the country's research and development landscape, in addition to the historical development of ethics assessment institutions in the country. The aim of the analysis is to make an international comparison of the ethics assessment infrastructure in the respective countries, with a focus on understanding those structures and agents that comprise the ethics assessment landscape, in addition to their funding and scope.

Chapter 7 provides an overview of the ethics assessment landscape at both EU and global levels, specifically with regard to the relation between EU and global counterparts in particular areas. The chapter offers a review of EU and *intergovernmental* and supranational organisational structures, laws, policies and procedures for ethical assessment and guidance; the role of publicly funded and private research and innovation organisations at the EU and global level in addressing ethical issues in research and innovation; and the manner in which ethical assessment plays a role in the activities of EU and international professional groups and associations for research and innovation.

Chapter 8 presents a general discussion and conclusions, in addition to a forward look to the next stage of the project.

1.3   METHODOLOGY

To support this deliverable, interviews and case study reports were used in order to gather data regarding ethics assessment and its stakeholders across scientific fields, organisations and countries.

The aim of the interviews was to gather information and opinions from and about different ethics assessment organisations, countries, scientific fields and non-assessor stakeholders regarding practices of, and attitudes towards, ethical assessment of research and innovation. In total, over 230 interviews were carried out, the vast majority of which were carried out in person (others were carried out via phone and Skype). Interview data was then used in the various sub-reports compiled for D1.1 (please see the annexes to this report). In addition to the interview data, desk research was employed to compile the case study reports, making use of a survey of the academic and non-academic (e.g. ethics codes) literature and material found online (e.g. website descriptions of ethics assessment organisations). The interviews were conducted between September 2014 and January 2015.

Countries were used as the main structuring principle for data collection. In addition to the US and China, eight representative European countries were chosen for in-depth study, including seven European Union (EU) members - Austria, France, Germany, The Netherlands, Poland, Spain and the United Kingdom (UK) - and one candidate for membership, Serbia. These countries were selected as they represent both small and large countries in different parts of the EU and associated states, with varying degrees of institutionalisation of ethics assessment and guidance and featuring different institutional and cultural arrangements. For each country, the main organisations that engage in ethics assessment or have a major stake in it were investigated. Each country study included an average of 14 interviews across these organisations (for details, please see Appendix 1). Appendix 4 contains the ethics assessor factsheet and interview questionnaire.

In addition to the country-based interviews, additional interviews were carried out in order to include different categories of ethics assessment organisations, different scientific fields and additional non-assessor stakeholders (mostly at the EU level) (for details, please see Appendix 2). Appendix 4 contains the non-ethics assessor factsheet and interview questionnaire.

Interview procedures

The SATORI consortium set out the interview procedure at the outset. Using the guidance developed in the WP, the SATORI consortium partners selected possible names for interviews, using the SATORI stakeholder contact list, existing relevant SATORI reports (which contained weblinks to and information about relevant ethics assessment organizations), and any other means. Interviewers checked the coordinator of the interview category if the organisation/person selected for the interview was the right one and also to ensure there was no duplication of people selected for interviewing. The coordinator checked that different partners did not solicit the same persons for interviews and checked that there was sufficient diversity in the group of candidates chosen. Interviewers invited potential interviewees using a standard invitation letter drafted specifically for the purpose and reminders were issued if required. If the potential interviewee declined or did not respond after repeated attempts, a different candidate was selected and agreed with the coordinator for invitation. Prior to the interview, the interviewer sent the interviewee a list of questions (see Appendices 3 and 4 for the templates used) for his or her interview category, and optionally the draft report in this category (e.g., "engineering", "country study Austria", "national ethics committees"), if available, so as to inform him/her about the context of the interview. Interviews were conducted either virtually or face to face, in one to one and half hourly slots. Interviewees were invited to provide any documents which provided answers to the factual questions in the interview templates.

During the interview, the interviewer informed the interviewee of the aim of the interview and the use that would be made of the information and opinions provided in the interview. They were informed that no full transcript of the interview would be produced, only a summary. Interviews were only taped with prior permission of the interviewee, and explanation was provided of the use of the tape. Interviewees were given a choice if they want ed any summaries or quotations that are used in reports to be accompanied by their real name, or whether these should be given anonymously. They were also asked whether the organization name could be used or not, and whether texts should contain any disclaimers to the effect that opinions given are only those of the individual and may not represent those of the

organization. The interview was conducted using the relevant interview template (see Appendices 3 and 4 of this Deliverable), but with the flexibility to use any additional relevant questions (including factual ones) that would be useful for gathering data for the SATORI reports. Interviewees were asked if they were interested in providing feedback on the current draft report in their interview category, or on future drafts.

After the interviews, a summary of the interview was made to help the author(s) of the report in that interview category to incorporate facts and opinions from the interviewees. They will usually not be included in full in the final report, although parts of it may be literally included (paragraphs, quotes, and the like). Summaries were generally be four to five A4 pages. If the interviewee had so requested, they were sent a copy of the summary for their comments. Once the summaries were completed, they were stored on the shared space and accessed by the authors of the relevant reports.

Scope and limitations of this study

While this study presents a comprehensive picture of the ethics assessment landscape in the EU, its scope is limited:
- in Annex 1 to the study of the following approaches and principles in ethics assessment: ethical and traditional impact assessment, scientific integrity, social responsibility, human subjects' research, institutional integrity, animal welfare, dual use and risk.
- in Annex 2 to in-depth case studies of current issues, principles and practices and institutionalisation of ethics assessment and/or guidance in the medical and life sciences, natural sciences, engineering sciences, social sciences and the humanities fields.
- in Annex 3 to an in-depth case studies of nine kinds of organisations that are variously engaged in ethics assessment/guidance across eight representative European countries, the US and China, i.e., research ethics committees, national ethics committees, research funding organisations, national science academies and national and international academic organisations, civil society organisations, industry, universities and governmental organisations involved in science, technology and innovation policy.
- in Annex 4 to the study of ethics assessment in US and China, and eight representative European countries including seven European Union (EU) members - Austria, France, Germany, The Netherlands, Poland, Spain and the United Kingdom (UK), and one candidate for membership, Serbia.
- in Annex 5 the study of ethics assessment at the EU and global levels offers a review of EU and intergovernmental and supranational organisational structures, laws, policies and procedures for ethical assessment and guidance; the role of publicly funded and private research and innovation organisations at the EU and global level in addressing ethical issues in research and innovation; and the manner in which ethical assessment and guidance play a role in the activities of EU and international professional groups and associations for research and innovation.

While there are have been advantages of having used interviews in this study e.g. more focussed and yet at the same time flexible discussions (with allowance for follow-up questions) with a variety of stakeholders; we also recognise that the interviews placed a large

resource burden in terms of time commitments on both the interviewees and the interviewers. In some cases e.g. due to the nature of national or local ethics assessment organisations , some of the data was not easily comparable and made it slightly more challenging to analyse. Another disadvantage is that interviewees may be biased or represent only a limited perspective, but SATORI tried to alleviate this by ensuring a broad representation of perspectives and non-duplication of organisations.

2   ETHICS ASSESSMENT AND ETHICAL GUIDANCE

2.1   INTRODUCTION

Consider the following three cases of research and innovation practices that have caused ethical controversy:

From 2009 to 2014, a European guideline was in place, issued by the European Society of Cardiology, that recommended the liberal use of beta-blockers in order to protect the heart during surgery for people undergoing non-cardiac surgery. This guideline was based in large part on a 1999 study performed by a surgeon, dr. Don Poldermans, which presumed to show that the risk of cardiac arrest in such operations was reduced by 90% if beta-blockers were used. Dr. Poldermans was also the then chairman of the committee which issued the guidelines. In 2012, an integrity committee ruled that Dr. Poldermans had fabricated date for several of his publications, including the 1999 publication.   In 2014, after other studies showed that beta-blockers were likely to actually increase the risk of cardiac arrest, the guideline was abolished.   A 2014 article in Forbes reported that the wrongheaded guideline may have caused as many as 800,000 deaths in Europe during the five years that it was in effect.[7]

From 1945 to 1989, more than 3400 human test subjects were subjected to nerve gas like sarin and mustard gas in Porton Down, a chemical warfare research installation in the UK. One subject may have died as a result, and there are unknown long-term health consequences for others.[8] A 2006 study concluded that test subjects were inadequately informed about the nature of the studies and misinformed about their health risks.[9] Porton Down returned in the news in the 2010s, when it was reported that almost 10,000 animal experiments were taking place at the facility every year, including many that inflicted substantial levels of suffering, such as live pigs being blasted with explosives, monkeys being infected with anthrax and ebola, and animals being killed with nerve agents, being smashed with heavy weights and having bullets fired into their eyes.[10]

In 1968, Ford Motor Company began development on a new car that was aimed to be inexpensive, small, and appealing to a wide variety of consumers. This resulted in the introduction in 1971 of the Ford Pinto, which quickly became a successful car. The Pinto had design flaws in the fuel system that were known to the company, and could result in car fires and gas tank explosions in case of a rear-end

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[7] Husten, Larry, "Medicine Or Mass Murder? Guideline Based on Discredited Research May Have Caused 800,000 Deaths In Europe Over The Last 5 Years", *Forbes*.
http://www.forbes.com/sites/larryhusten/2014/01/15/medicine-or-mass-murder-guideline-based-on-discredited-research-may-have-caused-800000-deaths-in-europe-over-the-last-5-years/
[8] Evans, Rob, "The past Porton Down can't hide", *The Guardian*.
http://www.theguardian.com/science/2004/may/06/science.research
[9] Schmidt, U., "Cold War at Porton Down: Informed Consent in Britain's Biological and Chemical Warfare Experiments", *Cambridge Quarterly of Healthcare Ethics*, Vol. 15, No. 4, 2006, pp. 366-380.
[10] See Robson, Steve, "Thousands of animals blown up, poisoned or given anthrax in secret military experiments at Porton Down last year", *Mail Online*. http://www.dailymail.co.uk/news/article-2250139/Thousands-animals-blown-poisoned-given-anthrax-secret-military-experiments-Porton-Down-year.html and Lines, Andy, "Outrage as animals 'tortured' in gruesome Porton Down military experiments", *The Mirror*,
http://www.mirror.co.uk/news/uk-news/outrage-animals-tortured-gruesome-porton-5316046

collision. The company also knew of a design upgrade that would cost $ 11 to implement, and that would fix the problem, avoiding an estimated 180 deaths. Ford chose, however, not to do the upgrade, based on cost-benefit analysis that showed that the cost of the company for doing the upgrade would be greater than the cost to the company and to society of the deaths, injuries and property damage resulting from collisions. This is now a well-known case in the business ethics and engineering ethics literature.[11]

These are three actual cases that have caused moral controversy and outrage and that show the importance of ethical issues in research and innovation to society. As cases go, they are rather extreme, involving death and injury on a large scale. Everyday ethical assessments of research and innovation usually deal with less extreme, but nonetheless, significant issues, such as whether children should be allowed to participate in experiments that expose them to adult situations, or whether personal data collected and transferred by new wearable devices violate the user's privacy.

It is now increasingly recognized in society that it is important for research and innovation to be performed responsibly and ethically. Organisations that perform, fund, monitor and regulate research and innovation (R&I) increasingly subject it to ethical consideration. Ethical assessment of R&I is increasingly institutionalized, and more and more often, R&I plans, protocols, procedures, practices, and products are subject to ethical review, by ethics committees, ethics officers, ethics divisions, and similar individuals and organisations. Figure 1 provides an overview of organisations that are involved in ethically assessing or providing ethical guidance for R&I activity. This report contains an in-depth analysis of the ways in which such *ethics assessment* is organized and realized in the European Union, the US and China, by different organisations and in different scientific fields. It contains a state-of-the art description of ethics assessment institutions and practices and a comparative analysis of institutions and practices across different scientific fields, types of organisations, and countries.

• 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 1: **Organisations that engage in ethics assessment and ethical guidance for R&I**

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[11] For example, Hoffman, M., "The Ford Pinto Case", in M. Hoffman and J. Moore, eds., *Business Ethics*. McGraw-Hill: New York, 1984, pp. 412–420.

In the next two sections of this chapter, we introduce basic terminology. In the next section, we offer definitions of "research", "innovation" and "ethics", and we define what we mean by "ethical issue" and "ethical principle". In section 2.3, we will define the notions of "ethics assessment", "ethical guidance" and related concepts, and we will distinguish various kinds of ethics assessment and guidance. In section 2.4, ethics assessment will be compared to other types of assessment or evaluation of research and innovation. These include quality assessments, assessments for social and economic relevance or potential, and assessments of social and environmental impacts. Finally, in section 2.5, we sketch the policy context for ethics assessment and guidance of R&I, with a particular focus on the EU.

2.2   BASIC CONCEPTS: RESEARCH, INNOVATION AND ETHICS

Research and Innovation

We define *research* as the systematic, methodical creation of new knowledge or the use of existing knowledge in a new and creative way so as to generate new concepts, methods or understandings. Our focus in this report is on scientific and scholarly research. Scientific research is research that takes place according to scientific methods, which, for the empirical sciences, involve systematic observation, measurement, and experimentation, and the formulation of hypotheses that are tested and modified using such methods. Our report covers research in all fields, including the natural sciences, engineering sciences, medical sciences, social sciences and humanities.

We define *innovation* as the development - based on new ideas or inventions - of new products, services, processes and methods believed to create added value for society. Many, perhaps most, innovations in contemporary society are technological innovations. *Technological innovation* is the technology-based development of new products, processes or features. Non-technological innovations are usually social or organisational in nature, and include *marketing innovation*, *organisational innovation*, and *social innovation*, which is the development of new strategies, organisational forms and ideas that strengthen civil society. In our report, we focus on science-based (or research-based) innovations, both technological and non-technological, but with a focus on the former.

We use the expression "research and innovation" (R&I) to refer to these two practices together. We use it instead of the frequently used term *research and development* (R&D), which is usually restricted to scientific-technological research and technological development, and therefore narrower in scope than the term "research and innovation" as defined here. Note that by these definitions, we will only be considering activities that are themselves activities of research and innovation; we will not be considering professional activities that merely depend on science and innovation. For example, medical treatment by health professionals is an activity that relies on medical research and earlier innovations in medicine, but is not itself an activity within the scope of research and innovation. It therefore falls outside the scope of this report, as does, as a result, the ethical assessment of such treatment. However, any research activity to enable or facilitate such treatment would fall under our scope.

Ethics

We define *ethics* as the systematic reflection on, and development of standards for, right and wrong conduct and their application to situations in which such standards may be violated. Ethics is an attempt to explicate our moral intuitions about what is good and evil, right and wrong. It is concerned with our duties and responsibilities towards others, to respect their rights and dignity, avoid harm, and promote their well-being. It is also concerned with justice and the fair treatment of others, and the good of society as a whole. Moral values that are often referred to in ethics include autonomy, freedom, dignity, privacy, justice, well-being and responsibility.

A first step towards an ethical analysis of some issue or problem is often the observation that there are ethical aspects to it. An *ethical aspect* of some phenomenon is a quality or feature of the phenomenon that raises ethical questions or poses an ethical or moral dilemma. *Ethical questions* are questions about whether some action or phenomenon is in conformity with ethical standards, and an *ethical issue* is a situation in which ethical aspects exist, or which poses ethical questions. An *ethical* or *moral dilemma* is an apparent conflict between two moral principles or requirements that somehow should be resolved. For example, it may be observed that there are ethical aspects concerning the use of CCTV cameras in public places, since they transmit and sometimes record images of people that some may find intrusive. The ethical question concerns whether the use of CCTV in public places violates privacy. The ethical dilemma concerns whether, in balancing several values associated with the use of CCTV cameras in public places, any violations of privacy are outweighed by their benefits for safety and security.

In order to be able to evaluate conduct as right or wrong, ethics has recourse to ethical or moral values, principles and norms that define ideals or standards of goodness. *Moral values* include previously mentioned notions such as autonomy, justice, and well-being. Such values identify abstract, general ethical ideals that we should support or strive for. A *moral norm* is usually derived from one or more moral values, and is a more specific standard that prescribes how people should act in order to be moral. Examples are "One should respect the privacy of others" and "Always ask for consent from test subjects before engaging them in experiments". *Ethical principles* are general moral norms and standards that express rights, responsibilities and other criteria for right and wrong conduct, such as "Killing is wrong", "People have an absolute right to privacy" and "One should always treat others as means, and never as ends".[12]

In general, ethical principles tend to fall into one of four categories:

(1) *Principles concerning individual rights and conditions deserving respect.* These include freedom (of movement, of assembly, of speech and expression, etc.), autonomy, human dignity, bodily integrity, privacy, and property.

(2) *Principles concerning benefits and harms*

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[12] It sometimes occurs that references is made to something as an ethical issue, but the issue is left implicit in the description. For example, in an analysis of ethical issues concerning robots, one mentioned ethical issue can be "the use of robots in war", which signifies that one or more ethical issues are raised by such use, but it is left unspecified what they are. Conversely, sometimes an ethical issue is only referred to by an ethical principle, and it has to be derived from context that the principle is really a shorthand reference to situation in a risk is posed to this principle being violated. For example, a discussion of social networking sites may mention "privacy" as an ethical issue, by which is meant that there is an ethical issue with the potential or actual implications of social networking sites for privacy.

These are principles to the effect that one should avoid harms and promote benefits, or that identify certain goods as being a benefit or harm, or an aspect of well-being or the good of society. They include principles of beneficence, non-maleficence, the no harm principle, and the principle of utility, amongst others. Harms include health and bodily harms, property damage, immaterial harms, environmental harms, harms to society, and others. Corresponding to benefits are, amongst others, principles of welfare (happiness, friendship, trust) and the common good (vital social institutions, cultural richness, etc.). Under benefits and harms, we can also subsume ethical principles involving *risks*, since risk is usually defined as the probability that some harm or benefit occurs.

(3) *Fairness principles*
These are principles of justice, fairness, equality, inclusion and nondiscrimination.

(4) *Virtues*
These are principles concerning good human character traits that people should extoll, like honesty, tolerance, integrity, diligence, and respectfulness. For example: "Be honest", "Avoid being jealous".

In ethics assessment of research and innovation, ethical principles are often tailored to specific issues that arise in R&I. For example, integrity in scientific research becomes "scientific integrity", and the principle of autonomy applied to research subjects becomes "informed consent". Often, to a general ethical principle, there correspond several specialized moral principles that are dedicated to different fields or issues in ethics assessment of R&I.

2.3 ETHICS ASSESSMENT, ETHICAL GUIDANCE AND RELATED ACTIVITIES

Ethics Assessment

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. Ethics 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. Examples of such moral judgments are:

- "The proposed experiment does not live up to standards of informed consent."

- "Web browsers that secretly include cookies violate privacy."

- "Human cloning is wrong."

- "Advising on research in which one participates presents a conflict of interest."

Ethics assessment is usually undertaken with the *prospective* aim of ensuring or encouraging the ethical conduct of research and innovation practices. Assessment is therefore directed at researchers, innovators, or those who are in a position to exercise control or influence over them. However, ethics assessment can also take place retrospectively, after a research project has been completed or a new innovation implemented, in order to evaluate compliance with earlier recommendations or to learn from past practice.

Ethics assessment can be directed at any of the following classes of entities:

- Research and innovation plans, programs and agendas
- Research and innovation practices
- Research and innovation systems and infrastructures
- Products of research and innovation
- Impacts of research and innovation

For example, there are assessments of research proposals to screen for ethical issues before research can begin, of designed products to assess whether they may have unethical consequences or uses, or of social impacts of new technologies in order to assess whether any of these impacts raise ethical issues.

Ethics assessment can be formal (or institutionalized) or informal, the distinction being a matter of degree. An *institutionalized* (or *formal*) *assessment* is one that is incorporated into a well-established system of practice for ethics assessment that takes place in an institutional setting. An informal assessment is one in which no such institutionalized practice exists, and it is merely the case that a set of moral judgments are made concerning research and/or innovation. For example, when an environmental organisation claims in a study that energy from fossil fuel is "wrong" or "harmful" or "unjust", without having any previously identified principles, frameworks, mission statements or practices that play a role in arriving at these conclusions, and without having any recognizable kind of ethics committee or unit, they engage in a form of informal ethics assessment.

It furthermore appears that there are three major kinds of ethics assessment:

- *Project- and practice-oriented assessment*: This assessment is concerned with research and innovation project proposals, projects and activities carried out by individual scientists, teams of scientists or organisations. It is performed by research ethics committees and ethics officers of various sorts. It may result in taking of positive measures to mitigate ethical impacts e.g. value-sensitive design[13].
  - *Example of moral judgment:* "The experiment has not been set up to include informed consent (or has not involved informed consent in practice), and this is not acceptable".

- *Policy-oriented assessment*: ethics assessment of (new) scientific fields, methods, techniques, technologies, devices or innovation areas. This kind of assessment is

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[13] According to value sensitive design is a "theoretically grounded approach to the design of technology that accounts for human values in a principled and comprehensive manner throughout the design process". Friedman, Batya, et al., "Value sensitive design and information systems", in N. Doorn, D. Schuurbiers, I. van de Poel, M.E.Gorman, (eds.), *Early engagement and new technologies: Opening up the laboratory*, Springer Netherlands, 2013, pp. 55-95.

performed by National Ethics Committees, government entities, CSOs (often informally), and other agents who are active in the policy arena.

  o *Example of moral judgment:* "Human cloning is morally wrong, and should be banned."[14]

- *Assessment of professional conduct:* This assessment often relates to alleged violations of scientific integrity or ethics codes (fraud, unethical conduct, etc.) by individual professionals in R&I. This assessment is carried out by integrity boards, ombudsmen, disciplinary committees, etc.

  o *Example of moral judgment:* "John Jones has not acted in the best interest of clients, and has not lived up to standards of honesty and truthfulness".

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

The third type, assessment of professional conduct, differs from policy-oriented assessment in that the focus is the on actions of scientists and innovators rather than on developments in science and technology. It differs from project- and practice-oriented assessment in that the focus is on the actions of individuals rather than on practices or projects. Practices, of course, depend on the actions of individuals but also depend on methods, tools, organisational structures, regulations, and so forth, and often depend on the actions of multiple individuals. Practices are hence not essentially coupled to an individual researcher or innovator.

To illustrate, the application of harmful chemicals to animals without anesthetics in medical experiments is a practice that would normally be evaluated in project- and practice-oriented assessment, but not in the assessment of individual professional conduct. Standards for professional conduct could include a standard that specifies that medical professionals should do no unnecessary harm to living creatures. In that case, the medical professional's engagement in the aforementioned practice could be a violation of this professional ethical principle as well. Generally, though, a distinction can be drawn between assessment of research and innovation practices and assessment of professional conduct by researchers and innovators.[15]

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[14] An extended example can be found in the report "Aspects of ICT Implants in the Human body" by the European Group on Ethics in Science and Technology; see http://ec.europa.eu/archives/bepa/european-group-ethics/docs/avis20_en.pdf. This report also contains ethics guidance, next to ethics assessments.

[15] Two other useful distinctions are: (1) Full and partial ethics assessment. In *full ethics assessment*, all ethical aspects or implications of some phenomenon are identified. In *partial ethics assessment*, only some ethical aspects of a phenomenon are identified, either because there is a focus on only some ethical values (e.g., privacy, justice) or because only some parts or aspects of the phenomenon are examined for their ethical issues; (2) Explicit and implicit ethics assessment. In *explicit ethics assessment*, the assessment is explicitly identified as ethical (the words "ethics", "ethical" or "moral" are contained in the term used for the assessment) and assessment takes place relative to explicitly stated ethical values or principles. In *implicit ethical assessment*,

Ethical Guidance

Next to ethical assessment, there is *ethical standard-setting* or *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, etc. are expected or recommended to adhere. Ethical guidance presents ideals to live up to or norms to follow. Ethical guidance differs from ethics assessment in that it does not in and of itself involve moral judgment: it is not the case that particular types of research and/or innovation, or their uses in society, are judged to be right or wrong. Rather, ethical guidance sets general standards for rightness or wrongness according to which any specific activities or outcomes of research and/or innovation may be guided or evaluated. Ethical guidance is typically given by national ethics committees, science academies, professional organisations and other organisations in a position of authority regarding research and innovation.

Ethical guidance appears to come in three different kinds that mirror the three kinds of ethics assessment:

- *Ethical guidance for projects and practices:* Ethical guidance for research projects, innovation projects and practices of individual scientists or teams of scientists (for example, advice to seek informed consent of research subjects, or standards for the ethical treatment of animals in experimentation).
  - *Example:* principles of informed consent in experimentation with human subjects.
  - *Extended examples:* statements of ethical guidelines for biomedical research on human participants;[16] guidelines for research ethics in science and technology.[17]

- *Policy-oriented ethical guidance:* Ethical guidance for broader developments in science and technology and related policies (i.e., a framework for assessing such developments, not the actual assessments themselves). This is, in a sense, guidance for society as a whole, as opposed to guidance for particular actors.
  - *Example*: the precautionary principle, principles of distributive justice and the rights of future generations.
  - *Extended example*: An ethical framework for assessing research, production and use of energy from the European Group on Ethics in Science and Technology.[18]

- *Ethical guidance for professional conduct by scientists and innovators/engineers:* This is usually provided in the form of professional ethical codes.

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assessment is not identified as ethical, but is nevertheless guided to a significant extent by ethical values or principles.

[16] E.g., Indian Council of Medical Research, *Ethical Guidelines for Medical Research on Human Participants*. http://icmr.nic.in/ethical_guidelines.pdf

[17] E.g., National Committee for Research Ethics in Norway, *Guidelines for Research Ethics in Science and Technology*. https://www.etikkom.no/globalassets/documents/english-publications/1/guidelines-for-research-ethics-in-science-and-technology-2008.pdf

[18] See European Group in Ethics in Science and New Technologies, Opinion No. 27 on an ethical framework for assessing research, production and use of energy, Brussels, 16 January 2013. http://ec.europa.eu/archives/bepa/european-group-ethics/docs/publications/opinion_no_27.pdf

- *Example*: principles of honesty and integrity, obligations to clients and the public.
- *Extended example*: The engineering code of ethics of the U.S. National Society of Professional Engineers (NSPE).[19]

It should be observed that the distinction between ethical guidance for projects and practices and policy-oriented guidance is sometimes blurred, because policy-oriented assessments sometimes focus strongly on particular research and innovation practices, and may for that reason have a secondary use for project and practice assessment. For example, the Oviedo convention on human rights and medicine gives general policy-oriented ethical guidance, but also goes into great detail regarding proper ways of doing biomedical research. Thus the Oviedo convention also offers guidance for medical practice.[20]

Ethical guidance has two major applications:

(1) Guidance decisions, behaviors and practices in R&I, and

(2) Ethics assessment of R&I

Regarding the first use, ethical guidance can be used to directly guide individual and collective decisions, behaviors and practices in R&I. For example, ethics codes for engineers may contain the principle "Be truthful". Engineers who learn the code could be inspired to shape their actions so that they adhere to this principle.[21] Ethical guidance is also used to guide ethics assessment. This occurs when its principles are used as a framework for making moral judgments in ethics assessment. For example, a principle of informed consent for ethical guidelines for medical practice may be used to assess whether or not a research proposal or practice properly incorporates informed consent in the research design.

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

Further Categories

A third category of ethics activity in relation to R&I is *ethical awareness raising*, which some ethics bodies seem to engage in. In ethical awareness raising, the principal aim is not to make

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[19] See National Society of Professional Engineers, "Code of Ethics". http://www.nspe.org/resources/ethics/code-ethics

[20] See Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.4.1997. .http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm

[21] It could be argued that ethical guidance of actions always involves some form of ethics assessment. The reasoning would be that before acting, the agent uses ethical principles to assess whether or not an intended action is ethical. If it is, the action is undertaken, and if not, it may be stopped from being executed. Apart from the fact that it is not clear that this is a psychologically accurate description of how moral principles constrain action, it seems that any such ethics assessment is highly informal, possibly unconscious, and not easily open for public inspection, since it involves unspoken self-assessment. It is perhaps best not to define the term "ethics assessment" to cover these tacit forms of self-assessment.

moral judgments or provide guidelines, but rather to understand possible or actual ethical implications of certain research and/or innovation practices, to alert others to these implications, and to suggest tools for approaching them. For example, it may be stated in ethical awareness raising that "service robots that store personal data raise privacy issues", "nanotechnology could potentially harm the environment", or "synthetic biology may cross moral boundaries". Ethical analysis is not always easy to distinguish from ethics assessment because its findings sometimes seem to include moral judgments, yet these tend to be more tentative than those in regular ethical assessment. When there is an emphasis on presenting tools for approaching the ethical issues that are identified, without specific ethical guidelines on how they should be approached, this type of ethical study could also be called *ethical advisement*.

The Nuffield Council on Bioethics is an example of an organisation that operates one step removed from direct ethics assessment in the sense that its task within its terms of reference is to identify ethical issues that are likely to arise in the context of new developments in biological and medical research. Moreover, the Council promotes discussion and understanding of such ethical issues but also develops reports including recommendations which are policy focused. However, the Council does not claim to offer direct guidance on specific questions. They 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.

Some organisations engage in *oversight of compliance with ethics guidelines*. This is not ethics guidance, because the organisations do not aim to offer guidelines themselves. It rather appears to be a form of ethics assessment, in which an assessment as to whether research and innovation practices are performed in compliance with stated guidelines is carried out. Finally, organisations may also engage in *ethics capacity building and training* as a major activity, in which case their role is to help other organisations or individuals to enhance their capacity to perform ethics assessment or guidance, or in incorporating ethical considerations in their professional work as researchers or innovators.[22]

Corporate Social Responsibility

Many companies that engage in research and innovation have policies in place to ethically guide and assess their R&I activity, but many of them do not refer to their policies as involving ethics. Instead, they tend to use the notion of *corporate social responsibility* (CSR). To the extent that companies refer to a notion of ethics, it is often in relation to standards of integrity and avoidance of conflict of interest for management and employees. CSR is a corporate initiative to assess and take responsibility for a company's effects on the environment and on the welfare of society. Companies may have guidelines in place for CSR that function as ethical guidance for the company's actions, including those in the area of R&I, and companies may have CSR officers or divisions that are responsible for CSR strategy and/or implementation. CSR is outward-looking in that it has a strong focus on impacts, rather than on ethical issues in research and innovation practices themselves. Recently, companies have also been using the term *sustainability* to give expression to their responsibility towards society, alongside, or instead of the CSR label. Often, "sustainability"

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[22] *Academic ethics of research and innovation*, performed by scholars, may take any of the mentioned forms: assessment, guidance, awareness raising, advisement and competence building. Much of academic ethics is aimed at creating new knowledge about ethical issues in R&I, rather than at having a direct impact on R&I performance.

is given a very broad meaning, to include not only environmental sustainability issues, but also issues concerning social impacts and human rights.

Ethics Assessors vs. Non-Assessors

We define *ethics assessors* as agents (organisations or individuals) that engage in ethics assessment, usually on a professional basis. Sometimes, we use this term more broadly, to include agents that engage in ethics assessment, guidance, awareness raising or advisement. A non-assessor is any person or organisation that does not (professionally) engage in ethics assessment. Our definition does not imply that an ethics assessor has ethics assessment as its primary mission, or even that it recognizes itself to be doing ethics assessment. We do stipulate, however, that to qualify as an ethics assessor, the agent should repeatedly and systematically engage in activities that can be analyzed as involving ethics assessment.

The distinction between assessors and non-assessors is not always clear. Notably, there is a grey area between organisations that regularly engage in informal types of ethics assessment or guidance as part of their professional activities and therefore qualify as (informal) ethics assessors, and those who only occasionally make moral judgments or advocate moral principles, but do not structurally engage in ethics assessment. An organisation for the elderly that issues a one-time statement opposing care robots because they are not believed to promote the well-being of the elderly engages in what looks like a superficial form of ethics assessment, but this does not make them an ethics assessor as defined above. In addition, there is not always a clear distinction between ethics assessments and other types of assessment, particularly social impact assessment and assessment of compliance with regulations or legal requirements. These other types of assessment will be covered in greater depth in the next section.

