



Ethics assessment and guidance in different types of organisations

National Ethics Committees

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June 2015

Annex 3.b

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

Deliverable 1.1

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



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1 Introduction

The aim of this report is to analyse and compare how ethics assessment and ethical guidance of research and innovation is performed by National Ethics Committees (NECs) in the European Union (EU) and the United States (US). The report is based on online and offline documentation, previous published reports, and interviews with representatives of organisations in 13 different Committees in the EU and at international and regional level. Ten representative European countries have been singled out for in-depth study, including nine EU member states and one candidate for EU membership: Austria (*Austrian Bioethics Commission*), Denmark (*Danish Council of Ethics*), Finland (*Finish National Advisory Board on Social Welfare and Health Care Ethics*), France (*Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé*), Germany (*German Ethics Council*), the Netherlands (*Health Council of the Netherlands*), Serbia (*Serbian National Committee for Bioethics*), Slovenia (*Slovenian National Medical Ethics Committee*), Spain (*Spanish Bioethics Committee*), and the United Kingdom (*Nuffield Council*). *The Presidential Commission for the Study on Bioethical Issues* has been analysed in this report for the US. In addition the *International Bioethics Committee* of UNESCO and the Ethics Committee of a regional organisation were analysed.

In the report, it will be investigated how these NECs are organised. It will be studied how NECs are institutionally embedded, how they perform ethics guidance and with what aims, and what the perceived strengths and weaknesses of their work are.

Ethics assessment, in the context of this report, is any kind of assessment, evaluation, review, appraisal or valuation of research or innovation that makes use of ethical principles and criteria. Ethical principles are criteria that aim to determine whether certain actions or developments are right or wrong. They define individual rights like rights to freedom and privacy, and include principles of justice and principles which state that harms to individuals and society should be avoided and benefits for them should be promoted. Ethical guidance is different from ethics assessment in so far as it does not concern an evaluation of practices and products of research and innovation that have already occurred, but rather presents rules, codes, and recommendations to which future scientific practices, innovation practices, and developments in science and technology are expected or recommended to adhere.

NECs play an important role in national and international deliberations on ethics in respect to new developments in science and technology, as on the one hand they advise governments, parliaments and politicians and on the other hand they promote public debate on issues which are intrinsically problematic. NECs provide ethics guidance, as defined above, primarily via recommendations to the political level and by reaching out to the general public.

The report will give an overview of basic characteristics and the distribution of NECs in Europe and the US. It will show that NECs have been established globally and will present international fora of NECs as well as Ethics Committees of International or Regional Organisation. The report will then analyse the institutional set-up of NECs and procedural aspects as well as the ethics assessment framework of their work. Finally, the report will give an overview of problems and possible future challenges for NECs. As NECs have a particular mission in regard to public dialogue this aspect will be discussed recurrently.

2 National Ethics Committees: Basic Characteristics and Distribution

The establishment of Ethics Committees is advocated for by the Universal Declaration on Bioethics and Human Rights. Article 19 of the Universal Declaration on Bioethics stipulates:¹

“Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

- Assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;
- Provide advice on ethical problems in clinical settings;
- Assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;
- Foster debate, education and public awareness of, and engagement in, bioethics.”

This article includes a call for the establishment of NECs and Research Ethics Committees. Typical traits which are formulated in this article relating to NECs concern their institutional set up as an independent, multidisciplinary and pluralist body, and to their aims in relation to the assessment of scientific and technological developments, to the formulation of recommendations and of fostering debate, education and public awareness of, and engagement in, bioethics.

The *Austrian Bioethics Commission* for instance is an independent, multidisciplinary body with the task to advise the Federal Chancellor from an ethical point of view on all social, scientific and legal issues arising from the scientific developments in human medicine and human biology. The *Comité Consultatif National d’Ethique pour les sciences de la vie et de la santé (Comité Consultatif National d’Ethique)* is a strictly consultative body. Its mission is to deliver opinions on ethical and social issues raised by the progress of knowledge in the fields of biology, medicine and health. The *Spanish Bioethics Committee* was established as an “independent and consultative professional body, which will develop its responsibilities, with full transparency, on materials related to the social and ethical implications of Biomedicine and Health Sciences”. The *German Ethics Council* is responsible for pursuing “the questions of ethics, society, science, medicine and law that arise and the probable consequences for the individual and society that result in connection with research and development, in particular in the field of the life sciences and their application to humanity”. The *Serbian National Committee for Bioethics* is primarily dealing with the issues of moral-ethical behaviour within the sphere of natural sciences and research. It pertains primarily to biological and medical sciences, their interrelations through biomedicine, as well as behaviour of scientists and physicians at work performed within their institutions. The *Presidential Commission for the Study of Bioethical Issues* “[...] is an advisory panel of the nation’s leaders in medicine, science, ethics, religion, law, and engineering. The *Presidential Commission for the Study of Bioethical Issues* advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The *Presidential Commission for the Study of Bioethical Issues* seeks to identify and promote policies and practices that ensure

¹ http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.” Some NECs also include ethical question in relation to social welfare and environmental issues in their mandate, such as the *Finish National Advisory Board on Social Welfare and Health Care Ethics (Finish National Advisory Board)* or the *Health Council of the Netherlands*, which has the task of bringing subjects concerning health and the environment to the attention of the Government and Parliament, and of highlighting respective threats and opportunities.

NECs usually also monitor and publish international trends in ethics and participate in international events as necessary. There are multi- and bilateral initiatives of NECs, such as the *NEC Forum*² sponsored by the European Commission, which meets on a yearly basis, the *European Commission's International Dialogue on Bioethics*, a platform bringing together the National Ethics Councils from 97 countries,³ the *European Conference of National Ethics Committees (COMETH)*⁴ sponsored by the Council of Europe, or the *Global Summit of National Bioethics Advisory Bodies*, meeting on a biannual basis supported by a secretariat at the World Health Organisation (WHO).⁵

In addition, the *German Ethics Council* interacts on the one hand with the French *Comité Consultatif National d’Ethique* and the *Nuffield Council* in yearly meetings, and on the other hand with the DACH (Germany/Austria/Switzerland) countries in order to support dialogue on bioethics among this regional group. Similar regional initiatives can be reported from the Nordic and Baltic countries.

NECs exist in all EU Member States, most other European States, the US, Canada, Middle and South America, Australia, and New Zealand.⁶ The first NEC established in Europe was the *Comité Consultatif National d’Ethique*, which was established in 1983.⁷

The counterpart of NECs at the EU level is the *European Group on Ethics in Science and New Technologies (EGE)*, an external advisory body which provides the European Commission with high quality and independent advice on ethical aspects of science and new technologies.⁸ The *International Bioethics Committee (IBC)*, whose primary objective is to promote reflection on the ethical and legal issues raised by research in the life sciences and their

² <http://demo.intrasoft.be/ssc/index.cfm?fuseaction=public.topic&id=1305>

Please note that the meetings have been reduced to one meeting per year.

³ http://ec.europa.eu/epsc/ege_en.htm

⁴ http://www.coe.int/t/dg3/healthbioethic/COMETH/national_ethics_committees/default_en.asp

It has to be noted that COMETH is not active at present.

⁵ <http://www.who.int/ethics/globalsummit/en/>

⁶ http://apps.who.int/ethics/nationalcommittees/NEC_full_web.pdf

<http://www.who.int/ethics/nationalcommittees>

<http://www.unesco.org/new/en/social-and-human-sciences/themes/global-ethics-observatory/access-geobs/>

These lists give a good overview of the National Ethics Committees being active globally. Please note that these lists may differ slightly as the different organisations maintaining these lists may have a different focus and diverging interests in listing organisations involved in ethics.

⁷ <http://www.ccne-ethique.fr/fr/pages/historique>

⁸ http://ec.europa.eu/epsc/ege_en.htm

applications, and the *World Commission on the Ethics of Scientific Knowledge and Technology* (COMEST) can be regarded as the counterpart of NECs at UNESCO level.⁹

3 Ethics Guidance by National Ethics Committees: Aims and Scope

Most NECs report to refer to their work as ethics guidance to the political level as well as to professionals, i.e. those people who are actually carrying out research or implementing new technologies in the areas of professional guidance or in professional self-governance in the case of the *Nuffield Council*.

The aim / 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. The *German Ethics Council* for instance pursues questions of ethics, society, science, medicine and law and the probable consequences for individuals and society that result from research and development. Particular attention is paid to the field of life sciences and their application. However, the Council also deals with issues beyond this area, for example the so called “life boxes”. The *Health Council of the Netherlands* discusses issues in relation to optimal healthcare, prevention, healthy nutrition, environmental health, healthy working conditions, and innovation and the knowledge infrastructure and thus contributes to a well-considered, ethically responsible health policy, aiming at good care for everyone. The *Nuffield Council* tries to identify developments in research, understand their social and ethical implications and tries to find an ethical approach that helps to offer solutions or policy approaches.

Expert advice / guidance to the political level is usually given in the form of recommendations to a given subject and is addressed to the respective authority. The *Austrian Bioethics Commission* acts under the authority of the Federal Chancellor, the *Finish National Advisory Board* acts under the authority of the Ministry of Social Affairs and Health, the *German Ethics Council* reports to the Parliament and the Government, the *Health Council of the Netherlands* has the task to advice ministers and Parliament, the *Spanish Bioethics Committee* reports to public authorities at state and regional level, and the *Presidential Commission for the Study of Bioethical Issues* advises the President of the US.

The *Nuffield Council* is an exception in this regard, as it was not tasked by a public authority, but was established by the Trustees of the Nuffield Foundation. The overall task of the *Nuffield Council* can however be regarded as similar to the tasks of the other NECs analysed in this report: To identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern; to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion.

Most NECs also indicate that their work reaches out to the general public and builds public opinion. Public debate can be initiated by NECs through public hearings, conferences or online consultations. The *German Ethics Council* for instance makes use of public hearings,

⁹ <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/>

online consultations including questionnaires and online debates with the public. The *Health Council of the Netherlands* indicates that their reports find their way to major societal groups in their field of work and are frequently used for educational purposes. The *Danish Council of Ethics* also indicates that they create public debate about developments in biotechnology on top of giving ethics guidance. Also the *Slovenian National Ethics Committee* reports to participate in public debates related to medical ethics. The *Nuffield Council* reports the promotion of public discussion and understanding regarding the social and ethical issues that arise in the context of new science as one of its special tasks.

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. The *Danish Council of Ethics* also reports stakeholders and relevant industries as beneficiaries. The *Nuffield Council* indicates that in their reports they might address recommendations to, for example, people in research councils, research funders and to national policymakers, but also potentially to, for example, the EU, as they have done with their reports on neurotechnologies and biofuels. Thus the group of beneficiaries is larger than reported by other NECs.

4 Institutional Setup of National Ethics Committees

NECs are usually established by law. Their term of office varies between a fixed period of about four years or their term of office is tied to the term of office of the appointing authority. As regards the institutional set-up, they usually consist of about 15 or more non-remunerated members based in different fields of scientific research. Appointment procedures, tasks, composition, convocation of meetings, procedures, and the establishment of secretariats are usually provided for by law.

The *Austrian Bioethics Commission* was established in 2001 by an order issued by Federal Chancellor. The members are appointed by the Federal Chancellor for a period of three years. The Commission consists of experts representing the fields of medicine (especially reproduction medicine, gynaecology, psychiatry, oncology, and pathology), molecular biology and genetics, law, sociology, philosophy and theology. The legal basis also provides for an equal gender distribution of the members.

The *Danish Council of Ethics* for instance was established in 1988 by an act of Parliament. It is an independent body under the Ministry of Interior and Health. The members of the *Danish Council of Ethics* are designated by the Parliament and relevant Ministries, and appointed by the Minister for the Interior and Health for a period of three years. The scientific disciplines include law, humanistic information studies, multimedia, science of public health and philosophy. The Law also provides for an equal gender distribution of the members.

The *Finish National Advisory Board* was set up pursuant to the Act on the Status and Rights of Social Welfare Clients and the Act on the Status and Rights of Patients. The duties and membership of the Advisory Board were defined by Government Decree 667/2009. The Government appoints the members of the *Finish National Advisory Board* for a term of four

years. The *Finish National Advisory Board* consists of a chair, vice-chair and 18 members. The board members are nominated by the Finnish Government. The *Finish National Advisory Board* consists of representatives of providers and users of social- and health care, health care and social care professionals, researchers in the field of social- and health care and ethics, lawyers, and members of the Finnish Parliament. The political parties of Finnish Parliament suggest candidates for the parliamentary representation (four members and four deputies). The *Finish National Advisory Board* is a multi-professional and multi-disciplinary board. There are university professors in health care, social care and ethics, doctors and nurses, social workers, members representing people with mental retardation and other types of disabled people, mental health, elderly care, communities and primary and specialist health care.

The *Comité Consultatif National d'Ethique* was established in 1983 by Article L1412-1 of the French Public Health Code or PHC. The *Comité Consultatif National d'Ethique* is composed of 39 members in addition to its President. Five members are selected by the President of the Republic from the main philosophical and spiritual families; 19 members are selected for their expertise and interest in bioethics;¹⁰ 15 members are selected from the research sector.¹¹ All members and the president are appointed by the President for a period of four years.

The *German Ethics Council* was established on the basis of the Act on the Establishment of the *German Ethics Council*. The *German Ethics Council* is composed of twenty-six members specialising in scientific, medical, theological, philosophical, ethical, social, economic and legal concerns. Members are appointed by the President of the German Bundestag – half on the proposal of the “German Bundestag” and half on the proposal of the Federal Government.

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

The *Slovenian National Ethics Committee* is based on a Ministerial Decree of 1995. The members are appointed by the Ministry of Health from those proposed by the Medical Faculties, the Republic of Slovenia Medical Council and Medical Chamber. The *Slovenian National Ethics Committee* has 15 members, the majority being medical science experts,

¹⁰ One member (*député*) and one senator (*sénateur*) chosen by the presidents of their respective assemblies; a member of the Council of State (*Conseil d'Etat*) chosen by the vice-president of the council; a counselor at the Court of Cassation (*Cour de Cassation*) chosen by the President of the court; a person chosen by the Prime Minister; a person chosen by the Minister for Justice; two persons chosen by the Minister for Research; a person chosen by the Minister for Industry; a person chosen by the Minister for Social Affairs; a person chosen by the Minister for Education; a person chosen by the Minister for Labor; four persons chosen by the Minister for Health; a person chosen by the Minister for Communications; a person chosen by the Minister for the Family; a person chosen by the Minister for Women's Rights.