2.4   ETHICS ASSESSMENT AND OTHER TYPES OF ASSESSMENT

Assessment in research

Ethics assessment is one of several types of assessment or evaluation of research and innovation. Types of assessment for scholarly research include quality assessments, assessments of social and economic relevance or potential, and assessments of social and environmental impacts.[23] *Quality assessment* or *quality assurance* of scholarly research is a form of assessment that aims to establish the scientific quality of research. It uses criteria like peer review, citations, science prizes and honorary doctorates, to establish the quality of publications, research programs and scientists. Various other types of assessment focus on the *social and economic value and impacts* of research rather than its quality. These types of assessment sometimes fall under the label of *social relevance, social and/or economic impact* or *valorization*. The aim is to determine the potential or actual benefits of the research for society, in terms of orientation towards issues of societal importance or even measurable positive impacts, including new policies, products, innovations, attitudes, or behaviors that have resulted from the research.

Ethics assessment and quality assurance of research have different aims, the former being concerned with ethical acceptability and the latter with scientific quality. They can be related, however, in two ways. First, scientific integrity is an ethical requirement for research and is a

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[23] An "impact" (or "effect") is typically defined as the difference between what would happen with the action and what would happen without it.

necessary condition for scientific quality. Second, having proper ethics protocols in place in research practice sometimes forms a criterion for scientific quality. Ethics assessment and impact assessment of research also have different aims, the first being concerned with the ethical acceptability of the research practice, and the second with the societal value and impact of that research practice. These criteria sometimes overlap: ethics assessment of research sometimes considers potential or actual impacts for their ethical acceptability, and impact assessment sometimes put ethical conditions on impacts as part of an assessment of their quality.

A third type of assessment in research that is different from ethics assessment is *compliance assessment*, or simply *compliance*. Research compliance is the conformity of research practices to laws and regulations, including institutional regulations. Research compliance is often enforced by research compliance officers whose job it is to help the institution ensure that its research practices are compliant. It can also be a responsibility of a committee. Research compliance often overlaps with ethics assessment, because many of the laws and regulations to which there must be compliance make reference to ethical values and principles, and because compliance officers often also have the responsibility to promote ethics and integrity. Indeed, many institutions have "ethics & compliance" officers or boards to promote both ethics and legal and regulatory compliance. In addition, many designated research ethics committees in practice hardly discuss ethical issues, but mostly focus on compliance.

Assessment in engineering and technology

In engineering, quality assessment also takes place, but is more diffuse in nature than for the case of scientific research. For individual engineers, there are various kinds of competency assessment and certification procedures. In addition, research programs in engineering are usually subject to quality assurance. There also are various quality assurance and quality control programs in place to ensure that engineering and design processes, the management of engineering firms, and large engineering processes meet quality standards. Ethical considerations often have a limited role in such quality assurance processes, although these processes may test for criteria like professionalism, integrity, stakeholder involvement, avoidance of conflict of interest and consideration of social and environmental impacts. As in research, there is also a focus on compliance in engineering, however, laws and regulations are often less easily recognizable as being based on ethical principles. Many engineering firms have ethics and compliance divisions or officers.

As for research, there are also assessments in technology and innovation of value and impact. The main type of assessment for this is *impact assessment*.[24] Impact assessment (IA) is a structured process for considering the social, economic and environmental considerations of proposed actions, at a stage at which there is still an opportunity to modify or even abandon them. It is often applied to large infrastructural projects, but there are also methods for assessing new industrial products. *Environmental impact assessment* (EIA) is an important type of impact assessment that predicts the environmental consequences (positive or negative) of a plan, program, or project prior to a decision to move forward with it. *Social impact assessment* (SIA) is a second major category that is concerned with the analysis, monitoring and managing of intended and unintended social consequences, both positive and negative, of

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[24] European Science Foundation, *The Challenges of Impact Assessment,* Working Group 2: Impact Assessment, ESF Member Organisation Forum on Evaluation of Publicly Funded Research, 2012. http://www.esf.org/coordinating-research/mo-fora/evaluation-of-publicly-funded-research.html.

proposed actions. Social impacts may include impacts on people's way of life and quality of life, culture, health, rights, property, safety, community and political systems. EIAs and SIAs are mandatory activities within a host of different international and European conventions as well as international environmental law.

Risk assessment (RA) is the quantitative or qualitative assessment of risk to life, health, environment, property or processes. It is often included in EIA and SIA, but also takes place as an independent exercise. *Health impact assessment* (HTA) is assessment of the potential effects of plans, programs or projects on the health of a population, and the distribution of those effects within the population. *Gender impact assessment* refers to the assessment of policies and actions for their different impacts on the position of men and women, with the aim of redirecting policies and initiatives towards gender equality.

While these types of impact assessment can be applied to any kind of project, policy, or plan, *technology assessment* (TA) is a form of impact assessment that is specifically developed to assess impacts of a new technology. TA investigates the potential and actual effects of new technologies on industry, the environment and society, evaluates such effects and develops instruments to steer technology development in more desirable directions.[25] TA makes such assessments on the basis of known or potential applications of the technology. It pays special attention to consequences that are unintended, indirect or delayed.

Ethics assessment is, overall, different from impact assessment since, as argued, a large part of ethics assessment is not concerned with impacts of research and innovation but with ethical issues within research and innovation practices. However, one approach within ethics assessment, *ethical impact assessment* (ETIA),[26] is very much concerned with impacts, and qualifies as a category of impact assessment. ETIA is different from other categories of impact assessment in two ways: first, it is only concerned with impacts that have ethical relevance or that raise ethical issues. These are impacts that concern or affect rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good. Second, EIA does not merely observe or describe impacts, but also ethically evaluates them. For example, it would not just observe that a new technology has a disproportionately negative effect on the health and well-being of women or minorities, but would also assess the ethical acceptability of these impacts through the application of principles of justice and non-discrimination.

In spite of these differences, ETIA still overlap with other types of impact assessment. First, ETIA often relies on other, more traditional types of assessment for identifying impacts. Second, some types of impact assessment incorporate ethical concerns. Particularly, contemporary values and principles of social impact assessment, as specified in the *International Principles for Social Impact Assessment* of the International Association for Impact Assessment (IAIA) that were established in 2003,[27] prescribe that both the SIA and the assessed project should contribute to the empowerment of vulnerable groups in communities, include considerations of gender, and be guided by respect for human rights.

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[25] Grunwald, A., "Technology Assessment: Concepts and Methods", in A. Meijers, *Philosophy of Technology and Engineering Sciences. Handbook of the Philosophy of Science vol. 9.* Amsterdam: Elsevier, Amsterdam, 2009; Tran, T. and T. Daim., "A taxonomic review of methods and tools applied in technology assessment", *Technological Forecasting and Social Change*, Vol. 75, No.9, 2008, pp. 1396-1405.

[26] Wright, David, "A framework for the ethical impact assessment of information technology", *Ethics and Information Technology*, Vol. 13, No. 3, September 2011, pp. 1-28.

[27] Vanclay, Frank, "International Principles For Social Impact Assessment", *International Association for Impact Assessment*. http://www.iaia.org/publicdocuments/sections/sia/IAIA-SIA-International-Principles.pdf

The IAIA framework includes rather explicit reference to ethical principles like human rights, equity, justice, democratization, and accountability.

So, contemporary social impact assessment is driven by moral concerns and goes beyond merely describing impacts to include measures for monitoring and managing these impacts in order to promote positive outcomes. Also, recent other impact assessment approaches serve to further blur the distinction between ETIA and traditional forms of impact assessment. These include *human rights impact assessment* (HRIA)[28] and *privacy impact assessment* (PIA)[29]. See figure 1 for a diagram which illustrates the relation between ethics assessment, ETIA, and other forms of impact assessment. This figure makes a distinction between *practice-internal* and *practice-external ethical issues*; ethical issues relating to impacts of R&I are external to the practice of R&I because they occur later on, whereas practice-internal ethical issues take place during and R&I practices or are directly linked to such practices. The relation between ETIA and other types of impact assessment is considered in greater detail in the subreport on impact assessment in annex 1.

ETHICS ASSESSMENT   IMPACT ASSESSMENT

practice-internal research ethics and engineering ethics (human subjects, integrity, etc.)

ETHICAL IMPACT ASSESSMENT (ethical assessment of societal impacts beyond R&D practice)

Technology assessment

Social impact assessment

Environmental impact assessment
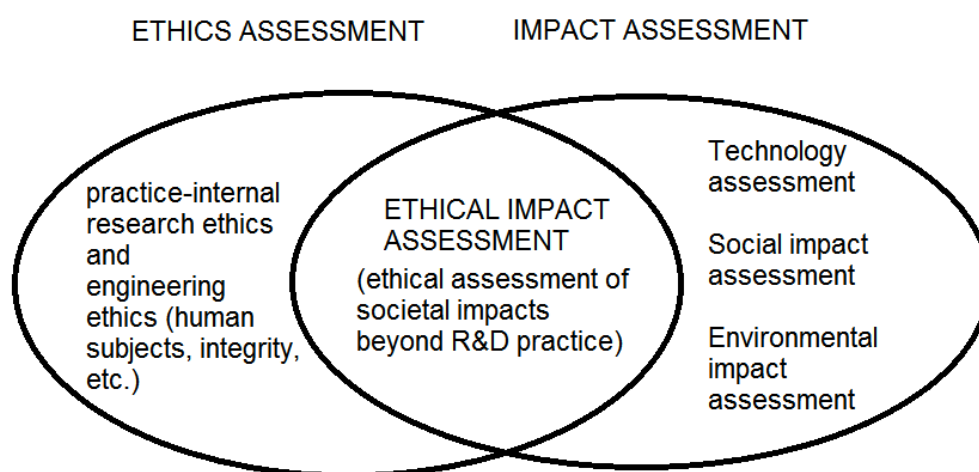
Fig. 1 **The intersection of ethics assessment and impact assessment**

Stakeholder engagement and public participation

Although not technically types of assessment, there are two other types of activities that also deserve mention alongside ethics assessment because they have similar aims. They are stakeholder engagement and public participation. *Stakeholder engagement* (or involvement or participation) is the inclusion of stakeholders in decision-making processes and activities in R&I. Stakeholders are individuals, groups or organisations who have an interest in an R&I activity because they can be affected by it, or that are in a position to influence the R&I activity. *Public participation* (or engagement) is the involvement of the general public in R&I activities and decision-making.

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[28] Wright, D. and P. De Hert (eds), *Privacy Impact Assessment*, Springer, 2012; Office of the Australian Information Commissioner, "Guide to undertaking privacy impact assessments".
http://www.oaic.gov.au/images/documents/privacy/privacy-resources/privacy-guides/guide-to-undertaking-pias.pdf
[29] The World Bank, *Human Rights Impact Assessments*.
http://siteresources.worldbank.org/PROJECTS/Resources/40940-1331068268558/HRIA_Web.pdf

An increasing number of research and innovation projects in both the public and private sector now include stakeholder engagement. A lesser number include public participation. These developments have been preceded by several others. The 1960s and 1970s saw a push for increased public dialogue about new developments in science and technology. The idea that morally controversial developments in science and technology should be the subject of a broad public dialogue has gained a foothold in many countries, and is often facilitated by governments.[30] The 1960s and 1970s also saw the emergence of a movement toward participatory design, which is an approach that aims to actively involve all stakeholders, such as end users, citizens and representatives of interest groups, in the design process in order to help ensure that products are usable and acceptable to stakeholders.[31] Corporations use stakeholder engagement and public participation to increase public acceptance for their activities and to enhance public trust. [32]

In principle, stakeholder engagement and public participation, on the one hand, and ethics assessment on the other, are distinct activities with different aims. The former are means of making R&I more socially inclusive and democratic and to enhance the social acceptability and societal quality of the products and impacts of R&I. This is not the same as ensuring that ethical issues in R&I are addressed. There is, however, a reasonable expectation that stakeholder engagement and public engagement lead to more ethical R&I, because a greater number of viewpoints and interests will be represented in the R&I process. However, it is not guaranteed that relevant ethical considerations will be represented in them, or that ethical issues will be considered carefully, unless they are explicitly made part of the discussion. Another development is that ethics assessment sometimes includes stakeholder engagement and public participation: ethics committees and officers sometimes consult stakeholders or the general public before issuing an opinion. In addition, ethics committees are sometimes set up to include stakeholders as members of the committee.

Responsible Research and Innovation

The recent approach of Responsible Research and Innovation (RRI) builds on ethics assessment and guidance, as well as on stakeholder involvement and public engagement, and attempts to incorporate them into one approach. This approach, supported by the European Commission, amongst others, aims to better align research and innovation processes with societal needs and to work towards desirable societal, environmental and sustainability outcomes.[33] RRI will be discussed in more detail in section 2.5.

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[30] Chopyak, J. and P. Levesque, "Public participation in science and technology decision making: trends for the future", *Technology in Society,* Vol. 24, No. 1-2, 2002, pp. 155–166.

[31] Simonsen, J. and T. Robertson, (eds.), *Routledge International Handbook of Participatory Design*, Routledge, 2013.

[32] Other relevant developments are the approach of *Value-Sensitive Design*, originally initiated by Batya Friedman, which includes values and stakeholders in design processes, and the *Living Labs approach*, which involves open-ended innovation platforms that bring together all stakeholders, including end-users, industrialists, policy-makers and others in order to experiment with innovations and create breakthroughs. See Friedman, B., P. Kahn, and A. Borning, (2006), Value Sensitive Design and Information Systems, in P. Zhang and D. Galletta (eds.), *Human-Computer Interaction in Management Information Systems: Foundations,* M. E. Sharpe, Armonk, NY, 2006, and European Commission, *Study on the potential of the Living Labs approach: Including its relation to experimental facilities: For future Internet related technologies.* Final report on a study performed by Altec, Version 1.1. 2009.

[33] Jacob, K., J. van den Hoven, et al., *Options for Strengthening Responsible Research and Innovation: Report of the Expert Group on the State of the Art in Europe on Responsible Research and Innovation,* European Commission, Brussels, 2013.

2.5 THE POLICY CONTEXT

The aim of this section is to provide insight into the policy context of ethics assessment and guidance of R&I. It will begin with a brief introduction to recent developments in EU science and innovation policy, and then move on to discuss EU policies and actions to address ethical issues in R&I and to better align R&I with the needs and values of society. The section ends with a discussion of global policies and guidelines for consideration of ethical and social issues in research and innovation by intergovernmental and supranational organisations. National policies will not be considered here, but are discussed in the country reports in annex 4 as well as in SATORI deliverable D3.1 (A report on the legal frameworks that guide or constrain ethical procedures within research in the EU).

EU research and innovation policy

Research and innovation first became a policy issue for the European Union in 1986. A major EU agreement, the *Single European Act*, made it an important policy goal to strengthen science and technology to support industry and increase international competitiveness. Research and innovation became still more central in EU policy in 2000, when another major EU agreement, the Lisbon Strategy, was established. The *Lisbon Strategy* was an action and development plan for the EU economy between 2000 and 2010. It aimed to make the EU "the most competitive and dynamic knowledge-based economy in the world capable of sustainable economic growth with more and better jobs and greater social cohesion".[34] It identified innovation as the motor for economic change, and gave importance to knowledge and learning as processes necessary for economic growth. It also put forward the goals of social, and environmental renewal and sustainability.

The Lisbon Strategy built on a previous document, also ratified in 2000, which established the *European Research Area* (ERA), a system of scientific research programmes, procedures and policies aimed at integrating the scientific resources of the European Union and creating the equivalent of a "common market" for science that included free circulation of researchers, knowledge and technology and international connectivity. The Lisbon Strategy and ERA led to the creation of the *Framework Programmes for Research and Technological Development* (FP1 through FP8, with FP8 being called "Horizon 2020"), which are funding programmes to support and foster research in ERA. Another product of the ERA includes *Joint Technology Initiatives* (JTIs), which are public-private partnership programs for research and innovation that aim to produce knowledge and innovations that are economically and politically important to the EU.

In 2010, the EU established a new ten-year economic strategy, *Europe 2020,* the objective of which is "smart, sustainable, inclusive growth" with enhanced coordination of national and European policy.[35] The Europe 2020 strategy contains, prominently, an initiative for an Innovation Union, which is the equivalent of an ERA for innovation and aims to strengthen the innovation chain. It has as a major aim to re-focus R&D and innovation policy on major

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[34] European Parliament and the Council, *Lisbon European Council 23 and 24 March Presidency Conclusion*
[35] European Commission, Europe 2020: A European strategy for smart, sustainable and inclusive growth, COM(2010) 2020, Brussels, 3.3.2010.
http://ec.europa.eu/eu2020/pdf/COMPLET%20EN%20BARROSO%20%20%20007%20-%20Europe%202020%20-%20EN%20version.pdf

EU and global societal challenges, such as climate change, energy security, the ageing population, and the protection of freedom and security.

Ethics and Society in EU R&I policy

From its beginning, it was not just economic growth but also the improvement of European society that was at the heart of EU R&I policy. This emphasis on society, including a reorientation of EU R&D and innovation towards societal challenges and sustainability, has increased over the years. This reorientation is achieved in large part through the Framework Programmes of the EU, which fund EU research. The latest framework programme, Horizon 2020, has a budget of 70 billion euros, a large part of which is devoted to funding research for meting grand societal challenges that face the EU.[36] These challenges are organised under seven themes:

- Health, demographic change and wellbeing;
- Food security, sustainable agriculture and forestry, marine and maritime and inland water research, and the bioeconomy;
- Secure, clean and efficient energy;
- Smart, green and integrated transport;
- Climate action, environment, resource efficiency and raw materials;
- Europe in a changing world - inclusive, innovative and reflective societies;
- Secure societies - protecting freedom and security of Europe and its citizens.

Since 2001, there have been initiatives in the framework programme to improve the science-society relationship, which is part of the policy for the development of the ERA. The Directorate-General for Research and Innovation of the European Commission first instituted the "Science and Society" Action Plan in 2001.[37] In the 7th Framework Programme (FP7), the name of the research policy was changed to "Science *in* Society" and had a greater emphasis on public engagement, involvement of civil society in research agenda-setting, and two-way dialogue between science and society stakeholders. More recently, the name became "Science *with and for* Society" so as to emphasize the goal of improved alignment of research with the societal values, needs and expectations of European society, and involves collaboration of all societal actors.

In line with these Science and Society programmes, the Directorate-General for Research and Innovation also started work in 2010 on a framework for Responsible Research and Innovation (RRI), with the objective that all societal actors (researchers, industry, policymakers and civil society) work together during the whole research and innovation process in order to better align both the process and its outcomes, with the values, needs and expectations of European Society. The RRI approach includes six central topics or "keys": societal engagement, gender equality, science education, open access, ethics and governance. The approach is fully implemented in Horizon 2020, the current framework programme. In Horizon 2020, RRI is the central focus of the Science with and for Society programme, but it

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[36] European Commission, *Horizon 2020 in brief.*
http://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/H2020_inBrief_EN_FinalBAT.pdf
[37] Commission of the European Communities, Commission Working Document: Science, society and the citizen in Europe, SEC(2000) 1973, Brussels, 14.11.2000. ftp://ftp.cordis.europa.eu/pub/rtd2002/docs/ss_en.pdf ;
European Commission, *Science and Society Action Plan*, 2001. http://ec.europa.eu/research/science-society/pdf/ss_ap_en.pdf.

is also a cross-cutting theme for the entire framework programme, and RRI areas of concern are formulated as requirements across all calls for research of Horizon 2020.

Many definitions of RRI exist, most of which state that it includes a goal that processes and products of research and innovation are socially desirable and ethically acceptable, and most of which emphasize the longer term consequences and impacts of R&I. The "official" EC definition of RRI similarly emphasises broad impact and the desire for inclusiveness in research and innovation processes, but it also clearly connects RRI with the values, needs and desires of European society:

> RRI is an inclusive approach to research and innovation (R&I), to ensure that societal actors work together during the whole research and innovation process. It aims to better align both the process and outcomes of R&I with the values, needs and expectations of European society.[38]

Ethics is a central concept in the definitions of RRI. Ethical acceptability or alignment with societal values is one important aspect of RRI. Ethics is an opportunity and a challenge in developing more 'RRI-like' research processes and aligning them with broader societal values.

The discourse and the policies on what an RRI approach entails and how it should be operationalised is still far from settled. In 2013 report, the EC outlines various options for implementing RRI in the EU, ranging from "business as usual" to legally binding initiatives.[39] The in-between option is currently at work: increased coordination between the Member States, and increased funding for RRI, but no legally binding initiatives. This includes the option for developing policy instruments like codes of conduct, and standards for RRI practice, as well as trainings of researchers, policymakers, funders and industry and business on RRI practice. The ambition of the SATORI project falls under this option as it develops a standard that can be adopted voluntarily, and that would be seen as a benchmark for ethics in an RRI approach. Already the ISO norm 26000 functions as the benchmark for Corporate Social Responsibility (CSR), and one could imagine similar standard norms developed for RRI.

Additional ethics regulations and guidelines for R&I at the EU level

The EU has produced a number of guidelines (soft-law instruments) for ethics assessment of research. Issues taken up here are diverse and include among others: research misconduct and misuse, issues in social sciences and humanities, clinical trials on medical products with paediatric subjects, informed consent, animals, dual use and research in developing countries. See the SATORI Deliverable 3.1 for a detailed account of EU and member state regulations and soft-law instruments[40]. An example of a soft law tool that has been developed within the discourse of 'responsible research and innovation' is the 2008 Code of Conduct for Responsible Nanosciences and Nanotechnologies Research.

The EU Convention on Human Rights and Biomedicine (the Oviedo Convention), adopted by the Ministers of the Council of Europe in 1997, is an important agreement that has been

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[38] European Commission, "Responsible Research and Innovation (RRI)".
http://ec.europa.eu/programmes/horizon2020/en/h2020-section/science-and-society
[39] European Commission, *Options for Strengthening Responsible Research and Innovation*, 2013.
http://ec.europa.eu/research/swafs/pdf/pub_public_engagement/options-for-strengthening_en.pdf
[40] Available here: http://satoriproject.eu/deliverables/

signed by most European states and sets out the fundamental principles that apply to day-to-day medicine, in addition to new technologies in human biology and medicine.[41] The Additional Protocol Concerning Biomedical Research[42] of the EU confirms the general principles and provides more specific rules for the role of ethics committees in research, the conditions for adequate informed consent, confidentiality and the right to information.[43] These two agreements have strongly shaped national legislation in the area of ethics of biomedicine.

The EU commission is also dedicated to developing a policy framework for a more responsible R&I in industry and business. The EU sees Corporate Social Responsibility (CSR) as key to the sustainability of EU industry and business, and it has developed a number of policies in this area. EU policies build, among others, on the ISO 26000 Guidance Standard on Social Responsibility. Recent EU strategy is taking a turn from emphasizing compliance to putting an emphasis on innovation.

In addition, all research funded under the EU Horizon 2020 work program must go through ethical evaluation, and there are restrictions based on ethical considerations on what research gets funded.[44]

Regulations and guidelines for R&I at the global level

The tendency to open up innovation processes for more actors and linking for thinking about broader impacts can be recognised outside the EU as well. Key intergovernmental and supranational organisations include the United Nations, UNESCO, OECD and the World Health Organization (WHO). These organisations have been instrumental in developing global policy frameworks for ethics, R&I and human rights. Policy frameworks from these organisations are often bound up with goals for societal development across a wide area of topics at the global level. These topics include: education, fair distribution of costs and benefits, access, empowerment, the application of knowledge to address societal challenges, capacity-building, research ethics, international collaboration and many more.

Global organisations such as UNESCO, the WHO and the UN argue for more inclusive and socially responsible models of health and life sciences research and for a fair distribution of the costs and benefits of scientific progress and its products. As relevant policy guidelines the organisations point to the Universal Declaration on Bioethics and Human Rights (2005), Article 27 of the Universal Declaration of Human Rights and Article 15 of the International Covenant on Economic, Social and Cultural Rights. UNESCO has developed several guidelines for ethics and human rights in research and innovation. The OECD has developed

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[41] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.4.1997. http://www.coe.int/t/dg3/healthbioethic/Activities/01_Oviedo%20Convention/default_en.asp

[42] Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS no. 195), Strasbourg, 25.1.2005.
http://conventions.coe.int/Treaty/EN/Summaries/Html/195.htm

[43] European Commission, *Ethics for researchers: Facilitating Research Excellence in FP7.* http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

[44] European Parliament and the Council, Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC, 11.12.2013.
http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf. Also see the report on ethics assessment in the EU in annex 5 to this report.

guidelines centering around innovation and CSR. The WHO has developed guidelines for (biomedical) ethics committees.

Global and EU policy initiatives are discussed in more detail in chapter 7 and in the reports on EU and global ethics assessment and guidance in annex 5 to this report.

3 ISSUES, PRINCIPLES AND APPROACHES IN ETHICS ASSESSMENT

3.1 INTRODUCTION

In this chapter, we introduce major traditions in ethics assessment of research and innovation, and the approaches, methods and issues that are characteristic of them. A rough division can be made between ethical approaches with a focus on research (*research ethics*) and those with a focus on technology and innovation (*engineering ethics*, *ethics of technology* and *ethics of innovation*). In section 3.2, we discuss research ethics, including its aims, historical development, typical approaches, and guiding principles. In section 3.3, we offer an analogous discussion of ethical approaches to technology and innovation. A more in-depth discussion of both of these areas can be found in chapter 4 and in the corresponding reports in annex 2 on ethics assessment in different scientific fields.

The aim of the final section is to bring the ethical assessment of impacts into sharper focus. This section offers an analysis of the role of impacts in research ethics and in the ethics of engineering, technology and innovation, and the kinds of novel approaches that have recently been developed to give a greater role to the consideration to ethical issues concerning the impacts of research and innovation.

Research and innovation involve different types of practices and a distinction can be drawn between the practices themselves and any consequences or impacts that later result from them. For example, research on cancer may later result in a new drug to fight cancer, and the development of a new hydrogen vehicle engine may later result in fewer emissions of CO_2 by automobiles, and perhaps also in an increase in explosions in car engines. The research and innovation practices are separate from these consequences, which take place later in time and at different locations. Ethical assessment both focuses on ethical issues that are inherent to research and innovation practices themselves, and on ethical issues concerning these later impacts. As impacts are not always easy to predict, the ethical assessment of impacts, and associated responsibilities for researchers and innovators, have previously received comparatively little attention in ethics assessment.

This chapter will not go into depth regarding the different *methodologies and frameworks for ethics assessment and guidance*. These will, instead, be discussed in chapter 4, which offers an analysis of ethical frameworks and methods for ethics assessment in different scientific fields, and in chapter 5, which provides a discussion of the frameworks, methods, procedures and protocols of different types of organisations that engage in ethics assessment and ethical guidance.

Many of the principles, issues and approaches discussed in this chapter will be discussed in depth in annex 1 to this report. This annex contains reports on the topics of ethical and

traditional impact assessment, scientific integrity, social responsibility, human subjects' research, institutional integrity, animal welfare, dual use and risk.

3.2   RESEARCH ETHICS

We define "research ethics" as the application of ethical principles and professional codes of conduct to the activity of doing scientific research and the practice of investigating and reflecting upon these principles and codes and their application. Research ethics emerged as a means of addressing ethical issues in clinical research in the 20th century. It is often understood to have its origins in the scandals that took place in Nazi Germany, namely medical experiments carried out by Nazi doctors on concentration camp prisoners during the Second World War. As a response to the malpractices that were revealed during the Nuremberg trials, the norms of modern (medical) research ethics were initially codified by the Nuremberg Code in 1947, which stated that the consent of the human subject was absolutely essential in medical research, and that the benefits of research must outweigh the risks. It was further developed in 1964 by the World Medical Association's Declaration of Helsinki, which contained recommendations guiding medical doctors in biomedical research involving human subjects. Concerns regarding the effectiveness of the existing regulation came to the fore when attention was drawn to various ethical concerns in ongoing research.[45] These concerns led to the revision of the Declaration in 1975, which introduced the requirement for a formal independent committee review of research protocols.[46]

The Declaration of Helsinki puts forward ethical principles for the conduct of medical research on human subjects, including research on identifiable human material and data.[47] The basic principle behind the declaration is that the well-being of the individual must take precedence over all other interests in all kinds of research.[48] The declaration also sets out principles for medical research conduct and principles for medical research combined with medical care.[49] The Declaration constitutes an international standard for good clinical practice.

There is now a wide array of guidelines for medical research in place, including the Council for International Organizations of Medical Sciences' (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects[50] and UNESCO's Universal Declaration on Bioethics and Human Rights.[51] Some guidelines, such as the CIOMS' guidelines have a merely advisory status, while others, such as the Declaration of Helsinki are binding on members of particular professions.[52] Others have legislative status, for example, national laws and European laws such as the European Union's Clinical Trials Directive.[53]

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[45] European Commission, *European Textbook on Ethics in Research*. http://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf
[46] Ibid.
[47] European Commission, *Ethics for researchers: Facilitating Research Excellence in FP7*. http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf
[48] Ibid.
[49] Ibid.
[50] Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. http://www.cioms.ch/publications/layout_guide2002.pdf
[51] United Nations Educational, Scientific and Cultural Organization (UNESCO), *Universal Declaration on Bioethics and Human Rights*. http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/
[52] European Commission, *European Textbook on Ethics in Research*. http://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf
[53] Ibid.

The 1960s and 1970s also saw the emergence of institutionalised research ethics committees and review boards, the principal task of which is to engage in independent oversight of clinical trials by assessing clinical trial proposals and by expressing an opinion on clinical trial protocols, investigators, facilities and practices of informed consent. Research ethics committees (RECs) are often local bodies within the organisations in which research is undertaken. They may comprise scientists, ethicists, members with other expertise and members of the general community. In the 1980s and later, National Ethics Committees (NECs) also emerged. NECs normally have an advisory or standard-setting role with respect to national policies and legislation for research. They may be part of national governments or instituted by national governments.

Although research ethics has long been synonymous with ethics of medical research, recent decades have seen an increasing focus on research ethics in the social and behavioural sciences.[54] As in the medical sciences, much research in these fields involves human subjects, which are the major focus of ethical consideration. Indeed, research ethics concerning human subjects is, to some extent, a field of its own that includes the medical, social and behavioural sciences, and even parts of the humanities and engineering sciences. Research ethics in the social and behavioural sciences has been greatly influenced by approaches developed for the medical sciences, but these fields have also started to develop their own approaches.[55] The natural sciences also have a tradition of research ethics, which has developed largely separately from that of the medical sciences. The natural sciences rarely involve human subjects in their research, and research ethics tends to focus on scientific integrity in research practice.[56] The engineering sciences do not have a distinct tradition of research ethics, but research is sometimes discussed as one of the practices in which engineers engage. The humanities do not have much of a tradition in research ethics, and mostly borrow research ethics concepts and approaches from the social sciences and medicine.

Research ethics and human rights

There is a strong link between research ethics and human rights, with significant overlaps and both fields influencing each other.[57] The EU Convention on Human Rights and Biomedicine (the Oviedo Convention),[58] adopted by the Ministers of the Council of Europe in 1997, is a good example. This international convention has been signed by most European states and sets out the fundamental principles that apply to day-to-day medicine, in addition to new technologies in human biology and medicine.[59] The Additional Protocol Concerning

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[54] See Israel, M., *Research Ethics and Integrity for Social Science: Beyond Regulatory Compliance*, Sage, 2014; Israel, M. and I. Hay, *Research Ethics for Social Scientists*, Sage, 2006; Dench, Sally, Ron Iphofen and Ursula Huws, "An EU Code of Ethics for Socio-Economic Research", *RESPECT Project*. http://www.respectproject.org/ethics/412ethics.pdf

[55] Ibid.