¹¹ A member of the Academy of Sciences (*Académie des Sciences*), chosen by its President; a member of the National Academy of Medicine (*Académie Nationale de Médecine*), chosen by its President; a representative of the *Collège de France*, chosen by its administrator; a representative of the *Institut Pasteur*, chosen by its director; four persons, including two researchers, from public research bodies, and two persons from public teaching hospital chosen by the executive directors of these bodies; two persons from public teaching hospitals chosen by the University Presidents' Conference (*la Conférence des Présidents d'Université*); a researcher of the National Institute for Agricultural Research (*l'Institut national de la recherche agronomique*), chosen by the President of the Institute.

representing major disciplines. The current membership also includes a psychologist, an expert in law, a philosopher, a moral theologian, and a layperson.

The *Spanish Bioethics Committee* was created by Law 14/2007 of July 3rd on Biomedical Research (BOE July 4th). The Committee was established on October 22nd 2008 and forms part of the Ministry of Health, Social Services and Equality. The appointment of members of the Committee is set by law: Half of the members are elected by the Autonomous Communities, through the Inter-Territorial Council of Health, and the rest by various Ministries. It is a multidisciplinary Committee, composed of people from different disciplines, primarily doctors, nurses, researchers in the field of biosciences, academics, university professors of these branches, lawyers, bioethicists and economists.

The *Nuffield Council* was established by the Trustees of the Nuffield Foundation in 1991 and has been funded jointly by the Foundation, the Wellcome Trust and the Medical Research Council since 1994 and therefore presents an exception among the other NECs as regards the legal basis. The Chair of the Council is appointed by the Nuffield Foundation, after consultation with the Council's other funders. When vacancies arise, the Council advertises for new members in the national press, through its widely distributed newsletter and on his website. In regard to other typical criteria for NECs, it however follows the usual line: It is an independent body that examines and reports on ethical issues in biology and medicine. The Council aims to maintain a wide range of expertise across the fields of science, medicine, social science, philosophy and law.

The *Presidential Commission for the Study of Bioethical Issues* is appointed by the President of the US. The Commission does not continue past a presidential election and the presidents have to choose to keep such a Commission. Therefore, when president Obama finishes his term in 2017, this particular Commission will also end. The “[...] members are selected by the Executive Office of the President and serve for the term of the Presidential Commission for the Study of Bioethical Issues.¹²” Current members include nine professors, two from the public administration, one from a private foundation and one colonel from the U.S. Army medical corps.¹³

The 36 members of the *International Bioethics Committee* of UNESCO are appointed by the Director-General to serve in their personal capacity for a four-year term. The following factors are considered during selection: cultural diversity, balanced geographical representation, and nominations from states regarding qualified specialists in life sciences and in the social and human sciences (including law, human rights, philosophy, education and communication).

NECs are usually supported by a permanent secretariat. If need be, they may also call for external advice in regard to specific topics. The *Danish Council of Ethics* reports that the Council has a permanent secretariat, which handles the daily operation regarding the Council's areas of business. The secretariat consists of scholars from different areas to ensure interdisciplinary and a broad area of expertise. The *Presidential Commission for the Study of Bioethical Issues* also reports on the existence of a staff of around 20 persons.

¹² <http://bioethics.gov/node/242>

¹³ <http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf>

5 Procedures for Ethics Guidance in National Ethics Committees

This section focuses on procedures for ethics guidance and is divided into procedures prior to guidance, during guidance, and after guidance.

The initial phase of a debate by NECs is characterised by the selection of the relevant topics. The discussion of a particular topic can either be requested by the authorities under which NECs are operating or NECs select a topic which they deem important by themselves. The *Danish Council of Ethics* for instance selects projects of societal and social concern, or focuses on issues in need of informed public debate. It follows the general developments in bioethics related areas and can address these on their own initiative. The *Danish Council of Ethics* might also be asked to take up issues of concern to the medical sector. The *Finish National Advisory Board* selects topics at the request of Ministries and other bodies, such as health care and social care professionals, regional bodies of health care ethics and other national Ethics Commissions (Advisory Board on Biotechnology (BTNK), Advisory Board on Research Ethics (TENK), National committee on medical research ethics (TUKIJA), Board for gene technology (GTLK), Council of Finnish Academies (TANK), and Committee for Public Information in Finland (TJNK), but also at its own initiative. The *German Ethics Council* up to now only worked on the request of the Government; in principle it can however also choose topics on its own initiative. Members of the *Nuffield Council* meet on a quarterly basis during which the Council reviews recent biomedical and biological advances that raise ethical questions and selects topics for further exploration. The *Presidential Commission for the Study of Bioethical Issues* takes on topics depending on the needs from the President and the administration. The Commission also has the capacity to create its own topics based on their expertise and knowledge. From a review of the current Commission's eight published reports, four were requested by the government administration (including three from the President), while four have been taken up by the *Presidential Commission for the Study of Bioethical Issues* themselves. The *International Bioethics Committee* reports to contribute to the dissemination of the principles set out in the UNESCO Declaration on Bioethics and Human Rights¹⁴ in the field of bioethics, and the further examination of issues raised by their applications and by the evolution of the technologies in question. The Committee was for instance invited to discuss the theoretical implication on the field of neurosciences, because of interest in non-discrimination and non-stigmatisation (Article 11, Universal Declaration on Bioethics and Human Rights).

The phase during guidance is characterised by the organisation of the discussion among the members of the NECs. Most NECs establish working groups, which interact with the plenary on a permanent basis. If need be, external experts are consulted during the discussion phase in the working groups or the plenary.

Once the *Danish Council of Ethics* for instance has identified a work topic, a working party is established to examine the issue. The working party designates a chairman, often the member with the most knowledge in the specific area of investigation. The party is assisted by a project manager from the *Danish Council of Ethics'* secretariat. The chairman and the project manager, in collaboration, decide what experts to consult. For the most part, the working party

¹⁴ http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

consists entirely of the *Danish Council of Ethics* members, but sometimes also external advisors. A diverse and thorough insight on the issue is sought. Experts contribute e.g. by reviewing working papers and by giving presentations at work meetings. There are no rules on consensus, but the *Danish Council of Ethics* recognises that recommendations may carry most weight when the members have general agreement. However, they appreciate diversity and the individual opinion of the members.

The *Finish National Advisory Board* usually works based on discussions at plenary meetings, at times prepared by working groups. The *Finish National Advisory Board* also interacts with experts of the Ministry of Social Affairs and Health, Parliament, and other Ministries and Government Agencies. Meetings and other events for facilitating cooperation are also held with other national Ethics Advisory Boards and regional actors, and the *Finish National Advisory Board* further engages with scientific and education institutions, non-governmental organisations (NGOs), the media and private citizens.

The *Spanish Bioethics Committee* can agree to setting-up working groups for the study or preparation of matters. Working groups can be formed by members of the Committee as well as by external experts. These groups are coordinated by a member of the Committee. The procedures for discussion of a particular topic are usually as follows: Presentation of the document by the rapporteur or chairman of the group; opening a period of fifteen days to submit written amendments by members of Parliament; discussion and decision on the proposed amendments; deliberation by the full Committee.

The *Nuffield Council* invites their funders to propose topics considered to be interesting to look at; however, the final decision remains with the Council. The Council also has a wider network of contacts, so called “affiliates” – these are people who have been involved with the Council as previous members of working parties or as Council members. The Council invites them to identify any possible future issues. Once the Council has identified a major ethical issue, it organises a workshop in order to examine the issue further. If appropriate, a Working Party is established to report on the issue. Some members of the Working Party will specialise in developing the description of the state of the art, while other members will start to develop the philosophical underpinning of an ethical approach. After a discussion within the Working Party, results will be referred to the Council and Council members for comments. It is a kind of iteration of a creative process in which once a problem has been examined and the issues at stake have been identified, they then interrogate it to evaluate the values and principles that people bring to bear in looking at this kind of problem. They then construct a prism through which they think it would be helpful to look at the issues in a way that can attract support from most people. The Council also carries out consultation with stakeholders and the public but this is difficult to achieve in practice.

Strategies of NECs after the publication of an opinion relate on the one hand to informing the responsible authorities about their views and discussing their recommendations with them; and on the other hand in disseminating the opinion to the public.

The *Danish Council of Ethics* does not document to what degree its recommendations and assessments influence research and innovation practice. However, the *Danish Council of Ethics* annually reports to a Parliamentary Committee designated to them as well as to the Committee on Health. The *Danish Council of Ethics* reports that it is highly possible that that

the various activities of the *Danish Council of Ethics* have an effect on the political decision making as well as deliberation among various groups in society including scientists.

The *Nuffield Council* reports to keeping a record of whether and to what extent their recommendations have been taken up. For example, using their report on the forensic use of bio-information, the European Court of Justice made specific references to the report and recommendations when it required the UK to change its legislation on the retention of DNA samples for criminal justice purposes. In this instance, the Council was specifically and directly influential in bringing about a change to UK law.

The *Presidential Commission for the Study of Bioethical Issues* reports are submitted to the President, but can be used by anyone. Results of the Commission's work are not subject to copyright. People can freely use the material and adapt it as they see fit. The *German Ethics Council* reports that opinions are submitted to the authorities who not in any way obliged to provide information on the follow-up.

The *Finish National Advisory Board* and the *Spanish Bioethics Committee* report that all opinions / reports issued by the Committee are published on the webpage. Products of the *Danish Council of Ethics* include curriculum material for primary- and high-school students, interactive platforms, public debates and participation in public hearings. The products are publically available. Following the publication of one of their reports, the *Nuffield Council* has an active programme of engagement with the people to whom they make recommendations and a wider audience.

The *International Bioethics Committee* of UNESCO reports that their advice and recommendations on specific issues are broadly disseminated by the Director General to member states, the Executive Board and the General Conference, as well as the larger world community. In line with its mission, this helps to promote reflection on the ethical and legal issues raised by research in the life sciences and their applications, to encourage the exchange of ideas and information, to heighten awareness and to contribute to the dissemination of the principles set out in the UNESCO Declarations in the field of bioethics.

In order to contribute to the international ethics debate, most NECs translate their opinions into English. The *German Ethics Council* also translates all its reports into French.

6 Principles and Issues for Ethics Guidance in National Ethics Committees

NECs report that they do not stick to fixed ethics principles and ethical issues in their deliberations and their reports. All analysed NECs report that the ethics framework differs according to the topic. A difference of ethics principles can also be witnessed according to differences as regards the mandate of NECs. It has to be noted that NECs do not use a tick-box approach in their deliberations, but usually refer to general principles, which are weighed against each other.

The *German Ethics Council* reports that there is no specific framework used for the assessments, nor a list of values or criteria. Neither did the Council try to develop a fixed framework. The members who have background in ethics provide their knowledge of ethics to

the Council. Moreover, all other members (judges, physicians etc.) bring their own knowledge and experience to the table.

The *Spanish Bioethics Committee* also reports not to have standard procedures for ethics guidance (tick-box system for ethics assessment), because its aims are more general. The most important values the Commission usually relates to in their opinions are dignity of the individual vs. collective interests. In addition, deliberations revolve around the necessity of balancing values such as autonomy vs. justice, particularly social justice.

The *Nuffield Council* reports on using ethics principles such as privacy, consent, solidarity, altruism and autonomy in their work.

The *Danish Council of Ethics* does not commit to any statement of ethical values or principles. The ethical assessments solely reflect the values, principles and opinions of the individual members. Ethics principles which are often alluded to in the reports are environmental impacts, human dignity, social impacts, autonomy, freedom and implications for privacy.

The *Finish National Advisory Board* has a set of general principles provided for in the legal base, which relate to the right to good health care, autonomy, and the right to information. In practice other classical ethics principles are included into their reports, such as human dignity, autonomy and freedom, justice and fairness, implications for health and safety, implications for quality of life, social impact, and implications for privacy.

The *Health Council of the Netherlands* reports that each topic has its own assessment criteria. Every time an innovation is assessed, also the assessment criteria are assessed whether still relevant or not.

The *Presidential Commission for the Study of Bioethical Issues* also reports not to use a single framework or a principle list approach when they perform ethical assessments on technology and emerging technologies.

The *International Bioethics Committee* of UNESCO reports to include the principle of social responsibility for health in its ethics framework. Social responsibility in this context is a “constitutional essential” for global bioethics to be included in all sectors of the society.

NECs report to alluding to the following ethics principles and ethical issues in their reports depending on the mandate and topic:

General ethics principles	<ul style="list-style-type: none"> • Justice / fairness • Human dignity (including individual vs. collective interests) • Equality / non-discrimination • Autonomy / freedom • Privacy • Solidarity / altruism • Right to information
General ethical	<ul style="list-style-type: none"> • Implications for health and/or safety (right to health care)

issues	<ul style="list-style-type: none"> • Human subjects research (including consent) • Implications for quality of life • Social impacts • Implications for civil rights • Implications for privacy • Social responsibility
Issues in relation to the “making of science”	<ul style="list-style-type: none"> • Scientific integrity • Professional integrity • Accessibility of research results • Scientific validity
Additional issues if provided for by the mandate	<ul style="list-style-type: none"> • Treatment of animals in R&I • Environmental impacts

Table 1: Principles and issues in ethics guidance.

7 Problems and Developments

All NECs report that the direct impact of their work on government policy is difficult to measure and implementation of recommendations often takes a while. A direct line between an opinion of a NEC and implementation of a policy can rarely be drawn. This is however not seen as a major problem, but rather as part of the methodology of NECs’ working procedures and intrinsic to political decision making. The NECs see reaching out to the public as one of their major tasks which could be improved from the side of the Committees, but also from the side of the public which needs to understand its important role in ethics deliberations.

The Ethics Committee of a regional organisation stresses that decisions by politicians are guided by many different and conflicting issues and not only ethics. It is not the Commission’s job to make political decisions – it is their job to lay out the kinds of considerations that should be taken when thinking about making a decision. In other words, they identify what is needed rather than being blunt and saying “don’t do this”. Political requirements may modify the politicians’ decisions and needs and “should” do so.¹⁵

The *International Bioethics Committee* of UNECSO reports that since it is a global forum for bioethics, providing a normative, non-judicial approach, the concrete impact of its efforts depends on the context, as there are recommendations which cannot be directly implemented.

The *Presidential Commission for the Study of Bioethical Issues* reports that evidence of the use of their material is mostly anecdotal. They will hear about people using the materials at, for example, conferences. The Commission monitors if their reports or advices are followed, but sometimes it takes a while before it is taken up or implemented. Some of the earlier Commissions have had large impacts, e.g. the first Commission that established ethical principles to ensure human subject protection. Their work also included the Belmont report

¹⁵ Interview, 5.12.2014

and that is, according to the interviewee, the most commonly cited piece of ethical literature ever. The next commission was extremely effective in getting a uniformed definition of death across the US. The interviewee considers this a big step.