[56] See for example: D'Angelo, J., *Ethics in Science: Ethical Misconduct in Scientific Research,* CRC Press, 2012.

[57] European Commission, *Ethics for researchers: Facilitating Research Excellence in FP7.* http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

[58] Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms, Rome, 4.XI.1950. https://ec.europa.eu/digital-agenda/sites/digital-agenda/files/Convention_ENG.pdf

[59] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.4.1997. http://www.coe.int/t/dg3/healthbioethic/Activities/01_Oviedo%20Convention/default_en.asp

Biomedical Research[60] of the EU confirms the general principles and provides more specific rules for the role of ethics committees in research, the conditions for adequate informed consent, confidentiality and the right to information.[61] At the global level, the Universal Declaration on Bioethics and Human Rights,[62] drafted by the International Bioethics Committee of UNESCO and adopted in 2005, provides a comprehensive framework of principles that should guide biomedical activities, in order to ensure that they are in conformity with international human rights law.

Research ethics within the European regulatory framework is based on the explicit commitment to human rights. Compliance with human rights is crucial for all policy domains and is enshrined in the European treaties.[63] In order to further strengthen this commitment, the European Union adopted its own human rights legislation, that is, the European Charter of Fundamental Rights.[64] The Charter of Fundamental Rights of the European Union (2010/C 83/02)[65] describes the rights, freedoms and principles of the citizens of the EU Member States. The core values of the Union are described as human dignity, freedom, equality and solidarity. Several principles from the Charter are relevant in the context of research, in providing the basis for important ethical guidelines and in supporting research conduct. These include, amongst others, the right to the integrity of the person (Article 3), respect for private and family life (Article 7), protection of personal data (Article 8) and freedom of the arts and sciences (Article 13).

Research ethics and professional ethics

There are two dimensions to research ethics that go hand in hand: they are (1) research practices (and corresponding proposals, protocols, and results) and (2) the conduct of individual researchers.   The primary focus of research ethics is to ensure that research practices, whether undertaken by individual researchers, groups of researchers, or research organisations, conform to ethical standards. But research ethics also concerns itself with professional ethics and standards of professional conduct for researchers. The researcher has a professional work ethic to consider, which includes, as a central component, the responsibility to ensure that research is of good quality.[66] Research activity is driven by a number of implicit and explicit norms that dictate what *good* science is. For example, the Helsinki Declaration sets out the requirements for medical research involving human subjects: such research "must conform to generally accepted scientific principles" and "be based on a thorough knowledge of the scientific literature".[67]

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[60] Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS no. 195), Strasbourg, 25.1.2005.
http://conventions.coe.int/Treaty/EN/Summaries/Html/195.htm
[61] European Commission, *Ethics for researchers: Facilitating Research Excellence in FP7*.
http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf
[62] United Nations Educational, Scientific and Cultural Organization (UNESCO), *Universal Declaration on Bioethics and Human Rights*. http://portal.unesco.org/en/ev.php-
URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
[63] Ibid.
[64] European Commission, *Ethics for researchers: Facilitating Research Excellence in FP7*.
http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf
[65] European Parliament and the Council, Charter of Fundamental Rights of the European Union, OJ C 364/1, 18.12.2000. http://www.europarl.europa.eu/charter/pdf/text_en.pdf
[66] German Reference Centre for Ethics in the Life Sciences, "Professional Ethics", *European Research Ethics*.
http://www.ethicsweb.eu/ere/forskarensetik.shtml
[67] World Medical Association, "Declaration of Helsinki".
http://www.wma.net/en/30publications/10policies/b3/17c.pdf

There have also been attempts to summarise central norms, in particular in the so-called CUDOS norms drawn up by Robert Merton in the early 1940s. [68] Merton argues that it is the entire structure of technical and moral norms which implement the institutional goal of science, i.e. the extension of certified knowledge. There are four 'institutional imperatives' – universalism, communism, disinterestedness and organized scepticism – which together comprise the ethos of science. Researchers, like all other professionals, must also follow national and local rules, directions and norms concerning workplace conduct regarding issues such as discrimination, harassment and correct conduct with colleagues and the public. [69] Various researcher categories also have their own professional codes of ethics that address various aspects of the researcher role and activity. [70] For example, the Code of Ethics and Conduct established by the British Psychological Society[71] sets out ethical principles and standards that work both to establish the foundation for reasoned judgements and the ethical conduct that the society expects of its members.

The European Commission has adopted a European Charter for Researchers and a Code of Conduct for the Recruitment of Researchers.[72] The European Charter for Researchers addresses the roles, responsibilities and entitlements of researchers and their employers or funding organisations. General principles and requirements applicable to researchers include research freedom, professional responsibility, accountability, good practice in research, dissemination and exploitation of results, public engagement, to name just some of the requirements. Professional responsibility includes ensuring relevance of research to society, avoiding plagiarism and abiding by the principle of intellectual property and joint data ownership in the case of research carried out in collaboration with a supervisor(s) and/or other researchers.

Issues and principles in research ethics

Research ethics has traditionally focused on six major issues in research:[73]

> (1) ethical issues in the use of human subjects
> (2) ethical issues in the use of animals
> (3) scientific integrity
> (4) collegiality
> (5) institutional integrity (the institutional setting for research)
> (6) social responsibility

The first two categories apply to many but not all scientific fields and practices, while the final four apply to all research fields and practices.

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[68] Merton, R.K., "The Normative Structure of Science", in N. W. Storer (ed.), *The Sociology of Science: Theoretical and Empirical Investigations*, The University of Chicago Press, Chicago, 1973, pp. 267.278; Merton, R.K., *Sociological Ambivalence and Other Essays*, The Free Press, A Division of Macmillan Publishing Co., Inc., New York, 1976.
[69] German Reference Centre for Ethics in the Life Sciences, "Professional Ethics", *European Research Ethics*. http://www.ethicsweb.eu/ere/forskarensetik.shtml
[70] Ibid.
[71] British Psychological Society, "Code of Ethics and Conduct". http://www.bps.org.uk/system/files/documents/code_of_ethics_and_conduct.pdf
[72] European Commission, "The European Charter and Code for Researchers". http://ec.europa.eu/euraxess/index.cfm/rights/whatIsAResearcher
[73] Pimple, K., "Six domains of research ethics: A heuristic framework for the responsible conduct of Research", *Science and Engineering Ethics,* Vol. 8, No. 2., 2002, pp. 191-205.

These six issues arise within the professional activity of doing research. Two issues, scientific integrity and collegiality, are exclusively issues within professional ethics: they only pertain to individual conduct, not to a research practice. Two other issues, ethical issues in the use of human subjects and animals, arise during the course of conducting research, and concern research practice. The remaining two, institutional integrity and social responsibility, both pertain to professional ethics and to research practice. We now briefly review these six issues.

(1) *Protection of human subjects*

These are ethical issues in the relationship between researchers and human subjects in research. Ethical issues include informed consent, assent, confidentiality and anonymity, deceit, debriefing, protection from harms, and the relation between research risks and potential benefits. Ethical issues concerning human subjects are most pervasive in the medical, social and behavioral sciences. For more detail, see the subreport on ethics of human subjects' research in annex 1 of this report.

(2) *Animal welfare*

These are ethical issues in the relationships between researchers and animal subjects. They concern consideration for pain and suffering of lab animals, animal rights, and whether sufficient action is taken to reduce the unnecessary use of lab animals. These issues seem to be most relevant to the medical and life sciences and to psychology. For more detail, see the subreport on animal welfare in annex 1 of this report.

(3) *Scientific integrity*

These are ethical issues in the relationship between researchers and the truth, or, put differently, regarding the trustworthiness of research activities. Scientific integrity underlines the necessity to undertake research in an honest, accurate, truthful, reliable and accountable manner. It prescribes values and practices such as truthfulness, honesty and openness in reporting and communicating, impartiality and independence in research activities, accuracy and duty of care. It involves the avoidance of fraud, data manipulation, falsification and fabrication, and the avoidance of bias, whether intentional or unintentional. For more detail, see the subreport on scientific integrity in annex 1 of this report.

(4) *Collegiality*

These are ethical issues in the relationship amongst researchers, such as plagiarism, data sharing and timely publishing, peer review, authorship, intellectual property, confidentiality, and candor. Some of these issues are discussed in the subreport on scientific integrity in annex 1 of this report.

(5) *Institutional integrity*

Ethical issues relating to institutional integrity concern the extent to which the institutions of research and innovation are organized and act in an ethical way. This includes relationships between researchers and research units, between research institutions and sponsoring

institutions (such as industry), funding agencies, and the government. Ethical issues include conflict of interest,[74] regulatory compliance, institutional oversight, and others. For more detail, see the subreport on scientific integrity in annex 1 of this report.

(6) *Social responsibility*

These are ethical issues concerning the relationship between research practices and the common good. They concern whether the activity is (potentially) valuable to society. Most centrally, this category includes the question as to whether potential or actual impacts on society of the research activity are justified. Other issues under this category include the setting of research priorities, fiscal responsibility in science funding, and the role of researchers and science institutions in advocacy and public service. Note that social responsibility is a type of ethical responsibility that concerns society and the common good. Researchers may have various other ethical responsibilities, such as responsibilities towards human and animal subjects, colleagues, clients, and the organisations they work for. For more detail, see the subreport on social responsibility in annex 1 of this report.

3.3 ENGINEERING ETHICS AND ETHICS OF TECHNOLOGY AND INNOVATION

While science is concerned with understanding phenomena and finding truth, innovation is concerned with creating goods or services that have value and meet needs. Innovation results in the creation of products, processes, methods or ideas that have use value and that can serve markets, governments or society at large. Due to the conceptually different aims of scientific research and innovation, the ethics of innovation has evolved largely separately from research ethics. Where in research ethics, the driving field has been medicine, in the ethics of innovation, it has been engineering. The ethics of innovation owes a large part of its heritage to *engineering ethics*, an area of professional ethics that has, itself, its early roots in the late 19th and early 20th century but gained shape in the 1960s and 1970s.[75] Engineering ethics has developed as a response to health, safety and environmental hazards resulting from engineered products and systems, and resulting from disasters such as collapsing bridges, exploding automobiles and environmental catastrophes. In the 20th century, engineering societies developed codes of ethics that prescribed, most centrally, that engineers should hold paramount the safety, health and welfare of the public and strive for environmentally sound practices.

In engineering, a distinction is sometimes made between engineering science and engineering design. *Engineering science* refers to applied scientific research concerned with the understanding of natural phenomena for practical applications. *Engineering design* concerns the development of plans for the realisation of technological products, systems and processes. The ethical issues in the two areas are somewhat different. Ethical issues in engineering research are mostly similar to those of research in the fundamental natural sciences, with human subjects and animal research as additional issues. Issues include scientific integrity, institutional integrity, social responsibility, human subjects' research, and similar issues.

Ethical issues in engineering design are somewhat different because the aim of design is not new knowledge, as in research, but interventions in the real world. Many of the ethical issues

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[74] This issue could also be categorized under scientific integrity. It can be caused by a failure by individual scientists to act responsibly, and institutional failure, or both.

[75] For an introduction, see Harris, C., M. Pritchard, M. Rabins, R. James, and E. Englehardt, *Engineering Ethics: Concepts and Cases*, 5th edition, Cengage Learning, 2013.

therefore concern the nature and potential impacts of these interventions. Other than these issues, however, there are also ethical issues more internal to the design practice, which are partially similar to those in scientific research. They include professional integrity (analogous to scientific integrity), and institutional integrity and collegiality, both involving somewhat different ethical issues than those found in scientific research. They sometimes also include human subjects' research and animal welfare. An important ethical issue in engineering design is the responsibility to clients. Social responsibility is also a central issue, with a strong focus on safety, health and environmental risks, and human welfare.

The *ethics of technology* is a field complementary to engineering ethics. It is concerned with ethical issues regarding the functioning of technology in society. Specifically, it investigates ethical issues associated with the introduction and use of technology in society. As such, it concerns itself with impacts of all kinds, including impacts on users, other stakeholders, the environment, and society at large. It is not a form of professional ethics but rather a field of applied ethics with a focus on social-ethical problems surrounding technology. Ethics of technology attempts to answer questions such as to what extent Internet users are entitled to privacy and whether the risks of new nanotechnologies are morally acceptable. Specific technologies have spawned entire new fields of applied ethics, such as computer and information ethics, roboethics (ethics of robotics) and nanoethics (ethics of nanotechnology). Technology is also an increasingly important subject in other fields of applied ethics, such as bioethics, environmental ethics and neuroethics.

In contrast to engineering ethics and ethics of technology, the *ethics of innovation* hardly constitutes an identifiable field. However, a considerable amount of work takes place that could be categorised as ethics of innovation. The ethics of technology has a strong focus on new and emerging technologies, and as such, on innovation.[76] In addition, in business ethics, there is a strong and increasing interest in the ethics of innovation, including both technological, social and organisational innovation.[77] With the increasing interest, both at the EU level and in EU member states, in the topic of Responsible Research and Innovation (RRI), it is conceivable that innovation ethics will, in the future, emerge as an identifiable field.

Issues and principles in engineering, technology and innovation ethics

Most ethical issues concerning technology and innovation can be classified into one of the following three categories:

(1) *Ethical issues in engineering research, design and other engineering practices*

These are issues concerning professional ethics and the ethics of engineering practices. For engineering science, the issues potentially include all of the issues of research ethics discussed in section 3.2. For engineering design and other engineering practices, issues include professional integrity, institutional integrity, collegiality, responsibility to clients, and social responsibility, specifically responsibility for the safety, health, and welfare of the public, for the environment, and for the public interest at large.

(2) *Ethical issues with technological innovations themselves*

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[76] See Sandler, R. (ed.), *Ethics and Emerging Technologies*, Palgrave MacMillan, 2014.
[77] Hanekamp, G. (ed.), *Business Ethics of Innovation,* Springer, 2007.

These are ethical issues that concern the very nature or character of certain technological innovations, and concern the question as to whether it is ethical to create these innovations, regardless of their impacts on society. This mainly pertains to innovations that are considered as unnatural, to violate nature, to go against divine prohibitions, or are thought to involve actions that should only be the province of gods and divine beings e.g., genetic technologies, human enhancement technologies.

(3) *Ethical concerns with impacts of technology*

The impacts of technology that raise ethical concerns include so-called *hard impacts* (physical impacts on environment, health and safety) and *soft impacts* (impacts on social realities and ideals such as justice, equality, individual rights, identity, etc.).[78] Environmental, health and safety impacts are often assessed together as so-called *EHS impacts*. When the impacts of a technology are uncertain, the language used to discuss these impacts is that of technological *risks*. One particular issue that has received much recent attention is that of *dual use*. This concerns the possibility that an innovation may be used for controversial military or harmful purposes (terrorism, substance abuse).

(4) *Ethical issues concerning social and organisational innovations*

Ethical issues include those concerning professional and institutional integrity and responsibility (violation of trust, fraud, misrepresentation, misappropriation of assets, conflicts of interest, misallocation of resources, inadequate accountability and transparency). There are also ethical issues concerning the impacts of innovation. The concerns are largely similar to those relating to impacts of technology.

For more detail on ethics in technology and engineering, see the subreport on engineering science in annex 2 of this report. For discussion on the ethics of social innovation, see the subreport on social sciences in annex 2 of this report. For studies of the ethics of risk and of dual use, see annex 1.

3.4   THE EVALUATION OF IMPACTS ON SOCIETY IN ETHICS ASSESSMENT

Research ethics traditionally focuses on ethical issues within research practice. It usually has limited consideration of the potential utilisation of research results and the resulting impact on society. To the extent that such impacts are addressed, they are usually referred to under the banner of social responsibility, or sometimes through related concepts, such as that of dual use. However, few approaches have been developed in research ethics to determine what the social responsibility of scientists is, or what social responsibility implies for actual research practice.

Ethics of engineering, technology and innovation is generally much more concerned with social responsibility and with ethical issues that arise from impacts on society. This is undoubtedly because inventions and innovations have a direct impact on society. The impact on society of scientific publications and other products of scientific research is often more

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[78] Swierstra, T., and H. te Molder, "Risk and soft impacts", in Sabine Roeser, Rafaela Hillerbrand, Per Sandin, Martin Peterson (eds.), *Handbook of risk theory. Epistemology, decision theory, ethics, and social implications of risk,* Springer, Dordrecht, 2012, pp. 1050 - 1066.

indirect. For example, a scientific account on the behavior of liquids in conditions of microgravity will probably only have a substantial impact on society if useful applications of this knowledge can be found in engineering. The focus on societal impacts is somewhat different in engineering ethics and in ethics of technology. In engineering ethics, the focus on impacts is usually limited to relatively immediate and specific impacts that concern users and other directly involved parties, and concern the engineer's responsibility for these impacts. More remote indirect impacts, or impacts at the general societal level, are less of a concern. The ethics of technology, in contrast, concerns itself with impacts of all kinds, including more indirect, remote or general societal impacts. In addition, engineering ethics is concerned with the social responsibility of engineers, whereas ethics of technology, to the extent that it raises issues of responsibility, tends to be concerned with the way in which social responsibility should be distributed across various social actors.

It could be argued that this is a fair state-of-affairs. Scientists, it may be argued, do not intervene in society as engineers do, but merely seek to find truth. Perhaps, therefore, they should have limited or no social responsibility for their findings; it is rather those who apply or utilise their finding who bear responsibility towards society. Engineers and innovators, in contrast, change society with their inventions, and therefore do bear social responsibility. There are, however, several problems with this line of reasoning. A first problem is that scientific concepts, laws and theories have important similarities to technological artefacts: they are human-produced tools that can be used by others to understand, interpret and intervene in reality. Moreover, it is also the case for technological artefacts that their effects on society are mediated by users who choose to use them in certain ways. Nevertheless, we believe that engineers bear responsibility for their design.

A second problem is that the division between science and technology or engineering is not always clear, and has become less distinct in recent decades. This distinction was never sharp to begin with, as many sciences have an orientation to intervention, and new technologies are often science-based. In recent decades, however, the distinction between science and technology has come to the point of near-collapse. Almost all new sciences of the past forty years have a strong orientation towards intervention and practical application. This is true, for example, for research in artificial intelligence (which Simon and Newell named "the science of intelligence"), genomics, environmental science, nanoscience, information science and synthetic biology, as well as for new computational approaches within science such as computational physics, computational biology and cognitive science. It is virtually impossible to classify these sciences as either fundamental or applied; all are concerned with both scientific discovery and technological intervention. In the field of science and technology studies, which is concerned with the multidisciplinary study of science and technology and its relation to society, it is now common not to speak of science or technology as separate phenomena, but of *technoscience*, as a single phenomenon.[79]

There are, therefore, reasons not to make a sharp distinction between science and innovation in developing frameworks for ethics assessment. This also means that the focus within the ethics of technology on societal consequences or impacts may well be transferable to the ethics of scientific research. Indeed, recent ethical approaches, including the broad approach of Responsible Research and Innovation (RRI) advocated, amongst others, by the European Commission, consider science and technology jointly, and have a major focus on the ethical assessment of potential and actual social impacts. In addition, recent approaches for the

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[79] Sismondo, S., *An Introduction to Science and Technology Studies*, Blackwell Publishing, 2004.

anticipation and ethical analysis of impacts of emerging technology, such as *anticipatory technology ethics*[80] and *ethical technology assessment*[81] can be adapted and extended to apply to scientific research as well. Jointly, these new approaches constitute a potential improvement on traditional research ethics, which has always only had a limited consideration of the potential utilisation of research results and the resulting impact on society.

The emerging notion of RRI requires a more systematic focus on scientific responsibility, which goes beyond what scientists do to consider the consequences of their actions. Given complex causal pathways of indirect use and impact, it is both important and challenging to establish the specific responsibilities to which individual scientists or scientific institutions may appropriately be held. Alongside established debates on social and environmental responsibility, the emerging category of "dual-use research of concern" points to the possibility that *bone fide* research may be misused outside the control or even knowledge of those who conducted it, and it therefore should be clear how responsibilities are distributed for such misuse.

The analysis of ethical issues that result from the utilisation of the products of science and innovation may be called, after David Wright, *ethical impact assessment*.[82] Ethical impact assessment requires anticipation of or the study of the utilisation of science and technology in society, an ethical assessment of such utilisation, and optionally, recommendations for responsible research and innovation that takes utilisations and impacts into account. Ethical impact assessment is different from social impact assessment in that it is only concerned with morally relevant impacts, and engages in an ethical evaluation of them. So for example, the European Commission is equipped with an Impact Assessment Board that assesses the economic, social and environmental consequences of new initiatives.[83] However, many of the impacts this board studies have only limited ethical importance, and the board does not engage in ethical evaluations of the impact it studies.

Ethical impact assessment of research and innovation typically considers potential societal harms, risks and implications for fundamental rights, justice, well-being of citizens and the common good. Such assessments may require a consideration of potential impacts on health, the environment, work, leisure, social relations, politics, values, and so on. To achieve this, ethical impact assessment often combines ethical analysis with social impact analysis, futures studies, scenario analysis, and technology assessment. Engagement with stakeholders and public dialogue are other actions within ethical impact assessment, as stakeholders can help to anticipate utilisations and impacts, and can voice their concerns and interests as part of the process of ethics assessment.

For more detail on ethical impact assessment, see the subreport on this topic in annex 1 of this report, and the subreport on engineering science in annex 2.

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[80] Brey, P., "Ethics for Emerging Technologies", *Nanoethics,* Vol. 6, No. 1, 2012, pp.1-13; Swierstra, T., and A. Rip, "Nano-ethics as NEST-ethics: patterns of moral argumentation about new and emerging science and technology", *Nanoethics* Vol. 1, No. 1, 2007, pp. 3-20.
[81] Palm, E. and S. O. Hansson, "The case for ethical technology assessment (eTA)", *Technological Forecasting & Social Change*, Vol. 73, No. 5, 2006, pp. 543–558.
[82] Wright, David, "A framework for the ethical impact assessment of information technology", *Ethics and Information Technology*, Vol. 13, No. 3, September 2011, pp. 1-28. Several other approaches also refer to the "ethical impact assessment".
[83] See European Commission, "Impact Assessment". http://ec.europa.eu/governance/impact/index_en.htm

4 COMPARATIVE ANALYSIS BY SCIENTIFIC FIELD

4.1 INTRODUCTION

This chapter offers a comparative analysis of approaches to ethics assessment and guidance in different scientific fields. The aim of the analysis is to understand similarities and differences between ethical approaches across scientific fields, with a view to determining the feasibility of transferring ethics frameworks, principles and practices from fields with well-developed ethics assessment frameworks to other fields. The comparative analysis is based on in-depth case studies of current issues, principles and practices and institutionalisation of ethics assessment and/or guidance in the medical and life sciences, natural sciences, engineering sciences, social sciences and the humanities fields. Individual reports were compiled for each of these five fields, in addition to sub-reports for disciplines within the field (see Annex 2 for downloadable reports). Each of these five reports includes the following sections:

- Introduction including a description of the nature and scope of the scientific field, including disciplines and subdivisions; overview of specific ethical issues in the field; brief discussion concerning the historical development of ethics assessment in the field, both in Europe and worldwide;
- Description of the major traditions of ethics assessment in both academic and non-academic contexts in the field;
- Elaboration of the main ethical issues discussed in ethical assessment in the field, including the degree of consensus in the field or discipline with respect to the issues;
- Discussion regarding the degree of institutionalisation of ethics assessment in the field at both EU and international levels, with regard to international legislation, and other initiatives; major EU and international organisations in the field; and major EU and international journals, publication series and conference series with a specific focus on ethics assessment in the field or its sub-fields
- Discussion regarding the degree of institutionalisation of ethics assessment/guidance at national level in seven EU Member States and one candidate for membership, the United States (US) and China, particularly with regard to the extent to which ethics assessment in the field is addressed in national legislation and other initiatives, in addition to the extent to which ethics assessment in the field is represented in or by major organisations such as national ethics committees, research ethics committees, national science funding organisations and so on.
- Evaluation as to the state-of-the-art of ethics assessment in the field compared to other scientific fields with regard to a number of dimensions including the volume of research on ethical issues, the degree of institutionalisation of ethics assessment, the range of ethical issues and so on;
- Discussion concerning possible gaps in ethics assessment; challenges regarding current approaches and current institutionalisation arrangements for ethics assessment; and future developments in the area of ethics assessment

In this chapter, we will take these issues in turn and compare and contrast the ways in which they are approached in the five scientific fields.

4.2   ETHICAL PRINCIPLES, ISSUES AND APPROACHES

Our analysis shows that there are four clusters of ethical issues with corresponding ethical principles that apply to all academic fields:

- *The proper conduct of research (so as to guarantee its quality)*. Principles include competence, scientific or research integrity, freedom from bias, independence, transparency, and openness. The core principle here is *scientific integrity*, which calls for avoidance of data fabrication, manipulation, plagiarism, conflicts of interests, and collegiality, amongst others.

- *Intellectual freedom.* It is generally believed in the sciences that researchers should have the freedom to perform any promising avenue of research, if these research activities are consistent with other ethical principles in research.

- *Professional behaviour and attitudes in R&I.* These are issues and principles that do not apply to research and innovation practices, but rather to the researchers and innovators considered as professionals. Principles include scientific integrity, professional integrity, collegiality, honesty, impartiality, fairness, and openness. These principles show some overlap with the first category.

- *Social responsibility* (both concerning the person and the practice)

These four clusters express shared values in research, regardless of field or discipline: academic research is generally expected to strive for excellence and intellectual independence; it is supposed to be a free pursuit; researchers and innovators, like other professionals, are expected to adhere to general professional standards such as integrity, honesty and collegiality; and R&I personnel and practices are expected to be socially responsible.

Besides these four clusters of ethical issues, there are two that recur in many but not all fields. The first concerns the study of human research subjects:

- *Protection of human subjects*. Humans who are the subject of research are held to deserve special protection. Principles include autonomy, informed consent and confidentiality, amongst others.

The study of human beings necessarily raises ethical concerns for any discipline engaging in it. The medical and life sciences frequently use a set of four principles to guide their research involving human subjects: respect for autonomy (recognising and respecting the participant's competence to make decisions), non-maleficence (avoiding harm), beneficence (acting for the benefit of participants and reducing risks where possible), and justice (risks, benefits and burdens should be distributed fairly). Other disciplines, such as engineering, the humanities, and the social sciences, have similar concepts of respecting people's rights and dignity, in addition to the need to obtain voluntary and informed consent. Gaining voluntary and informed consent also requires awareness of the ways in which cultural differences may affect the participant's understanding of the research, and the need for safeguards to prevent vulnerable people (such as children) from being exploited if alternatives to voluntary and informed consent are required to study them. As participants will necessarily be revealing information about themselves to the researchers, the confidentiality of the information

collected must be protected. The privacy of participants must also not be unnecessarily invaded, and the identities of participants should be anonymised where possible.

A final issue in many fields concerns the use of animals in experiments:

- *Animal welfare.* The consideration of the welfare of animals in animal experimentations, with the aim to minimise suffering.

Animal welfare is a significant concern in the use of animals in experimentation. It is generally held that that the use of animals should be limited as much as possible, and that their suffering should be minimised and be in proportion to the potential benefits of the research. In many fields and many countries the three R's are advanced: replacement (of animal experiments with alternative techniques), reduction (of the number of animals used) and refinement (of experiments to reduce animal suffering).[84]

It is remarkable that, apart from these quite general categories of ethical issues and principles, there are virtually no other issues and principles that are shared by the five academic fields, rather there are many issues that appear unique to them. We hypothesize that this is not the contingent result of different traditions of research ethics in the five fields, but because the five fields have at their core very different ethical concerns. Their different concerns stem from the fact that their subject matter, and the relation of researchers to this subject matter, is substantially different for each of them. In addition, the subject matter can also be quite different within each of the five fields. In particular, as for their ethical issues and principles, it makes sense to divide up the medical and life sciences in medical sciences and life sciences, and treat the computer and information sciences as a field separate from the engineering sciences. As we show, the resulting seven fields have different subject matter that raise different ethical issues and require mostly different ethical principles to address them:

- *Medical sciences:* Medical ethics has traditionally centered around the *doctor-patient relationship*, which concerns standards of ethical behaviour of doctors towards their patients. In medical research ethics, this relationship has turned into the *relationship between medical researcher and human subject*. Ethical issues therefore concern those relating to the proper treatment of human subjects (especially in clinical trials), involving medical principles such as autonomy, informed consent, beneficence, human dignity, and justice.

- *Life sciences:* The life sciences centre around the *relationship of researchers to living biological systems, ecosystems and the environment*. Ethical issues therefore concern the proper treatment of living beings, impacts on ecosystems, and environmental impacts, and ethical principles include animal welfare, ecosystems integrity, sustainability, health and environmental risks, naturalness and playing God.

- *Natural sciences:* The natural sciences have, at their core, the *relation to truth*: accurate measurement and representation of natural phenomena, including criteria

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[84] The above six categories correspond quite well to an influential categorization of issues in research ethics into the six categories by Kenneth Pimple that were discussed in chapter 3. Pimple, however, does not consider innovation practices. He does not identify categories of professional ethical issues and intellectual freedom, but instead distinguishes collegiality (which is here subsumed under proper conduct of research) and institutional integrity. Institutional integrity is undoubtedly a shared concern in research ethics, but it does not often show up in ethics codes, protocols and analyses of the different scientific fields.

like exactness, objectivity, verifiability, and reproducibility. Ethical issues therefore concern those that threaten this relation to truth, such as data manipulation, falsification, fabrication, unintentional bias and conflict of interest. Corresponding ethical principles include scientific integrity, data integrity, freedom from bias, and honesty.

- *Social sciences:* At the core of the social sciences is the *relation between the researcher and human beings*. This relation however differs than that in the medical sciences, since it does not involve medical interventions but instead involves behavioural experimentation with and observation of humans, collection of personal information, and the representation of and intervention into the lives of individuals, social groups and society at large. This leads to ethical issues e.g. the proper treatment of human subjects, privacy of data, and issues such as bias and unequal treatment (in theory and intervention). It involves ethical principles such as informed consent, equality, anonymity, confidentiality, privacy, fairness, non-discrimination, human rights, avoidance of cultural and social bias, and respect. In addition to having a focus on human beings, the social sciences also have a *strong concern for proper methodology* so as to ensure the quality and objectivity of research. There is therefore also a focus on ethical issues and principles concerning data integrity, research integrity, freedom from methodological bias, objectivity, and others.

- *Engineering sciences:* At the core of the engineering sciences *is the technological intervention into society*: engineers develop technological concepts, artefacts, processes and systems that directly or indirectly have an impact on people, the environment, and society at large. Ethical issues therefore concern impacts, especially those concerning health, well-being, and harms and benefits to society and the environment, as well as corresponding risks (that harmful impacts will occur), and responsibility for these impacts. Ethical principles include social responsibility, well-being, impacts on rights, the precautionary principle,[85] sustainability, and the good of society, amongst others.

- *Computer and information sciences:* These are sciences that are concerned, in different ways, with the *processing, storage and dissemination of information.* As a result, the focus is on the way in which these activities are enabled and concern issues and principles that include informational privacy, surveillance, information security, intellectual property, censorship and freedom of information.

- *Humanities:* The humanities, finally, have as their concern *the study of human culture and the human condition*. This subject's matter involves a special focus on interpretation, narrative, imagination, art, and the documentation and preservation of cultural heritage. Ethical issues therefore concern the proper conduct of the interpretation and construction of narratives, the proper role of works of imagination and art in society and our evaluation of them, and our responsibilities in the preservation of cultural heritage. In addition, because the humanities may include human subjects in their research, they share ethical issues and principles concerning human subjects' research with the social sciences.

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[85] This is the principle that uncertainty about the risks involved in developing a new technology should not be used to justify inaction in addressing them.

Besides differences in ethical issues that result from different subject matter, some differences between ethics assessment of scientific fields also result from different methodologies in these fields (e.g., quantitative vs. qualitative, experimental vs. interpretive) that raise different ethical issues concerning the proper use of methodology. Another relevant difference is that between research and innovation: research practices are mostly concerned with a particular representation or interpretation of reality, whereas innovation practices are concerned with changing reality and having an impact on it. As one may expect, the latter practices generally have a greater ethical focus on impacts, risks, and responsibility for society, whereas the former have a greater focus on accuracy and objectivity, and on ethical issues internal to the research practice, such as the treatment of test subjects.

To the extent that there is ethical concern about impacts, there are also differences in the kinds of impacts that fields are concerned with. A distinction can be made between hard and soft impacts.[86] *Hard impacts* affect health and physical well-being, the environment and increased risk. *Soft impacts* affect social goals and ideals such as justice, equality, and individual identity. The humanities and social sciences primarily focus on soft rather than hard impacts, as they are concerned with describing and understanding human experiences and the social condition.[87] These soft impacts include the effects research may have on public policy, risks of political and social controversy, and effects on vulnerable and marginalised groups in society. Engineering, medicine, and the life and natural sciences have both hard and soft impacts, but most attention traditionally is focused on hard impacts, public health and safety and harm to the environment.

In spite of these substantial differences between fields, there is no strong evidence that when two fields share an ethical issue, the ethical values and principles they apply to that issue are substantially different and incompatible with each other. Many scientific fields involve human subjects' research, and all of these are concerned with issues of autonomy, informed consent, and confidentiality, even if the terminology for these concepts sometimes differs. Several of the fields involve experimentation on animals, and they all employ principles that express a concern for animal welfare and the proportionality of harm to the animal to the expected benefits of the research. Those fields in which personal information is processed all show a concern for privacy and advocate efforts to protect it.

Therefore, although there are quite different traditions of research ethics across and within the sciences, that include different conceptualisations of ethical issues and principles, there often appear to be shared values behind these different conceptualisations, values such as autonomy, privacy, justice, beneficence, and dignity. However, it is usually only a subset of such values that is relevant for ethical assessments in particular scientific fields, and these fields often adopt specialised ethical principles, such as "informed consent" or "ecosystems integrity", to express particular ethical concerns.

An additional reason as to why there are bound to be differences in ethical principles between different scientific fields and subfields is that fields may adopt different standards and

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[86] Swierstra, T., and H. te Molder, "Risk and soft impacts", in Sabine Roeser, Rafaela Hillerbrand, Per Sandin, Martin Peterson (eds.), *Handbook of risk theory. Epistemology, decision theory, ethics, and social implications of risk,* Springer, Dordrecht, 2012, pp. 1050 - 1066.
[87] Humanities research conducted on cultural artefacts and physical monuments carries the risk of hard impact effects from damage to the monuments and artefacts themselves.

conventions for ethics in research. In one field, it may be permissible for informed consent to be given by children through their parents, whereas in another field, it may be held that informed consent for children is not possible. In one field, it may be held that privacy is an absolute right that always requires informed consent, whereas in another, certain types of collecting and processing personal information without informed consent are permitted because their harm to individuals is limited. Therefore, even if ethical principles adopted in ethical codes or research ethics protocols refer to the same underlying values, they may differ in the particular conventions, standards and moral choices that they embody.

The above discussion shows that the expansion of research ethics to a new field with no tradition in research ethics should generally not proceed with attempts to transpose ethical principles and issues from other fields. A partial transfer of principles and issues will often be possible, but it is also important to discover and express those issues and principles that are unique to a field. The only principles that appear to apply to all fields have been found to be a limited set of principles concerning the proper conduct of research, professional conduct, and social responsibility, as well as some fundamental, underlying ethical values that may result in different concrete principles in different scientific fields.

4.3 INSTITUTIONALISATION AT THE EU AND INTERNATIONAL LEVEL

In this section, we consider EU and international legislation, standards, frameworks and protocols that concern ethical principles and issues for research and innovation. We will first consider EU and international legislation for the five fields, and then will do so for EU and international organisations, and EU and international journals, publication series and conference series.

There appears to be little international legislation that specifically considers ethical issues in engineering. At the EU level, however, there is legislation, guidelines and standards concerning health, safety and environmental risks of engineering. Such legislation, guidelines and standards concern general management of health and safety at work, environmental liability, industrial emissions, resource use, etc. Besides EU-level legislation, guidelines and standards, there are also several international codes of engineering ethics, offered by international organisations and at the EU level.

The most developed ethical frameworks in natural sciences with an international scope concerns research publication. Areas of natural sciences research, especially those that present potential high risk to society and the environment, are governed by international frameworks and protocols, which are further adopted at national level. Beyond regulation, the aim of these frameworks is to foster international collaboration among scientists, to contribute to the development of systematic and harmonised risk assessment, and to transfer risk assessment methodologies and knowledge to emerging regions of the world.[88]

The main European and international legislation, standards, frameworks, and protocols in the field of medical and life sciences concerns clinical trials. There is also legislation dealing with the necessary practices for producing medicines and testing medical products, and the safety and performance of medical devices. There are also guidelines for supporting agricultural

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[88] OECD, "OECD Guidelines for the testing of chemicals and related documents", http://www.oecd.org/env/testguidelines

research for development,[89] and relating to food security. International standards developed by the International Organization for Standardization (ISO) are also relevant to the medical and life sciences.[90]

In the social science domain, the European Commission issued the *Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research* as part of the FP7 documentation to provide applicants and evaluators of SSH research projects with advice and practical guidance on dealing with the ethical aspects of such research. The RESPECT project produced a voluntary code for European socio-economic research. UNESCO published Ethical Guidelines for International Comparative Social Science Research "to provide a framework to guide research practice".[91] Principles and values of social science research are mostly addressed in a variety of professional ethics codes formulated for professions in different social sciences. International professional associations also play a major part.

The level of institutionalisation of ethics assessment in humanities cannot be compared to that in the biomedical or even social sciences. However, with the growing awareness of the differences in risks and methodologies between fields, the extent of ethics assessment institutionalisation in humanities is increasing. Changes in data protection legislation and the growth of universities are contributing factors. Increasing institutionalisation has been encouraged at the European level through the attention given by the European Commission to acknowledging differences between fields in the ethics assessment procedures within its Framework Programmes.

Major EU and international organisations

At the EU level, there is no academic professional organisation specifically focused on the *ethics of technology*, although there are several associations that include ethics of technology in their focus. There is no professional organisation or research centre for *engineering ethics*, although there are several working groups and sub-organisations for this within engineering organisations. There are however several international organizations with a (partial or specialized) focus on ethics and technology, such as the Society for Philosophy and Technology and the International Society for Ethics and Information Technology. In the natural sciences, ethical discussions are often taken up by major national, European and international societies. In the medical and life sciences domain, the most important international institutions are the institutional review boards (IRBs) in the USA, and the independent ethics committees in Europe.

In social science, international ethical guidance for social science research is generally performed by international academic and professional associations in a specific discipline. Our research has determined the key organisations include the European Commission, UNESCO, European Federation of Psychologists' Associations, International Sociological Association, International Union of Psychological Science (IUPsyS), the International Association of Applied Psychology (IAAP) and the International Association for Cross-Cultural Psychology (IACCP). There are no major international organisations dedicated to

[89] European Commission, *Research and Innovation for Sustainable Agriculture and Food and Nutrition Security*, November 2014, p. 7. https://ec.europa.eu/europeaid/sites/devco/files/guide-approach-paper-ar4d-2014_en_0.pdf
[90] E.g. ISO 14155-1:2009, ISO 14155-2:2009, ISO 14155:2011, ISO 17511:2003, ISO 18153:2003, ISO 15193:2009, ISO 15194:2009.
[91] UNESCO, "Ethical Guidelines for International Comparative Social Science Research in the framework of MOST". http://www.unesco.org/most/ethical.htm.

research ethics in humanities. However, the number of specialised national and university ethics committees is growing. Some humanities research ethics journals have a partial focus or have dedicated special issues to the topic, and papers on research ethics appear sporadically. Ethical assessment in humanities is often covered in the literature together with the social sciences.

Major EU and international journals, publication series and conference series

In engineering ethics, there is not a lot of EU and international institutionalisation as regards international journals, publication series and conference series. There is just one major international journal, *Science and Engineering Ethics,* devoted in large part to ethical issues in engineering. There also exist a number of internationally published (text) books on engineering ethics. There is no conference series in engineering ethics that has shown longevity. The situation in the ethics of technology is somewhat better than it is in engineering ethics. There are several international journals and book series in the ethics of technology, and there are several conference series that focus in part on the ethics of technology—although there is no conference series that focuses exclusively on the ethics of technology. Furthermore, of the various international journals, book series and conference series on research ethics, none seem specifically focused on engineering research.

There is evidence of ethics-related articles, newsletters and bulletins in the natural sciences. Areas of focus include responsible research, ethical challenges in science, societal implications of science and technology, ethical issues in peer review and authorship, ethics training in the sciences and education. Though journals, publication series and conference series are seldom dedicated to ethics assessment, they do aim to improve the standard of respective scientific discipline.

In the medical and life sciences, ethics is rather more institutionalised in relation to publications and events, compared to the other analysed scientific disciplines. Journals not only cover ethical issues but some are also devoted specifically to ethics.[92] Events also focus more specifically on ethics topics.[93]

In social science, publications focus on ethics frameworks, human rights, ethical issues in social science, privacy, and social research ethics. There are journals dedicated to business ethics, ethical human psychology, ethics and behaviour, human research ethics, internet research ethics, etc.[94] There is also evidence of international events devoted to research ethics in social science. Publications in the humanities focus on ethical regulation, ethics review, etc. There are some journals with a partial focus on research ethics in humanities.[95]

4.4   INSTITUTIONALISATION AT THE NATIONAL LEVEL

This section discusses and compares institutionalisation at the national level in the analysed scientific disciplines.

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[92] See See SATORI, D1.1, Medical & Life Science report.
[93] See See SATORI, D1.1, Medical & Life Science report.
[94] See SATORI, D1.1, Social science report.
[95] See SATORI, D1.1, Humanities report.

Institutionalisation occurs at various levels within the analysed scientific disciplines.[96] It seems more advanced and highly organised in the natural sciences and the medical and life science domains, than in the engineering, humanities or social science domains. This might be due to the fact that ethics assessment is often mandated by law in the natural science, and medical and life science domains.

In the **natural sciences**, in the Netherlands, Germany and Austria, legislation and practices of ethics assessment in science are, for the most part, decentralised and independent of government. Various national ethics committees evaluate scientific research, especially in intrusive areas of scientific research, such as research involving human subjects, animal experimentation, or environmental issues, among others. In most cases, the committees have regulatory authority and issue legally required permissions for conducting such research. Furthermore, a number of public-private partnerships exist relating to ethics assessment, and civil society organisations are represented in various stakeholder dialogues organised on important ethical issues. In most EU countries, a number of government (or associated) bodies engage in activities related to ethics assessment, such as environmental impact assessment, social impact assessment, and technology assessment.[97] Some legislation and policies are field-specific. Provisions with regard to ethics assessment in scientific research might be fairly abstract and formulated as general values (e.g. Austria). Ethics assessment might be organised at the regional and state levels, and at the level of research institutes. Ethics assessment at the governmental level also relates to policy guidance. In science and research, mandatory ethics assessment is provided by Research Ethics Committees for respective scientific fields and/or topics, and other designated agencies. At the university level, many universities have established Ethics Committees, which provide reviews on individual research projects or advise on ethical issues.

Research in the **medical and life science domain** is subject to ethical assessment, particularly in the context of clinical trials, human subject research, medical devices, the use of animals for scientific purposes, and the use of personal data. Most of these areas are regulated by EU and/or national law. Often licences or approvals must be obtained from designated bodies such as research ethics committees or commissions prior to the start of the research. These committees or commissions are responsible for ethical advice and the authorisation of research. They set guidelines and general principles for the drafting of codes of good practice in the area and their activities include writing issue reports, proposals, and recommendations on matters. Research ethics committees are under the direct supervision of a specific ministry or government department. There are also a number of advisory bodies linked to ethics assessment bodies. In addition, there are national organisations for institutional review boards and local ethics committees that connect similarly natured organisations and aim to foster best practices, discuss medical ethical issues and maintain relationships with other relevant bodies and provide information and training for members. Some organisations concerned with ethical assessment have international links with similar groups to foster collaboration between them.

Within EU countries, there is some national legislation that specifically considers ethical issues in **engineering.** There are national legislation and standards concerning the health, safety and environmental risks of engineering. Many of these are based on EU legislation and guidelines. Furthermore, many national organisations for engineering professionals have formulated their own codes of engineering ethics. These codes are similar to those offered by international organisations. Within European national ethics committees, there is little

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[96] See individual scientific discipline reports for domain specific details.
[97] Please see individual SATORI country reports.

attention paid to ethics assessment in engineering. Ethics assessment in these organisations mostly covers the medical sciences, and sometimes the social sciences (in particular psychology). Often, their focus on the medical sciences is clearly apparent in their name, through use of the term bioethics. Any attention to engineering is often in the context of bioethical issues. There seem to be only few research ethics committees with a focus on engineering. In Europe, there are a number of national organisations for technology assessment (TA) e.g. the European Parliamentary Technology Assessment (EPTA)[98]. The assessments performed by these TA institutions often cover ethical questions surrounding new technologies. Generally, they do not have a special focus on medical technology. In the US, a national organisation for technology assessment is notably absent as the US Office of Technology Assessment was abolished in 1995.

Since the 1980s and 1990s, there has been an increasing trend towards the institutionalisation of ethics assessment in the **social sciences** (and to some extent **the humanities**) including the emergence of field-specific ethical guidelines (at the national level), specialised committees, assessment protocols journal issues, etc. However, there are significant differences from country to country regarding the level of institutionalisation reached, with some countries such as Norway displaying more advancement than others. There are also different attitudes towards the need for ethics assessment in the social sciences. National professional and scientific associations provide ethical guidelines in many other countries. Furthermore, universities across Europe are establishing their own field-specific committees in order to assess projects and their ethical implications. However, the ways in which universities deal with ethics and the structure of their committees varies. There is some evidence of ethics committees and offices being established at social science faculties and departments (confirmed by SATORI country reports and interviews in the cases of Spain, Poland, Austria and the Netherlands).

4.5 EVALUATION

All of the research fields discussed share ethical concerns about research integrity and being socially responsible. These fields differ in the degree to which their methods of ethics assessment are formal and institutionalised, the specific ethical concerns raised by their distinct methods and subject matter, and the particular risks of different harms that may be caused by their research. These risks of harm can be roughly classified as physical (medical and life sciences, natural sciences), psychological (social sciences, humanities, medical and life sciences), social (social sciences, humanities, engineering), and environmental (natural sciences, engineering).

The medical and life sciences, particularly in the area of biomedical research, have the most extensive literature and institutional structure for ethics assessment. The direct risks of physical harm to human research participants and the need to address animal welfare have inspired this greater emphasis on ethics assessment in this field compared to the others. Fields such as the social sciences and the humanities often pose greater risks of psychological harm and social stigmatisation than biomedical research. Existing institutions and forms of ethics assessment from biomedical research have sometimes been applied to other fields, such as the social sciences. However, the different methods and risks of harm make the methods of biomedical ethics assessment a poor fit for many other fields. A greater emphasis on developing institutions, frameworks and guidelines that are tailored to other research fields is

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[98] European Parliamentary Technology Assessment, http://www.eptanetwork.org

needed to better address the ethical concerns raised by different methodologies and subject matter.

While no other field shares the degree of institutionalisation in ethics assessment that the medical and life sciences does, changes to legislation in areas such as data protection and greater public awareness of ethical concerns in science and technology is encouraging greater institutionalisation elsewhere. Even the humanities, currently the least institutionalised in terms of ethics assessment, acknowledge the need for specific principles and methods of ethics assessment for ethical concerns raised by research. The institutionalisation of ethics assessment outside of biomedical research is often performed by professional organisations. Such organisations for practitioners of engineering, the natural sciences, and the social sciences establish codes of conduct and ethical guidelines for their members to follow. Unlike the medical and life sciences, ethics committees do not play a major role in the ethics assessment of these fields, outside of the assessment necessary for grant applications and in cases where research involves human participants.

There is another concern that the existing forms of ethics assessment in fields such as the natural sciences and engineering do not adequately address the current concerns in these fields. In engineering ethics, for example, there is a greater emphasis on the specific issues raised by specific technologies, rather than a broader analysis of how these technologies may affect society as a whole.

5 COMPARATIVE ANALYSIS BY TYPE OF ORGANISATION

5.1 INTRODUCTION

This chapter offers a comparative analysis of the performance of ethics assessment and/or guidance by a variety of organisations involved in the area of ethics assessment and guidance. The aim of the analysis is to understand the manner in which such organisations are institutionally embedded, the ways in which they perform ethics assessment and associated aims, and the perceived strengths and weaknesses of their participation in ethics assessment and guidance. The comparative analysis will determine the extent to which these organisations - or "ethics assessors" - use different ethical frameworks and procedures and the extent to which there are similarities. The comparative analysis is based on in-depth case studies of nine kinds of organisation that are variously engaged in ethics assessment/guidance across eight representative European countries, the US and China (see Annex 4). The organisations include research ethics committees, national ethics committees, research funding organisations, national science academies and national and international academic organisations, civil society organisations, industry, universities and governmental organisations involved in science, technology and innovation policy. Individual reports were compiled for each organisation across the ten countries and include the following sections:

- Brief introduction to the assessor or organisation type, its role in society, distribution throughout the EU and the world, and its historical emergence;
- More elaborate description of assessor type including a description of its typical aims and institutional/organisational structure and relation to other organisations/institutions;
- Discussion of the extent to which organisations of the assessor type engage in ethics assessment/guidance with regard to the aims, motivations, focus and beneficiaries of assessment;
- Description of the institutional set up for ethics assessment employed by the organisation;
- Description of procedures for ethics assessment/guidance prior to, during and after assessment/guidance;
- Discussion of the role and prominence of ethical principles and issues in ethics assessment/guidance;
- Discussion of the main strengths and weakness of existing institutional setups, procedures and approaches for ethics assessment in the assessor category; in addition to plans and expectations regarding future developments (based on views of interviewees)

In total, almost 200 organisations were interviewed for our investigation, which also included desk research. Based on these report, we now present an analysis that compares and contrasts the nine organisation types along these parameters.

5.2 ORGANISATIONS WITH A ROLE IN ETHICS ASSESSMENT OR GUIDANCE

Our report considers 15 types of organisations that routinely or occasionally engage in ethics assessment. These correspond to the nine categories of organisations that are discussed in our in-depth reports; some reports include more than one type of organisation in their category. This section provides a brief description of the fifteen types and gives an indication of their

prevalence, their role in ethics assessment or guidance and the beneficiaries of their assessment or guidance activities. There is some overlap between the categories.

(1) *Research Ethics Committees (RECs)*

Research ethics committees (sometimes called Institutional Review Boards or Ethical Review Boards) are bodies that have been formally designated for independent oversight over research. They approve, monitor, and review research for its ethical aspects. RECs often have the power not only to assess research and make recommendations, and also to constrain or prohibit certain research projects or activities. RECs can be local, regional or national. *Local RECs* are often embedded in the organisation in which research is undertaken: universities, hospitals or research institutes. *Regional RECs* assess research ethical issues within a particular area. *National RECs* are embedded in or instituted by a government organisation, and unlike local and regional RECs, they often have an advisory or standard-setting role for national policies and legislation for research, in addition to a role in the assessment of research.

RECs display diverse profiles and the aims and objects of their ethics assessment depends on their mandate. In some cases where REC evaluations are mandatory by law, compliance with their recommendations is not optional; in other cases their recommendations might be non-binding (of advisory or persuasive nature). RECs deal with issues such as conflicts of interest, human subject research, informed consent issues, and research performed in developing countries. Ethics assessment procedures in RECs can be formalised to a high degree or less formal in nature (though widely recognised).

RECs provide evaluations that in most cases are addressed to researchers, research groups or institutions who have submitted research proposals. Assessments by RECs help increase the confidence of the public in research; thus they are in the public interest. They protect both researchers (including their institutions) and the research subjects (humans, vulnerable groups such as children, patients, animals, etc.). Other beneficiaries include funders of research.

(2) *Associations and Networks of Research Ethics Committees*

Associations of RECs work to harmonise and standardise procedures for RECs, provide education and training for members of RECs, coordinate activities between RECs and represent RECs at regional, national or international levels. *Networks of RECs* usually have a more limited role that is focused on coordination.

To substantiate further, associations of RECs may provide harmonised material and templates for informed consent forms, provide the public with information about the work of RECs, participate in consultation and comment on draft laws. Associations of RECs do not assess individual research projects and they perform more of a 'guidance' role. There are both national (e.g. ANCEI, AfRE, CNPC, and AMEK) and international associations of RECs (e.g. EUREC).

The beneficiaries of their ethics assessment-related work are primarily their member RECs. Other organisations such as research sponsors/funders, universities and research institutes also benefit from their activities. Government agencies may consult with them and benefit from their expertise.

(3)   *National Ethics Committees (NECs)*

National ethics committees are government-instituted, independent bodies whose aim it is to formulate recommendations and foster debate, education and public awareness of, and engagement in, bioethics. All existing NECs have a strong focus on bioethics, often including the fields of medicine and health, biology and life sciences. Some NECs are slightly broader, and may include issues such as social welfare and the environment. NECs usually have an advisory or consultative role for national governments, and monitor and publish international trends in ethics and participate in international events. NECs exist in all EU member states. There are also international counterparts of NECs at the EU and global level. Countries usually have only one NEC, although there may be other government-instituted ethics bodies with roles that resemble those of NECs.

Most NECs report to refer to their work as ethics guidance to the political level as well as to professionals, i.e. those actually carry out research or implement new technologies in the areas of professional guidance or in professional self-governance. The aim or objective of ethical guidance and promoting public debate of NECs does not relate to the evaluation of research protocols, or taking up individual cases, but focuses on the discussion of general principles on ethical issues in the field of their mandate. Expert advice or guidance at the political level is usually given in the form of recommendations to a given subject and is addressed to the respective authority

Beneficiaries of the work of NECs are the authorities who ask NECs for advice on a special topic, such as parliaments, individual ministers, regional or national governments, research professionals and respective associations, which can build their individual guidance on principles and arguments developed by NECs in a specific field of research, and the general public by prompting debate. Other beneficiaries include: stakeholders and relevant industries, people in research councils, research funders and national policymakers, European Union agencies. The public engagement efforts of NECs also indicate the public is a beneficiary of their activities.

(4)   *Governmental Organisations and Councils*

Next to NECs and national RECs, governments sometimes institute other ethics bodies or bodies with a partial focus on ethics that are embedded in ministries or have existence as a council or independent advisory organ. They may also engage in ethics assessment or guidance in the absence of such specialised bodies. Some governments have ethics bodies or bodies with a partial ethics signature, embedded in ministries or as separate councils or advisory boards, that give policy advice, for example on research and innovation policy, health policy, environmental policy or data protection policy. Some governments have research funding organisations embedded in them that may set ethical criteria on funding. Some governments include national bodies for scientific integrity that set standards for research integrity and investigate potential cases of scientific misconduct. And finally, some ministries issue ethical guidelines for, or relevant to, R&I, or have policies and support measures in place for more ethical and responsible R&I.

The SATORI report on governmental and government-funded organisations[99] indicates that a significant number of governmental organisations perform some form of ethics assessment or

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[99] Ibsen-Jensen, Jakob, & Anne Kirstine Lygum, "Ethics Assessment in Different Types of Organisations: Government and Government-Funded Organizations", SATORI D1.1 Report, June 2015.

guidance, often as a result of a mandated requirement. In some cases, the ethics assessment procedures are quite informal. The aim of the ethics assessment is to promote policies and practices for ethically sound research and innovation and create an ethical culture within the organisation itself.

Beneficiaries of the assessments include the government organisations themselves, other government bodies and agencies, policy makers, the scientific community, and the public.

(5)   *Universities and Research Institutes*

Universities are institutions that educate new generations of scientists and perform research. Ethics plays a role both in educational programmes and in relation to research. There are more than 3,300 universities and higher education institutes in the EU, ranging from over 400 in Germany to only in 4 in Malta. The US has more than 3,200, and China has around 1,200 universities.[100] In addition, there are hundreds of publicly funded *research institutes* that specialise in research only. Many *hospitals* also engage in research, especially clinical research, often in collaboration with universities. *Universities*, and *associations of universities*, may also have their own ethical codes, and may also have a *research ethics* or *research integrity office*. Universities often institute RECs to monitor their own research.

Motivations for ethical considerations of research and innovation at universities come from external (laws and regulations, funders, academic publishers) and internal sources (with goal of enhancing excellence of research). While it is common for universities to include research ethics or at least research integrity-related provisions in their general codes of conduct, more and more universities are establishing more specific codes of ethics or even more integrated ethics policies. This entails the establishment of research ethics offices, providing guidance for students and researchers, research ethics committees, assessing individual project proposals, and integration of ethics into courses and trainings. Ethics committees are becoming the central organisational form of ethical activities at universities, and are frequently charged with developing and implementing ethical guidelines, assessment protocols and training programmes for staff and students – to the extent that this is not taken up by a central research integrity office or an ethics department or unit in the university.

As research institutions, universities are subject to the general ethical assessment system and regulation in a country. In some countries this entails that some university research projects are reviewed by external ethical committees, depending on research regulation in each county. Nevertheless, many universities establish their own research ethics committees (RECs), guidelines and protocols to complement external review. These committees often have a guidance role and their advice is non-binding. In fields not covered by a national review system (as is often the case in non-medical research), university committees may act as replacements for the external review and have the power to stop ethically inappropriate research from being carried out. In some countries, however, ethical assessment is officially assigned to research ethics committees at the institutions where research takes place. In these cases, internal assessment by a university's research ethics committee is obligatory and binding.

Beneficiaries of ethics assessment by Universities would include staff and researchers, external funders, academic publishers and the public.

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[100] http://www.webometrics.info/en/node/24

(6) *Associations of Universities and Research Institutes*

Universities have established *associations* at regional, national and international levels for the purposes of mutual cooperation. These associations often have an important role in setting standards or issuing guidelines for the associated universities, including ethical standards and guidelines on topics such as personal data, scientific integrity, animal experiments, and good governance. There are also associations of research institutes.

In general, the aims of ethical assessment and guidance at universities and university associations are:
- To ensure that research, conducted at a university, is in line with national and international standards and regulations, as well as with publishers' and funders' requirements by providing in-house ethical assessment of research projects;
- To provide internal ethics assessment in fields and disciplines (especially in non-medical research), where the assessment is not fully institutionalised and there are no obligatory external assessing procedures;
- To offer ethical guidance in the form of general ethical codes or advice on requests made by the institution or individual researchers;
- To promote high ethical standards and ethical debate among their employees and to integrate it in the educational process through courses or trainings.[101]

International associations of universities at EU level participate in ethics discussions at the regional level, collaborate in working groups, and produce EU-level codes, guidelines and recommendations that help members and national level organisations develop, improve or strengthen their policies.

The beneficiaries include: Universities and their ethics committees/boards, academic publishers, research groups and individual researchers at universities. Sometimes the beneficiaries can also include the government.

(7) *Research funding organisations*

Research funding organisations financially support research activities through funding programmes. Research performing institutions can apply for this funding. The funds are either public or private. Research funding is either managed by ministries, agencies charged by the government, international institutions or private trusts. Research funding organisations provide large-scale, long-term research programmes focussed on specific targets or themes (top-down programmes). They also provide for collaboration between researchers or between researchers and other partners e.g. from the industry (bottom-up programmes). They may also provide funding based on research excellence, regardless of theme. Countries usually have at least one national, government-funded funding organisation, and may have several privately funded ones that usually have more limited funds. There are many international funding organisations, including the European Commission which controls major funds for research at the EU level. Research funding organisations often set out ethical guidelines for research proposals that they fund, and submit such proposals to ethics assessment (often called "ethics review").

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[101] Benčin, Rok, Jelica Šumič-Riha, Gregor Strle, Rado Riha, "Ethics Assessment in Different Types of Organisations: Universities", SATORI D1.1 Report, June 2015.

According to the report on ethics assessment in Research funding Organisations,[102] ethics assessment is perceived as a pertinent question in all analysed funding organisations and has become an integral part of the project selection process. The prevalence of ethics assessment in its various forms is high in Europe, China, and the US. The necessity of research being "perfectly clean" ethically-speaking[103] is recognised by funding organisations in order to achieve real research excellence.[104]

The focus within ethics assessment can however differ between research funding organisations, i.e., some might not conduct ethics assessment but take an interest in how the external ethics review process is being carried out and whether it is an impediment to research in some areas. Others might focus on training of research ethics committees (RECs) to ensure that the RECs themselves are aware of the issues and know how to deal with them. Others focus on supporting researchers to include considerations with regard to thinking widely about ethical issues at an early stage.[105] The term "ethics assessment" is used by all analysed organisations; this includes the notions of ethics review and ethics appraisal.[106] Ethics assessment has been integrated to a very large extent into the regulatory framework of the analysed European countries and the US.

The aims of ethics assessment in Europe and the US relates to the protection of research subjects, enhancing ethical conduct of research staff, justifying the research funded by the organisation vis-à-vis the public, and complying with national legislation. In addition, organisations which provide for in-house ethics assessment[107] have, in principle, the possibility to refuse a project on ethical grounds, although this rarely happens in practice.
The model relying on external ethics approval by a competent body does not give a funding organisation an independent possibility to reject a project on ethical grounds. The project selection committee only verifies that there are ethics approvals by a competent body in place. This means that the funding organisation does not have an influence on the ethics approval decision. The funding organisation is satisfied as long as a competent body has provided a positive ethical review. Organisations relying on a mixed-model (an approach in between relying on external ethics assessment and having an in-house procedure) provide room for discussion on ethical grounds; there are no legally binding consequences, as ethics review in this case is not provided for by law.

All analysed funding organisations specify the organisation itself and the applicants as the possible beneficiaries of ethics assessment.[108]

(8) *Science Academies and Associations of Science Academies*

Science academies are associations of distinguished scholars or scientists. They usually have as their primary aim the advancement of science and its integration into society, mostly with a national agenda. They aim to shape or influence national research policies, provide a forum

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[102] Wolfslehner, Doris, *"Ethics assessment in different types of organisations: Research Funding Organisations"*, SATORI D1.1 report, June 2015.
[103] Ibid.
[104] Wolfslehner, op. cit., 2015.
[105] See Wolfslehner, Doris, *"Ethics assessment in different types of organisations: Research Funding Organisations"*, SATORI D1.1 report, June 2015.
[106] Ibid.
[107] Wolfslehner, op. cit., 2015.
[108] Ibid.

for interdisciplinary scientific debates, and confer awards for outstanding achievements. Their advisory work (on their own initiative or by request from other stakeholders) also includes statements on current scientific developments, special reports on specific issues and foresight studies on new technologies. Many academies include research institutes, and many also offer funding. All countries have national science academies, and some also contain regional ones. Some countries have only one science academy that encompasses all fields, whereas others have several that specialise in a field, e.g., in engineering or medicine. Science academies have formed several *international associations* that allow them to collaborate on common agendas and pursue their aims by providing advice and influencing policy-makers at the international level.

Science Academies often perceive themselves as having a role in standard-setting and regulation of ethical conduct in science, and often set standard for professional ethical conduct, including scientific integrity and social responsibility. Their specific goals concerning ethical issues in research include:

- Initiating debate and providing a platform for reflection on ethical assessment in science;
- Using their advisory role and influence on governments and research institutions to raise awareness on these issues, providing advice and coordinating solutions;
- Addressing current ethical dilemmas in science;
- Implementing ethical guidelines in research policies;
- Providing ethics codes for researchers;
- Modelling procedures for ethics assessment and dealing with cases of misconduct.

International associations of science academies provide individual national academies with information and advice and co-ordinate national activities internationally with a view to alignment around common principles, and deal with misconduct in international research projects.[109]

The beneficiaries of assessment include governments, fellow academies, research institutions, researchers.