The *Danish Council of Ethics* draws attention to its purpose and sphere of activity, which is to generate public debate and awareness of ethical issues. The *Spanish Bioethics Committee* draws the attention to the fact that it is a consultative body for the national and regional government. One of the objectives of the Committee is to reach the public, even if it is not one of its functions. Monitoring of compliance with the recommendations is therefore not a priority. The *Finish National Advisory Board* also reports that its recommendations are non-binding, they are not always followed neither does the *Finish National Advisory Board* monitor compliance with its recommendations.

The *Nuffield Council* reports that one potential problem concerns the fact that expectations may be too high. The Council looks at issues that are intrinsically problematic. While the Council cannot offer definitive solutions to problems, it can help people to think through the problems and to pursue continuous reflection. Solutions are contingent and subject to evolution as technologies and social environments change. This approach needs to be communicated to politicians who like things to be clear-cut, or policymakers who want to set a policy in place and then leave it alone for five years or the public who would like to have reassurance. Enabling people to engage in ethics and discussion of issues is important. There is a need to facilitate a much wider mechanism for public discussion to discover people's concerns and values. The language and discourse around ethics is a different one to the discourse around science. People make ethical decisions on a daily basis and largely do it well. It is part of the Council's job to take the process of ethical decision-making that people do in their daily lives and see how that relates to decision-making within policy environments. The next step is to make the connection so that people can be exposed to the kind of thinking that goes on and can realise that they can be involved in this on a wider basis.

The *Danish Council of Ethics* also reports that the Council could benefit from more consultation of citizens, experts and other groups, where relevant. The *Finish National Advisory Board* reports on their difficulty in consulting the public due to a shortage of staff. The *Spanish Bioethics Committee* reports that there is little direct participation of the public in deliberations. Interaction with other ethical assessment organisations could also be improved.

Future challenges therefore relate to improving NECs ways and possibilities to reach out to the public and convincing the public that they should actively participate in ethics deliberations on new developments in science and research, as these developments might have a direct impact on their own lives.

An additional challenge, which has however not been reported in the interviews is the fact that the debate in NECs is still very much focused on areas which have traditionally produced ethical conflicts, such as new developments in the life sciences or in the field of environment (agriculture). New developments regarding emerging technologies (e.g. challenges to human identity and integrity by neurosciences; challenges of uncertainty and complexity by nanotechnology; challenges to human autonomy and privacy by information and

communication technologies)¹⁶ are still not respected in the mandates of most NECs. A widening of NECs mandates is therefore a precondition in order to keep track with ethical challenges in science and new technologies.

8 Annex: Ethics Guidance in Specific National Ethics Committees

This Annex contains 12 reports on particular surveyed NECs. One regional organisation which was surveyed asked for anonymity. For each NEC that was surveyed, and did not ask for anonymity, basic data is provided about the organisation, its mission, structure, and role in ethics assessment and/or ethical guidance, and its procedures for assessment and guidance. The following organisations were surveyed:

- Austria: Austrian Bioethics Commission (ABC)
- Denmark: The Danish Council of Ethics (DER)
- Finland: The Finish National Advisory Board on Social Welfare and Health Care Ethics (ETENE)
- France: Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé
- Germany: German Ethics Council (GEC)
- The Netherlands: Health Council of the Netherlands (HC)
- Serbia: Serbian National Committee for Bioethics (NCB)
- Slovenia: Slovenian National Medical Ethics Committee (NMEC)
- Spain: Spanish Bioethics Committee (SBC)
- United Kingdom: Nuffield Council
- United States: The Presidential Commission for the Study on Bioethical Issues (PCSBI)
- UNESCO: International Bioethics Committee (IBC)
- Ethics Committee of a regional organisation: Organisation, anonymous

¹⁶ http://www.coe.int/t/dg3/healthbioethic/Activities/12_Emerging%20technologies/BergenStudy%20e.pdf

Name of organisation	Austrian Bioethics Commission (ABC) (Bioethikkommission beim Bundeskanzleramt Österreich)
Type of organisation	National Ethics Committee
Country	Austria
Website address	<i>General:</i> https://www.bka.gv.at/site/3455/default.aspx (http://www.bka.gv.at/site/3575/default.aspx for English) <i>Main page(s) on ethics assessment:</i> same as general address
Basic description (organisation and mission)	The task of the Bioethics Commission is to advise the Federal Chancellor from an ethical point of view on all social, scientific and legal issues arising from the scientific developments in human medicine and human biology. This includes in particular the submission of recommendations for practical use and suggestions for enacting the necessary legal provisions as well as the preparation of expert opinions on specific issues. The Commission exercises its advisory function independently. The 25 members of ABC are appointed by the Federal Chancellor for a period of three years and represent medical disciplines and other fields. The Commission was established by an order issued by Federal Chancellor Schüssel on 29 June 2001 (Order of the Federal Chancellor Regarding the Establishment of a Bioethics Commission, Federal Law Gazette II No. 226/2001, http://www.bka.gv.at/DocView.axd?CobId=52858)
Interest in research and innovation	The task of the Commission is to advise on ethical aspects of scientific developments.
Ethics assessment and/or guidance	Assessment [] Guidance [x] Other [] None [] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [] Other []
Terminology for ethics assessment / guidance	Ethics.
Name and description of ethics unit(s)	Same as the organisation itself.
Aims and motivation for ethics assessment	The tasks of the Commission are as follows: 1. Providing information and promoting discussion within society on key findings in the fields of human medicine and biology and the related ethical issues; 2. Submitting recommendations for practical use; 3. Submitting suggestions concerning necessary legal measures; 4. Preparing expert reports on particular issues.

	Ethical guidance is mandated by the order of Chancellor.
Objects and scope of assessment	ABC provides recommendations, opinions, and reports on ethical issues regarding ethical issues of developments in human medicine and human biology and related legal aspects.
Beneficiaries of assessment	Beneficiaries are Federal Chancellor, the government and other policy-makers, professional and general public.
Ethics assessment unit: appointment process	The composition of the Commission is established in the Order of the Chancellor. The members of ABC are appointed by the Federal Chancellor for a period of three years. The Commission consists of 25 members representing the fields of medicine (especially reproduction medicine, gynaecology, psychiatry, oncology, and pathology), molecular biology and genetics, law, sociology, philosophy and theology. The length of the term is three years and membership renewals are possible. A chairperson and two vice chairpersons are appointed by the Federal Chancellor. Membership of the Commission is an honorary unpaid position.
Procedure for ethics assessment: before	The provisional agenda of ABC meetings includes 1. any item which the Commission decided at earlier meetings to put on the agenda; 2. any item proposed by the Chairperson.
Procedure for ethics assessment: during	The final agenda is set by the Commission at the start of the meeting. A written record must be kept of the outcome of the Commission's deliberations. This record must also lay down views which dissent from the majority opinion. The presence of at least one third of the members is necessary for the Commission to have a quorum. The Commission must strive to achieve the greatest possible degree of consensus when adopting resolutions. Resolutions are adopted by a majority of the votes cast.
Procedure for ethics assessment: after	ABC's recommendations, opinions and reports are published.
Principles and issues in assessment / guidance	<input type="checkbox"/> scientific integrity <input checked="" type="checkbox"/> justice / fairness <input type="checkbox"/> professional integrity <input checked="" type="checkbox"/> implications for health and/or safety <input checked="" type="checkbox"/> human subjects research <input checked="" type="checkbox"/> implications for quality of life <input type="checkbox"/> treatment of animals in R&I <input type="checkbox"/> environmental impacts <input checked="" type="checkbox"/> human dignity <input type="checkbox"/> social impacts <input checked="" type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing <input checked="" type="checkbox"/> autonomy / freedom countries with lower ethics standards <input type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses) <input checked="" type="checkbox"/> implications for privacy <input type="checkbox"/> other, specify:

	<input checked="" type="checkbox"/> social responsibility
Self-assessments, strengths and weaknesses	N/A
Other	N/A

Name of organisation	Det Etiske Råd (DER) (The Danish Council of Ethics)
Type of organisation	National Ethics Committee
Country	Denmark
Website address	<i>General:</i> http://www.etiskraad.dk/da-DK.aspx?sc_lang=en <i>Main page(s) on ethics assessment:</i> Same as general address
Basic description (organisation and mission)	DER was established in 1988 by an act of parliament. It is an independent under the Ministry of Interior and Health. According to the act DER has to work together with e.g. the Council for Animal Ethics. Furthermore is a secretariat connected with DER. According to the act of Parliament, the council shall work out of respect for humankind and future generation's integrity, this includes respect for life and nature ¹⁷ .
Interest in research and innovation	<ul style="list-style-type: none"> • DER selects their projects based on societal and social concerns. The interviewee mentioned several relevant and contemporary issues within the field of R&I: • The consumption of antibiotics in both the human and the veterinary sector. • Ethical dilemmas that concern the use of genome testing at hospitals, in research and the industry. • Ethical issues regarding a growing commercialisation of the body.
Ethics assessment and/or guidance	Assessment <input checked="" type="checkbox"/> Guidance <input type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary: If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/>

¹⁷ For the Act of Parliament establishing DER (in Danish):
<https://www.retsinformation.dk/Forms/R0710.aspx?id=9909>

Terminology for ethics assessment / guidance	N/A
Name and description of ethics unit(s)	The entire organisation is an ethics unit.
Aims and motivation for ethics assessment	DER aims to provide advice to the Danish Parliament and to create public debate about developments in biotechnology, which are seen to affect human life, food, nature, and the environment, as well as ethical issues arising in health care, especially with regard to reproductive technology.
Objects and scope of assessment	DER selects projects of societal and social concern, or focuses on issues in need of informed public debate.
Beneficiaries of assessment	The receivers of the ethics assessments are in particular the Danish Parliament, and government, regional politicians and decision makers. Other beneficiaries include stakeholders, relevant industries and the public.
Ethics assessment unit: appointment process	The members of The Council are designated by the Parliament and relevant ministries, and appointed by the minister for the Interior and Health for a period of three years (The members can be reappointed once). The Law regarding The Council requires that The Council has an equal gender distribution – so just one of the sexes totals one more than the other sex. The Council also has a secretariat, which handles the daily operation regarding the Council's areas of business. The secretariat consists of scholars from different areas to ensure interdisciplinary and a broad area of expertise. The scientific disciplines include law, humanistic information studies, multimedia, science of public health and philosophy.
Procedure for ethics assessment: before	<ul style="list-style-type: none"> DER selects projects of societal and social concern, or focuses on issues in need of informed public debate. It follows the general developments in bioethics related area and can address these on their own initiative. DER might also be asked to take up issues of concern to the medical sector.
Procedure for ethics assessment: during	<p>Once DER has identified a work topic, a working party is established to examine the issue. Topics within The Council's sphere of activity are: ethical issues associated with the researching and application of biotechnologies and genetic engineering pertaining to human beings, nature, the environment and foodstuffs. The Council's sphere of activity also includes other ethical issues associated with health services and biomedical research relating to human beings.</p> <p>The working party designate a chairman, often the member with the most knowledge on the specific area of investigation. The party is assisted by a project manager from DER secretariat. The chairman and the project manager, in collaboration, decide what experts, broadly speaking, to consult. For the most part, the working party consists entirely of members from The Council, but sometimes also external advisors. A diverse and thorough insight on the issue is sought. Experts contribute e.g. by reviewing workings papers and by giving presentations at work meetings.</p>

	<p>There are no rules on consensus. DER recognises that recommendations may carry most weight when the members have general agreement. However, they appreciate diversity and the individual opinion of the members.</p>
<p>Procedure for ethics assessment: after</p>	<p>The products of DER include curriculum material for primary- and high-school students, interactive platforms, public debates and participation in public hearings. The products are publically available.</p>
<p>Principles and issues in assessment / guidance</p>	<p> <input type="checkbox"/> scientific integrity <input type="checkbox"/> justice / fairness <input type="checkbox"/> professional integrity <input type="checkbox"/> implications for health and/or safety <input type="checkbox"/> human subjects research <input type="checkbox"/> implications for quality of life <input type="checkbox"/> treatment of animals in R&I <input checked="" type="checkbox"/> environmental impacts <input checked="" type="checkbox"/> human dignity <input checked="" type="checkbox"/> social impacts <input type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing <input checked="" type="checkbox"/> autonomy / freedom <input checked="" type="checkbox"/> countries with lower ethics standards <input type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses) <input checked="" type="checkbox"/> implications for privacy <input checked="" type="checkbox"/> other, specify: Bodily integrity <input type="checkbox"/> social responsibility </p> <p> Commentary: The Council does not commit to any statement of ethical values or principles. The ethical assessments solely reflect the values, principles and opinions of the individual members. The above list was stated by the interviewee. </p>
<p>Self-assessments, strengths and weaknesses</p>	<p>DER does not document to what degree its recommendations and assessments influence research and innovation practice. However, DER annually reports to a parliamentary committee designated to them as well as to the committee on Health. It is highly possible that that the various activities of DER have an effect on the political decision making as well as deliberation among various groups in society including scientists.</p> <p>DER annually performs self-evaluations of their work and discuss, but there are no methods or procedures for assessing the impact of the recommendations and assessments made by The Council. The interviewee draws attention to the <i>purpose and sphere of activity</i>, in The Act on The Danish Council of Ethics, which underlines that the object of The Council is to generate public debate and awareness of ethical issues.</p> <p>The interviewee stresses that DER has no direct influence or mandate for decision making. In addition it is important to keep the official purpose of The Council in mind. As it is stated in the establishing act the purpose is "(...) to conduct</p>

	<p>information and debate-generating activities concerning the ethical problems and challenges faced by society.¹⁸</p> <p>In the opinion of the interviewee, the work of The Council could benefit from more consultation of citizens, experts and other groups, where relevant.</p>
Other	<p>The interviewee noted that Research Ethics Committees have a more direct influence on research and innovation, due to their particular focus on health research projects.</p>

Name of organisation	The National Advisory Board on Social Welfare and Health Care Ethics (ETENE) (Valtakunnallinen sosiaali- ja terveystieteiden neuvottelukunta)
Type of organisation	National ethics committee
Country	Finland
Website address	<i>General:</i> http://www.etene.fi/en <i>Main page(s) on ethics assessment:</i> http://www.etene.fi/en
Basic description (organisation and mission)	<p>ETENE is an advisory board on social welfare and health care ethics. It evaluates issues in health care and social care from the ethical point of view on principal level. ETENE serves thus as governmental ethical assessor of social welfare and health care in that it gives recommendations on ethical issues. The purpose of ETENE is to discuss general principles in ethical issues as well as to publish recommendations on them.</p> <p>ETENE operates under the Ministry of Social Affairs and Health. It was set up in 1998. Initially its brief concerned ethical issues in health care, but in 2009 this was broadened to include social welfare.</p>
Interest in research and innovation	<p>ETENE submits initiatives, publishes statements and provides expert assistance, prompts public debate, and disseminates information on national and international ethical issues in the field of social welfare and health care. ETENE monitors and publicises international trends in ethics and participates in international events as necessary. There is bilateral cooperation primarily with the Nordic and Baltic countries.</p>
Ethics assessment and/or guidance	Assessment <input type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary: If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input checked="" type="checkbox"/> Other <input type="checkbox"/>