(9) *Academic and Professional Organisations in R&I*

Academic organisations are voluntary and non-profit organisations, open to researchers working in a specific discipline or field. The aim of such associations is first and foremost to advance and promote a specific discipline or field, and may also include efforts to put the discipline in the service of the public good. *Professional associations* (bodies, organisations) in the R&I field have similar aims while also concentrating on the professional interests and working conditions of its members. There exist thousands of academic and professional organisations, at local, regional, national and international levels. In many countries, there exist national organisations for the larger academic professions, such as associations for engineers, psychologists, and computer scientists. Often, there will be highly specialised national organisations as well, such as a national thoracic society for research into respiratory diseases, or a national organisation for corrosion engineers. There are also many international academic organisations and, in lesser numbers, professional organisations. Professional organisations often develop *ethical codes of conduct* for members of their profession, and scientific associations sometimes develop ethical guidelines for research in their field.

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[109] Drenth, Pieter J. D., "Scientific Integrity and Social Responsibility: The Role of Academies of Sciences", *ALLEA Annual Report*, ALLEA, Amsterdam, 2003, pp. 17-28 [p. 18].

The aim of ethics-related activities of academic and professional organisations is to consolidate ethical standards within a discipline at the national or the international level and to put them into effect as widely as possible. In fields where ethics assessment is already institutionalised to a significant degree, the role of associations is to review their guidelines according to the latest scientific developments and motivate their member institutions to update their assessment procedures and regulations.[110] In other fields, where ethics assessment is less institutionalised, e.g. social sciences, scientific associations have a big role to play in standard setting and guidance. Academic and professional organisations also play an important role in controversial areas where consensus on good practice is not yet achieved. In such cases, international associations and societies can play an important role by engaging in the discussion on particular issues from a professional or scientific perspective. The organisations may:[111]

- Issue declarations, ethical codes, guidelines and best practices,
- Issue statements in response to new scientific developments,
- Comment on new regulations and legislations proposals,
- Include acceptance of ethical codes in terms of membership and consider ethical aspects when defining and approving operating procedures or providing peer-reviews, accreditations or licenses,
- Provide consultancy and guidance on ethical issues to members.

The beneficiaries of guidance include members of the academic and professional organisations.

(10) *Companies*

Companies are organisations engaged in commercial activities, usually with a for-profit motive. The vast majority of companies are *SMEs* (small and medium-sized companies), which are companies with less than 250 employees and a turnover of less than €50 million. A *corporation* is a company that is recognized as having a legal existence as an agent separate from its owners, and is owned by shareholders. A *multinational corporation* is a corporation that owns or controls production of goods or services in one or more countries other than their home country, causing it to fall under multiple jurisdictions. Our concern in this report is with companies with a strong focus on R&I, which prominently include industrial companies, which are companies that engage in manufacturing and technical production.

In the business sector, many companies are engaged in research and innovation processes. Many large corporations have separate R&D divisions that are a driving force behind the company's success. Most corporations nowadays have policies, and officers or divisions, for *Corporate Social Responsibility* (CSR). CSR policy is intended to function as a self-regulating mechanism for business to ensure its compliance not just with laws, but also with the spirit of the law, with international norms and with ethical standards. An important

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[110] ICT Professional Societies in Europe. Role and Impact of Professional and Scientific Societies in ICT Research, Education and Innovation (SMART 2009/0061).
http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=7222
[111] Strle, Gregor, Rok Benčin, Jelica Šumič-Riha, Rado Riha, *"Ethics assessment in different types of organisations: National Science Academies and Academic & Professional Organisations"*, SATORI D1.1 Report, June 2015.

element of CSR is *social accounting*, which is the communication of social and environmental effects of a company's actions to stakeholders and to society at large. CSR may also include ethics training within the company. For companies that focus heavily on R&D activities, CSR will naturally focus to a significant extent on the company's R&D activities, and will normally consider ethical aspects of this activity.

Though large multi- and transnational corporations (MNCs and TNCs) have developed CSR strategies, though their motivations have been criticised as being "symbolic" rather than "substantive".[112] Big companies have developed their CSR strategies including codes of conduct and engage in CSR initiatives in order to develop positive image and impacts in the society and minimise risks to their business. CSR manifests in forms of: sustainability or sustainable development, business ethics, corporate social performance and corporate citizenship. CSR is less evident in smaller companies; the motivational pressures that may engage SMEs in CSR are not the same as for large companies.

The beneficiaries of CSR in companies include: the company itself, employees, company shareholders, clients/customers, and the public. Other beneficiaries include regulators, civil society organisations, and academia.

(11) *Business and Industry Associations*

Business and Industry Associations (also known as trade organisations and industry trade groups) are organisations that support businesses in a particular industry. They are usually not-for-profit. They usually provide information to companies in their sector, provide training and education programs, help companies meet industry standards, are involved in setting such standards, facilitate networking and collaboration between companies, arrange advertising and promotional programs for the industry, and lobby to influence governmental policy. *Chambers of commerce* are local, regional or national business associations that are not limited to a particular branch, and that represent business interests in a particular area. Their aim is to improve the economic and regulatory environment in which businesses operate, and to help their members prosper. They are often involved in the promotion of standards and quality of service, and may as such be involved setting ethical standards.

With a few exceptions, industry associations and networks do not play a very hands-on approach in setting and enforcing ethical standards and practices for their member organisations. Some associations develop Codes of Conduct or Business Practice, share good practice guidelines and also make relevant recommendations.
The beneficiaries of guidance, in this case, are primarily the companies that are industry association members.

(12) *Civil Society Organisations (CSOs)*

Civil Society Organisations are non-governmental, not-for-profit organisations that represent the interests and will of citizens. They may be based on cultural, political, ethical, scientific, economic, religious or philanthropic considerations. There is great diversity in CSOs; included are private voluntary organisations, cultural groups, not-for-profit social enterprises, civic groups, community organisations, consumer organisations, environmental organisations,

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[112] See discussion e.g. in Perez-Batres, Luis A., et al, "Stakeholder Pressures as Determinants of CSR Strategic Choice: Why do Firms Choose Symbolic Versus Substantive Self-Regulatory Codes of Conduct?", *Journal of Business Ethics*, Vol. 110, No. 2, 2012, pp. 157–172.

religious organisations, political parties, professional associations, non-governmental policy institutions, charities, activist groups, and social and sports groups. Trade unions and employers' organisations, the so-called social partners, constitute a specific category of CSOs. The organisational structure of CSOs is also very diverse. The level of operation of CSOs can be local (community, city), regional, national or international. The term "CSO" is sometimes used synonymously with "NGO" (non-governmental organisation), but some hold NGOs to be are a subset of CSOs that have a focus on development, human rights, and political causes. Some CSOs have a direct interest R&I (for instance, an organisation for amateur astronomers, a professional association of engineers), whereas for others, the interest is more indirect. CSOs may also engage in research and innovation themselves, or fund R&I.

CSOs sometimes engage in ethical assessment of research and innovation, although their activities may not always be labeled as such. For example, civil rights organisations may evaluate R&I activities for their positive or negative impacts on civil rights such as privacy, protection of personal data; patient organisations may assess new innovations and practices in medicine; and environmental organisations may evaluate new innovations for their consequences for the environment.

The objects of assessment or guidance are numerous, and include: research and innovation agendas, technological innovations, e.g. biofuels, scientific conduct of professionals, research grant applications for medicines, principles of research ethics, draft laws, the conduct of companies, professional conduct, guidance, societal impacts of R&I, ethics of journalistic practice etc.[113] For the majority of CSOs here, ethical reflection is perceived as a crosscutting issue. Thus assessment or guidance is closely related to the overall mission of the organisation which is value-based. The aims of assessment/guidance identified include: influencing agendas, performing a 'watchdog' function, promoting ethical behaviour, defending citizen and consumer rights, facilitating dialogue between research and global development practices.

Beneficiaries of assessment are wide, depending on the nature and the work of the CSO.[114] These include: Policy makers, governments, institutional review boards, ethics committees, institutional animal care and use committees, scientists and researchers, other CSOs/NGOs, industry, the public etc.

(13) *Standards Organisations*

A *standards organisation* (standardisation organisation, standards development organisation (SDO)) is any organisation whose primary activities are in developing standards, or specifications, to which products, services and systems should conform. Standards organisations focus mostly on technical standards, but some occasionally also develop non-technical standards, especially standards for the operations of businesses and organisations in certain domains, like risk management, sustainability of organised events and social responsibility. Standards organisations exist at national, EU and international levels. Standardisation organisations work closely with interested stakeholders in formulating standards. Most are voluntary and not encoded in law, but some mandatory when they are adopted by regulators as legal requirements in particular domains.

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[113] For an expanded list see: Warso, Zuzanna, *"Ethics assessment in different types of organisations: Civil Society Organisations (CSOs)"*, SATORI D1.1, June 2015.
[114] Ibid.

The aims of standardisation have been stated, by the ISO Committee for the Study of the Principles of Standardization, as being, the "promotion of:

- Overall economy in terms of human effort, materials, power etc. in the production and exchange of goods
- The protection of consumer interest through adequate and consistent quality of goods and services
- Safety, health and protection of life
- Provision of a means of expression and communication amongst all interested parties.[115]

To the extent that standards organisations provide standards that are based on ethical principles, they provide ethical guidance for organisations that follow the standard in question.

The beneficiaries of the assessment include: regulators, industry, consumers, and other interested parties.

(14) *Certification and Accreditation Organisations*

Certification organisations (or certification bodies) are independent entities that provide an assurance that a product, service, system, person or organisation meets specific requirements. Certification is usually dependent on a positive outcome of an assessment, external review or audit. In *professional certification*, a person is being certified as being able to competently complete a job or task, usually after passing an exam or completing a training or educational program. Another common type of certification is *product certification*, which refers to processes intended to determine if a product meets minimum standards (as in quality assurance). Certification organisations provide third-party certification; when individuals or organisations, or the associations to which they belong offer assurances that they meet certain claims, this is called first- and second-party certification.

Accreditation organisations are organisations that ensure that organisations that offer certifications employ acceptable certification practices, meaning that they are competent to test and certify third parties, operate with integrity and employ suitable quality assurance. For example, universities, which issue diplomas to students and thereby perform second-party certification, may have to pass accreditation for their educational programs by a third-party accreditation body. Certification and accreditation organisations usually operate at national and international levels.

The aims and objects of their assessment include: quality assurance for higher education, accreditation of educational courses, accreditation of organisations conducting clinical trials, accreditation of organisations using animals in research, teaching or testing, accreditation of the basic requirements for undertaking primary care research, certification of quality and protections for human research, accreditation of audit research ethics committees (REC) administrative procedures, standards for social responsibility and managing ethical and social risk in the supply chain, certification of ethical behaviour/corporate social responsibility/responsible business practice, of ethics compliance programs and practices, developing risk assessment tools to manage ethical risk in supply chains, and certification of professionals. In some cases, therefore, accreditation and certification are explicitly focused

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[115] Sanders, T.R.B, *The Aims and Priniciples of Standardization,* ISO, 1972.

on quality assurance in the realm of ethics. In other cases, meeting ethical criteria or paying attention to ethics may be one of the parameters that are assessed in accreditation or certification.

Beneficiaries of assessment include certified organisations/individuals, accredited organisations/individuals, parties relying on the certification, industry, consumers, and the public.

(15)   *Academic Ethics Centres and Departments*

Research in the area of ethics of research and innovation is often done by professional ethicists who work in universities and other research institutions. They are often part of specialised groups or units that focus on ethics research. These include *ethics centres*, *ethics units, departments,* or *divisions within departments*, or disciplinary or interdisciplinary *centres* that have (research and innovation) ethics as part of their mission. Researchers in ethics publish in academic journals, and often choose their own topics to address. Medical schools often have a division of group in medical ethics, which addresses ethical issues in medical research. Other schools (e.g., in engineering) may have similar groups. Qua discipline, ethics is usually considered to be part of philosophy, and philosophy departments usually include ethicists, although many may not include ethicists of research and innovation.

(16)   *Individuals*

Not all ethics assessment is performed by organisations. Individuals may, by their own initiative, also perform ethics assessment. Such *individual ethics assessment* is sometimes performed in an informal manner by scientists and innovators who explore the ethical aspects of their own activity. It should also be kept in mind that ethicists at universities and other research institutions often take the initiative themselves what they want to investigate and which practices or products of research and innovation they want to assess. In addition, any professional and any citizen can perform informal, non-professional ethics assessments and let their opinions be known to others, whether within organisations or through media.

Based on the discussion above, we can see that each category of assessors performs a significant but different role in ethics assessment. Sometimes the role is well-established (RECs, NECs), in other cases not so (e.g. companies, CSOs). The levels of ethics assessment activities might be greater (e.g. in areas of high ethical risk and where risk assessment is legally mandated) and sometimes less so (e.g. CSR). Even within each category there are some variances in how organisations envisage and perform ethics assessment (this could be due to national and cultural differences).

Ethics assessment takes different forms in the analysed categories. For some, it might be called ethics, ethical review; in the industry context it is CSR. Ethics assessment procedures are formal and rigorous in some organisations and in others very informal and highly flexible.

For some of the organisations, ethics assessment and the provision of ethics guidance is a regular and ongoing activity (NECs, RECs), for others it might be an occasional needs-based (Universities, companies). For some, it is a critical part of their mandate (RECs, NECs), while for others it is highly optional and ancillary to their activities (SMEs).

The aims and objects of assessment vary per category; some common themes that emerge include: facilitating and/or conducting ethically sound research, protection of research subjects' interests, providing platforms for sharing good practice, and providing advice on ethical issues and concerns.

Beneficiaries of assessment also vary per category. There are common beneficiaries across categories (e.g. research subjects' interests, the public interest). Sometimes the primary beneficiary is the ethics assessor organisation itself (e.g. Universities), at other times, the beneficiaries are more and even outside the organisation (e.g. CSR).

5.3 INSTITUTIONAL SETUP OF ETHICS ASSESSMENT IN ORGANISATIONS

Organisations may perform ethics assessment for research proposals internally (using an in-house assessment group), externally (by employing the services of outside experts or ethics committees), or some combination of the two. Such assessment will either be formal or informal, depending on the organisations involved and the available infrastructure. National ethics committees, government and government-funded organisations, national science academies, universities, and professional organisations typically have formal groups that perform ethics assessment, while civil society organisations tend to rely on informal groups. Depending on the relevant legislation and standards, industry may have formal or informal groups to perform ethics assessment or corporate social responsibility (CSR) reporting.

The function and procedures of national ethics committees and their procedures are usually described in law, and the government appoints the members of these committees. Universities, science academies, and professional organisations typically have their own internal ethics committees and working groups, although a significant number of universities have yet to establish their own research ethics committees. Government and government-funded organisations also tend to employ internal ethics assessment, although organisations that advise on policy sometimes seek out external advice and consult with relevant authorities. Research funding organisations tend to rely on external ethics assessments that are performed the relevant national body, although some funding organisations do perform internal assessment in collaboration with outside experts. Academic and professional organisations may also invite external experts to join their ethics committees.

Ethics assessment within universities may be performed by ethics committees established within individual departments and faculties. An alternative is to have a central ethics committee or research ethics office that performs assessment for the entire university. Such committees may also have subcommittees that specialise in particular areas of concern in research, such as genetically modified organisms (GMOs), human research participants, and animal experimentation.

Interdisciplinary memberships of ethics committees are a common feature of ethics assessment. University and national ethics committees typically have members from various disciplines, both within and outside of science, to ensure that a variety of perspectives are taken into account. In addition to those with expertise in the relevant research field, lawyers, theologians, philosophers and ethicists, laypersons and patient advocates (for medical research) may belong to ethics committees.

Consultation with stakeholders and members of organisations are another common feature of organisations and groups that establish guidelines and standards for ethics assessment.

Standards organisations consult with their member states, industry groups and companies, NGOs and civil society groups, and public authorities in developing standards for ethics assessment. Certification and accreditation organisations have representatives from their member organisations to advise them on the requirements for ethics assessment that will be incorporated into their certifications and accreditations. Ethics committees in different universities may also collaborate to develop standards and expertise, such as the UK University Research Ethics Committees Forum.

Academic and professional organisations define codes of conduct and ethical guidelines for their members. Universities also have their own codes of conducts and guidelines for acceptable research practice. National and international university associations, such as the VSNU in the Netherlands and the Joint IAU-MCO (International Association of Universities and the Magna Charta Observatory) Working Group on Ethics in Higher Education, may also promote guidelines and standards for ethics assessment. Civil society, standards, certification, and accreditation organisations may also develop guidelines and codes of conduct, although they will usually be voluntary. These organisations may also perform assessments and consultations for organisations and companies that seek to follow their guidelines. The Clinical Research Society (CRS) and the Association and Accreditation of Laboratory Animal Care (AAALAC) are two examples of such organisations.

The concept of CSR has a major influence on how industry performs ethics (or 'impact') assessment. The relevant legislation and official reporting requirements in the countries that they operate in, in addition to whatever voluntary guidelines and codes of conduct the industry supports, will affect what assessment takes place and how it will be performed. The Global Reporting Initiative (GRI)[116] and the ISO 26000 standard for social responsibility[117] are two such voluntary standards.

5.4 PROCEDURES FOR ETHICS ASSESSMENT

The organisations examined serve roles in ethics guidance, ethics assessment, or a combination of the two. National ethics committees, national science academies, and professional organisations provide ethics guidance for research, while standards organisations and government and government-funded organisations focus on ethics assessment. Certification and accreditation organisations may perform both functions.

The procedures institutions use to conduct ethics guidance and assessment vary depending on the role of the institution and the risks associated with the proposed research. National ethics committees typically form a working group to examine a project or an issue, and consult external experts if necessary. These committees will present their findings to the relevant authority, and often will also disseminate their conclusions to the public. Some forms of research, such as research involving human or animal participants, have a legal requirement for ethics assessment to be performed. For non-biomedical research it will depend on the level of risk posed by the particular study. Ethics assessment may either be distinct from technical or scientific assessments of a research proposal or it may be incorporated into the general technical assessment.

The procedures for ethics assessment will differ depending on whether it is performed before, during, or after the completion of the research project. Before a research proposal is approved,

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[116] Global Reporting Initiative (GRI). http://www.globalreporting.org/
[117] ISO, *Discovering ISO 26000*. http://www.iso.org/iso/discovering_iso_26000.pdf

government and government-funded organisations that control research funding will provide technical and administrative support to research proposals, even though they may not otherwise have formal ethics assessment procedures. Research funding organisations will verify that the proposal meets the relevant legal requirements for ethics review, and will confirm that it complies with the relevant guidelines and policies. If a proposal is particularly controversial, funding organisations may seek further information from the researchers and may consult with other parties. Policy advice organisations may form a working group to define the appropriate ethics assessment for a proposed project. National ethics committees may either select their own topic for assessment or have one assigned to them by whoever has the authority to do so.

Once a research proposal is approved, the procedures for ethics assessment will focus on whether the project is complying with the requirements that have been set for it. This includes verifying that research is performed only after ethical clearance for it has been gained, and that organisational policies on conflicts of interest and confidentiality are being followed. Appropriate action may also be taken if there is evidence of research misconduct. Ethics assessment conducted by funding organisations is primarily focused on dealing with instances of scientific misconduct rather than specific issues with the subject matter of the research project itself. However, policy advice organisations rarely have procedures for assessing research projects that are underway.

After the completion of an ethics assessment or a research project, organisations have different procedures to address ethical issues. Funding organisations sometimes need to be informed of difficulties that emerged during the project and how the researchers addressed them. Organisations in charge of government research funding will sometimes have procedures to ensure that the research project funding was in accordance with the approved proposal. Certification, and accreditation organisations typically have similar procedures for conducting ethics assessments. An organisation seeking approval from such organisations will first perform an internal review to see if it meets their requirements. Accreditation and certification organisations may conduct an initial review to identify changes that are necessary to meet their requirements. Once the assessment has been successfully completed and approved by the organisation behind the standard or accreditation, the assessment procedure may be repeated after a given period to ensure that the standard continues to be met.

Industry has a variety of possible procedures for performing ethics assessments. Rather than 'ethics assessments', these procedures may be called 'impact assessments', such as social impact assessment (SIA) and environmental impact assessment (EIA). While they avoid the language of ethics, these assessments still attempt to find the best outcomes for society and the environment from the actions they assess. Existing procedures for risk assessment and cost-benefit analysis can be employed to perform impact assessments. These assessments might be performed internally or may involve external auditors, such as relevant civil society organisations or government-funded organisations, such as data protection agencies for privacy impact assessments. Financial reporting requirements and guidelines such as the GRI (Global Reporting Initiative)[118] may also describe procedures companies must follow. For example, the Directive 2014/95/EU on disclosure of non-financial and diversity information requires companies to disclose information in their management reports about the social and

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[118] Global Reporting Initiative (GRI), http://www.globalreporting.org/

environmental impact of their policies and practices.[119] Mandatory reporting requirements give companies an incentive to perform ethics assessment even when it would be more profitable for them to avoid it.

National science academies may be directly or indirectly involved in ethics guidance. Science academies are directly involved in investigating claims of scientific misconduct. They may influence ethics assessment procedures through giving advice and defining standards for research. Standards, certification, accreditation, academic and professional organisations, and university associations similarly provide advice and define standards acceptable research practice. Academic and professional organisations may also have their own working groups and professional ethics committees to assess cases of misconduct. Such organisations may also operate training courses on research ethics.

Unlike most of the other organisations examined here, civil society organisations have informal procedures for ethics assessment or guidance that will depend on the civil society organisation itself, the project or issue being assessed, and the intended audience for the assessment. Such organisations may perform public education and awareness campaigns, serve as 'watchdogs' by monitoring the activities of government and industry, produce reports and recommendations on ethical practice, or form expert panels and forums to discuss particular issues.

5.5   PRINCIPLES AND ISSUES FOR ETHICS ASSESSMENT

In this section, we will analyze and compare the kinds of ethical issues and principles that different categories of organisations involved in ethics assessment and guidance are concerned with.

National ethics committees (NECs)

National ethics committees (NECs) tend not to include fixed ethics principles and ethical issues in their deliberations and reports. Ethics frameworks vary according to the topics at hand. Ethics principles also vary according to differences in the mandate of NECs. Reports produced by national ethics committees allude to general ethical principles (e.g. justice/fairness, human dignity) and general ethical issues (e.g. implications for health and/or safety and implications for quality of life). Additional issues such as the treatment of animals in R&I and environmental impacts are addressed if provided for by the mandate of the NEC.

Civil society organisations

Guiding principles for ethics guidance and assessment by civil society organisations (CSOs) are often enshrined in the document establishing an organisation. Moreover, values and principles referred to by CSOs are often based on human rights. In order to influence policy-making, CSOs often refer to the six values found in the Charter of Fundamental Rights of the European Union, namely, justice, dignity, freedom, citizens' rights, solidarity and equality. CSOs also have recourse to international legal instruments in order to further justify and legitimise their activities. Religious organisations refer to values inherent to a given religion in their (informal) assessments and guidance. Finally, some CSOs establish their own

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[119] European Parliament and the Council, Directive 2014/95/EU of the European Parliament and of the Council of 22 October 2014 amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups, *OJ L* 330/1, 15.11.2014.

frameworks - these frameworks may take, for example, the form of formalised key claims, codes of conduct, a charter of good practice or practical guide for scientists and researchers.

Research ethics committees (RECs)

Research ethics committees (RECs) are required to adhere to national and international laws and regulations in their assessments. RECs assessing biomedical research base their ethics assessment on codes such as the Declaration of Helsinki, the Oviedo Convention, the Nuremburg Code and the EU Charter of Human Rights. European directives in the areas of clinical trials, protection of animals and data protection are also relevant in the assessment work of RECs. The principle of Three Rs is relevant for RECs assessing research involving animals. The most important aspects evaluated by RECs include human subjects research, autonomy of participants (includes informed consent), implications for health and/or safety (non-maleficence), scientific integrity, implications for privacy and human dignity.

Research funding organisations

Ethics assessment of research proposals by research funding organisations is not always formalised, thus specific principles and issues can be difficult to identify. The minimum standard of ethics assessment relates to ethical principles provided for by law - these principles usually relate to human subjects research, animal research and data protection. The European Commission's Horizon 2020 funding programme goes beyond the issues mentioned to a more comprehensive ethics assessment. Areas that are covered include research on human embryo/foetuses, human subject research, human cells/tissue, protection of personal data, animal research and third countries. Some organisations in Europe include gender, open access strategies, quality of the research team, scientific impact and the usefulness of science as principles by which research proposals are evaluated.

National science academies

The general values and principles promoted by national science academies can be categorised into different groups, depending on the aims of the organisations. They include the advancement of science (freedom and autonomy, universality and excellence); scientific integrity and social responsibility, and prevention of harm (human dignity, informed consent, regard for vulnerable groups, privacy and confidentiality). Different sets of values are not always easily reconcilable; for example, a tension exists between freedom and scientific autonomy, on the one hand, and social responsibility, on the other.

Academic and professional organisations

Academic and professional organisations address two aspects of ethical values and principles, namely those general values and principles that apply to the research and innovation community as a whole, and specific ethical values and principles that relate to the characteristics of a particular field. With regard to the latter, there are a range of public policy issues across the engineering, IT and technology areas in issues ranging from accessibility to intellectual property, and security and privacy. As regards the former, academic and professional organisations provide ethical guidance by setting out discipline-specific ethical values and guidelines for good conduct. For example, the European College of Pscyhopharmacology's Code of Conduct includes commitment to the health and wellbeing of

patients and research subjects and the scrutiny of benefits and risks as top priorities for its members.

Universities

The most universally accepted principles for universities include autonomy and freedom, social responsibility and cultural importance, inseparability of teaching and research and rejection of intolerance and openness to dialogue. Individual universities draft their own ethical codes and guidelines, which often focus on different dimensions of scientific integrity, impartiality, collegiality, and social responsibility.

Certification and accreditation organisations

Principles and issues for certification and accreditation organisations vary according to the particular area in which the organisation is involved and its particular mandate. Thus values and principles vary from humane care and use of laboratory animals to transparency and the use of external expertise in quality assurance processes for standards for higher education.

Industry

The most salient issues in Corporate Social Responsibility (CSR) include sustainability, sustainable development, environmental management, philanthropy and community investment, environmental and social impacts, ESIA (Environmental and Social Impact Assessment), stakeholder engagement, business ethics, worker rights and welfare, human rights, corruption, corporate governance, legal compliance, and animal rights. Human rights comprise a crucial reference point in companies' CSR strategies. Key examples of global initiatives include the Universal Declaration on Human Rights (and Charter of Fundamental Rights of the European Union and the European Convention on Human Rights); United Nations Guiding Principles on Business and Human Rights; United Nations Global Compact; and the OECD Guidelines for Multinational Enterprises (OECD Guidelines).

CSR priorities across sectors include respect for human rights, respect for workers' rights and occupational health and safety, sustainability (both internal and external to the company's activities) and professional ethics and responsibility towards all stakeholders.

Government organisations and government-funded organisations

Principles and issues for government and government-funded organisations range from social impacts to human dignity, and dual use. However, the most important issues in ethics assessment across the organisations surveyed include social impact, professional integrity, environmental impact and social responsibility.

Principles and issues used in ethics assessment/guidance practices across different organisations

Scientific integrity comprises an ethical principle in ethics assessment carried out by CSOs, national ethics committees, research funding organisations, national science academies, academic and professional organisations and universities. For NECs and research funding organisations, scientific integrity refers to the "making of science", e.g. the quality of research according to scientific standards, quality of the research team, scientific impact and avoiding

scientific misconduct such as misuse of resources and plagiarism. National science academies, academic and professional organisations and universities tend to codify principles for research integrity in codes of conduct and ethical guidelines. Ethical values and principles for academic and professional organisations tend to be more practically oriented - they aim to motivate professional conduct and competency and responsibility towards society.

Professional integrity is an important principle in ethics assessment practices employed by CSOs, research funding organisations, national science academies, academic and professional organisations and government and government funded organisations. Under the latter category of organisation, professional integrity is an important principle for national ethics committees and committees providing policy advice. For this category, the principle of professional integrity includes items such as research integrity, responsibility and transparency. Professional integrity is key to business ethics.

Principles and issues concerning *human subjects' research* are particularly salient for research funding organisations and research ethics committees. For research funding organisations, criteria for human subjects' research include autonomy, integrity, protection of human beings, informed consent, beneficence, justice and balance of benefit and harm. Protection of personal data is also a key issue. The majority of research ethics committees assess research involving human subjects' research. One particularly important issue concerns informed consent. RECs are particularly interested in information sheets and consent requirements, and pay special attention to vulnerable research participants in this regard. Autonomy is an important guiding principle in the work of RECs on informed consent. Considerations regarding human subjects research are also part of the work of CSOs and NECs (general ethical issues), while principles and issues relating to human subjects research arise in specific disciplines and fields addressed by universities and academic and professional organisations. The healthcare sector is engaged in safeguarding the rights of patients.

Ethics assessment regarding the *treatment of animals in experiments* is an important aspect for the majority of organisations. Ethics assessment frameworks for RECs regarding animal welfare have recourse to the principles of replacement, reduction and refinement (The Three Rs or 3Rs) as laid down by the European Directive on the protection of animals used for scientific purposes. RECs judge that animal welfare can be justified when the benefits of research outweigh the harms. CSOs and research funding organisations also have recourse to the 3Rs principle.

Certification and accreditation organisations and initiatives appear to be strong in this area, with attention given to the humane care and use of laboratory animals, accreditation of medical research ethics committees and requirements for undertaking primary care research (in the UK) by the organisations surveyed. Issues regarding the treatment of animals in experiments are important for the healthcare sector.

Consideration of implications for *individuals and civil rights* in terms of specific items such as *autonomy, freedom, privacy, human dignity, bodily integrity and non-discrimination and equality* takes place across all organisations but to varying degrees. National science academies have a particular focus on the advancement of science and advancing the role of freedom and autonomy, and the prevention of harm (human dignity, privacy and confidentiality). Given the importance of informed consent for NECs, informed consent and regard for vulnerable groups are important issues in assessment by NECs. These issues are very important for RECs, given their central focus on human subjects' research. These issues

form part of general ethical issues for CSOs and academic and professional organisations. For the latter category, the issues may be more pertinent in certain areas than in others. For research funding organisations, principles and related ethical issues in human subjects' research are provided for by law. The Horizon 2020 programme includes free and informed consent, risks/benefits evaluation, particularly in the case of invasive techniques, inclusion of vulnerable populations and protection of personal data as issues in this area. Accreditation initiatives for research involving human subjects are relevant here, as are standards for social accountability and social responsibility. Implications for individuals and civil rights are key across all sectors of industry. Issues within the electronics/information technologies sector, for example, include privacy, authenticity and identity and integrity and dignity (including bodily integrity).

Implications for *distributive justice* in ethics assessment practices are important for the majority of organisations. Issues falling within this category are particularly important for research funding organisations. For example, under H2020, ethics review requires that researchers should be aware of the potential exploitation of research participants and/or local resources in third countries. Moreover, important elements of distributive justice addressed by some research funding organisations include the gender aspect and open access issues. Academic and professional organisations include the cultivation of respect for life and human dignity (without discrimination with regard to age, race, religion, nationality, social situation or political ideology) as important principles. Universities espouse the rejection of intolerance and solidarity with and fair treatment of international partners, as reflected in major international guidelines setting out universal principles. Implications for distributive justice are particularly relevant in the energy sector.

Implications for *health and safety* are important in ethics assessments conducted by RECs, research funding organisations and NECs (but only if committees have a mandate to address issues in this area). Implications for health and safety are important for RECs given their focus on human subjects' research, animal welfare and vulnerable subjects. Research funding organisations also focus on this issue - consideration of health and safety risks faced by researchers and staff is an important element in doing research, according to guidance for the H2020 programme. Respect for workers' rights and occupational health and safety are key priorities for CSR activities across all industry sectors. Universities address this issue depending on the specific discipline or field. Specific professional associations such as the European College of Neuropharmapsychology include the health and wellbeing of patients and research subjects as a priority for high standards of research.