¹⁸ <https://www.retsinformation.dk/Forms/R0710.aspx?id=9909> (Translated from Danish)

	Commentary: ETENE does not assess research protocols.
Terminology for ethics assessment / guidance	The organisation is aware of the concept "ethics guidance" and considers itself as an advisor/expert in the field of social welfare and health care ethics.
Name and description of ethics unit(s)	ETENE is a multi-professional and multi-disciplinary board. There are university professors in health care, social care and ethics, doctors and nurses, social workers, members representing people with mental retardation and other types of disabled people, mental health, elderly care, communities and primary and specialist health care. Politicians represent different parties and different professional fields as their backgrounds. Sometimes there can also be consultation of stakeholders, depending on the issue.
Aims and motivation for ethics assessment	The Advisory Board was set up pursuant to the Act on the Status and Rights of Social Welfare Clients and the Act on the Status and Rights of Patients. The duties and membership of the Advisory Board were defined by Government Decree 667/2009. The Government appoints the members of the Advisory Board for a term of four years.
Objects and scope of assessment	Mainly policies are assessed. ETENE does not evaluate research protocols, does not solve conflicts, or take individual cases into its consideration. Advisory board is a public body, so it cannot handle confidential issues. ETENE can make recommendations, guidelines, opinions and reports, but it cannot give binding rules.
Beneficiaries of assessment	ETENE publications discuss general principles in ethical issues in the field of social welfare and health care and concerning the status of patients and clients. Recommendations issued are intended for ordinary citizens, for social welfare and health care professionals, and for political elected officials and decision-makers. The purpose of the guidelines is to guide social welfare and health care professionals to ethically sustainable practices. ETENE tries to evoke societal discussion on all levels.
Ethics assessment unit: appointment process	According to a Decree of National Advisory Board on Social Welfare and Health Care Ethics (667/2009) the Advisory Board has a chair, vice-chair and 18 members. The board members are nominated by Finnish Government. Preparatory work is done in the Ministry of Social Affairs and Health that suggests the nominees. All the members have a personal deputy. The Advisory Board shall have representatives of providers and users of social and health care, health care and social care professionals, researchers in the field of social and health care and ethics, lawyers, and members of the Finnish Parliament. The political parties of Finnish Parliament suggest candidates for the parliamentary representation (four members and four deputies).
Procedure for ethics assessment: before	ETENE does not assess individual cases or research plans. It gives recommendations and guidelines. ETENE has issued statements at the request of ministries and other bodies, and also at its own initiative. All

	fields are used as background information of ETENE's working papers, publications, opinions and guidelines. ETENE interacts with health care and social care professionals, regional bodies of health care ethics and other national ethics commissions (Advisory Board on Biotechnology (BTNK), Advisory Board on Research Ethics (TENK), National committee on medical research ethics (TUKIJA), Board for gene technology (GTLK), Council of Finnish Academies (TANK), and Committee for Public Information in Finland (TJNK).																				
Procedure for ethics assessment: during	The statements are based on discussions at ETENE meetings. Some of them are prepared by working groups specifically appointed for the task. ETENE works with the Ministry of Social Affairs and Health, Parliament, and other ministries and government agencies. Meetings and other events for facilitating cooperation are also held with other national ethics advisory boards and regional actors, and ETENE further engages with scientific and education institutions, NGOs, the media and private citizens.																				
Procedure for ethics assessment: after	ETENE publishes recommendations as reports. A standard methodology is to write reports together with different experts on the field of social welfare, health care and technology. The reports are recommendations and guidelines by nature. To date, ETENE has published recommendations on the shared value base in health care, on terminal care, and on the ethics of care for the elderly, mental health and technology. Other publications discuss current ethical topics, for instance following their discussion at ETENE seminars. The latter are online publications. Some of the materials are available in Swedish and English. Printed ETENE publications may be ordered free of charge.																				
Principles and issues in assessment / guidance	<table border="0"> <tr> <td><input type="checkbox"/> scientific integrity</td> <td><input checked="" type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input type="checkbox"/> professional integrity</td> <td><input checked="" type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input type="checkbox"/> human subjects research</td> <td><input checked="" type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input checked="" type="checkbox"/> human dignity</td> <td><input checked="" type="checkbox"/> social impacts</td> </tr> <tr> <td><input type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input checked="" type="checkbox"/> autonomy / freedom</td> <td></td> </tr> <tr> <td><input type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input checked="" type="checkbox"/> implications for privacy</td> <td><input type="checkbox"/> other, specify:</td> </tr> <tr> <td><input type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary: The advisory board was established and nominated in 1998 by amending the Act on the status and rights of patients (785/1992,</p>	<input type="checkbox"/> scientific integrity	<input checked="" type="checkbox"/> justice / fairness	<input type="checkbox"/> professional integrity	<input checked="" type="checkbox"/> implications for health and/or safety	<input type="checkbox"/> human subjects research	<input checked="" type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input type="checkbox"/> environmental impacts	<input checked="" type="checkbox"/> human dignity	<input checked="" type="checkbox"/> social impacts	<input type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input checked="" type="checkbox"/> autonomy / freedom		<input type="checkbox"/> implications for civil rights	<input type="checkbox"/> dual use (possible military uses)	<input checked="" type="checkbox"/> implications for privacy	<input type="checkbox"/> other, specify:	<input type="checkbox"/> social responsibility	
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<input type="checkbox"/> social responsibility																					

	amendments 333/1998 and 658/2009) (translated in English) and amending the Act on the status and rights of social care customer (657/2009) (only in Finnish). Therefore the ethical principles set in this Act is the basis of the work of ETENE (right to good health care, autonomy, right to information). Other classical ethical principles are included into the principles that ETENE has published.
Self-assessments, strengths and weaknesses	The expertise of the advisory board (including deputies) is a good resource, but wide consultation processes (as for example in Nuffield Council of Bioethics or Danish Council of Ethics) are practically impossible with only 1,5 person's staff. As the recommendations of ETENE are non-binding, they are not always followed. ETENE does not have resources for monitoring of compliance with its recommendations, and does not have sufficient ways to monitor. The Ministry of Social affairs and Health may even give instructions that are against the opinion of ETENE.
Other	

Name of organisation	The National Consultative Ethics Committee for health and life sciences(CCNE) Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé.
Type of organisation	National ethics committee
Country	France
Website address	<i>General:</i> http://www.ccne-ethique.fr/ <i>Main page(s) on ethics assessment:</i> same as general address
Basic description (organisation and mission)	<p>The CCNE is a strictly consultative body. Its mission is to deliver opinions on ethical and social issues raised by the progress of knowledge in the fields of biology, medicine and health (Article L1412-1 of the French Public Health Code or PHC). The CCNE can publish recommendations on matters within his competence (Article L1412-3 of the PHC). The CCNE is required to organise public debates at least every five years and prior to any reform bill on ethical or social issues raised by progress in knowledge in biology, medicine and health (Article L1412-1-1 of the PHC). The CCNE is also responsible for documentation and information of the public on questions raised by the life sciences and health (Article R1412-13 of the PHC).</p> <p>Provisions about this committee can be found in Articles L1412-1 to 6 and Articles R1412-1 to 14 of the PHC. This committee was instituted by the presidential decrees n°83-132 February 23th 1983 on the creation of a National Consultative Ethics Committee for health and life sciences (<i>Décret n°83-132 du 23 février 1983 portant création d'un Comité consultatif national d'éthique pour les sciences de la vie et de la santé</i>).</p>
Interest in research	The CCNE addresses ethical issues and social issues raised by the progress of

and innovation	knowledge in the fields of biology, medicine and health (Article L1412-1 of the French Public Health Code or PHC).
Ethics assessment and/or guidance	Assessment [x] Guidance [x] Other [] None [] Commentary: If assessment/guidance is undertaken: In-house [x] Outsourced [] Other [] Commentary: The CCNE issues opinions that can be used as guidelines. The CCNE can request the participation of external experts when needed.
Terminology for ethics assessment / guidance	The law and the official web site of the CCNE use words “opinion” (“ <i>avis</i> ”) and “recommendations” (“ <i>recommandations</i> ”). Moreover, the official web site of the CCNE uses the expression “ethical reflection” (“ <i>réflexion éthique</i> ”). According to the official web site of the CCNE: <p style="padding-left: 40px;">Enlighten the progress of science, raise new social challenges and pose an ethical perspective on these developments ... This is the mission of the [CCNE], which is at the heart of the social debate. The CCNE constantly stimulates reflection on bioethics by contributing to fuel debates within society without ever confiscate [this reflexion]</p> <p style="padding-left: 40px;">Éclairer les progrès de la science, soulever des enjeux de société nouveaux et poser un regard éthique sur ces évolutions... Telle est la mission du Comité d'éthique qui s'inscrit au cœur des débats de société. Le CCNE stimule sans cesse la réflexion sur la bioéthique en contribuant à alimenter des débats contradictoires au sein de la société sans jamais la confisquer.</p>
Name and description of ethics unit(s)	The whole CCNE is involved in ethics assessment. The CCNE is an independent authority funded by the State (Article L1412-4 of the PHC).
Aims and motivation for ethics assessment	The CCNE's duties are stated by the legislation. Ethics assessment is the core CCNE's mission.
Objects and scope of assessment	The CCNE addresses ethical issues and social issues raised by the progress of knowledge in the fields of biology, medicine and health (Article L1412-1 of the French Public Health Code or PHC).
Beneficiaries of assessment	The CCNE's opinions are publically available, thus benefiting the whole society: healthcare professionals, researchers, the Government, media (a press conference is organised each time an opinion is issued), the general public, etc. ...
Ethics assessment unit: appointment process	According to the official web site of the CCNE: “The law ensures to the CCNE a multidisciplinary approach and pluralism that allows to cross the looks and the opinions on each issue.” According to Article L.1412-2 of the PHC, the CCNE is composed of 39 members in addition to its President: 1° Five persons selected by the President of the Republic from the main philosophical and spiritual families; 2° Nineteen members selected for their expertise and interest in ethical issues, including: <ul style="list-style-type: none"> • One member (<i>député</i>) and one senator (<i>sénateur</i>) chosen by the

	<p>presidents of their respective assemblies</p> <ul style="list-style-type: none"> • A member of the Council of State (<i>Conseil d'Etat</i>) chosen by the vice-president of the council • A counsellor at the Court of Cassation (<i>Cour de Cassation</i>) chosen by the President of the court • A person chosen by the Prime Minister • A person chosen by the Minister for Justice • Two persons chosen by the Minister for Research • A person chosen by the Minister for Industry • A person chosen by the Minister for Social Affairs • A person chosen by the Minister for Education • A person chosen by the Minister for Labour • Four persons chosen by the Minister for Health • A person chosen by the Minister for Communications • A person chosen by the Minister for the Family • A person chosen by the Minister for Women's Rights <p>3° Fifteen personalities from the research sector:</p> <ul style="list-style-type: none"> • A member of the Academy of Sciences (<i>Académie des Sciences</i>), chosen by its President; • A member of the National Academy of Medicine (<i>Académie Nationale de Médecine</i>), chosen by its President; • A representative of the <i>Collège de France</i>, chosen by its administrator; • A representative of the <i>Institut Pasteur</i>, chosen by its director; • Four persons, including two researchers, from public research bodies, and two persons from public teaching hospital chosen by the executive directors of these bodies; • Two persons from public teaching hospitals chosen by the University Presidents' Conference (<i>la Conférence des Présidents d'Université</i>); • A researcher of the National Institute for Agricultural Research (<i>l'Institut national de la recherche agronomique</i>), chosen by the President of the Institute. <p>Members are appointed by the President of the Republic for a renewable two-year term.</p>
<p>Procedure for ethics assessment: before</p>	<p>The CCNE may be referred by/receive requests from:</p> <ul style="list-style-type: none"> • The President of the Republic; • The Presidents of the Parliamentary Assemblies; • Government members; • A higher education institution; • A public institution; • A foundation of public utility whose main activity is related to the research, the technological development and the promotion / protection of health. <p>Furthermore, the CCNE can self-refer/ choose to work on any question asked by any citizen or one of its own members. According to the official web site of the CCNE, this self-referral power/power of choosing questions to address allows the CCNE to be attentive to the ethical concerns of society and guarantees its independence.</p>
<p>Procedure for ethics</p>	<p>The CCNE's work is carried out by three bodies:</p>

assessment: during	<ul style="list-style-type: none"> • The Committee of the Whole is the greater CCNE's deliberative body. It holds monthly meetings to discuss opinions underway. The quorum to adopt an opinion is half of the members. • The technical section is the body in charge with the requests received by the CCNE. It is composed of 12 members who respond directly to the question if the question is limited or prepare a case file before its submission to the Committee of the Whole for an opinion. • The working groups - composed of members of CCNE - handles each question beforehand. They are able to call on experts from the outside in order to provide insight on the topic. <p>Neither the meetings of the Committee of the Whole, nor those of the technical section are public.</p>																				
Procedure for ethics assessment: after	<p>At the end of the discussion, a final report is written together with recommendations or opinions. Since its creation, the CCNE has published 122 opinions. All opinions issued by the CCNE to date can be found following this link http://www.ccne-ethique.fr/fr/type_publication/avis.</p>																				
Principles and issues in assessment / guidance	<table border="0"> <tr> <td><input type="checkbox"/> scientific integrity</td> <td><input checked="" type="checkbox"/> justice / fairness</td> </tr> <tr> <td><input type="checkbox"/> professional integrity</td> <td><input checked="" type="checkbox"/> implications for health and/or safety</td> </tr> <tr> <td><input checked="" type="checkbox"/> human subjects research</td> <td><input checked="" type="checkbox"/> implications for quality of life</td> </tr> <tr> <td><input type="checkbox"/> treatment of animals in R&I</td> <td><input type="checkbox"/> environmental impacts</td> </tr> <tr> <td><input checked="" type="checkbox"/> human dignity</td> <td><input checked="" type="checkbox"/> social impacts</td> </tr> <tr> <td><input checked="" type="checkbox"/> equality / non-discrimination</td> <td><input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards</td> </tr> <tr> <td><input checked="" type="checkbox"/> autonomy / freedom</td> <td><input checked="" type="checkbox"/> dual use (possible military uses)</td> </tr> <tr> <td><input checked="" type="checkbox"/> implications for civil rights</td> <td><input type="checkbox"/> other, specify:</td> </tr> <tr> <td><input checked="" type="checkbox"/> implications for privacy</td> <td></td> </tr> <tr> <td><input type="checkbox"/> social responsibility</td> <td></td> </tr> </table> <p>Commentary:</p>	<input type="checkbox"/> scientific integrity	<input checked="" type="checkbox"/> justice / fairness	<input type="checkbox"/> professional integrity	<input checked="" type="checkbox"/> implications for health and/or safety	<input checked="" type="checkbox"/> human subjects research	<input checked="" type="checkbox"/> implications for quality of life	<input type="checkbox"/> treatment of animals in R&I	<input type="checkbox"/> environmental impacts	<input checked="" type="checkbox"/> human dignity	<input checked="" type="checkbox"/> social impacts	<input checked="" type="checkbox"/> equality / non-discrimination	<input type="checkbox"/> outsourcing of R&I to developing countries with lower ethics standards	<input checked="" type="checkbox"/> autonomy / freedom	<input checked="" type="checkbox"/> dual use (possible military uses)	<input checked="" type="checkbox"/> implications for civil rights	<input type="checkbox"/> other, specify:	<input checked="" type="checkbox"/> implications for privacy		<input type="checkbox"/> social responsibility	
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<input checked="" type="checkbox"/> implications for civil rights	<input type="checkbox"/> other, specify:																				
<input checked="" type="checkbox"/> implications for privacy																					
<input type="checkbox"/> social responsibility																					
Self-assessments, strengths and weaknesses	<p>None to our knowledge.</p>																				
Other																					