Implications for *the environment* are linked to the latter implications and are considered in the activities of CSOs, NECs (if mandated to deal with such issues), research funding organisations and industry. Specific issues for industry include sustainability, environmental performance and climate change (prevention, mitigation and adaptation). These issues are also taken up in certifications and standards for ethical business practices. Specific professional associations may include this issue in their assessments. For example, the Center for Engineering Ethics and Society addressees ethical issues that arise in engineering and scientific research, education and practice, including environment, safety and sustainability which includes focused collections on climate change, engineered systems and society and energy ethics. Several governmental and government-funded organisations view environmental implications as key to their work.

Quality of life is an important issue for most of the organisations. Implications for the quality of life comprise general ethical issues for both CSOs and NECs. Promotion of the common good is a policy criterion for research funding organisations in the "making of research" and could be said to fall under "quality of life". Some national science academies put special emphasis on quality of life criteria, including, for example, the French Academy of Medicine's focus on the emotional and sexual quality of life of people with disabilities. Quality of life is addressed by government and government-funded organisations under the principle of social impacts and is viewed as being specific to the particular situation in which the organisation is involved. Thus, for example, quality of life is a crucial focus in the work carried out by the European and Developing Countries Clinical Trials Partnership. Quality of life can be seen as part of the International Organization for Standardization's 26000 standard on social responsibility, as it aims to provide guidance on contributing to the health and welfare of society.

Dual use issues comprise specific issues for ethics assessment practices of research funding organisations, industry and in the work of some CSOs. Dual use is highlighted as a key issue in ethics review for the H2020 programme, with an emphasis on the need for special measures to be taken in order to ensure that the potential for misuse of research is adequately addressed and managed. The electronics/information technology sector has to grapple with the issue of dual use. Dual use may also arise in specific areas addressed by academic and professional organisations, for example, in the fields of engineering, IT and technology.

Outsourcing of research and/or innovation to developing countries with lower ethics or other standards is a particular issue for research funding organisations. The H2020 programme, for example, stipulates that research carried out in developing countries must comply with all relevant European and national legislation and with relevant accepted international standards. This issue is particularly salient for the materials and energy sectors, in which land rights may not be respected and 'land grabs' made for coal, biomass and in the extraction of raw materials. This outsourcing issue is also relevant in ethics assessments carried out by CSOs.

5.6 PROBLEMS AND DEVELOPMENTS

The ethics assessor organisations analysed in the SATORI studies vary both in their perception and assessment of their problems and the challenges they face. The following table compares the problems and challenges reportedly faced by the different types of ethics assessor organisations. The table is prepared based on the information received from the organisations interviewed in the course of work package 1 of this project and reported in the individual reports on ethics assessment in different organisations. A tick is marked against the category that explicitly highlighted the problem and sees it as a key challenge.

Problem/challenge related to ethics assessment	RECs	NECs	RFOs	NSAs/ A&POs	CSOs	Industry	Universities	G,GFOs
Lack of clear procedures (standards, protocols, guidelines, tools) for ethics assessment	✓		✓					✓
Fragmentary nature of procedures			✓					

Problem/challenge related to ethics assessment	RECs	NECs	RFOs	NSAs/ A&POs	CSOs	Industry	Universities	G,GFOs
Heterogeneity in approaches & guideline implementation				✓		✓	✓	✓
Lack of user friendly policies			✓					
Overloaded ethics committees, lack of fruitful discussion, human factors, inconsistence reviews	✓			✓				
Increase in bureaucracy			✓					
Lack of knowledge of legal requirements	✓							
Political conflicts/relationship with ethics (issue avoidance, disregard)		✓		✓				
Lack of awareness of ethics issues & structured approaches	✓				✓	✓	✓	
Lack of (focus on) compliance monitoring	✓	✓		✓				
Lack of resources (financial, human, time, knowledge)	✓	✓	✓	✓	✓	✓ (for SMEs)	✓	✓
Training and awareness	✓			✓				
Lack of public engagement & outreach	✓	✓						
Lack of self-assessment of the effectiveness & impact of ethics assessment practices	✓				✓			
Inability to implement non-binding/Failures of self-regulation		✓				✓	✓	
Lack of evidence of uptake of ethical reports		✓						
Overtly high expectations		✓						

Problem/challenge related to ethics assessment	RECs	NECs	RFOs	NSAs/ A&POs	CSOs	Industry	Universities	G,GFOs
Focus on areas which have traditionally produced ethical conflicts		✓						
Narrow scope of ethics assessment			✓					
No data on proposals rejected for non-compliance			✓					
Difficulty in determining during application phase potential ethical threats and dangers			✓					
Problem accepting ethical criteria in the research community (beyond what is provided for by law)			✓				✓	
Difficulties in including gender aspects as an ethical principal			✓					
Reactiveness of approaches				✓				
Independence of public research and innovation from government influence				✓				
Window-dressing nature of ethics					✓			
Weak institutional or structural "anchorage" in influencing the decision making process					✓			
Additional ethical constraints might limit creativity						✓		

Table 2: Comparison of problems across ethics assessor categories

All categories of ethics assessor organisations face the problem of lack of resources (financial, human, time, knowledge). The two other significant problems highlighted are: heterogeneity in ethics assessment approaches & guideline implementation within the organisational categories themselves and across countries; and a lack of awareness of ethics issues within the organisations, and a lack of structured approaches. Also significant is the lack of focus on and

resources devoted to compliance monitoring (the monitoring of whether those whose plans, activities or behaviors are assessed comply with voluntary or mandatory recommendations).

In conjunction with measures to address the above mentioned challenges, the analysis suggests it is significant to ensure:

- That the challenges posed by new technologies are taken into account in ethics assessment and ethics assessment mandates (RECs & NECs)
- Investment in education and training of people (RECs)
- People are better able to engage in ethics and discussion of ethical issues, and there is more consultation with citizens, and interaction with other ethical assessment organisations is improved (NECs & NSAs/A&POs)
- Critical new problems are identified (RFOs)
- CSO participation in, and access to ethics review panels and the ethics debate is increased (leaving ethical considerations to the public sector and research funders alone is a risky approach) (RFOs & CSOs)
- Ethical behaviour in the private sector needs clear and precise rules and can be strengthened by legal regulation (Industry)

6   COMPARATIVE ANALYSIS BY COUNTRY

6.1   INTRODUCTION

This chapter offers a comparative analysis of the existing structures and agents for the ethical assessment and guidance of research and innovation in both the public and private sectors in Europe, the United States (US) and China. The aim of the analysis is to understand similarities and differences in the ways in which ethics assessment and guidance are organised in different countries. Such understanding will be used in subsequent reports in order to develop and evaluate proposals for harmonising and improving ethics assessment in EU member states. This comparative analysis is based on in-depth case studies of the ethics assessment and guidance landscape and infrastructure in ten countries. In addition to the US and China, eight representative European countries have been chosen for in-depth study, including seven European Union (EU) members - Austria, France, Germany, The Netherlands, Poland, Spain and the United Kingdom (UK) - and one candidate for membership, Serbia. Individual reports were compiled for each country (see Annex 4) and include the following sections:

- basic information about the country's research and innovation landscape, in addition to a description of the historical development of ethics assessment institutions in the country;
- an overview of national and regional government institutions and policies;
- a description of public and private research and innovation systems and their role in and methods of ethics assessment;
- a description of the role of ethics assessment in the activities of professional groups and associations for research and innovation and in the activities of civil society organisations (CSOs).
- a discussion of the findings of the country study, in addition to the strong and weak points in the current ethics assessment infrastructure.

The country reports are based on desktop research and on interviews (an average of 14 per country) with organisations that engage in ethics assessment and guidance (an average of 12 such organisations) and other stakeholders (CSOs and governmental organisations). For more detailed information about the interview categories, please see appendix 1.

6.2   GOVERNMENT INSTITUTIONS AND POLICIES

At the national level, advisory councils for research, technology and innovation policy are common within the countries examined, with only Austria, Spain, and the UK lacking such organisations. Both China and the US have comparable advisory organisations.

The countries examined also have advisory groups dedicated to specific issues in science and technology. All of the European countries covered have at least one national advisory group for public health and healthcare policy. The US and China have comparable advisory organisations. Spain, Poland, France, the UK, and China also have advisory organisations devoted to issues concerning human genetics and assisted reproduction technology.

Several countries also possess advisory organisations that are concerned with other areas of research. Spain, Poland, France, China and the US possess advisory groups on research ethics and integrity. The Netherlands, Germany, the UK, Serbia, Poland, Austria and France also

have advisory groups for government policy on genetic modification. China also has a similar organisation, while the US does not. The Netherlands, Germany, the UK, Spain, Austria, and France have advisory groups on animal experimentation. The Netherlands, Germany, and China also have advisory groups on the environment, and France has an advisory committee on agricultural research.

Most of the countries considered have national ethics committees in some form. In Germany, ethics assessment is mostly performed at the regional rather than national level. The Netherlands, Serbia, Poland, Austria, France, and the UK have national organisations that review at least some proposals for animal experimentation. National ethics committees that specifically review research involving human participants exist in the Netherlands, Serbia, Austria, France, the UK, the US, and China. There are national ethics committees for health and bioethics in Poland, Serbia, France, the UK, the US, and China. Serbia, France, and China also national ethics committees for the life sciences. Spain, Serbia, Poland, France, China and the US have national committees on research ethics. Serbia and the US have national committees that deal with ethical issues raised by the conduct of officials.

All of the countries considered have some form of environmental or social impact assessment agency. The Netherlands, Germany, Serbia, Poland, France, the US, and China have agencies concerned with assessing environmental impacts. The Netherlands, France, the US and China have agencies that consider the effects of the environment on human health. Germany and Austria have agencies that assess the impact of climate change and assess renewable energy sources. The UK, Austria, and China have agencies assessing the impact of GM crops on agriculture.

Only a few of the European countries examined have a general technology assessment agency, with only the Netherlands, Germany, and France having such agencies. Germany also has a nanotechnology assessment agency. Spain and the UK have agencies that assess medical devices. The UK also has agencies that assess the social impact of human genetics research and development and healthcare research. Both the US and China have general technology assessment agencies, with China also having an agency devoted to assessing the use of genetic engineering.

All of the European countries considered have a watchdog agency on data protection. Outside of data protection, the watchdog agencies within European countries vary in their remit. The Netherlands, Germany, and the UK have food safety watchdog agencies, and the Netherlands, Germany, and Poland have agencies responsible for consumer products as well. Both the Netherlands and the UK have watchdog agencies for animal welfare and experimentation, and Germany and France have agencies concerned with public health and biomedicine. The UK also has a watchdog agency for the environment and the use of genetic modification. Serbia also has a watchdog agency devoted to the protection of citizen's rights by authorities. Neither the US or China have watchdog agencies that fall within the scope of the SATORI project.

Only the Netherlands and Germany have discussion forums relevant to this area. There is no overlap in the topics of these forums, however. The Dutch forums are concerned with biotechnology and genetics, while the German forum discusses renewable energy.

All of the countries covered have national laws and policies regarding experiments involving human participants and animal experimentation. There is less consensus on national law and

policies in other research areas, however. The Netherlands, Spain, Austria, France, Germany, and the UK all have data protection laws and policies. Austria, France, Germany, China, and the US have laws and policies concerning environmental impact assessments, while the Netherlands, China, and the UK have laws and policies on environmental management. The Netherlands, Serbia, Poland, Austria, and Germany legally guarantee academic freedom in pursuing research (within the limits set by human rights and other obligations).

There is much less consensus on national laws and policies in other areas of research among the countries examined. Austria, France, Germany, and the UK have (or in the case of Austria, are developing) such policies on the development and testing of new medical devices. Austria and Germany regulate the development of 'dual use' technologies. Poland, Austria and France have specific legislation dealing with genetically modified organisms. Spain, Germany and the US have laws and policies on stem cell research, while Germany and the US also have regulations regarding genetic testing. China and the UK have laws and policies on human artificial reproduction technologies. The Netherlands has legislation that requires research institutes to have an ethical code. Serbia has similar legislation, although it only requires health institutes to possess an ethical code. The UK has legislation concerning food safety. Finally, Germany has legislation that covers research integrity.

Only Spain, Germany, the UK and the US have noteworthy regional institutions and policies in research. In both Spain and Germany, regional administrations have their own ethics committees who must approve research conducted in their area. Wales and Northern Ireland in the UK also require ethical review for research involving human participants in independent medical facilities. The US has a significant amount of regional control in regulation due to its political structure, which means that individual states may have different regulations on research ethics.

6.3   PUBLIC RESEARCH AND INNOVATION SYSTEMS

1.   General structure and role of government

In most of the analysed countries, different structures of public research and innovation systems exist, and the role of government varies in nature (ranging from autonomous, supportive, significant and even highly regulated) and level (decentralised or centralised). In the case of the US for example, the system of higher education and government-funded research is highly decentralised and even though private universities are licensed by the state, universities are independent of state control. The federal government only has limited direct authority over institutions for higher education and research in the US. The direct authority of state governments over higher education is far more substantial than that of the federal government. In contrast, the Chinese government plays a very important role in the public research and innovation and the independence and freedom of important research institutions is restricted because they are all directly under the leadership of the central government (most are directly under the Ministry of Education).

The role of the government may also change in time (e.g. Serbia) based on political developments. In some of the analysed countries, there are a variety of institutions involved in policy making in research and higher education, however, research and education have a high level of independence from the involvement of government (e.g. the Netherlands). Many of the policies that affect the practices of ethics assessment at the research institutes are

developed by organisations created by law and directly funded by government, though not part of the central government.

The different types of bodies part of the public research and innovation system include: Ministries and government departments, policy advisory bodies, platforms for standard setting, funding organisations, higher education institutions, research institutions, and other research performing institutions (including non-profit), foundations. In some cases, there are a large number of bodies and organisations that make up a part of the public R&I system (e.g., the Netherlands), while in others such as France, the public research and innovation system is structured around a small number of agencies that fund research projects carried out mostly by public research institutions.[120]

Governments may use identify strategic priorities (e.g. UK where public research funding operates under 'Haldane principle'[121],) and use strategic tools such as performance agreements (e.g. Austria) between the universities and the federal authorities.[122]

2. *National research associations and standard-setting bodies*

National research associations might be general or field-specific.[123] They play various roles in ethics assessment. Associations in some countries play a more proactive role than others (e.g. Serbia where one of the key organisations does not make recommendations with regards to ethics assessment or mention it in their documents). Based on the country reports, national research associations and standard-setting bodies play the following roles in relation to ethics assessment:

- Formulating agendas, national visions and policies on ethical issues in higher education and scientific research (e.g. Austria, China, Germany, the Netherlands, Poland, US)
- Identifying ethical issues, providing expert advice and opinions on specific ethical issues (e.g. China, France, Germany, the Netherlands, Poland, Serbia) and offering support to the public, researchers and organisations to further good practice in academic, scientific and medical research (e.g. UK)
- Governing, overseeing and setting standards for higher education and scientific research systems (e.g. Austria, the Netherlands, Spain)
- Conducting evidence-based external reviews of higher education providers and reporting findings publicly on the basis of established criteria; investigating concerns about academic quality and standards (e.g. France, UK, US)
- Evaluating whether accreditation standards of institutions contain mechanisms for internal quality control (e.g. Serbia)
- Advocacy and campaigning, coordinating sector wide efforts (e.g. UK)

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[120] These agencies include the National Research Agency (ANR), Bpifrance, the Agency for Environment and Energy Management (ADEME) as well as the French National Agency for Research on Aids and viral hepatitis (ANRS).
[121] British House of Commons, "The Haldane Principle".
http://www.publications.parliament.uk/pa/cm200809/cmselect/cmdius/168/16807.htm
[122] Bundesministerium für Wissenschaft, Forschung und Wirtschaft, *Universitätsbericht 2014*,
http://www.bmwfw.gv.at/Presse/AktuellePresseMeldungen/Documents/Universitätsbericht_2014.pdf
[123] See SATORI D1.1 Country report: the Netherlands.

- Facilitating relationships and dialogue between government, private sector, professions and sector agencies (e.g. Spain, UK, US)
- Promoting integrity and high ethical standards in research, and robust and fair methods to address poor practice and misconduct (e.g. Poland, UK, US)
- Supervising and administering the academic ethics of researchers and scientists (e.g. China)
- Providing training to help higher education providers develop and improve their quality assurance processes (e.g. UK)

3. Research funding organisations

The individual country reports elaborate in detail the type of public research and funding organisations in each analysed country. In most analysed countries, there is a small number of public research funding organisations. In others such as China, Serbia and Spain, government is the most important, if not the only body that performs systematic funding of scientific research. In Germany, most of the public funding for research and innovation is organised through organisations that are partly independent from the government and usually organised as foundations or associations.

Research funders regard the ethics in research proposals as an important issue. Their ethics evaluation might cover the following topics: research on animals; informed consent; privacy and data protection; research on human embryonic stem cells; research involving developing countries; and bio-security/dual use. In Spain, for biomedical research projects involving human beings or/and human materials or data, and animal research, the needed documents include the positive ethical evaluation by an authorised ethics committee, as required by law. Even in the case of private foundations, research projects funded must have the positive ethical evaluation by an authorised ethics committee, when required by law.[124] In Austria, as regards ethics, the latest three-year performance agreements contain the obligation of setting up ethics committees at universities.[125] In France, all research projects on human beings or on animals must obtain ethical clearance by the State boards. In China, funded candidates, are required to adhere to legal requirements and relevant standards on scientific research ethics and R&D integrity.[126] In the US too, funding applications (following national legislation) are assessed according to ethical principles and include consideration of ethical problems related to the protection of human subjects from research risks and in the use of vertebrate animals, human subjects.[127]

Ethics evaluation might be conducted in-house, or outsourced (e.g. as in the case of the NWO to accredited Dutch ethics committees[128]). Funding applications if raising ethical concerns (e.g. research involving human subjects and/or animals) might require a statement of approval or by law,[129] a permit.[130] Applicants are generally responsible for obtaining the necessary

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[124] Fundación Alicia Koplowitz, Convocatoria de Ayudas a Proyectos de Investigación 2015, Bases Convocatoria 2015. Fundación BBVA, Convocatoria Fundación BBVA de Ayudas a Proyectos de Investigación, http://www.fbbva.es/TLFU/dat/Bases_convocatoria_ayudas_proyectos_investigacion_.pdf http://www.fundacionaliciakoplowitz.org/en/component/jdownloads/finish/2/221
[125] Bundesministerium für Wissenschaft, Forschung und Wirtschaft, *Universitätsbericht 2014*, http://www.bmwfw.gv.at/Presse/AktuellePresseMeldungen/Documents/Universitätsbericht_2014.pdf
[126] See SATORI D1.1 Country report: China.
[127] See SATORI D1.1 Country report: USA.
[128] See SATORI D1.1 Country report: the Netherlands.
[129] Dutch Parliament, Wet op het bevolkingsonderzoek, BWBR0005699. http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum_29-09-2014

statement(s) of approval or permit(s) by the proper ethical committee(s). Research projects can commence only once necessary ethical clearances have been obtained.

Some concerns have been expressed in relation to ethics in public research funding organisations: one, relates to non-transparency of the ethics assessment process[131]; two, lack of ethics assessment in areas of research such as social or technological development research[132]; three; the field specific outlook of the review committees which has the implication that most of these focus on field-specific requirements rather than consulting each other on possible cross-disciplinary concerns[133].

4. Research performing institutions

Public sector research performing institutions include universities, research institutes, hospitals, semi-public organisations (e.g. *Netherlands Organisation for Applied Scientific Research* (TNO) in Netherlands), and a number of other state-owned research and advisory bodies. They vary in size, coverage and nature.[134] The degree of ethics assessment performed in, or by these institutions varies and in some cases (e.g. ethics assessment outside biomedical science in Serbia) might be minimal. In many cases, higher education institutions (HEIs) such as universities, academies, colleges have their own ethics policies and procedures, and require that funded, and PhD research in particular, is ethically sound and approved.

A large number of public research performing institutions have developed internal ethical standards or ethics codes of conduct that deal with aspects such as: confidentiality, privacy, conflict of interest/conflict of commitment, human resources, financial reporting, compliance with laws, use of university resources, scientific integrity, and reporting suspected violations.

In most of the countries analysed, especially if prescribed by law, scientific research conducted by these institutions might require, or, is subject to ethical review by authorised research ethics committees (e.g. Medical Research Ethics Committees or MRECs in Netherlands, National Research Ethics Service in the UK), or require permission from other designated bodies (e.g. Polish law requires all medical experiments involving human beings, as well as animal experimentation, research that involves protected species or is conducted in protected areas and research on GMOs requires a permission of a relevant state authority).

The procedures for ethics review in public research performing institutions varies generally and depends upon the nature of the research. Many public research performing institutions such as universities have internal RECs (e.g. the Netherlands) that assess research not legally requiring external review. Often, universities require that all research involving human subjects—whether it is medical or non-medical, by staff or by students— is reviewed by the institution's REC before it commences. The RECs examine whether subjects are exposed to disproportional or excessive risks, have consented to the research while being sufficiently informed on any potential risks, and are sufficiently protected by precautionary measures against those risks. These considerations stem from principles such as those outlined in the Helsinki Declaration[135] or the Belmont Report[136]. Many RECs work with a checklist to

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[130] Ibid.
[131] See SATORI D1.1 Country report: Serbia.
[132] See SATORI D1.1 Country report: Serbia.
[133] See SATORI D1.1 Country report: Germany.
[134] See individual country reports.
[135] WMA, "Declaration of Helsinki", http://www.wma.net/en/30publications/10policies/b3/

determine whether a proposed study can go ahead as planned or whether adaptations need to be made. RECs may also deal with questions related to intellectual property. [137]

Research performing institutions such as universities and hospitals may offer ethics counselling, advice,[138] training and education to researchers on various aspects of their research, compliance with ethics legislation, and procedures relating to human subjects, animal research etc. (the Netherlands), responsible conduct of research (USA), and general research ethics. They may organise collaborative events such as fora, face to face workshops and individual drop-in sessions, to discuss research ethics and developments.[139]

6.4 PRIVATE RESEARCH AND INNOVATION SYSTEMS

All of the countries examined have many organisations representing the interests of various industries. Only a few of these industries and organisations can be mentioned here. Organisations representing the pharmaceutical industry include Nefarma in the Netherlands, INOVIA in Serbia and Leem in France. These organisations (as well as those in other European countries) belong to the European Federation of Pharmaceutical Industries and Associations.[140] Outside of Europe, both China and the US have similar pharmaceutical industry organisations (the China Pharmaceutical Industry Association and PhRMA, respectively). Other industries with representative organisations within the countries examined include information technology, chemicals, medical technology, and biotechnology.

The adoption of Corporate Social Responsibility (CSR) practices and reporting, while supported by governments, is largely voluntary in the countries examined. However, a few countries have introduced requirements for reporting how their operations follow at least some elements of CSR. The Netherlands requires stock exchange-listed companies to include CSR information relevant to their business in their annual report. Austria has similar requirements that are based on EU Directive 2003/51, and France requires listed companies to provide information about the environmental and social consequences of their operations. Laws that require environmental impact assessment, such as those in China, are another method of enforcing behaviours consistent with CSR.

Several countries have introduced national CSR strategies to further promote the use of CSR by business. The Netherlands has the Sustainable Trade Initiative (IDH), Serbia has a Strategy for the Development and Promotion of CSR, there is the 2014-2020 Spanish Strategy of CSR, and Germany has a National Sustainable Development Strategy (NSDS). The Polish government has long-term development strategies that emphasise quality of life and sustainable development as national goals.

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[136] US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*, http://videocast.nih.gov/pdf/ohrp_appendix_belmont_report_vol_2.pdf

[137] Example http://www.univ-paris8.fr/Le-comite-d-ethique

[138] See for instance, Great Ormond Street Hospital, "Clinical Ethics service information for health professionals". http://www.gosh.nhs.uk/health-professionals/clinical-specialties/clinical-ethics-service-information-for-health-professionals/. In France, the Advisory Committee on deontology and ethics (CCDE) reviews research protocols from an ethical point of view and has established a "Good Practice Guide" for research.

[139] E.g. see SATORI D1.1 Country report: UK.

[140] EFPIA, "Membership", *European Federation of Pharmaceutical Industries and Associations*, http://www.efpia.eu/about-us/membership.

The UN Working Group on human rights and transnational corporations and other business enterprises has produced a set of guidelines for developing 'national action plans' for business and human rights.[141] These Guiding Principles on Business and Human Rights have been endorsed by the EU as a part of its 2011 CSR strategy, and it is committed to supporting their implementation.[142] Of the countries examined, both the Netherlands and the UK have produced such plans, while a draft National Plan on Business and Human Rights was introduced in Spain in 2014 but it currently has no legal force. Similarly, a draft National Action Plan to encourage 'responsible business conduct' was produced in the US in 2014. Germany is also committed to developing such a plan. However, Austria has not drafted or committed to developing its own an Action Plan on Business and Human Rights. Serbia, Poland, France, and China have also yet to commit to developing their own National Action Plans.

Governments have sought to support the adoption of CSR by establishing organisations to assist businesses in incorporating CSR and by producing guidelines for businesses to follow. These organisations include CSR Netherlands, the Group for Social Corporate Responsibility in Poland, the Spanish National Council for CSR, the National Council for Sustainable Development in France, the German Council for Sustainable Development, and the Chinese Research Centre for Corporate Social Responsibility. Serbia, Spain, and Germany all have national CSR strategies. While the US does not have national regulations on CSR, various US government organisations assist in promoting elements of CSR. For example, the US Environmental Protection Agency has a Centre for Corporate Climate Leadership. The UK is notable for lacking a significant government effort to promote CSR, with it being largely promoted by NGOs and seen as the responsibility of businesses themselves rather than an appropriate area for government involvement.

Several governments, including the Netherlands, Germany, Poland, and the US, also present awards to companies that score highly in CSR activities. Such awards include The Crystal award for the Transparency Benchmark produced by the Dutch Ministry of Economic Affairs, the CSR Award of the German Federal Ministry, and the Award for Corporate Excellence (ACE) of the US Department of State.

Many of these countries also promote the ISO 26000 standard that presents guidance on social responsibility and the OECD Guidelines for Multinational Enterprises. Both of these sets of guidelines include CSR. National standards organisations, such as PKN in Poland, AFNOR in France, the BSI in the UK and ANSI in the US, are also often involved in promoting the guidelines contained in the ISO 26000 standard. China is also developing national polices that reflect the ISO 26000 standard. CSR certification programmes are available in the Netherlands, Serbia and France. The Dutch certification programmes are based on the ISO 26000 standard. The Netherlands and Poland have also established National Contact Points to promote the OECD Guidelines.

Network organisations that establish links between businesses and promote CSR strategies within industries also exist in several of the countries examined. General examples includes the Dutch Sustainable Growth Coalition, the Responsible Business Forum in Poland, IMS in

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[141] OHCHR, "State National Action Plans", *United Nations Office of the Commissioner for Human Rights*, http://www.ohchr.org/EN/Issues/Business/Pages/NationalActionPlans.aspx.
[142] European Commission, "Corporate Social Responsibility in Practice", http://ec.europa.eu/growth/industry/corporate-social-responsibility/in-practice/index_en.htm

France, and Econsense in Germany. More specialised examples include the Defence Industry Initiative (DII) in the US and the Blue Competence Initiative of the Germany mechanical engineering industry. 'Observatories' that collect and analyse CSR information can be found in France and Spain.

Public-private partnerships are another method for governments to assist businesses in adopting CSR strategies. Both the Netherlands and Serbia have Social and Economic Councils, and Poland similarly has a Tri-partite Commission for Socio-Economic Issues. All three of these groups include representatives from the government, business associations, and trade unions.

A trend noticed in several countries is that large corporations place a greater emphasis on CSR than small and medium-sized enterprises (SMEs). This trend was noticed in the Netherlands, Poland, Spain, Germany, the UK, and the US. A source in the UK Country Report suggests that this may be due to differing motivations for engaging in CSR programmes. SMEs tend to have a greater focus on employee morale and local community issues than multinational corporations, who have greater concerns with public accountability and reputation.[143]

Research ethics committees (RECs) are necessary to approve research involving human participants in all the countries examined, and all of the countries except for China require an ethics committee to approve animal experimentation. Outside of biomedical research, there are few requirements for ethics approval in the countries examined, although the Netherlands requires approval to be sought from the Committee on Population Screening of the Health Council. For example, Serbia does not require ethics assessment for non-biomedical research.

6.5   PROFESSIONAL GROUPS AND ASSOCIATIONS IN THE R&I FIELD

National associations for R&D professions across all countries engage in ethics assessment to varying degrees. Some associations focus on enhancing their members' career opportunities within the profession. Many professional associations for R&D professions across the countries surveyed focus on professional ethics and upholding ethical standards in the field or area of research. Spain and Serbia had particularly interesting initiatives in this regard. As specified by the Law on Professional Associations in Spain, professional associations are responsible for organising the professional activities of their members, ensuring professional ethics and dignity, guaranteeing respect for individual rights and exercising disciplinary power in their field. The majority of associations in Serbia include a Court of Honour which deals with ethical issues, primarily in the context of maintaining professional standards and norms and enhancing members' career opportunities within the profession.

Larger associations in Serbia, Spain, Poland, Austria, the Netherlands, the United States and China engage members on ethical issues within the profession, by organising lectures, facilitating discussion and creating codes of conduct. Some organisations in Austria, particularly in the field of medicine, are involved in elaborating recommendations or guidelines which can be helpful in determining national standards. Indeed, codes of ethics for medical doctors have a special status, e.g. the code of ethics for medical doctors is guaranteed in French legislation, while specific items within Germany's Medical Association's

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[143] Jenkins, Heledd, *Corporate Social Responsibility: Engaging Small and Medium Sized Enterprises in the Debate*, The Centre For Business Relationships, Accountability, Sustainability and Society, Working Paper No. 18, 2004, p. 6.

Professional Code - such as regulation of the ethical and professional obligations of physicians and tailored training regulation - lie within the legal competence of German states.

There are also national associations for ethics assessment of research and innovation that contribute to ethics assessment practices by promoting, variously, reflection and discussion on important ethics topics among members of the profession and society at large. Such associations are present in Serbia, Poland, Spain and the Netherlands. For example, the Center for the Study of Bioethics in Serbia includes scientists from different fields, especially the social and medical sciences. The Center stimulates scientific debate on a variety of bioethical issues and organises scientific conferences, lectures and round tables on bioethical issues.

Some associations focus in on specific elements of ethics assessment such as the functioning of research ethics committees (RECs), training, standardisation of procedures and so on. Spain's Network of Ethics Committees in Universities and Public Research Centres was established in response to the need for RECs to share information and experience; to define or standardise procedures for Committees, research and society; and to achieve common guidelines of agreed procedures. The Permanent Working Party of Research Ethics Committees in Germany is an association of research ethics committees that works to harmonise the work of committees and works on common assessment procedures. The working party also organises training for members of RECs. Similar associations exist in Austria, the UK, the Netherlands, France, the US, and China. There are two major national organisations for ethics assessors in France which focus on the protection of persons and ethical guidance for research projects using animals for scientific purpose.

As mentioned above, associations of ethics assessors also work to promote the area in the public sphere. For example, the Association of Ethicists in the Netherlands works to stimulate public debate through articles about ethical issues in public life in its quarterly magazine, *Philosophy & Practice*, while the Polish Bioethics Society engages in educational activities, public communication, mediation and formation of public opinion, in addition to providing advice in cooperation with state and local government institutions, as well as non-governmental organisations. This focus on public awareness can be found in similar associations in almost all of the countries.