Name of organisation	<p>German Ethics Council Deutscher Ethikrat</p>
Type of organisation	<p>National ethics committee</p>
Country	<p>Germany</p>

Website address	<p><i>General:</i> http://www.ethikrat.org/welcome</p> <p><i>Main page(s) on ethics assessment:</i> the same as the general address</p>
Basic description (organisation and mission)	<p>The German Ethics Council was established on the basis of The Act on the Establishment of the German Ethics Council (Ethics Council Act - EthRG) (Deutscher Ethikrat)¹⁹. According to section 2 of the Act it is an independent body, that pursues</p> <p style="padding-left: 40px;">The questions of ethics, society, science, medicine and law that arise and the probable consequences for the individual and society that result in connection with research and development, in particular in the field of the life sciences and their application to humanity.</p> <p>The Council interacts with other national ethics committees at the European level. Every year a meeting is organised. In addition, French, British and German councils meet once a year. Moreover cooperation with Austrian and Swiss committees has been established.</p> <p>The Council makes use of public hearings. Furthermore, in the case of some issues the council organises online platforms with questionnaire and online dialogues. The Council informs groups and organisations working on a specific topic. This method was used, for example, in the course of preparing the opinion on intersexuality.</p> <p>In some cases when very specific expertise is required external experts may be invited to participate in the work of the Council. Similarly in some cases the Council contacts civil society organisation.</p>
Interest in research and innovation	<p>The Council deals with questions that arise from research and development.</p>
Ethics assessment and/or guidance	<p>Assessment <input checked="" type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary:</p> <p>If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input checked="" type="checkbox"/> Other <input type="checkbox"/></p> <p>Commentary: The German Ethics Council may establish working groups and have reports prepared by third parties.</p>
Terminology for ethics assessment / guidance	<p>In Germany no ethics assessment of broad research programmes is performed when the decisions on the programme are made. Ethical assessment can only be done in the case of concrete themes, concrete questions. In the case of defined projects the ethical considerations do play an important role.</p>
Name and description of ethics unit(s)	<p>There is no specific unit. Working groups may be established though.</p>

¹⁹ Act on the Establishment of the German Ethics Council (Gesetz zur Einrichtung des Deutschen Ethikrats), 16.07.2007.

Aims and motivation for ethics assessment	The goal of the assessment is to advise the government and the parliament. These are the main target groups, however the assessments also reach the general public.
Objects and scope of assessment	The Council pursues the questions of ethics, society, science, medicine and law and the probable consequences for individual and society that result in connection with research and development. Particular attention is paid to the field of life sciences and their application. However the Council also looks at issues beyond this area (for example, one of the opinions was about the so called “life boxes” – Babyklappe).
Beneficiaries of assessment	The main target groups are the government and the parliament. However, the assessments also reach the general public.
Ethics assessment unit: appointment process	<p>The German Ethics Council is composed of twenty-six members specialising in scientific, medical, theological, philosophical, ethical, social, economic and legal concerns. There are also former politicians. Currently the main groups represented in the Council are lawyers. The goal is to have a trans-disciplinary body. Members are appointed by the President of the German Bundestag - half on the proposal of the German Bundestag and half on the proposal of the Federal Government.</p> <p>There is no other public involvement in the appointment of members.</p> <p>The members are appointed for a four-year term. They may be re-appointed once. Council elects a chair and vice-chair or vice-chairs from among its members by secret ballot for a four-year term. They may be re-elected once.</p>
Procedure for ethics assessment: before	The Council is looking at fundamental questions and principles. The Government and the Parliament can ask the Council for advice, it can also choose topics on its own initiative. So far, only the Government has asked the Council to give its opinion on a particular topic.
Procedure for ethics assessment: during	There is no specific framework used for the assessments. According to the rules of procedure, the Council decide by the majority of members present and there should be more than half of the members present. It issues its opinions and recommendations in writing.
Procedure for ethics assessment: after	<p>Recommendations of the Council are not legally binding. They are handed to the Parliament and then they are discussed in the plenary and in the commissions. In addition once or twice a year the Council organises “parliamentary evenings” where all parliamentarians are invited and the latest work of the Council is presented. Within those meetings parliamentarians may suggest what they would like the Council to look at.</p> <p>Moreover regular meeting with ministries are organised. These meetings provide the opportunity to discuss the current work of the Council, as well as inquire about the impact of the past opinions. The ministries are not in any way obliged to provide information on the follow-up.</p>

	<p>There is no system of monitoring the compliance with Council's advice. The impact of the opinions varies and depends on the topic. It would be difficult to observe any trends.</p>
Principles and issues in assessment / guidance	<p> <input type="checkbox"/> scientific integrity <input type="checkbox"/> justice / fairness <input type="checkbox"/> professional integrity <input type="checkbox"/> implications for health and/or safety <input type="checkbox"/> human subjects research <input type="checkbox"/> implications for quality of life <input type="checkbox"/> treatment of animals in R&I <input type="checkbox"/> environmental impacts <input type="checkbox"/> human dignity <input type="checkbox"/> social impacts <input type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing <input type="checkbox"/> autonomy / freedom <input type="checkbox"/> countries with lower ethics standards <input type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses) <input type="checkbox"/> implications for privacy <input type="checkbox"/> other, specify: <input type="checkbox"/> social responsibility </p> <p> Commentary: There is no specific framework used for the assessments, nor a list of values or criteria. The Council did not try to develop them. The members who have background in ethics provide their knowledge of ethics to the Council. Moreover all other members (judges, physicians etc.) bring their own knowledge and experience to the table. </p>
Self-assessments, strengths and weaknesses	<p>No weaknesses or challenges have been identified.</p> <p> In the field of research and innovation the most important ethical problems dealt with by the Council concern the need to react to rapid scientific progress and the consequences it has on everyday life. In some cases it is difficult to predict what impact scientific developments will bring (this is the case of, for example, the dual-use research), in other cases new developments can considerably influence everyday life of people who are not prepared to handle the consequences (for example the direct-to-consumer genetic tests). </p> <p> The opinions of the Council will not solve the problems but they help in dealing with them. </p>
Other	<p>In Germany the Council enjoys a high level of independence, which may not be the case in some other countries.</p>

Name of organisation	Health Council Gezondheidsraad
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Type of organisation	Assessor
Country	The Netherlands
Website address	http://www.gezondheidsraad.nl/en <i>Main page(s) on ethics assessment:</i> www.ceg.nl
Basic description (organisation and mission)	<p>The Health Council of the Netherlands is an independent scientific advisory body whose legal task it is to advise ministers and Parliament in the field of public health and health/healthcare research. Ministers ask the Council for advice which they can use to substantiate policy decisions. The Health Council also has an “alerting” function: it can give unsolicited advice (http://www.gezondheidsraad.nl/en/task-and-procedure/legal-task)</p> <p>The focus areas of the Health Council are:</p> <p>Optimum healthcare What is the optimum result of cure and care in view of the risks and opportunities?</p> <p>Prevention Which forms of prevention can help realise significant health benefits?</p> <p>Healthy nutrition Which foods promote good health and which carry certain health risks?</p> <p>Environmental health Which environmental influences could have a positive or negative effect on health?</p> <p>Healthy working conditions How can employees be protected against working conditions that could harm their health?</p> <p>Innovation and the knowledge infrastructure Before we can harvest knowledge in the field of healthcare, we first need to ensure that the right seeds are sown.</p>
Interest in research and innovation	The Health Council has the task of bringing subjects concerning health and the environment to the attention of the government and Parliament, and of highlighting threats and opportunities. This may be in relation to new issues but may equally concern topics that require attention once again.
Ethics assessment and/or guidance	Assessment <input checked="" type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary: If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced [...] Other <input type="checkbox"/> Commentary: the Health Council advises the government on new developments in public health.
Terminology for ethics assessment / guidance	Scientific validity: has the subject been researched before, has the new test a sensitivity that is better or comparable with the old test, including outcome indicators, has the acceptance of the new test by the research population been

	<p>addressed, has the research been properly set up; process including pilots/pretests.</p> <p>Balance of benefit and risks: What are the benefits. What are the risks of false positives and false negatives, how is this assessed, how does this compare to the former test. What is the burden of the novel test to the participants being tested and how does this compare with the former test. Are women confident they can adequately perform the test.</p> <p>Legal requirements: Are the participants properly informed about the test, the advantages and the disadvantages. Are participants requested consent. Are the health professionals involved willing and competent to inform the participants, solicit informed consent and implement the study protocol.</p> <p>Interest of public health: Does the research contribute to potential improvement in public health care.</p>
Name and description of ethics unit(s)	The Netherlands Centre for Ethics and Health (CEG) was established on 16 May 2003. The CEG is a joint venture of the Health Council of the Netherlands and the Council for Public Health and Healthcare (RVZ). See also www.ceg.nl .
Aims and motivation for ethics assessment	The Health Council's permanent activities is scanning the entire healthcare domain for ethical dilemmas that warrant consideration by the government and Parliament. This may be in relation to new issues but may equally concern topics that require attention once again.
Objects and scope of assessment	<p>The objects of assessment are determined by the broad focus areas.</p> <p>Optimum healthcare What is the optimum result of cure and care in view of the risks and opportunities?</p> <p>Prevention Which forms of prevention can help realise significant health benefits?</p> <p>Healthy nutrition Which foods promote good health and which carry certain health risks?</p> <p>Environmental health Which environmental influences could have a positive or negative effect on health?</p> <p>Healthy working conditions How can employees be protected against working conditions that could harm their health?</p> <p>Innovation and the knowledge infrastructure Before we can harvest knowledge in the field of healthcare, we first need to ensure that the right seeds are sown.</p>
Beneficiaries of assessment	The most important target group is the government, in particular the minister of Health, Welfare and Sport. Monitoring reports draw the government's and Parliament's attention to moral dilemmas of our age and explore solutions. Thus, the Health Council/CEG contributes to a well-considered, ethically responsible health policy, aiming at good care for everyone. Government and the parliament.

	<p>Many other people also make use of the Health Council/CEG analyses. The monitoring reports find their way to major groups in the field and are frequently used for educational purposes.</p>
<p>Ethics assessment unit: appointment process</p>	<p>Every year the Council produces a work program with the topics that are eligible for further examination and clarification.</p> <p>In 2013: [1] the dilemmas of wish fulfilling medicine (medical treatment for non-medical purposes at the consumer's request); [2] the pros and cons of the new guideline concerning <i>Perinatal Policy on Extremely Premature Birth</i>; [3] the medical and societal aspects of deep brain stimulation, a neurosurgical treatment involving the insertion of an electrode into a particular area of the brain with the aim of modifying its functioning.</p> <p>In 2014: [1] the dilemmas of lifestyle medicine (medical treatment for non-medical purposes at the consumer's request); [2] the pros and cons of the new guideline concerning <i>Perinatal Policy on Extremely Premature Birth</i>.</p> <p>The list of recent publications list provides an idea of the topics assessed by the Health council:</p> <p>Advisory letter Health risks associated with LED's (2015/2)</p> <p>Adriamycine - Health-based calculated occupational cancer risk values (2015/6))</p> <p>Checking checked: appropriate use of health checks (2015/5)</p> <p>Thiotepa (2015)</p> <p>Next generation sequencing in diagnosis (2015/1)</p> <p>2,6-Xylidine (2015)</p> <p>Population screening act: study into self-sampling as primary screening for cervical cancer (2014/32))</p> <p>Population Screening Act: first trimester scan for prenatal screening (2014/31)</p> <p>Employees and infectious diseases - Criteria for vaccination (2014/30)</p> <p>Fitness to drive requirements: some recommendations (2014/29)</p>
<p>Procedure for ethics assessment: before</p>	<p>Procedure http://www.gezondheidsraad.nl/en/task-and-procedure/procedure</p> <p>The Health Council provides scientific substantiation for the ministries' development of their policies. The Council charts – both solicited and unsolicited – the latest scientific knowledge. It compares the different options for efficiently improving public health. This is a complex task, because researchers often produce divergent results, and data is not always easy to interpret.</p> <p>To do justice to this complexity, the Council has recruited some 170 experts to respond to the requests for advice. The Health Council does not meet on a plenary basis, but rather works on a case-by-case basis within ad hoc committees. In</p>

	<p>addition, there are permanent committees which are responsible for providing advice on frequently returning topics.</p> <p>The committees are made up of Council members who are specialists in the relevant field and of experts who are not members of the Health Council. Together, these experts aim to reach consensus on the interpretation and weighing of the current level of knowledge. Draft advisory reports are reviewed by at least one of the eight Standing Committees before being presented to the relevant minister.</p> <p>The work program of the Health Council identifies the topics to be researched. A committee is established for each of the topics.</p>
Procedure for ethics assessment: during	The committee does its research and draws conclusions
Procedure for ethics assessment: after	The Health Council produces a report Each advisory report is reviewed by at least one Standing committee The Health Council cooperates with a number of international organisations.
Principles and issues in assessment / guidance	<p> <input checked="" type="checkbox"/> scientific integrity <input checked="" type="checkbox"/> justice / fairness <input checked="" type="checkbox"/> professional integrity <input checked="" type="checkbox"/> implications for health and/or safety <input checked="" type="checkbox"/> human subjects research <input checked="" type="checkbox"/> implications for quality of life <input type="checkbox"/> treatment of animals in R&I <input checked="" type="checkbox"/> environmental impacts <input checked="" type="checkbox"/> human dignity <input checked="" type="checkbox"/> social impacts <input checked="" type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing <input checked="" type="checkbox"/> autonomy / freedom <input type="checkbox"/> countries with lower ethics standards <input checked="" type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses) <input checked="" type="checkbox"/> implications for privacy <input checked="" type="checkbox"/> other, specify: <input checked="" type="checkbox"/> social responsibility <input checked="" type="checkbox"/> accessibility of research results <input checked="" type="checkbox"/> scientific validity </p> <p>Commentary: Each topic has its own assessment criteria. Every time an innovation is assessed also the assessment criteria are assessed whether still relevant or not.</p>
Self-assessments, strengths and weaknesses	The Health Council makes use of existing research results to advise the government and parliament the on policy issues, evaluates existing policies and suggests amendments/updates.

Other	References in the interview report on Health Council
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Name of organisation	National Committee for Bioethics
Type of organisation	Assessor
Country	Serbia
Website address	<p><i>General:</i> http://www.sanu.ac.rs/English/Bioethics/Bioethics.aspx</p> <p><i>Main page(s) on ethics assessment:</i></p>
Basic description (organisation and mission)	<p>The National Committee for Bioethics of the Republic of Serbia (NCB) is an independent body, performing its activity independently with respect to the authorities, research centres and other persons and institutions, whereas it shall advise about its decisions the Commissions for Cooperation with the UNESCO of the Ministry of Foreign Affairs of Serbia, as well as the Serbian Academy of Sciences and Arts. NCB was founded in 2003. In 2005 the NCB became a member of the European Conference of National Ethics Committees (COMETH), and in autumn of 2009, at the 35th UNESCO Assembly in Paris, it was elected a member of the Intergovernmental Bioethical Committee (IGBC).</p> <p>NCB aims to promote the position towards ethical and legal matters resulting from research in life science, their implementation, as well as stimulates the exchange of ideas and information, primarily through h education; takes positions, passes decisions and provide opinions on ethical-moral issues related to life itself, at all its levels and development stages; studies, evaluates and holds its position with respect to human activity within classical medical ethics, but also other scientific areas, such as biology, philosophy, law, economics, politics, that involve the question of life and death, health and illness; takes position and provides opinion on ethical issues significant for securing good scientific practice and preservation of main principles and obligations of scientific workers and researchers; supports the activities in order to raise the general level of public awareness, with specialised and sensitive groups and decisions of general and private type related to bioethics;</p> <p>NCB has advisory role so their decisions are not binding.</p>
Interest in research and innovation	NCB is primarily dealing with the issues of moral-ethical behaviour within the sphere of natural sciences and research. It pertains primarily to biological and medical sciences, their interrelations through biomedicine, as well as behaviour of scientists and physicians at work performed within their institutions.
Ethics assessment	Assessment <input checked="" type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary:

and/or guidance	If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/> Commentary:
Terminology for ethics assessment / guidance	
Name and description of ethics unit(s)	
Aims and motivation for ethics assessment	NCB aims to promote the position towards ethical and legal matters resulting from research in life science, their implementation, as well as stimulates the exchange of ideas and information, primarily through education;
Objects and scope of assessment	NCB is primarily dealing with the issues of moral-ethical behaviour within the sphere of natural sciences. It pertains primarily to biological and medical sciences, their interrelations through biomedicine, as well as behaviour of scientists and physicians at work performed within their institutions. NBC monitors whether the individuals, institutions and professions in the respective field uphold the rules and codes adopted in civilised countries of Europe and the world over the past decades. The Committee supports all activities focused on enhancing the general level of public awareness and general and private type of decisions related to bioethics.
Beneficiaries of assessment	Researchers, patients, institutes, scientists, public at large.
Ethics assessment unit: appointment process	
Procedure for ethics assessment: before	
Procedure for ethics assessment: during	
Procedure for ethics assessment: after	
Principles and issues in assessment / guidance	<input type="checkbox"/> scientific integrity <input checked="" type="checkbox"/> justice / fairness <input type="checkbox"/> professional integrity <input checked="" type="checkbox"/> implications for health and/or safety <input checked="" type="checkbox"/> human subjects research <input type="checkbox"/> implications for quality of life <input checked="" type="checkbox"/> treatment of animals in R&I <input type="checkbox"/> environmental impacts

	<input checked="" type="checkbox"/> human dignity <input type="checkbox"/> social impacts <input checked="" type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing <input checked="" type="checkbox"/> autonomy / freedom <input type="checkbox"/> countries with lower ethics standards <input checked="" type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses) <input checked="" type="checkbox"/> implications for privacy <input type="checkbox"/> other, specify: <input type="checkbox"/> social responsibility Commentary:
Self-assessments, strengths and weaknesses	There is no Self-evaluations practice and procedure in NCB. Ethic assessments were neglected in the past but situation is now slightly better. However, we are still at the begging and there is lot of work if we are expecting that ethics assessment become one of the most important forms of assessment.
Other	

Name of organisation	Republic of Slovenia National Medical Ethics Committee (NMEC) Komisija Republike Slovenije za medicinsko etiko (KME)
Type of organisation	National ethics committee
Country	Slovenia
Website address	<i>General:</i> http://www.kme-nmec.si/ <i>Main page(s) on ethics assessment:</i> same as general address
Basic description (organisation and mission)	NMEC is the highest State authority on medical issues related to research involving human beings. As a central national ethics committee, NMEC assesses research proposals and clinical trials. It also serves as the national ethics council. The Committee can, on its own initiative, publish statements on ethical issues related to medicine that are important to society. NMEC has its representative in the Council of Europe's Committee on Bioethics (DH-BIO). It interacts with local ethics committees in Slovenia and with similar national and international organisations. NMEC has 15 members, the majority being medical science experts, representing major disciplines. The members are appointed by the Ministry of Health from those proposed by the Medical Faculties, the Republic of Slovenia Medical Council and Medical Chamber. NMEC was established as an ethics committee at the Ljubljana Medical School in 1960s and was elevated to the rank of a state supervisory body in the 1970s. Its current structure and status

	was defined by a Ministerial Decree in 1995.
Interest in research and innovation	The NMEC as an independent authorised body reviews proposals for biomedical research on human beings for their ethical acceptability. It also deals with other issues in the field of ethics and bioethics, either on the initiative of the Government, the Ministries, public agencies, public services and individuals or on its own initiative.
Ethics assessment and/or guidance	Assessment <input checked="" type="checkbox"/> Guidance <input checked="" type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary: If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/> Commentary:
Terminology for ethics assessment / guidance	Terms “ethical review” and “ethical assessment” are used.
Name and description of ethics unit(s)	The Committee membership includes medical science experts, representing major disciplines, but also a psychologist, an expert in law, a philosopher, a moral theologian, and a lay person. The variety of specialised expertise is important in assessing specific applications.
Aims and motivation for ethics assessment	The goal of assessments is to protect patients and other participants in medical research and patients in health services in terms of ensuring their safety, protecting their dignity and preventing harm. The research motive must never be harmful to participants, e. g. causing harm for the benefit of scientific curiosity. NMEC is mandated to assess research projects involving human beings. The duties and responsibilities of NMEC have been determined by a Ministerial Order.
Objects and scope of assessment	The objects of assessment are biomedical as well as psychological and sociological research project proposals.
Beneficiaries of assessment	Users of assessment are researchers, students and pharmaceutical companies. The Committee also participates in public debates related to medical ethics.
Ethics assessment unit: appointment process	NMEC has 15 members, the majority being medical science experts, representing major disciplines. The current membership also includes a psychologist, an expert in law, a philosopher, a moral theologian, and a lay person The members are appointed by the Ministry of Health from those proposed by the Medical Faculties, the Republic of Slovenia Medical Council and Medical Chamber. The multidisciplinary composition, appointment of members, duration of their mandate, duties and responsibilities have been determined by the Ministerial Order, published in the Official Gazette of the Republic of Slovenia No. 30, 2nd June 1995.
Procedure for ethics assessment: before	It is responsible for ethical review of all biomedical research funded by the State agencies or institutions, all multicentre and multinational clinical trials, all biomedical research on man conducted in the framework of M.Sc. or D.Sc.

	<p>theses, as well as all research on man raising important ethical questions. Such projects submitted to local committees must be referred to the NMEC. Guidelines for the “Application for Ethical Review of Proposed Research Studies Involving Intervention on, or Interaction with, Human Subjects” have been published in a professional journal and are available on the website.</p>
Procedure for ethics assessment: during	<p>For each project, a rapporteur is appointed (in case of need 2 or 3, if several important issues are involved). The requirements and the procedures of review are in agreement with relevant international documents, in particular the Draft Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research, the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, the Tripartite Guideline for Good Clinical Practice (ICH GCP), and Povel Riis: Ethical review of biomedical research in Europe: Suggestions for best national practices, Council of Europe, CDBI-CO-GT2 (98).</p> <p>Whenever the scientific side of the proposed research needs a peer review, an external expert may be appointed. The NMEC may invite the proposer to attend the session if considered necessary. Members having a conflict of interest related to a particular project may not participate in the discussion and decision taking procedure. The NMEC deliberates and adopts its opinions and positions during regular and special sessions, exceptionally also on correspondence sessions. As a rule, the decisions are taken by consensus. Exceptionally, when consensus cannot be reached even after thorough discussion, decisions are taken by a two-third majority vote of all members.</p>
Procedure for ethics assessment: after	<p>The work of the NMEC is open to public. However, the sessions are most often closed, due to the sensitivity of many of ethical issues discussed, respect for privacy and confidentiality. Position papers on ethical issues are made public. Decisions of NMEC are binding under Health Services Act. If the NMEC decides that a research project is ethically unacceptable or objects to parts of the project, the applicant is given the reasons for such decision in writing. The applicant may resubmit the project amended according to the criticism and suggestions. Alternatively, he or she may file an appeal against the NMEC's decision. This must be considered on the next session of the NMEC. The second rejection is final. A further appeal may be submitted to the responsible body of the Council of Europe. So far there were no major problems with noncompliance. Therefore, no special monitoring procedures are needed.</p>
Principles and issues in assessment / guidance	<p><input checked="" type="checkbox"/> scientific integrity <input type="checkbox"/> justice / fairness</p> <p><input checked="" type="checkbox"/> professional integrity <input checked="" type="checkbox"/> implications for health and/or safety</p> <p><input checked="" type="checkbox"/> human subjects research <input checked="" type="checkbox"/> implications for quality of life</p> <p><input type="checkbox"/> treatment of animals in R&I <input type="checkbox"/> environmental impacts</p> <p><input checked="" type="checkbox"/> human dignity <input checked="" type="checkbox"/> social impacts</p> <p><input type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing</p>

	<input checked="" type="checkbox"/> autonomy / freedom <input type="checkbox"/> countries with lower ethics standards <input checked="" type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses) <input checked="" type="checkbox"/> implications for privacy <input type="checkbox"/> other, specify: <input checked="" type="checkbox"/> social responsibility
Self-assessments, strengths and weaknesses	Ethics assessment in Slovenia has a long and good standing tradition. Assessment protocols are well defined and essential values reflect those well established in society (e. g. inviolability of life).
Other	<p>Relations between the NMEC and the Ministry of Health and the government have traditionally been good. The Ministry respects the autonomy of the Committee. The NMEC has actively participated in drafting several laws, e.g. Patient Rights' Act, Law on Infertility Treatment and on Biomedically Assisted Procreation, Slovenian Mental Health Act etc.</p> <p>Apart from its regular assessments of research proposals, NMEC issues public statements of opinion on important issues, related to ethics in medicine. Some of these issues (e. g. euthanasia) are controversial and reflect fundamental divisions in society in terms of world views.</p>

Name of organisation	Spanish Bioethics Committee (SBC) – Comité de Bioética de España (CBE)
Type of organisation	National Ethics Committee
Country	Spain
Website address	<i>General:</i> http://www.comitedebioetica.es <i>Main page(s) on ethics assessment:</i>
Basic description (organisation and mission)	<p>The Spanish Bioethics Committee was created through Law 14/2007 of July 3rd on Biomedical Research (BOE July 4th) as a "collegiate, independent and consultative professional body, which will develop its responsibilities, with full transparency, on materials related to the social and ethical implications of Biomedicine and Health Sciences". The Committee was established on October 22nd 2008 and forms part of the Ministry of Health, Social Services and Equality.</p> <p>Its mission is to issue reports, proposals and recommendations for public authorities at state and regional level on matters related to the ethical and social implications of Biomedicine and Health Sciences. Equally, it is responsible for establishing the general principles for the production of codes of good practice in scientific research and for representing Spain in supranational and international forums and bodies involved in bioethics.</p>

Interest in research and innovation	The Spanish Bioethics Committee may act either on its own initiative, writing reports on issues affecting bioethics and bioresearch, or at the request of the government or some other Spanish public authority asking to assess, from the ethical point of view, draft laws or certain projects affecting bioethics and therefore the bioresearch.
Ethics assessment and/or guidance	Assessment [] Guidance [] Other [x] None [] Commentary: The Spanish Bioethics Committee is an advisory body, it performs ethical advisement to the government or any public authority. If assessment/guidance is undertaken: In-house [x] Outsourced [] Other [] Commentary:
Terminology for ethics assessment / guidance	The Law on Biomedical Research defines the Committee as a “consultative body”. Terminology (according to SATORI conceptualisation): ethical advisement.
Name and description of ethics unit(s)	
Aims and motivation for ethics assessment	See above
Objects and scope of assessment	The Committee may issue reports on matters affecting bioethics and bioresearch, as well as any draft law or regulation affecting this matters.
Beneficiaries of assessment	Public authorities, the public in general (all reports are published in the website).
Ethics assessment unit: appointment process	The appointment of members of the Committee is set by law: half of the members are elected by the Autonomous Communities, through the Inter-Territorial Council of Health, and the rest by various Ministries. It is a multidisciplinary committee, composed of people from different disciplines, primarily health sciences, doctors, nurses, researchers in the field of biosciences, academics, university professors of the same branches, lawyers, bioethicists and economists.
Procedure for ethics assessment: before	According to the Law on Biomedical Research and the Committee’s Regulations, the Plenary can agree the setting up, in its midst, of papers or working groups for the study or preparation of matters on which it must declare an opinion. The Plenary can agree the setting up of the working groups formed as much by the members of the Committee as by external members. These groups are coordinated by a member of the Committee. The Plenary, at the proposal of the spokesperson of the working group, can ask for the report or the collaboration of experts outside the Committee. The external experts will need to commit to keeping the matters dealt with confidential.