6.6 CIVIL SOCIETY ORGANISATIONS

CSOs in the EU countries and Serbia appear to be rather well-established, with CSOs having active roles in many spheres of civil society as reflected by the presence of religious organisations, environmental organisations, civil liberties/human rights organisations, consumer organisations, developmental (humanitarian) organisations, animal rights organisations, disease charities and patient and disabled rights associations. Labour unions and trade unions also fall under the umbrella of CSOs in France, Poland, Spain and the Netherlands. Both the US and China have a large number of CSOs operating in the areas mentioned above. Many CSOs are international organisations such as Greenpeace and Friends of the Earth which also operate beyond the borders of the respective countries. National legislation for CSOs is both specific and more general, with most countries having a law of associations, supplemented by specific laws for specific organisations such as consumer organisations, religious organisations and so on. There is no national law for the establishment and management of CSOs in China but there have been calls for a national law regulating the management of CSOs and the protection of their rights.

CSOs across all countries, with the exception of China, receive a significant amount of funding from public funding sources, including local, national, EU and international funding. CSOs in China obtain their funding through public fundraising activities. Private funding sources also play an important role across countries, with sources including membership fees, fees for services and events, private donations, lotteries and merchandising. Disease charities in the Netherlands and the US play an important role in funding research. The American Cancer Society, for example, is the largest non-governmental funder of cancer research in the US.

CSOs in several countries perform R&I. The United States is particularly striking in this regard, with many CSOs, specifically environmental, consumer, and science organisations, and disease charities performing R&I. Indeed, some of these CSOs include a large number of scientists on their staff. CSOs in Germany have a rather formalised role in assessing R&I agendas and policies. For example, ForschungsWende - a civil society for environmental organisations and agencies for discussion of R&I policies - assesses R&I budget plans and provides feedback and recommendations to the Parliament and the Ministry of Education and Research. As mentioned above, specific disease - based charities (e.g. for heart disease, cancer research, etc.) operate across several countries and are vital funders of research. A few CSOs also carry out research themselves, e.g. Cancer Research UK, while others such as the Netherlands' Dutch Proefdiervrij (Dutch Society for the Replacement of Animal Testing) collaborate closely with scientists, universities, health organisations and a health research funding organisation. While most CSOs in China lack the financial and technological resources to carry out R&I, several CSOs, especially disease-related charities and environmental organisations, spend funds on scientific research.

The role of CSOs in ethics assessment varies across countries. CSOs in most of the countries surveyed are active in public discussion. While CSOs do not have a long history in China, CSOs do deal with social issues and act as stakeholders in public discussion. Countries vary with regard to the participation of CSOs on ethics assessment panels. CSOs participate in ethics assessment panels in Serbia, Austria and Poland, with CSO participation legislated for in the latter two countries.[144] The importance of religious organisations in ethical assessment is reflected in both the Netherlands, where only religious organisations are allowed representation on such committees and Serbia, where priests often act as lay representatives on ethics committees for biomedical research. Interestingly, given the rather formalised role of CSOs in German society, CSOs are not directly involved in ethical assessment councils or research ethics committees. CSOs in the US can participate in institutional review boards (IRBs) and often participate in public hearings. Most ethics assessment in China is carried out by government officials or professionals in relevant fields - CSOs are not officially invited to attend ethics assessment committees or panels. However, many large and influential CSOs include government officials or are affiliated with a ministry of the State Council. Thus CSOs in China have a role in ethics assessment, however it is often indirect and not independent.

The views and experiences of CSOs varied as regards their role in ethics assessment. CSOs in a number of countries - Poland, Austria, Germany, the UK, the Netherlands and the US - are active, to varying degrees, in carrying out ethics assessment. CSOs in the Netherlands, Germany and the UK are quite active in ethics assessment, with activities including the issuing of position statements on ethical issues, for example, in biomedicine and ethics; the investigation of ethical issues as part of investigative and critical research work; and the

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[144] For example, in Poland, the representation of CSOs in ethics committees in animal experimentation has been legislated for and the inclusion of patient organisations guaranteed.

provision of input to ethics policies and guidance through collaboration with organisations that actively engage in ethics assessment, to name just a few activities. Many CSOs in Poland carry out assessment regarding the ways in which the implementation of some technologies affect basic human rights, while CSOs in Austria engage in ethics assessment in the field of environmental impact assessment. While labour unions in France do not play a direct role in ethics assessment, they can establish ethics charters and intervene in societal debate. CSOs in the US can engage in ethics assessment by developing specific requirements for scientific research. For example, the Scientific Responsibility, Human Rights and Law Program (SRHRL) within the American Association for the Advancement of Science (AAAS) carries out a number of research projects which investigate social, ethical and legal issues in research including stem cell research and inheritable human genetic modification. A number of Chinese CSOs, particularly involved in environmental protection, recognise the importance of ethics assessment but do not engage in it themselves. However, CSOs in China are becoming increasingly important agents of ethics assessment through increased collaboration among CSOs, between CSOs and companies and between CSOs and the government.

6.7 DISCUSSION

In comparing the variety of institutions, organisations, policies, strategies and frameworks for ethics assessment and guidance in the ten countries considered here, one striking observation is that all countries are currently expanding their efforts in the area of ethics assessment and guidance. Many countries are developing their REC system, or expanding it from biomedicine into other fields. CSOs and industry are becoming more engaged with issues of ethics and social responsibility. Research funding organisations are considering ways to better address ethical issues in research funding.

Another striking observation is that there are significant differences in the extent to which ethics of R&I is institutionalised in the ten countries that were examined. It is highly institutionalised in countries such as the Netherlands, Germany and Austria, in which one can find extensive regulation and a large number of organisations engaging in ethics assessment in both the public and private sectors. It is only beginning to be institutionalised in a country such as Serbia, which has only been developing a focus on ethics assessment over the past ten years, and is still developing its infrastructure in this domain. Poland also has a long road, and China is currently making major efforts to develop its infrastructure in this area. In general, countries with strong and knowledge-intensive economies appear to have a more developed structure for ethics assessment and guidance than countries with less advanced economies. However, there are also exceptions that may have cultural, political or historical roots. For example, the United States certainly has a strong and knowledge-intensive industry, yet its infrastructure for ethics assessment and guidance is somewhat less developed than one would expect.

A third observation concerns the focus of different countries on particular ethical issues and principles, or a lack of consideration thereof. In Germany, one of the key values in the ethical debate is human dignity, which has a prominent place in the German Constitution. One sees an orientation towards deontological argumentation which focuses on the autonomy of persons. Privacy also has a strong emphasis. The UK and US, in contrast, tend to have a more utilitarian approach. In China, there is a strong focus on scientific integrity, perhaps due in part to problems of corruption in Chinese society that also extend to the scientific community. In contrast, there is little attention given to animal welfare, which is not a prominent concept in Chinese society, and the implementation of protections for human

subjects in research is somewhat lacking. In the US, individual rights are often considered as superior compared to other ethical considerations, especially social justice issues. This appears to follow the political orientation of the country.

A fourth observation concerns the role of government. In the US, federal and state regulation of ethical issues is comparatively weak, and there are comparatively few government organisations for ethical assessment and guidance. In China, in contrast, the government has a very active role in setting policies for ethics and controls many of the R&I organisations with ethics roles. EU countries lie between. Relatively strong control is exercised in France, which has a very rigorous legal framework for ethics assessment and strong government control over RECs. In Spain, ethical assessment is decentralised and largely independent from government, but there are strong regulations in place for biomedical research and research involving animals. In most EU countries, government regulation for ethics in biomedicine is shaped by the Oviedo Convention, which went into effect in 1999 and provides binding principles for human rights and dignity in biomedicine that were applied in national law by many EU states. The UK did not sign the Convention because it found it too restrictive, while Germany did not sign it because it found it too permissive.

A fifth observation concerns the role of corporate social responsibility (CSR) in industry. While CSR is largely voluntary in all of the countries investigated, some countries, including France, the Netherlands, Austria and China, have introduced mandatory reporting concerning some aspects of CSR for (large or stock-exchange listed) companies. Spain, the Netherlands, Serbia, Germany and Poland have established national CSR strategies. Countries differ in the extent to which they mandate environmental and social impact assessments for large infrastructural projects.

A sixth and final observation concerns the role of CSOs. In all of the countries investigated, CSOs have a role in public discussions, and engage in informal forms of ethics assessment and guidance. Their role in government policy, representation in ethics assessment panels and committees, and in doing ethics assessment varies considerably, however. In Germany, CSOs have a formal role in assessing government R&I policies and agendas, but do not usually participate in ethics assessment panels. CSOs participate in ethics assessment panels and committees in Serbia, Austria, Poland, the Netherlands, and the US. Some CSOs engage in ethics assessment themselves, and have been observed to do so in Poland, Austria, Germany, the UK, the Netherlands and the US. In the US, many CSOs also engage in R&I activity. In China, the number of CSOs is small, and their role in ethics assessment and public discussions is limited but growing.

7   EU AND GLOBAL ETHICS ASSESSMENT AND GUIDANCE

7.1   INTRODUCTION

The aim of this chapter is to provide an overview of the ethics assessment landscape at both EU and global levels, specifically with regard to the relation between EU and global counterparts in particular areas. The chapter offers a review of EU and intergovernmental and supranational organisational structures, laws, policies and procedures for ethical assessment and guidance; the role of publicly funded and private research and innovation organisations at the EU and global level in addressing ethical issues in research and innovation; and the manner in which ethical assessment and guidance play a role in the activities of EU and international professional groups and associations for research and innovation.

This overview is based on two in-depth reports, on ethics assessment and guidance at the EU and global level - both can be found in Annex 5.

7.2   GOVERNMENTAL INSTITUTIONS AND POLICIES

European Union

The EU has a unique institutional set-up in which:

- the EU's broad priorities are set by the European Council, which brings together national and EU-level leaders
- directly elected Members of the European Parliament (MEPs) represent European citizens in the European Parliament
- the interests of the EU as a whole are promoted by the European Commission, whose members are appointed by national governments
- governments defend their own country's national interests in the Council of the European Union.[145]

Together, the European Parliament, the Council of the European Union and the European Commission institutions produce, through the 'Ordinary Legislative Procedure', the policies and laws applicable throughout the EU. In principle, the Commission proposes new laws, and Parliament and Council adopt them. In most cases, the Commission makes proposals in order to meet its obligations under the EU treaties, or because another EU institution, country or stakeholders has requested it to act.[146] The Commission and the member countries implement legislation, and the Commission ensures that the laws are properly applied and implemented. According to the subsidiarity principle, "the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level" (Treaty on European Union (TEU) Article 5).[147]

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[145] Europa.eu, "EU institutions and other bodies". http://europa.eu/about-eu/institutions-bodies/
[146] Ibid.
[147] Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union - Consolidated version of the Treaty on European Union - Protocols - Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, signed on 13 December 2007, *Official Journal C 326 , 26/10/2012 P. 0001 – 0390.*

Two other institutions that play vital roles are the Court of Justice of the EU[148] (which interprets EU law to make sure it is applied in the same way in all EU countries and settles legal disputes between EU governments and EU institutions), and the European Court of Auditors[149] which checks the financing of the EU's activities. The EU has a number of other institutions and inter-institutional bodies[150] that play specialised roles.[151]

Policies

Ethics is an integral part, from beginning to end, of all research activities funded by the European Union, and ethical compliance is viewed as pivotal to the achievement of real research excellence.[152] Ethical research conduct implies the application of fundamental ethical principles - including the principle of proportionality, the right to privacy, the right to the protection of personal data and human health protection - and legislation to scientific research in all domains of research, including biomedical research, the natural sciences and the social sciences and humanities.[153] All activities carried out under the EU research funding programme Horizon 2020[154] must comply with ethical principles and relevant national, EU and international legislation, for example, the Charter of Fundamental Rights of the European Union[155] and the European Convention on Human Rights.[156] Importantly, the incorporation of the Charter into the Lisbon Treaty in 2009[157] means that the Charter is fundamentally binding and has the same status as primary EU law. The European Convention on Human Rights and the relevant case-law of the European Court of Human Rights, especially regarding Article 8 (Right to Respect for Private and Family Life)[158] is also an important point of reference for ethics review.

Relevant international legislation for research carried out in the EU includes UNESCO's Universal Declaration on Bioethics and Human Rights and the Council for International Organizations of Medical Sciences' (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (these items are discussed below). UNESCO's Universal Declaration on the Human Genome and Human Rights [159] is relevant for research on human

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[148] http://curia.europa.eu/jcms/jcms/Jo2_6999/

[149] http://www.eca.europa.eu/en/Pages/ecadefault.aspx

[150] http://europa.eu/about-eu/institutions-bodies/interinstitutional-bodies/index_en.htm

[151] I.e., European Central Bank, responsible for European monetary policy; the European External Action Service (EEAS) which assists the High Representative of the Union for Foreign Affairs and Security Policy; the European Economic and Social Committee which represents civil society, employers and employees; the Committee of the Regions which represents regional and local authorities; the European Investment Bank finances EU investment projects and helps small businesses through the European Investment Fund; the European Ombudsman who investigates complaints about maladministration by EU institutions and bodies; the European Data Protection Supervisor (EDPS), the independent supervisory authority that protects personal data and privacy and promotes good practice in EU institutions and bodies; the Publications Office that publishes information about the EU; the European Personnel Selection Office that recruits staff for the EU institutions and other bodies; and the European School of Administration which provides training in specific areas for members of EU staff.

[152] http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

[153] http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=ethics

[154] These requirements also apply to the Seventh Framework Programme. As Horizon2020 is the current funding programme, requirements are discussed in relation to this programme.

[155] http://www.europarl.europa.eu/charter/pdf/text_en.pdf

[156] http://www.echr.coe.int/Documents/Convention_ENG.pdf

[157] http://europa.eu/legislation_summaries/institutional_affairs/treaties/lisbon_treaty/ai0033_en.htm

[158] http://www.echr.coe.int/Documents/Convention_ENG.pdf

[159] http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/

embryos and researchers and for data protection and privacy issues in certain kinds of research. The World Health Organisation's "Biorisk management: Laboratory biosecurity guidance" applies to dual use research.[160] The Oviedo Convention[161], adopted by Ministers of the Council of Europe in 1996 (please see section below for a description of this intergovernmental organisation) and signed by most European states, is meant to address the ethical issues raised by research within a framework of the protection of human rights and establishes common standards for all members of the Council of Europe.[162] The Oviedo Convention also sets standards for the use of the human genome and research on human embryos.[163] The Additional Protocol Concerning Biomedical Research[164] confirms the general principles and offers more specific rules on the role of ethics committees in research, the conditions for adequate informed consent, confidentiality and the right to information.[165] Governmental and government funded/controlled organs and institutions at EU level - at both the European Commission and the European Parliament - play a crucial role in ethics assessment (particularly ethics review) and ethics guidance.

The European Commission places particular importance on the role of scientific expertise in policy-making. To that end, a number of expert groups, committees and organisations - both external and in-house - have been established. Some of these groups carry out explicit ethics assessment, i.e., ethics assessment or review is a clear aspect of their mandates, while others may encounter ethical issues and discussion in the course of carrying out different kinds of assessment, i.e. ethical issue are *among* the issues investigated in assessments.

The President of the Commission has a number of advisory councils and bodies at his disposal regarding science and technology issues and promoting evidence-based policy-making. These include the Science and Technology Advisory Council[166], the European Political Strategy Centre[167] and a mechanism for high quality, timely, independent scientific advice.[168] In addition, the Joint Research Centre functions as the European Commission's in-house science service and employs scientists to carry out research for the provision of independent scientific advice and support to EU policy.[169]

Ethics expertise has an important role to play at Commission level with regard to guiding policies and new legislation concerning ethics in science and new technologies. The European Group on Ethics in Science and New Technologies (EGE) is a particularly important body in this regard and has adopted Opinions on issues ranging from nanotechnology to internet governance.[170] The incorporation of the European Charter of Fundamental Rights into the Lisbon Treaty has generally enhanced the consideration of ethics and human rights at EU level and the work of advisory bodies such as the EGE, in particular.

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[160] http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/

[161] http://www.coe.int/t/dg3/healthbioethic/Activities/01_Oviedo%20Convention/default_en.asp

[162] http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

[163] Ibid.

[164] http://conventions.coe.int/Treaty/en/Treaties/Html/203.htm

[165] http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

[166] http://ec.europa.eu/archives/commission_2010-2014/president/advisory-council/index_en.htm

[167] http://ec.europa.eu/epsc/

[168] This mechanism will replace the Chief Scientific Advisor role, the mandate of which was ended in 2014.

[169] https://ec.europa.eu/jrc/

[170]

http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/eu/euorganisation/europeanorg_mig_0043

The Ethics and Research Integrity Sector at the Directorate General (DG) for Research and Innovation[171] is responsible for organising ethics assessment of proposals submitted to the Commission for funding. [172] The National Ethics Councils Forum (NEC Forum) is a European Commission expert group for which DG Research and Innovation is the lead DG.[173] The NEC Forum is an independent network of representatives of the National Ethics Councils for the exchange of information, experience and best practices on issues of common interest in the field of ethics and science.[174]

Many of the issues that come before the European Parliament have a scientific or technological dimension to them. The European Parliament defines its position on these issues through reports prepared by its Committees. [175] If Committees decide that expert, independent assessment of the various scientific or technological options in the policy sectors concerned would be helpful to their policy-making role, they can make use of the services of STOA.[176] STOA is the Parliament's *Science and Technology Options Assessment* unit. STOA provides policy advice to decision-making bodies concerning the impact of science and technology on EU policy.

The European Group on Ethics (mentioned above) is a core component in a wider set of coordinated activities with the aim of, first, embedding EU policymaking on science and new technologies within a firm ethical foundation and, second, enhancing global cooperation on ethics.[177] These include the Inter-service group on Ethics and EU Policies which coordinates Commission activities in the fields of bioethics and ethics of science and new technologies; cooperation with the international organisations whose responsibility it is to examine the ethical implications of science and new technologies (the UN and its agencies, OECD, Council of Europe); and the organisation of the European Commission's International Dialogue on Bioethics, a platform bringing together the National Ethics Councils from 97 countries (EU-G20 forum and beyond).[178]

Global level

Organisations and policies

The main intergovernmental and supranational organisations engaged in policy development for ethics in R&I include the United Nations (UN), The United Nations Educational, Social, and Cultural Organisation (UNESCO), the Organisation for Economic Co-operation and Development (OECD), the World Health Organization (WHO), the Council for International Organizations of Medical Sciences (CIOMS) and the Council of Europe.

UNESCO includes two prominent bioethics committees, namely the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC), both of which are key players in developing policy for bioethics. As mentioned already, the European Commission has clear links and engages in activities with these committees. UNESCO also functions as the secretariat of the United Nations Inter-Agency Committee on Bioethics.

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[171] http://ec.europa.eu/research/dgs/pdf/organisation_en.pdf
[172] http://ec.europa.eu/research/index.cfm?pg=dg
[173] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1806
[174] Ibid.
[175] http://www.europarl.europa.eu/stoa/cms/home/about
[176] Ibid.
[177] http://ec.europa.eu/epsc/ege_en.htm
[178] Ibid.

UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) is made up of leading representatives of the global science community and is mandated to formulate ethical principles to provide decision-makers with criteria that extend beyond purely economic considerations. [179] Human rights and bioethics, and human rights related to the genome and genetic data are prominent themes within UNESCO policy and are highlighted by the European Commission as important items to take into account in ethics review of research projects. The Universal Declaration on Bioethics and Human rights produced by UNESCO, in particular the IBC, aims to provide a comprehensive framework of principles to guide biomedical activities. [180]

The World Health Organization (WHO) is involved in ethics of R&I with regard to the protection of the interests of human health throughout the research process.[181] WHO's "Operational guidelines for ethics committees that review biomedical research", targeted at national and local bodies, define the role and constituents of an ethics committee and specify the requirements for submitting an application for review.[182]

The Council for International Organizations of Medical Sciences (CIOMS) was established jointly by WHO and UNESCO and functions as a representative organisation for the biomedical scientific community. [183] The CIOMS ethics subcommittee is at the fore in the global integration of ethical issues such as informed consent, subject recruitment and standards of review. [184]

The Organisation for Economic Co-operation and Development (OECD) is also involved in developing ethics policy, particularly with regard to innovation.[185] The OECD sets international standards that align with its objectives of enhancing global productivity and growth. OECD recommendations address the economic implications of R&I on populations and seek to maintain the well-being of citizens in this regard. These recommendations are aimed at both governmental institutions and the private sector. Moreover, the OECD has developed a number of evidence-based research policies related to the ethics of R&I from an economic perspective for both developing and developed nations.

The Council of Europe is an intergovernmental organisation which aims to protect human rights, democracy and the rule of law.[186] In 1992, the Steering Committee on Bioethics (CDBI) was established. The Committee's mission is to investigate ethical problems, especially the challenges for human rights raised by the biomedical sciences and to frame legal instruments to deal with such problems. The first international legally binding instrument in the field, the Convention on Human Rights and Biomedicine (Oviedo Convention, ETS, No, 164), was adopted in 1997. The Oviedo Convention sets the standard for the use of the human genome and research on human embryos.[187] In 2012, the CDBI

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[179] http://www.unesco.org/new/en/social-and-human-sciences/themes/comest/
[180] http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/
[181] http://www.who.int/en/
[182] http://www.who.int/tdr/publications/training-guideline-publications/operational-guidelines-ethics-biomedical-research/en/
[183] http://www.cioms.ch/
[184] See SATORI Deliverable D3.3 report: "How Globalisation is Changing Research Agendas, Activities and Assessment Procedures within Research & Innovation"
[185] The following paragraph has been adapted from D3.3
[186] http://bookshop.europa.eu/en/how-the-european-union-works-pbNA0414810/
[187] http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

became the Committee on Bioethics (DH-BIO) and is now attached to the Steering Committee for Human Rights (CDDH). [188]

In addition to these institutions, there has been a rise in collaborative efforts between ethics committees in different regions. The Global Summit of National Bioethics Advisory Bodies[189] is a good example of such efforts. The Global Summit "is a unique platform for the exchange of information about the on-going work of national ethics Advisory Boards or commissions, and thus represents an opportunity for open, quality dialogue."[190]

7.3   PUBLIC RESEARCH AND INNOVATION SYSTEMS

This section centres on the different organisations at EU and global levels within the public research and innovation system and their roles in ethics assessment and ethics guidance.

European Union

The EU public research and innovation system is characterised by key EU-level research and university associations and associations of science academies that have a role in representing public R&I institutions and in coordinating their activities. Accreditation, certification and standard-setting organisations for publicly funded research, and research funding organisations also play an important role. Specifically, these organisations engage in a variety of activities relevant to ethics assessment, e.g. providing advice, promoting ethical values and principles, developing ethical guidelines and best practice, networking and information sharing, and standard setting and quality assurance. For example, the European Council of Academies of Applied Sciences, Technologies and Engineering[191] issued *Guidelines on advising policy makers and society* applicable to itself, policy advisory bodies, its experts, and its clients.[192] The European Association for Quality Assurance in Higher Education (ENQA) promotes European co-operation in the field of quality assurance in higher education and disseminates information and expertise among its members and towards stakeholders in order to develop and share good practice and to foster the European dimension of quality assurance.[193]

Research funding organisations at the EU level include the European Commission and the European Research Council (ERC). At European level, research funding organisations have established ethics requirements as conditions for research funding. In particular, the European Commission is keen to emphasise the importance of ethics throughout the whole research process.[194] All research activities in the Horizon 2020 framework programme must respect fundamental ethical principles and are submitted to ethics review. [195]   The ERC is a flagship component of Horizon 2020.[196] For this reason, ERC grants are subject to the Ethics Review mechanism. [197]

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[188] http://www.coe.int/t/dg3/healthbioethic/cdbi/default_en.asp
[189] http://www.who.int/ethics/globalsummit/en/
[190] Ibid.
[191] http://www.euro-case.org/index.php
[192] http://www.euro-case.org/images/stories/pdf/position-paper/Euro-CASEguidelines2013.pdf
[193] http://www.enqa.eu/
[194] http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf
[195] http://erc.europa.eu/glossary/8/lettere
[196] http://erc.europa.eu/about-erc/mission
[197] Ibid.

Other than non-profit research entities such as the Bill and Melinda Gates Foundation[198], there is no public research and innovation system to speak of at the global level. Current global activities in public research and innovation are exemplified by efforts such as the Global Forum on Research and Innovation for Health 2015 [199] and the Global Research Alliance on Agricultural Greenhouse Gases. [200] As regards ethics assessment, the latter organisation takes up ethical issues related to the environment.

Global level

Similar to public research organisations at the EU level, global research organisations tend to be associations that further specific goals such as the advancement of science (Community of Science[201]), the provision of grants for the development of training programmes in international research ethics (International Research Ethics Education and Curriculum Development Program[202]) and the streamlining and harmonisation of the ethics review process for specific types of projects (The International Federation for Ethics Review[203]).

Global research funding organisations demonstrate the interconnectivity of global efforts and the broad reach of ethics requirements. The European and Developing Countries Clinical Trials Partnership (EDCTP)[204] is particularly interesting in this regard. EDCTP is a partnership between the EU, Norway and Switzerland, and developing countries, and other donors such as the pharmaceutical industry, to enable clinical trials and the development of new medicines and vaccines against HIV/AIDS, tuberculosis and malaria. The second EDCTP programme was implemented as part of the Horizon 2020 programme. The European Union will provide a contribution of up to €683 million for the 10-year programme (2014-2024), provided this is matched by contributions from the European Participating States. Partners must ensure adherence and compliance with the H2020 ethics review mechanism.

Additional global research funding organisations with a specific focus on developing countries include the International Foundation for Science[205] and the US National Institutes of Health's Fogarty International Research Ethics Education and Curriculum Development Program (also mentioned above).[206] The latter engages in ethics guidance through the provision of grants for the development of training programmes in international research ethics for low and middle-income countries, while the former provides grants to young researchers in low income countries, in addition to local training courses aimed at capacity-building in developing countries.

7.4   PRIVATE RESEARCH AND INNOVATION SYSTEMS

The following section offers a general description of the private research and innovation system at EU and global levels, namely research and innovation funded and developed by industry, with regard to major organisations that represent industry, government policies and

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[198] http://www.gatesfoundation.org/
[199] http://www.who.int/alliance-hpsr/events/forum15/en/
[200] http://www.globalresearchalliance.org/
[201] http://www.cos.com/#/
[202] http://grants.nih.gov/grants/guide/pa-files/PAR-13-027.html
[203] http://jlb.oxfordjournals.org/content/1/1/3.full
[204] http://www.edctp.org/
[205] http://www.ifs.se/
[206] http://www.fic.nih.gov/programs/pages/bioethics.aspx

initiates to support ethics assessment in private industry and the role of industry associations in ethics assessment and guidance.

EU level

The *State of the Innovation Union* report, outlines that despite the deep economic recession, "research and innovation remains alive and well in Europe".[207] While it suggests that the "European economy is transforming into a knowledge-based Innovation Union", "the path from ideas to market is still not a smooth one", and "there is still much to be done both at the European and at the national level.[208] This is the case for reform of research and innovation systems as well as for funding. The EU still lags behind major players such as the US, Japan and South Korea in terms of R&D investment relative to GDP. There are also large differences between EU Member States in funding and innovation performance". It also reports:

> Overall, European enterprises have slightly increased their investments in R&D as a share of GDP since 2008. They also expect to increase their investment in R&D globally by an annual average of 4% over the period 2012 – 2014. However, there are large differences between Member States and between industrial sectors and actors. Some countries are suffering cuts in R&D investment by the private sector, in particular by SMEs. Larger international corporations tend to increase their level of investment but not necessarily in their country of origin, confronting innovation leaders with the challenge of knowledge specialisation and cluster building on a global scale. As regards sectors, many countries have seen an increase in R&D intensity in more traditional medium-tech industries (metals, rubber and plastics, food products) and in growing markets that are influenced by societal challenges such as waste treatment and the need for clean energy and water.[209]

Major EU organisations that represent industry

The *2014 EU Industrial R&D Investment Scoreboard* (the Scoreboard) contains economic and financial data for the world's top 2500 companies ranked by their investments in research and development (R&D).[210] The Scoreboard suggests, "companies based in Germany, the top R&D investor, continued to increase R&D in 2013, at 5.8%, above the world (4.9%) and EU (2.5%) averages. Companies based in the UK showed also a significant increase of R&D (4.9%) and French companies, on the contrary, reduced R&D investment by 3.3%. The largest wealth creation efficiency (ratio of value-added to costs of employees and depreciation) is found in Pharmaceuticals and biotechnology, three times more 'efficient' than the Electronic & Electrical Equipment sector".[211] The top eight sectors identified in the report are: aerospace and defence; automobiles and parts; chemicals; electronic and electrical

[207] European Commission, Research and Innovation performance in EU Member States and Associated countries Innovation Union progress at country level, 2013. http://ec.europa.eu/research/innovation-union/pdf/state-of-the-union/2012/innovation_union_progress_at_country_level_2013.pdf
[208] Ibid.
[209] European Commission, Research and Innovation performance in EU Member States and Associated countries Innovation Union progress at country level, 2013. http://ec.europa.eu/research/innovation-union/pdf/state-of-the-union/2012/innovation_union_progress_at_country_level_2013.pdf
[210] Hernández, Héctor, Alexander Tübke, Fernando Hervás, Antonio Vezzani, Mafii Dosso, Sara Amoroso, Nicola
Grassano., *The 2014 EU Industrial R&D Investment Scoreboard,* European Commission. 2014. http://iri.jrc.ec.europa.eu/scoreboard14.html
[211] Ibid.

equipment; industrial engineering; pharmaceuticals and biotechnology; software and computer services; and technology and hardware equipment.

Industry associations and accreditation, certification and standard-setting organisations

There are a large number and variety of associations representing various types of R&D industries at the EU level, including the Aerospace and Defence Industries Association (ASD), Eucomed (representing the medical technology industry in Europe) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Associations develop specific strategies on relevant aspects, such as sustainable competitiveness.[212] The European CRO Federation (EUCROF) has a working group on 'Clinical Trials Legislation' (WG CTL).[213] Some organisations investigate, discuss and raise awareness about ethical issues among their members. For instance, the European Consumer Organisation (BEUC) investigates EU decisions and developments likely to affect consumers, with a special focus on eight areas identified as priorities by its members, namely, Financial Services, Food, Digital Rights, Consumer Rights, Sustainability, Safety, Health and Energy. It publishes position papers, factsheets, reports, brochures, EU Presidency Memos etc.[214] EFPIA partners in EU Research programmes, such as the IMI (Innovative Medicines Initiative), Europe's largest public-private partnerships.[215]

<u>*Role* in the setting and enforcement or promotion of standards and practices w.r.t. ethics assessment and CSR</u>

Industry associations help members comply with ethical and professional standards by developing codes of practice, guidelines etc. Eucomed, for instance, has developed a *Code of Ethical Business Practice*[216] and a *Procedural Framework* (grounded on the Code) based on principles of autonomy, proportionality, speed, due process, fairness and transparency. It provides consistent principles and enforcement structures for Europe, building on the existing processes at national level. The EFPIA *Code of Practice* lays down fundamental rules for members on the promotion of medicines to, and interactions, with healthcare professionals and recognises the importance of voluntary control of advertising medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise.[217] The code is enforced at national level, through EFPIA member associations, which in some cases goes beyond existing laws and regulations.[218]

Corporate Social Responsibility (CSR)

The European Commission "believes that CSR is important for the sustainability, competitiveness, and innovation of EU enterprises and the EU economy. It brings benefits for

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[212] http://www.eccredi.org/navigation/library_set.html
[213] http://www.eucrof.eu/index.php/eucrof/working-groups/119-list-of-working-group/28-clinical-trials-legislation
[214] http://www.beuc.org/about-beuc/who-we-are
[215] http://www.efpia.eu/our-work
[216]
http://www.eucomed.org/uploads/Modules/Publications/110504_eucomedcebp_broch_210x297mm_v20_pbp.pdf
[217] http://www.efpia.eu/topics/building-trust/codes-of-practice
[218] Ibid.

risk management, cost savings, access to capital, customer relationships, and human resource management".[219] The Commission promotes CSR in the EU and encourages enterprises to adhere to international guidelines and principles, some of which have been listed below. The EU's policy is built on an agenda for action to support this approach.[220] The new EU CSR agenda (2015-2019) will move from compliance to innovation.[221]

Global level

The development of private research and innovation systems has driven national and regional political agendas to adopt strategies to increase the amount of research and innovation taking place within their boundaries. For example, the European Union aims "To achieve the target of investing 3% of GDP in R&D in particular by improving the conditions for R&D investment by the private sector, and develop a new indicator to track innovation."[222] Similarly, India has launched a "Make in India" campaign in 2014 to increase international investment in manufacturing in India, including IT, pharmaceuticals, biotechnology, energy, and mining.[223] These efforts track the increasing leveraging of research and innovation systems in order to strengthen economic positions by incentivising private research and innovation within political boundaries.

The OECD Innovation Strategy, for example, suggests that governments can work to accommodate innovation by implementing "structural reforms in education and training policies, in entrepreneurship policies, in product and labour markets, in public research institutions, and [establishing policies such as pro-growth tax reform] to help develop networks and markets for knowledge."[224] The ethical component within the *Innovation Strategy* is the application of innovation to the mitigation of global and social challenges. The most salient ethical points concern the parallel maintenance of flexibility to develop innovation by autonomous means and encouraging enterprises to promote valuable technologies that are cost-effective and applicable to current global challenges. The underpinning priorities are: "empowering people to innovate, unleashing innovation in forms, creating and applying knowledge, applying innovation to address global and social challenges, and improving the governance and measurement of policies for innovation."[225] Furthermore, the policy acknowledges that R&D is not the only mode of innovation in today's climate; firms are capitalising on "a wide range of complementary technological and non-technological changes and innovations," coupled with international collaboration to achieve progress.[226]

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[219] European Commission, "Corporate social responsibility". http://ec.europa.eu/growth/industry/corporate-social-responsibility/index_en.htm
[220] http://ec.europa.eu/enterprise/policies/sustainable-business/corporate-social-responsibility/index_en.htm
[221] The preceding paragraph has been adapted from the EU report.
[222] http://ec.europa.eu/eu2020/pdf/annex1.pdf
[223] www.makeinindia.com
[224] Organisation for Economic Co-operation and Development, *Ministerial Report on the OECD Innovation Strategy*, OECD, Paris, 2010.
[225] *The OECD Innovation Strategy: Getting a Head Start on Tomorrow,* OECD, Paris, 2010. http://www.oecd.org/sti/inno/theoecdinnovationstrategygettingaheadstartontomorrow.htm
[226] Ibid.

Corporate Social Responsibility (CSR)

Corporate Social Responsibility (CSR) strategies provide ethical assessment and ethical guidance opportunities and tools for industry.[227] CSR tools include standards, principles, codes of conduct and reporting initiatives on social responsibility performance. CSR is an internationally recognised concept and is acknowledged at international, regional and national levels. Key examples of global initiatives include the Universal Declaration on Human Rights[228] (and Charter of Fundamental Rights of the European Union[229] and the European Convention on Human Rights[230]); United Nations Guiding Principles on Business and Human Rights[231]; United Nations Global Compact[232]; and the OECD Guidelines for Multinational Enterprises (OECD Guidelines)[233]. Global international protocols set out overarching key principles for responsible and ethical behaviour. The International Organization for Standardisation (ISO) is an independent, non-governmental membership organisation comprising representatives of various national standards bodies. [234] ISO 26000 is a standard that provides guidance on how businesses and organisations can operate in a socially responsible way. [235] In the field of ethics assessment and CSR, compliance with ISO recommendations can reduce costs and promote international cooperation.

Private companies can also help ensure ethical compliance and may provide related and advisory services. One example is US based NAVEX Global has more than 8,000 clients, and provides ethics and compliance software, content and services in over 200 countries.[236] Another example is the Ethisphere® Institute whose initiatives include the a listing of the World's Most Ethical Companies (that honours superior achievements in transparency, integrity, ethics and compliance), the Business Ethics Leadership Alliance (BELA), the *Ethisphere Magazine* focusing on business ethics, and third-party, independent verification of corporate programs that include: Ethics Inside® Certification and Compliance Leader Verification.[237] Another example is Standard Ethics (an independent European sustainability reporting and rating agency which aims to promote corporate ethics, corporate social responsibility, socially responsible investing and corporate governance according to the principles and guidelines of the UN, the OECD, and the EU)[238] and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)[239], a private, non-profit organisation that promotes the humane treatment of animals in science through voluntary accreditation and assessment processes.[240] Companies and other organisations may use the services of such organisations voluntarily.

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[227] The following paragraph has been adapted from the industry report (see Annex 3h)
[228] http://www.un.org/en/documents/udhr/
[229] http://ec.europa.eu/justice/fundamental-rights/charter/index_en.htm
[230] http://www.echr.coe.int/Documents/Convention_ENG.pdf
[231] http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf
[232] https://www.unglobalcompact.org/
[233] http://www.oecd.org/corporate/mne/
[234] http://www.iso.org/iso/home.html
[235] http://www.iso.org/iso/home/standards/iso26000.htm
[236] http://www.navexglobal.com/resources/videos/navex-global-approach-ethics-compliance
[237] http://ethisphere.com/about/
[238] http://www.standardethics.eu/home
[239] Further examples of organisations that set up principles and initiatives serving to promote ethics assessment practices are the International fertilizer industry association (IFA) in the scope of fertilizer production, distribution and sales, and International Railway Industry Standard (IRIS), with a focus on the railway industry.
[240] More than 950 companies, universities, hospitals, government agencies and other research institutions in 40 countries have earned AAALAC accreditation, demonstrating their commitment to responsible animal care and use.

The International Organisation for Standardization (ISO) is an independent, non-governmental membership organisation composed of representatives from various national standards bodies. With 163 member countries, it is the world's largest developer of voluntary International Standards.[241] Although its guidelines are not formally binding, they often become part of national legislations through treaties or the development of national standards. Also, as the ISO itself explains "ISO International Standards ensure that products and services are safe, reliable and of good quality. For business, they are strategic tools that reduce costs by minimizing waste and errors, and increasing productivity. They help companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade".[242]

In relation to impact assessment, the International Association for Impact Assessment (IAIA), for example, is the leading global network on best practice in the use of impact assessment for informed decision-making regarding policies, programs, plans and projects.[243] It is an international forum with members that include both individuals and organisations representing over 120 different nations. IAIA believes the assessment of the environmental, social, economic, cultural, and health implications of policy proposals represents a critical contribution to sound decision-making processes, and to equitable and sustainable development.

7.5 PROFESSIONAL GROUPS AND ASSOCIATIONS IN THE R&I FIELD

Professional groups and associations in the R&I field have an important role to play in developing policies and issuing guidelines and best practices at both EU and global levels. Collaboration between national and European branches of these organisations appears to be strong. For example, the British Psychological Society interacts with the European Federation of Psychologists' Association (EFPA), particularly with regard to the EFPA's Meta Code of Ethics. International associations of professional groups and R&I professions have the same mission and objectives but potentially greater impact given the greater number of member countries at global level. For example, the Clinical Research Society (CRS) includes more than 23,000 professionals in over 160 countries working in the area of clinical and transitional medicine and aims to develop a common understanding of ethical principles for research on human subjects, amongst other objectives. [244] Many EU countries will be members of such organisations, thus further enhancing the reach and salience of ethics assessment practices.

7.6 DISCUSSION [245]

Ethics assessment and guidance of research and innovation takes place across both private and public research and innovation systems in the EU. Ethics review is well organised at European Commission level and is supported and enhanced by European research funding organisations. In addition, there are a variety of organisations at both the Commission and European Parliament that carry out ethics assessment/guidance as part of their mandate, or encounter ethical issues in other kinds of assessment activities. Specific laws and policy mechanisms set a solid base for ethics assessment of R&I. The incorporation of the European

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[241] See more : http://www.iso.org/iso/home/about.htm
[242] http://www.iso.org/iso/home/standards.htm
[243] http://www.iaia.org/?AspxAutoDetectCookieSupport=1
[244] http://www.clinicalresearchsociety.org/
[245] This discussion text has been adapted from both the EU and global report discussions.

Charter of Fundamental Rights into the Lisbon Treaty has generally enhanced the consideration of ethics and human rights at EU level and the work of advisory bodies such as the EGE, in particular. The importance of international guidelines and frameworks at EU level is clear, particularly in the ethics review of research proposals and projects. The global ethics landscape reflects the increasing interconnectivity between regional actors.

8   GENERAL DISCUSSION AND CONCLUSION

This report has presented a comparative analysis of how ethics assessment and guidance of research and innovation is practiced in different scientific fields, types of organisations, and countries. It has also introduced basic terminology, including the central concepts of ethics assessment and ethical guidance, has discussed major traditions, approaches, principles and issues in ethics assessment, and has analysed ethics assessment and guidance policies and institutions at the EU and global level.

In the report, a fundamental distinction was made between *ethics assessment*, which is any kind of institutionalised assessment, evaluation, review, appraisal or valuation of practices, products and uses of research and innovation that primarily makes use of ethical principles or criteria, and *ethical guidance*, which is the statement of ethical guidelines, principles, rules, codes, and recommendations to which plans, practices and products of research and innovation are expected or recommended to adhere. We explained that ethics assessment and ethical guidance can be directed at (1) R&I practices and products, (2) R&I policies, and (3) professional conduct in R&I, and that each of these forms of assessment and guidance is different.

We then continued to introduce major traditions and approaches in ethics assessment, including *research ethics*, *engineering ethics*, and *ethics of technology and innovation*. We paid special attention to the approach of *ethical impact assessment*, which is a type of impact assessment that focuses on actual or potential impacts of R&I that have ethical relevance. We discussed major issues in research ethics, such as the protection of human subjects, the use of animals, research integrity, and social responsibility. We also discussed the focus of engineering ethics on issues in professional conduct of engineers, including issues and principles of professional integrity, honesty, impartiality and responsibility for the safety, health, and welfare of the public. The ethics of technology and innovation was found to be concerned with the value-ladenness of technology and its impact on society, both regarding so-called hard impacts (health, safety and environmental) and soft impacts (regarding human rights, culture, identity and the social good).

Next, in our comparative analysis of ethics assessment in different scientific fields, we found that the most extensive institutions, policies and activities in the areas of ethics assessment and guidance exist in the medical and life sciences, while the humanities have not yet established a clear tradition in ethics assessment. Notwithstanding the particular emphasis given by the EU and supranational organisations to ethics assessment in the medical sciences, one sees the growing institutionalisation of ethics assessment in non-medical fields. However, it appears that this institutionalisation is developing somewhat independently of the influence of medical research ethics. While the five major scientific fields that we studied share the same concerns and are concerned with the protection of human subjects in research, for example, many ethical issues and principles appear to be specific to the fields. This is reflected in the variety of approaches to ethical assessment within and across the scientific fields. Moreover, attempts to transfer and take up the principlism approach to biomedicine in other areas such as the social sciences have been met with limited success. The "Generic Ethics Principles in Social Science" that are being developed by UK's Academy of Social Sciences, are for example taking a step away from biomedically imposed principlism to explore the benefits of virtue ethics.[246] Thus, there is reason to doubt the feasibility of

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[246] See http://acss.org.uk/developing-generic-ethics-principles-social-science/.

transferring ethics frameworks, principles and practices from fields with well-developed ethics assessment frameworks to other fields. While there are certainly aspects that can be usefully transferred, some areas such as the social sciences and humanities are faced with the challenge of dealing with familiar issues, such as informed consent and data protection, in rather novel, and largely unknown, contexts. Also, different topics and methods of research in the social sciences generate (as discussed in more detail in report on *Ethics assessment in different fields: Social sciences*[247]) significant differences in the nature of risks and benefits and consequentially in the measures taken to avoid or achieve them. This is why transferring an ethical assessment framework, developed for example for biomedicine, may therefore misjudge the risks at stake in an individual research project in the social sciences.

In our comparative analysis of ethics assessment and guidance in different kinds of organisations, we found that principles and practices for the fifteen kinds of ethics assessors we studied vary, both in the particular role of the respective organisations in ethics assessment and in the objects or foci of assessment and guidance. Perhaps unsurprisingly, given the strong tradition of ethics assessment in the medical and life sciences, national ethics committees and research ethics committees have a well-established role in ethics assessment. The beneficiaries of assessment are very diverse and there is great diversity in the use of specific frameworks and procedures. For certain kinds of organisations, ethics assessment or guidance is an optional activity or perhaps an implicit part of activities that are specifically mandated - this appears to be the case for some companies and industry associations. It is rather more surprising that *some* universities and research funding organisations do not pay much attention to ethics assessment, given their undeniable link to potential ethical issues in research. It appears that incentives, hard and soft law and organisational context play an important role in encouraging and facilitating ethics assessment for these and other organisations. Various challenges have been identified in the practice and implementation of ethics assessment and guidance ranging from a lack of clear procedures and guidelines to insufficient capacity to incorporate new issues and challenges. Thus, it appears that the baseline from which organisations develop and practice ethics assessment and guidance varies.

In our comparative analysis of ethics assessment in countries, we found that all of the countries we studied are currently expanding their ethics assessment and guidance infrastructures. The expansion of non-medical research ethics committees and ethics assessment in non-medical areas is particularly striking. Significant differences exist in the degree to which ethics assessment of R&I is institutionalised, ranging from limited to extensive institutionalisation. The degree of institutionalisation might nominally be linked to the role of government in ethics assessment and guidance, ranging from strong (China) to little (US) regulation and intervention with EU countries somewhere in the middle, although this requires further investigation. It is also interesting to observe the role of certain organisations in ethics assessment. For example, governments stimulate CSR for industry to different degrees while CSOs engage in informal ethics assessment and guidance in public discussion and have a role in ethics assessment procedures carried out by other organisations.

As regards ethics assessment at EU and global levels, one sees increasing coordination and cooperation across regional levels. While many international guidelines and documents set the

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[247] Gurzawska, Agata, Rok Benčin, "Ethics assessment in different fields: Social sciences", Annex 2.d, *Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries*, Deliverable 1.1, June 2015.

benchmark for ethics assessment in the EU, the EU has a very well developed system of ethics assessment which is reinforced by the collective effort of a variety of organisations within the R&I system.

Let us now look forward. We offer this public report, and its 47 annexed in-depth reports, as a major repository of information on the state of the art in ethical analysis, assessment and guidance of research and innovation, in particular in the EU, the US and China and at the supranational, global level. For the SATORI project, it is in addition an important means by which we will take our next step: the identification of best practices, the development of proposals for harmonisation and shared standards, and, to the extent possible, the proposal of common principles, protocols, procedures and methodologies for the ethical assessment of research and innovation in the European Union and beyond.

We believe that through careful analysis of existing approaches, institutions and protocols, and through mutual learning between scientific fields, organizations and countries, it will be possible to arrive at better practices in ethics assessment and guidance, and to a certain extent, shared standards. Further steps towards this goal will be made in the deliverables of work package 4 (Roadmap for A Common EU Ethics Assessment Framework) in the SATORI project, as well as deliverables in later work packages. Our proposals will be based on our findings so far about the state of the art, and on the opinions and recommendations of hundreds of stakeholders that have been and will be consulted, including the partners in the SATORI consortium. We invite readers of this report to consider our constructive proposals in our forthcoming reports.

9   ANNEXES

Annex 1: Principles and Approaches in Ethics Assessment

1.a   Ethical impact assessment and conventional impact assessment
1.b   Research integrity
1.c   Social responsibility
1.d   Human subjects research
1.e   Institutional integrity
1.f   The use of animals in research
1.g   Dual-use in research
1.h   Ethics and Risk

Annex 2: Ethics Assessment in Different Fields

2.a   Natural Sciences
2.b   Engineering Sciences
            2.b.1   Information Technology
            2.b.2   Emerging technologies: The case of nanotechnologies
2.c   Medical and Life Sciences
            2.c.1   Neurosciences and neurotechnologies
            2.c.2   Pharmaceutics
            2.c.3   Social gerontechnology
            2.c.4   Biobanking
            2.c.5   Public health ethics
            2.c.6   Genetics
            2.c.7   Stem cell research
            2.c.8   Agricultural research
2.d   Social Sciences
            2.d.1   Psychology
            2.d.2   Internet research ethics
2.e   Humanities

Annex 3: Ethics Assessment and Guidance in Organisations

3.a   Research Ethics Committees
3.b   National Ethics Committees
3.c   Research Funding Organisations
3.d   National science academies and academic & professional organisations
3.e   Universities
3.f   Government and government-funded organisations
3.g   Civil Society Organisations
3.h   Industry
3.i   Standards, certification and accreditation organisations

Annex 4: Ethics Assessment in Different Countries

4.a   Austria
4.b   China

Annex 5: Ethics Assessment and Guidance at the EU and Global Level

10 APPENDICES

APPENDIX 1 COUNTRY STUDY INTERVIEW CATEGORIES

Each country study includes *14 interviews*, encompassing the following categories:

- 1-2 representatives from national ethics committee(s)

- 1-2 representatives from national funding organisation(s) (the representatives should be knowledgeable of ethics review activities within the organisation)

- 2 representatives from national organisations for research ethics committees (at least one interview, if such an organisation exists), a national expert on research ethics committees and/or a chair of a local/regional REC

- 1-2 representatives from national ethics associations (preferably for R&I) and/or professional associations for R&I professions (the representatives should be knowledgeable of ethics assessment for R&I within the organisation)

- 1-2 representatives from national academy/ies of sciences, preferably representing different fields (the representatives should be knowledgeable of ethics assessment activities within the academy)

- 1 representative from government agency involved in or responsible for overseeing ethics assessment of research and innovation (other than a national ethics committee)

- 1 representative from a national organisation that represents industry or a major national company (the representatives should be knowledgeable of ethics assessment and/or corporate social responsibility activities upheld by organisation)

- 2 representatives from national civil society organisations that may or may not engage in ethics assessment of research and innovation, but in any case are stakeholders in it. CSO organisations to be taken from the following categories: religious; consumer; environmental; human rights / civil liberties, developmental, animal rights, science journalism

- 1-2 representatives from national organisations that represent universities and/or (leading national) universities and/or accreditation organisations for universities (the representatives should be knowledgeable of research ethics arrangements and regulations at universities)

APPENDIX 2 ADDITIONAL INTERVIEW CATEGORIES

In addition to the country-based interviews, *additional interviews* were carried out in order to adequately cover (1) different categories of ethics assessment organisations, (2) different scientific fields, and (3) additional non-assessing stakeholders (mostly at the EU level).

(1) Additional interviews ethics assessment organisations: 50

- European and international ethics assessment organisations (total: 18)

  - e.g., EU-H2020 Ethics review, EU Ethics group, ESF, EUREC, UNESCO Bioethics, international and European academic organisations. Also a couple of international accreditation and certification organisations that may be involved with ethics assessment and one EU-level organisation for (soc/env) impact assessment.

- National ethics assessment organisations in the EU outside the 8 countries that were chosen (total: 10)

  - National Ethics Committees in Finland, Denmark, Sweden (both the national committee and representatives from national RECs; 3 in total), Norway (national ethics committees: 3), Slovenia, Italy

- Organisations responsible for impact assessment (total: 6)

- EU and International industry (multinationals and international industry-representing organisations); possibly also business ethics experts (total: 16)

(2) Additional interviews scientific discipline representatives: 15

- 4 experts on ethics assessment in medicine

- 4 experts on ethics assessment in social science

- 4 experts on ethics assessment in engineering

- 2 experts on ethics assessment in natural science

- 1 expert on ethics assessment in humanities

Above interviews to be combined with interviews of experts on specific topics:

- use of lab animals (3 interviews)

- human subjects research (4 interviews)

- scientific integrity (3 interviews)

- institutional integrity (3 interviews)

- social responsibility of scientists (3 interviews)

- dual use (2 interviews)

(3) Additional interviews non-assessor stakeholders (national and international): 22

- o EU-level civil society organisations in various categories (science journalism; religious; consumer; environmental; developmental; etc.): 15

    - o religious: 2

    - o civil liberties / human rights: 2

    - o science journalism: 1

    - o developmental: 2

    - o consumer: 2

    - o environmental: 3

    - o animal rights: 1

    - o ethic minority/women/elderly/children/disabled/patient organisations : 2

- o governmental (EU-level (most) or UN): 7

We ask interviewees to take a look at these questions before the interview. There are interview questions and additional factual questions. The additional factual questions will not be asked during the interview if documents are available from your organization that answer these questions and that are written in a language that is understood by the interviewer. These could be online documents or internal documents that you provide the interviewer with.

We are interested in receiving any documents about ethical assessment in your organization, including documents that explain the aims and goals of ethical assessment, the ethical principles and protocols that are used, the organizations and persons responsible for the ethical assessment, the relation between ethical assessment and laws and directives, statistics about ethical assessment, or publications that discuss ethical assessment of research and innovation in your organization. If no such documents are available, or if the interviewer does not master the language of the documents, then we would like to ask the additional factual questions during the interview as well.

A. Interview Questions
1) (Questions about the way in which ethics assessment of research and/or innovation in performed)
   a) Can you describe what kind of ethical assessment your organization does and what is its goal?

   b) And what is assessed: e.g., research proposals, research programs, policies, research results, technological innovations, behaviors of scientists and/ or innovators, etc.

   c) Who are the users (consumers) of the assessments?

   d) Which fields are covered by ethics assessment in your organization (medical science, natural science, engineering science, social science, humanities, or all fields?). If certain fields are not covered, why not? *[NB – this question only applies to (semi) scientific/academic organizations]*

   e) What kind of committee(s) or persons do the ethics assessment?

      i) What is their expertise?

      ii) How were they are chosen for this task?

      iii) Is there any consultation of stakeholders or of the public?

   f) Can you say which ethical values, principles or directives are used in ethical assessment in your organization? For example, integrity, protection of human beings, promotion of the social good, informed consent, beneficence, justice, protection of the environment?

      i) Is there a shared framework of such values and principles or do individual assessors (also) bring their own values and principles to the table?

   g) Which, if any, are the most important other organizations that you interact with in relation to ethics assessment? These may be organizations that have input into your assessments, regulate the way your organization does assessments, are clients of your assessments, or that otherwise function as stakeholders.

   h) Can you say how ethical assessment by your organization is used and what its impact is?

i)   Are your recommendations binding or nonbinding?

ii) Are they generally followed; if not, how frequently are they followed, and what are the reasons that people or organizations have for not following them?

iii) Is there any monitoring of compliance with your recommendations? If not, why not?

i)   if you have performed any evaluations or assessments of the impact of ethics assessment as performed by your organization,

i)   what have you found the impact to be?

ii) where does ethics assessment function as desired, and where is it found wanting?

2) How would you assess the relative influence or importance of ethics assessment on research and innovation as compared to other forms of assessment, generally, and specifically within your company?

3) How would you describe the most important ethical problems in research and innovation that are assessed by your organization?

   a)   Can ethical assessment performed by your organization help solve these problems?

   b)   If not, what else is needed to solve them?

4) Are there weaknesses or problems in how ethical assessment takes place at your organisation? If so, can you please elaborate on their nature?

   a)   What actions are currently being taken or planned to improve ethical assessment?

   b)   What needs to change within or outside your organization to make further improvements possible?

5)   Do you think it would be is desirable to have a shared European approach for ethics assessment of research and innovation, with shared standards, procedures, and protocols for all European countries, and all organizations that engage in ethics assessment?

   a)   Do you believe it is possible?

   b)   What would be the obstacles to such an approach? What would be the benefits?

   c)   Would it be desirable for such an approach to have shared ethical values and principles, or only protocols and procedures?

   d)   If you are not sure if a shared approach for all types of organizations is desirable or feasible, do you think that it would be desirable for organizations of your type alone, that is, would you be interested in more shared standards and approaches with similar organizations in European member states?

National ethics committees

- How is your advice used by government and/or, and what has been its impact on legislation and policy? Can you be specific about these impacts, perhaps with examples?

- Are there any departments or units within ministries or instituted by the government or parliament that also engage in ethics assessment?

    o If so, what are they, and how does your role and your advice relate to theirs?

National organizations
- What do you believe to be specific to ethics assessment in your country, if anything, as compared to other countries?
    o Are there specific ethical values, principles, problems, or approaches that are typical of your country? Could you describe them? Can you explain why these issues are particular to your country (political, societal landscape, etc.)
    o Is the way in which ethics assessment is practiced in your organization uniquely different in some ways from how it is practiced in other countries? If so, how?
    o Are there also particular types of organizations, policies or legislations for ethics assessment that are possibly unique to your country? Can you describe them?

B. Additional Factual Questions

6) What is the full name of the organization (in original language and in English, if available), and what is the name of the unit that engages in ethics assessment, if it is different? What is the website address?

7) Does the organization have any policies or assessment procedures for the following, and if so, how are they used and how is compliance monitored, if at all?

   a) scientific integrity (avoiding scientific misconduct, such as fraud, data falsification, plagiarism, etc.)

   b) professional integrity (especially for innovators / engineers) (rules and principles for interacting with clients, employers, and other stakeholders, avoiding conflicts of interest, honesty, responsibilities to the environment, to general welfare, etc.)

   c) human subjects research (including special provisions for children and individuals who lack full autonomy)

   d) treatment of animal in experiments

   e) dealing with risks and anticipating social and environmental impacts, including

      i) implications for individual and civil rights Specifically:

         - freedom   - non-discrimination and equality (are any specific

         - autonomy   groups mentioned, e.g., women, minorities, disabled, etc.)

         - privacy   - bodily integrity

         - human dignity

      ii) implications for (distributive) justice

      iii) implications for health and safety

iv) implications for the environment

v) implications for quality of life

vi) dual use (the possibility of military use of research and innovations)

f) outsourcing of research and / or innovation to developing countries which may have lower ethics and / or social/environmental standards than the country in which the outsourcing agent is located.

8) Does the organization have any methods or procedures for assessing the impact of ethics assessment as performed by the organization? Please state what they are.

National ethics committees

- What is the role of the committee in national legislation? How does it advise the government or parliament?
- Is its purpose also to advise nongovernmental bodies or the general public ? If so, how does it do this?

We ask interviewees to take a look at these questions before the interview. There are interview questions and additional factual questions. The additional factual questions will not be asked during the interview if documents are available from your organization that answer these questions and that are written in a language that is understood by the interviewer. These could be online documents or internal documents that you provide the interviewer with.

We are interested in receiving any documents about ethical assessment in your organization, including documents that explain the aims and goals of ethical assessment, the ethical principles and protocols that are used, the organizations and persons responsible for the ethical assessment, the relation between ethical assessment and laws and directives, statistics about ethical assessment, or publications that discuss ethical assessment of research and innovation in your organization. If no such documents are available, or if the interviewer does not master the language of the documents, then we would like to ask the additional factual questions during the interview as well.

Questions for all non-ethics assessors

a) Is there any unit within your organization that deals with ethical issues, particularly in research and innovation (including science-based social and technological innovation)? What is the mission of your organization? What kind of constituency do you represent (size, makeup, etc.)?

b) To what extent does your organization have an interest in research and innovation, in particular in its ethical, social and environmental implications? Can you describe the particular interest for your organization?

c) Following up on the previous question, what specific ethical issues in general is your organization concerned with, and which ones of those relate to developments in research and/or innovation? For example, ethical issues relating to civil and individual rights, non-discrimination and justice, care for health, safety, quality of life and the environment, and professional ethics and integrity.

d) Do you in any way, directly or indirectly, engage in ethics assessment, by investigating or commenting on ethical issues such as mentioned in the previous question, even if you do not identify them as ethical issues? Please specify.

e) Do you collaborate in any way with organizations that systematically engage in ethics assessment? Please specify.

f) Do you think it would be is desirable to have a shared European approach for ethics assessment of research and innovation, with a certain amount of shared standards, procedures, and protocols for all European countries, and all organizations that engage in ethics assessment?

   i) Do you believe it is possible?

   ii) What would be the obstacles to such an approach? What would be the benefits?

   iii) Would it be desirable for such an approach to have shared ethical values and principles, or only protocols and procedures?

Additional questions CSO's

g) Are there any ethical values or principles that are explicitly promoted by your organization, for example, example, integrity, privacy, protection of human beings, informed consent, beneficence, justice, environmental protection, or more specific versions of such principles?

h) How do you see the role of civil society organizations generally, and specifically your type of organization (e.g., religious, consumer, environmental) in the evaluation, assessment and discussion of ethical issues in research and innovation?

    i) What is your role as compared to, e.g., national ethics committees, ethics committees at universities, and other organizations who perform ethics assessment?

    ii) What is your added value?

i) Regarding the ethical issues that your organization is most concerned with, are you satisfied with the current way in which these ethical issues are dealt with in research and innovation and their ethical assessment by various organization? If not, what are the negative effects you are concerned with, particularly for the constituents you represent, and what needs to change? What improvements could be made?

Do you think any gaps might be addressed through capacity building and training activities? If yes, what kinds of needs should these activities address?

Additional questions governmental organizations

j) How do you see the role of ethical issues and their assessment in political decision making? Specifically, what is the role of assessments of ethical issues in research and innovation?

k) How can ethics assessment of research be better integrated with political decision making, not only for policies in the area of research and innovation, but also in other areas?
Do you think any gaps might be addressed through capacity building and training activities? If yes, what kinds of needs should these activities address?

APPENDIX 5 SATORI PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Stakeholders Acting Together On the ethical impact assessment of Research and Innovation (SATORI)
http://satoriproject.eu/

Participant information sheet

By signing the attached form, I understand that I am consenting to participate in the European Union-funded (Grant agreement number 612231) SATORI research project conducted by the University of Twente, Trilateral Research & Consulting and other SATORI partners. I am aware that the purpose of this research is to understand current practices and principles in ethics assessment within scientific fields and among different kinds of ethics assessors and countries. This research will involve an interview lasting up to one hour where I will be invited to discuss my knowledge about this area.

I understand that I am participating in this research voluntarily and that I am free to terminate the interview at any time. I am also aware that I am free to refuse to answer any questions that I feel are commercially or institutionally sensitive or relate to topics that I do not wish to discuss. I understand that I have the right to ask questions and receive understandable answers before making any decision.

I understand that I will only be asked to provide professional, not personal, information and that the record of my involvement in the research will be kept confidential. The interview data will be recorded via voice recorder. A summary of the interview will be produced and used as input to a deliverable. I understand that I can request a copy of the interview summary. I understand that this research will be used to produce an up-to-date and detailed comparative analysis of EU and international practices related to ethics assessment in scientific research and related innovation activities. I understand that the interview will be stored and can be used for later research; however, it can only be used for publicly funded research.

I understand that this research conforms to European Commission guidelines and that it has been approved by the Ethics Committee in the Co-operation theme of the 7th Framework Programme. Finally, I have been given the contact details of the research team and I have been informed that I am free to contact Philip Brey (Project Coordinator) or Clare Shelley-Egan (the work package leader) about any queries relating to my data or the project itself. Philip Brey's e-mail address is p.a.e.brey@utwente.nl and his telephone number is +31-53-4894426. Clare Shelley-Egan can be contacted at clare.shelleyegan@trilateralresearch.com.

Consent form

Issue	Respondent's initial
I confirm that I have read the information sheet dated *[insert date]* explaining the above research project and I have had the opportunity to ask questions about the project. My participation is voluntary. I agree that the data collected from me can be used for the purpose of a SATORI deliverable which will be made publicly available.	
I wish for my name to be anonymised for the purpose of this research. However, I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research.	
I wish for the name of the organisation to be anonymised for the purpose of this research.	
I agree that the data may be used for non-SATORI publicly funded research.	