Procedure for ethics assessment: during	<p>The procedure to follow in the Plenary is:</p> <p>Presentation of the document by the rapporteur or chairman of the group.</p> <p>Opening a period of fifteen days to submit written amendments by members of Parliament.</p> <p>Discussion and decision on the proposed amendments.</p> <p>Deliberation by the full Committee. At this stage, members may submit amendments in plenary voice to be accepted or reject by the plenary and if discussed in single procedure.</p> <p>Approval by the full Committee.</p> <p>Presentation of individual opinions if any.</p>
Procedure for ethics assessment: after	<p>All reports issued by the Committee are published in the webpage.</p>
Principles and issues in assessment / guidance	<p><input type="checkbox"/> scientific integrity <input type="checkbox"/> justice / fairness</p> <p><input type="checkbox"/> professional integrity <input type="checkbox"/> implications for health and/or safety</p> <p><input type="checkbox"/> human subjects research <input type="checkbox"/> implications for quality of life</p> <p><input type="checkbox"/> treatment of animals in R&I <input type="checkbox"/> environmental impacts</p> <p><input type="checkbox"/> human dignity <input type="checkbox"/> social impacts</p> <p><input type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing</p> <p><input type="checkbox"/> autonomy / freedom <input type="checkbox"/> countries with lower ethics standards</p> <p><input type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses)</p> <p><input type="checkbox"/> implications for privacy <input type="checkbox"/> other, specify:</p> <p><input type="checkbox"/> social responsibility</p> <p>Commentary: The Committee does not have procedures for ethical assessment, because its aim is more general. It does not work on projects, so it is not procedural. There is no check list system. The most important value is the dignity of the individual, balanced with the collective interest. It is necessary to balance values such as autonomy to justice, particularly social justice.</p>
Self-assessments, strengths and weaknesses	<p>No monitoring of compliance with the recommendations is done, nor is there a posteriori monitoring of laws.</p> <p>There is no participation of stakeholders and citizens in the Committee's meetings, it is necessary to make the Committee more notorious to get the stakeholders to want to participate. Then the issue would be to establish a</p>

	<p>protocol of participation.</p> <p>The Committee could also be a part of the training of members of Research Ethics Committees, as there is a lack of uniformity in values (in Spain and in other countries), especially in Health Care Ethics Committees, and the CBE can help to harmonise.</p>
Other	<p>There is no interaction with other ethical assessment organisations. There is a connection with public authorities, particularly the Ministry of Health and regional departments of health. A challenge would be to interact more, organise open sessions with agents.</p> <p>One of the future challenges for the Committee will be to establish a procedure to assess the impact of its ethical guidance.</p> <p>The Committee is a consultative body for the national and regional government. Any draft law with bioethical content must be sent to the Committee for consultation, as established by law.</p> <p>One of the objectives of the Committee is to reach the public, even if it is not one of its functions.</p>

Name of organisation	Nuffield Council on Bioethics
Type of organisation	National ethics advisory council
Country	United Kingdom
Website address	<i>General:</i> http://nuffieldbioethics.org/
Basic description (organisation and mission)	<p>The Nuffield Council on Bioethics is an independent body that examines and reports on ethical issues in biology and medicine. It was established by the Trustees of the Nuffield Foundation in 1991 and has been funded jointly by the Foundation, the Wellcome Trust and the Medical Research Council since 1994.</p> <p>The Council's terms of reference are as follows:</p> <p>To identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;</p> <p>To make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;</p> <p>In the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.</p> <p>In terms of impact regarding their guidance and advice, they interact with</p>

	<p>government departments, professional associations and regulatory bodies. For example, they interacted with the Human Fertilisation and Embryology Authority around some of the work they did on donor conception and on mitochondrial DNA. At the European level, they have interacted with the Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) regarding their recommendations concerning regulation of brain stimulating devices.</p>
Interest in research and innovation	<p>Nuffield Council examines and reports on ethical issues in biology and medicine. Throughout 2014, the Council undertook a series of engagement activities that aimed to inform and advance debate about the ethical consequences of the culture of scientific research.</p>
Ethics assessment and/or guidance	<p>Assessment <input type="checkbox"/> Guidance <input type="checkbox"/> Other <input checked="" type="checkbox"/> None <input type="checkbox"/> Commentary: The Nuffield Council provides ethical advisement.</p> <p>Ethical advisement: In-house <input checked="" type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/></p> <p>Commentary: The Nuffield Council on Bioethics operates at a step removed from direct ethics assessment in the sense that their task within their 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 those 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. They do this in an independent way, i.e. they are not interested in any particular philosophical approach, academic approach or financial investment.</p>
Terminology	<p>The website states the following: “The Nuffield Council on Bioethics has achieved an international reputation as an independent body <i>advising</i> policy makers and stimulating debate in bioethics. Terminology (according to SATORI conceptualisation): ethical advisement.</p>
Name and description of ethics unit(s)	
Aims and motivation for ethics advice	<p>Please see “Basic description” above.</p>
Objects and scope of ethics advice	<p>As regards the focus of guidance, the Council has a broad remit but the basic focus is new developments in research in the biosciences. In some cases, it might be highly specific, e.g. developments in treatments for mitochondrial disease. In other cases, the focus might be very broad, such as a report on emerging biotechnologies. The Council’s report on the culture of scientific research involved looking at some of the effects of the research environment on the way in which people behave. The Council has a process of looking at a long list of</p>

	<p>possible topics which they study to identify what is urgent, what is timely and where they can make a reasonable contribution.</p>
Beneficiaries of advice	<p>As regards “consumers” of the guidance, there are four constituencies. One is the public – a specific task is the promotion of public discussion and understanding regarding the social and ethical issues that arise in the context of new science. The second constituency is that of professionals, i.e. those people who are actually carrying out research or implementing new technologies in the areas of professional guidance or in professional self-governance. The Council also focuses on policymakers and parliamentarians, depending on whether the implications of their work need to be taken up in the context of new legislation or new policy directions. This can be local, national or even international. Thus in one of their reports they might address recommendations to, for example, people in research councils, research funders and to national policymakers, but also potentially to, for example, the European Union, as they have done with their reports on neurotechnologies and biofuels.</p>
Council members: appointment process	<p>The Council aims to maintain a wide range of expertise across the fields of science, medicine, social science, philosophy and law. When vacancies arise, the Council advertises for new members in the national press, through its widely-distributed newsletter and on this website. The Council’s Membership Subgroup considers and makes recommendations to the Council on future members selected from the respondents to the advertisements.</p> <p>Selection is based on the following criteria:</p> <ul style="list-style-type: none"> • If professionally engaged in bioethics and/or biomedicine, members should be nationally or internationally recognised in their field, or show the potential for being so; • Must be able to demonstrate an interest in bioethics; • Must be willing to contribute to bioethical debate in an open and constructive manner; • Must be prepared and able to work with others; • Must have good skills in analysis and communication. <p>The Council aims to achieve an appropriate balance as regards gender and ethnic background. Members do not receive remuneration, but reasonable travel expenses are paid. The Chair of the Council is appointed by the Nuffield Foundation, after consultation with the Council’s other funders.</p>
Procedure for the provision of ethics advice: before	<p>Members of the Council meet on a quarterly basis. During these meetings, the Council reviews recent biomedical and biological advances that raise ethical questions and selects topics for further exploration. Once the Council has identified a major ethical issue, it organises a workshop in order to examine the issue further. If appropriate, a Working Party is then established to report on the issue. The Council does carry out consultation with stakeholders and the public but this is difficult to achieve in practice. They invite their funders to tell them about any topics that they think might be interesting to look at, however, the final decision remains with the Council. The Council also has a wider network of contacts who they call “affiliates” – these are people who have been involved with the Council as previous members of working parties or as Council members.</p>

	<p>The Council invites them to identify any possible future issues. The respondent estimates that they send out an invitation to around 5000 people in total through these networks.</p>
<p>Procedure for the provision of ethics advice: during</p>	<p>When the Council takes on a new topic, it poses the question as to what it can bring to discussion of the topic that isn't already out there. The Council believes that it's much more productive and also much more helpful for policy purposes to develop an approach that is very much specific to that problem, otherwise they're bringing solutions before they've identified a problem, potentially. The Council goes through a process of gathering together a range of people who are involved in the working party and come from different perspectives. They talk to a wider group of people who have got more perspectives and engage them with this interrogation of their views and their reasoning.</p> <p>Some members of the Working Party will specialise in developing the description of the state of the art, while other members will start to develop the philosophical underpinning of an ethical approach. Then this will be discussed within the working party. It will then be referred to the Council and Council members will then comment and contribute as well. It is a kind of iteration of a creative process in which once a problem has been examined and the issues at stake have been identified, they then interrogate it to see what are the values and the principles that people bring to bear in looking at this kind of problem. They then construct a prism through which they think it would be helpful to look at the issues in a way that can attract support from most people.</p>
<p>Procedure for the provision of ethics advice: after</p>	<p>The Working Party produces its report in consultation with the Council. The Council reviews drafts of the report before it is submitted for peer review and then approves the final report prior to publication. External experts, chosen by the Working Party and members of Council, carry out the peer review. These experts are selected to represent a spectrum of opinion and are expected to provide constructive criticism. Once the report is approved by the Council, it becomes the report of the Council.</p> <p>Following the publication of one of their reports, the Council has an active programme of engagement with the people to whom they make recommendations and a wider audience. The Council keeps a record of whether and to what extent their recommendations have been taken up. For example, using their report on the forensic use of bio-information, the European Court of Justice made specific references to the report and recommendations when it required the UK to change its legislation on the retention of DNA samples for criminal justice purposes. In this instance, the Council was specifically and directly influential in bringing about a change to UK law.</p> <p>The Council does not only engage with actors on the publication of their reports but follows a more extensive process of involvement throughout the development of the report. Typically, their working party will, during the course of their work over a year, hold several meetings to which they invite people to talk to the working party in groups. These include policy-makers, scientists, professional practitioners, civil society groups, etc. The Council also looks at effectiveness and impacts regarding the extent to which recommendations are taken up, how often reports are downloaded, how often reports are cited in academic literature and in</p>

	the international media.
Principles and issues in ethics advice	<input type="checkbox"/> scientific integrity <input type="checkbox"/> justice / fairness <input type="checkbox"/> professional integrity <input type="checkbox"/> implications for health and/or safety <input type="checkbox"/> human subjects research <input type="checkbox"/> implications for quality of life <input type="checkbox"/> treatment of animals in R&I <input type="checkbox"/> environmental impacts <input type="checkbox"/> human dignity <input type="checkbox"/> social impacts <input type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing <input type="checkbox"/> autonomy / freedom <input type="checkbox"/> countries with lower ethics standards <input type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses) <input type="checkbox"/> implications for privacy <input type="checkbox"/> other, specify: <input type="checkbox"/> social responsibility <p>Commentary: The Nuffield Council has investigated and reported upon topics ranging from biological and health data to donor conception and the culture of scientific research. Principles include privacy, consent, solidarity, altruism and autonomy.</p>
Self-assessments, strengths and weaknesses	<p>One potential problem concerns the fact that expectations may be too high. The Council looks at issues that are intrinsically problematic. While the Council cannot offer definitive solutions to problems, it can help people to think through the problems and to pursue continuous reflection. Solutions are contingent and subject to evolution as technologies change and social environments change. This approach needs to be communicated to politicians who like things to be clear-cut, or policymakers who want to set a policy in place and then leave it alone for five years or the public who would like to have reassurance.</p> <p>Enabling people to engage in ethics and discussion of issues is important. There is a need to facilitate a much wider mechanism for public discussion to discover people's concerns and values. The language and discourse around ethics is a different one to the discourse around science. People make ethical decisions on a daily basis and largely do it well. It is part of the Council's job to take the process of ethical decision-making that people do in their daily lives and see how that relates to decision-making within policy environments. The next step is to make the connection so that people can be exposed to the kind of thinking that goes on and can realise that they can be involved in this on a wider basis.</p>
Other	

Name of organisation	The Presidential Commission for the Study of Bioethical Issues (PCSBI)
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Type of organisation	National governmental agency
Country	USA
Website address	<p><i>General:</i> http://bioethics.gov/ PCSBI does further have a blog: http://blog.bioethics.gov/</p> <p><i>Main page(s) on ethics assessment:</i> Same as general address.</p>
Basic description (organisation and mission)	<p>PCSBI:</p> <p>[...] is an advisory panel of the nation's leaders in medicine, science, ethics, religion, law, and engineering. [PCSBI] advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. [PCSBI] seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.²⁰</p> <p>There has been a bioethical commission in the U.S. since the 70s, but the commission does not continue past a presidential election and the presidents have to choose to keep such a commission. Therefore when president Obama finishes his term in 2017 this particular commission will also end.</p>
Interest in research and innovation	While not assessing individual research grants, PCSBI does assess research legislation.
Ethics assessment and/or guidance	<p>Assessment <input checked="" type="checkbox"/> Guidance <input type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Commentary:</p> <p>If assessment/guidance is undertaken: In-house <input checked="" type="checkbox"/> Outsourced <input type="checkbox"/> Other <input type="checkbox"/></p> <p>Commentary:</p>
Terminology for ethics assessment / guidance	N/A
Name and description of ethics unit(s)	The ethics unit is self-contained.
Aims and motivation for ethics assessment	[PCSBI] is guided by a commitment to critically examine and explore diverse perspectives, to engage and educate the public on bioethics issues, and to pursue international collaboration to advance ethically responsible practices and policies. ²¹

²⁰ <http://bioethics.gov/about>

²¹ <http://bioethics.gov/node/242>

Objects and scope of assessment	Recent examples of PCSBs work included topics related to ethics and neuroscience, Ebola, Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts and Paediatric Medical Countermeasure Research ²² .
Beneficiaries of assessment	The users of the assessments can be the president, the administration or a specific agency within the government. The commission also makes recommendations for scientists, social scientists, practitioners or groups who are connected to a topic they have investigated and needs to be involved in the situation. They make recommendations for educational agencies.
Ethics assessment unit: appointment process	<p>The “[...] members are selected by the Executive Office of the President and serve for the term of the [PCSBI].²³” Current members include nine professors, two from the public administration, one from a private foundation and one colonel from the U.S. Army medical corps²⁴.</p> <p>The commission has furthermore a staff of around 20 persons.</p>
Procedure for ethics assessment: before	<p>The commission takes on topics depending on the needs from the president and the administration. The commission also has the capacity to create its own topics based on their expertise and knowledge.</p> <p>From a review of the current commissions eight published reports four was requested by the government administration (including three from the president), while four seems to have been taken up by PCSBI themselves²⁵.</p>
Procedure for ethics assessment: during	<p>The commission operate according to democratic deliberation and therefore bring in expertise to contribute to the conversation based on what the problem is. The commission have access to whomever expertise that they need both internal to the government and external to the government.</p> <p>Because the commission advices the federal government they are subject to the rules and laws on being a federal advisory commission called FACA. That requires the commission to do all of the work in a transparent way. All meetings are open to the public; anyone who wishes to contribute to one of the topics is welcome to do so. Depending on the topic the commission get between 20-100 comments from the public. The commission also broadcasts meetings online. The meetings are published in advance with topic and location. They also make sure to invite via networks so people who are interested in particular areas can be invited and so that leading experts both nationally and internationally are able to attend.</p>
Procedure for ethics assessment: after	The resulting report with recommendations to the president can be used by anyone. Nothing of what the commission does is subject to copyright. People can

²² <http://bioethics.gov/studies>

²³ <http://bioethics.gov/node/242>

²⁴ <http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf>

²⁵ <http://bioethics.gov/studies>

	<p>freely use the material and adapt it as they see fit.</p> <p>The commission gives non-binding, advice and are required by FACA to monitor what gets implemented. They have some recommendations that they know has been implemented and rely on people telling them.</p> <p>According to the interviewee does ethical deliberation on tough topics require time, many conversations, reflections and thoughtful approaches. Therefore there is not an immediate turnaround. It is a voluntary commission so they meet four times a year and have regular jobs on the side. The most important partners are the white house and the executive office. In terms of implementing their recommendations they are working closely with the groups they have recommended things to. For instance if they have recommended that scientists incorporate things from the start of their research they will work with university communities, and other federal agencies who can acquire this kind of incorporation. The commission create a lot of educational material on the topics in order to have contemporary issues in the hands of people who teach.</p>
Principles and issues in assessment / guidance	<p><input type="checkbox"/> scientific integrity <input checked="" type="checkbox"/> justice / fairness</p> <p><input type="checkbox"/> professional integrity <input checked="" type="checkbox"/> implications for health and/or safety</p> <p><input checked="" type="checkbox"/> human subjects research <input checked="" type="checkbox"/> implications for quality of life</p> <p><input type="checkbox"/> treatment of animals in R&I <input type="checkbox"/> environmental impacts</p> <p><input checked="" type="checkbox"/> human dignity <input type="checkbox"/> social impacts</p> <p><input checked="" type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing</p> <p><input checked="" type="checkbox"/> autonomy / freedom <input type="checkbox"/> countries with lower ethics standards</p> <p><input type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses)</p> <p><input checked="" type="checkbox"/> implications for privacy <input type="checkbox"/> other, specify:</p> <p><input type="checkbox"/> social responsibility</p> <p>Commentary: The commission does not use a single framework or a principle list approach when they perform ethical assessments on technology and emerging technologies. The above has been found from a sample of recent rapports or have been stated by the interviewee.</p>
Self-assessments, strengths and weaknesses	<p>Evidence of the use of PCSBIs material is mostly anecdotal. They will hear about people using the materials at for example conferences. PCSBI does further count citations.</p> <p>The commission monitor if their reports or advices are followed but sometimes it takes a while before t is taken up or implemented. Those that they see get taken up are those that can be done right away. For example that agencies actually account for what kind of research they do with human participants. Other things like ethics training for all researchers and scientists associated with a certain kind</p>

	<p>of technology is really hard to measure.</p> <p>The Wilson Centre has been very interested in the commission' recommendations on synthetic biology and they maintain a page on their website that keep track on all of the commission' recommendations and where they are in terms of being implemented.</p> <p>In general does the interviewee find it difficult to say something of their impact now because the PCSBI is still in the middle of their work. Usually is it first when the commission ends that people will retrospectively evaluate how they did, what happened and the things they took up.</p>
Other	<p>Some of the earlier commissions have had large impacts, e.g. the first commission that established ethical principles to ensure human subject protection, e.g. the IRB law. Their work also included the Belmont report and that is, according to the interviewee, the most commonly cited piece of ethical literature ever.</p> <p>The next commission was extremely effective in getting a uniformed definition of death across the U.S. The interviewee considers this a big step.</p> <p>Many of the commissions have however produced reports that have not used. According to the interviewee is the consent capacity problem still an on-going issue.</p>

Name of organisation	UNESCO International Bioethics Committee (IBC)
Type of organisation	<ul style="list-style-type: none"> • International ethics association • International social impact / technology assessment organisation
Country	International organisation (headquarters: France)
Website address	<p><i>General:</i> http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/</p> <p><i>Ethics assessment:</i> http://unesdoc.unesco.org/images/0013/001382/138292E.pdf</p> <p>http://unesdoc.unesco.org/images/0018/001892/189208E.pdf</p> <p>http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/reports-and-advice/</p>
Basic description (organisation and mission)	As described by UNESCO, "The International Bioethics Committee (IBC), created in 1993, is a body of 36 independent experts that follows progress in the life sciences and its applications in order to ensure respect for human dignity and freedom. Its primary tasks are to:

	<ul style="list-style-type: none"> • To promote reflection on the ethical and legal issues raised by research in the life sciences and their applications. • To encourage the exchange of ideas and information. • To encourage action to heighten awareness among the general public, specialised groups and public and private decision-makers involved in bioethics. • To co-operate with the international governmental and non-governmental organisations concerned by the issues raised in the field of bioethics as well as with the national and regional bioethics committees and similar bodies. • To contribute to the dissemination of the principles set out in the UNESCO Declarations in the field of bioethics, and to the further examination of issues raised by their applications and by the evolution of the technologies in question.”
Interest in research and innovation	<p>As noted in the tasks of the IBC, one of its primary objectives is to, “to promote reflection on the ethical and legal issues raised by research in the life sciences and their applications.”</p> <p>The IBC was instrumental in the development of the Universal Declaration of Human Rights and Bioethics (2005) which established the linkage between human rights and bioethics (science and research), but also emphasised the environmental implications of the latter.</p>
Ethics assessment and/or guidance	<p>Assessment [] Guidance [] Other [x] None [] Commentary:</p> <p>The IBC does not engage directly in ethics assessment or guidance. However, it does provide a forum for ethical reflection.</p> <p>In the words of the Chairperson of IBC, it is a consultative body of independent experts, so it is supposed not to address too specific questions [direct ethical assessment] ... It is much different from the committees that can be found in the member states, because of the fact it represents a global forum for bioethics which brings together independent experts and does not represent their countries. Therefore, it provides a normative, non-judicial approach, which is supposed to produce specific lines of questions, corresponding to specific conditions, juridical systems, etc.</p> <p>If assessment/guidance is undertaken: In-house [x] Outsourced [] Other []</p>
Terminology for ethics assessment / guidance	<p>The IBC does not engage directly in ethics assessment or guidance. However, it does provide a forum for ethical reflection. IBC is a global forum for bioethics, bringing together independent experts, not representing their countries, but representing difference cultures and sensitivities, competences, etc. As a body of independent experts, it is supposed not to address too specific questions [direct ethical assessment]</p>
Name and description of ethics unit(s)	<p>The IBC’s 36 members are appointed by the Director-General to serve in their personal capacity for a four-year term. The following factors are considered during selection: cultural diversity, balanced geographical representation, and nominations from states regarding qualified specialists in life sciences and in the</p>

	<p>social and human sciences (including law, human rights, philosophy, education and communication). The IBC convenes at least once a year and additionally produces advice and recommendations on specific issues that are adopted by consensus. These are then broadly disseminated by the Director General to member states, the Executive Board and the General Conference, as well as the larger world community.</p>
<p>Aims and motivation for ethics assessment</p>	<p>As described by UNESCO, IBC is a body of independent experts that follows progress in the life sciences and its applications in order to ensure respect for human dignity and freedom. Its primary tasks are to promote reflection on the ethical and legal issues raised by research in the life sciences and their applications, to encourage the exchange of ideas and heighten the awareness of bioethical issues among the specialists and general public, as well as to contribute to the dissemination of the principles set out in the UNESCO Declarations in the field of bioethics. Ethical assessment is therefore an indispensable part of IBC's activity and is undertaken voluntarily in order to accomplish its goals.</p>
<p>Objects and scope of assessment</p>	<p>The IBC convenes at least once a year and additionally produces advice and recommendations on specific issues that are adopted by consensus. These are then broadly disseminated by the Director General to member states, the Executive Board and the General Conference, as well as the larger world community. IBC is a global forum for bioethics bringing together independent experts and providing a normative, non-judicial approach, which is supposed to produce specific lines of questions, corresponding to specific conditions, juridical systems, etc. Therefore, ethical and social implications of research and innovation are at the basis of the analysis in the IBC. However, major emphasis is also put on environmental implications.</p>
<p>Beneficiaries of assessment</p>	<p>IBC is a global forum for bioethics. Its tasks are to heighten awareness among the general public, specialised groups and public and private decision-makers involved in bioethics, to co-operate with the international governmental and non-governmental organisations concerned by bioethical issues as well as with the national and regional bioethics committees and similar bodies and to contribute to the dissemination of the principles set out in the UNESCO Declarations in the field of bioethics. All of the mentioned entities are therefore beneficiaries of its activities.</p>
<p>Ethics assessment unit: appointment process</p>	<p>The IBC's 36 members are appointed by the Director-General to serve in their personal capacity for a four-year term. When being selected, the following factors are considered: cultural diversity, balanced geographical representation, and nominations from states regarding qualified specialists in life sciences and in the social and human sciences (including law, human rights, philosophy, education and communication). The IBC convenes at least once a year and additionally produces advice and recommendations on specific issues that are adopted by consensus. These are then broadly disseminated by the Director General to member states, the Executive Board and the General Conference, as well as the larger world community.</p>
<p>Procedure for ethics</p>	<p>The IBC convenes at least once a year and additionally produces advice and</p>

assessment: before	recommendations on specific issues that are adopted by consensus. In light of the tasks of the IBC, “to promote reflection on the ethical and legal issues raised by research in the life sciences and their applications”, special consideration is given to ethical and social implications of research and innovation. However, as can be discerned from several articles of Universal Declaration on Human Rights and Bioethics, environmental implications are an additional major point of IBC’s concern.
Procedure for ethics assessment: during	The IBC convenes at least once a year and additionally produces advice and recommendations on specific issues that are adopted by consensus. These are then broadly disseminated by the Director General to member states, the Executive Board and the General Conference, as well as the larger world community. Namely, IBC is a global forum for bioethics, bringing together independent experts, not representing their countries, but representing difference cultures and sensitivities, competences, etc. Therefore, it provides a normative, non-judicial approach, which is supposed to produce specific lines of questions, corresponding to specific conditions, juridical systems, etc. Since it is a consultative body, it is not supposed to address too specific questions. The concrete outcome of its efforts depends on the context of how the IBC documents are read and the possibility of being implemented.
Procedure for ethics assessment: after	IBC’s advice and recommendations on specific issues are broadly disseminated by the Director General to member states, the Executive Board and the General Conference, as well as the larger world community. In line with its mission, this helps to promote reflection on the ethical and legal issues raised by research in the life sciences and their applications, to encourage the exchange of ideas and information, to heighten awareness and to contribute to the dissemination of the principles set out in the UNESCO Declarations in the field of bioethics. Since IBC is a global forum for bioethics, providing a normative, non-judicial approach, the concrete outcome of its efforts depends on the context of how the IBC documents are read and the possibility of them being implemented.
Principles and issues in assessment / guidance	<ul style="list-style-type: none"> <input type="checkbox"/> scientific integrity <input checked="" type="checkbox"/> justice / fairness <input type="checkbox"/> professional integrity <input checked="" type="checkbox"/> implications for health and/or safety <input type="checkbox"/> human subjects research <input checked="" type="checkbox"/> implications for quality of life <input type="checkbox"/> treatment of animals in R&I <input checked="" type="checkbox"/> environmental impacts <input type="checkbox"/> human dignity <input checked="" type="checkbox"/> social impacts <input checked="" type="checkbox"/> equality / non-discrimination <input type="checkbox"/> outsourcing of R&I to developing <input type="checkbox"/> autonomy / freedom countries with lower ethics standards <input checked="" type="checkbox"/> implications for civil rights <input type="checkbox"/> dual use (possible military uses) <input type="checkbox"/> implications for privacy <input type="checkbox"/> other, specify: <input checked="" type="checkbox"/> social responsibility

	<p>Commentary: From the provided list, justice, implications for civil rights, equality / non-discrimination, environmental impacts, social impacts, implications for health and/or safety, implications for quality of life, social responsibility, all fall under ethical issues of concern for the IBC. The documents produced by the IBC can best highlight the main areas of IBC's interest. Therefore, Articles 14 & 15 of the Universal Declaration of Human Rights and Bioethics: Social Responsibility & Health and Benefits Sharing, are examples for understanding ethical issues of concern to the organisation. Namely, according to the Chairperson of IBC, ethical issues are interconnected and exhaustive. There were many objections about including the principle of social responsibility for health in a declaration about bioethics. But social responsibility is actually constitutional and essential for global bioethics. It encompasses the responsibility of the states, social responsibility of corporate sector, etc. Ethical and social implications of research and innovation, as well as environmental ones, are at the basis of the analysis in the IBC.</p>
<p>Self-assessments, strengths and weaknesses</p>	<p>The IBC does not engage directly in ethics assessment or guidance. However, it does provide a forum for ethical reflection. IBC's Chairperson emphasises that it is a consultative body of independent experts. It is therefore supposed to not address too specific questions [direct ethical assessment]. This also makes it different from committees in the member states. As a global forum for bioethics, IBC brings together independent experts, not representing their countries, but representing different cultures and sensitivities, competences, etc. In line with the interdisciplinary character of bioethics, IBC provides a normative, non-judicial approach, which is supposed to produce specific lines of questions, corresponding to specific conditions, juridical systems, etc. The concrete outcome of its efforts depends on the context of how the IBC documents are read and the possibility of being implemented. Such a procedure stems not from indifference, but from a long and deeply rooted tradition where the work at UNESCO is considered a global reflection. Although the proclaimed aims of IBC probably impose the system as the only effective one, it is evident that its effectiveness largely depends on the preferences of its target groups.</p>
<p>Other</p>	<p>IBC is a body created by UNESCO. UNESCO itself is one of the actors of a UN network working on all the legal social and environmental issues in the advancement of scientific knowledge and technological issues (namely, the so-called Interagency Committee brings together all the agencies working on the bioethical perspective). The instruments produced by the IBC also provide a basis for the work done by the UNESCO bioethics section, which assists in the establishment of bioethics committees, provides training in bioethics curriculum, and engages regularly with organisations that engage in ethics assessment/guidance.</p> <p>Speaking in his own capacity, IBC's Chairperson believes it would be desirable and feasible to have a shared European approach to ethics assessment of R&I. There are however two sorts of obstacles - that such issues usually affect the domain of exclusive member states competences, and the methodological question, namely that Europe has a problem of trust and legitimacy of institutions. However, he believes the process has already begun and is to some extent inevitable because of relevant commercial interests.</p>

