Ethics assessment in Different Fields
Medical and Life Sciences

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Annex 2.c
Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries
Deliverable 1.1

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1 Introduction

This is a report on ethics assessment of medical and life sciences. Ethics assessment concerns the question what is good and bad or right and wrong about a certain technology or practice. Such assessments help organisations determine to what extent ethical standards should influence decision making at both organisational and individual levels. The aim of this report is to cover both the academic and non-academic traditions of ethical assessment, and the institutionalisation of ethics assessment in different types of organisations, including national and international standards and legislation. This report is a part of a larger study of the SATORI project.

The medical and life sciences are a broad scientific field with many different branches. Research and development in medical and life sciences is often directed towards developing new health care practices and improving current medical practice. The life sciences study all living things, including plants, animals, and human beings. Life sciences is the combination of the biological and medical branches. Biology includes branches such as biochemistry, bioengineering, microbiology, and molecular biology. Medicine is the science or practice of the diagnosis, treatment, and prevention of human disease. It encompasses a variety of health care practices that have evolved to maintain and restore health by prevention and treatment of illnesses, and the use of medical technology to diagnose, treat, and/or prevent injuries and diseases. It includes branches such as biomedical science, biomedical research and genetics.

The field of medicine in a narrow sense refers to health care practices, but includes biomedical engineering (applying engineering methods to address medical problems) in a wider sense. The basic sciences of medicine, such as physiology, biochemistry, genetics, and immunology are included in the education of doctors and physicians. Medicine also includes more specific disciplines such as pharmaceutics, neurosciences, and gerontology. Some of the subfields of medicine are covered by the case studies within the larger SATORI project.

The central ethical issues in the medical sciences concern research on persons. These concerns include potential harm to health, informed consent, justice, and access to care. Animal welfare is another ethical issue introduced by lab animal research, which is often used in medical sciences. Other ethical issues in ethical assessment include scientific integrity, institutional integrity, privacy and confidentiality, collegiality, and responsibility. Different subfields in medicine also raise specific ethical issues.

Ethical assessment in medicine has developed considerably over the past century. The first set of ethical guidelines in medicine that was recognised internationally was the Nuremberg Code.

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4 Ibid.
6 For an extended overview of the basic sciences, see http://en.wikipedia.org/wiki/Medicine#Basic_sciences.
of 1947. It has since been superseded by the Declaration of Helsinki that was first adopted by the World Health Organisation (WHO) in 1964, which was last revised in 2013.

In addition to the Declaration of Helsinki, other important legal guidelines and instruments include the European Convention on Human Rights and Biomedicine (the Oviedo Convention), and the International Ethical Guidelines for Epidemiological Studies developed by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO).

The most important institutions in ethics assessment are the institutional review boards (IRBs) in the US and the independent ethics committees in Europe. Health research ethics committees in Europe follow systems specific to their country. For example, Denmark has had an ethical committee system consisting of a national committee and eleven regional committees since 1980. It is the responsibility of the committee system on health research ethics to ensure that from the perspective of research ethics, projects are performed responsibly, and that the rights, safety, and well-being of participants in such research are protected. While each country has its own system and committees, the tasks and responsibilities are similar. Decisions are made according to legal requirements, empirical evidence, and ethical principles such as utilitarianism and deontology. Criteria for project evaluation are included in international agreements and regulations such as the Oviedo Convention and EU Directive 2001/20/EC.

Health research ethics committees consist of members with varying backgrounds, with medical experts usually joined by lawyers, sociologists, philosophers, theologians and some lay persons. Committee members will have different perspectives on the cases. Some may have a more deontological approach that focuses on respect for persons and autonomy over evaluating the social costs and benefits. Others might follow utilitarianism and focus more on the social benefits and costs. The ethics committee will conclude with a favourable or not favourable opinion of the proposed research. A favourable review is often needed to proceed with the research project.

This report is divided into descriptions of approaches and principles in ethical assessments, ethical issues and institutionalisation. The following chapter will describe the major traditions of ethical assessment in medicine that have developed in the academic and non-academic context. Different traditions have developed in practice and can be distinguished on the basis

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of their aims, methodologies, guiding principles, and/or actors and organisations are covered in this chapter. The third chapter lists ethical issues that occur in medical research. The institutionalisation of ethics assessment in the EU, international and national contexts is described in the fourth and fifth chapters. Finally, the report offers a list of key publications, journals and conference series, and a list of organisations that focus on or engage in ethical assessment in medicine, and a list of case studies in the subfields of medicine.

2 Ethical Assessment: Approaches and Principles

2.1 Research Ethics

The Hippocratic Oath originated in Greece almost 2500 years ago. Hippocrates set high ethical standards for future physicians to follow, for example the protection of the doctor-patient confidentiality.\(^\text{13}\) It is still influential as an inspiration for defining the duties and commitments expected of medical professionals.\(^\text{14}\) The Oath includes the statement that physicians “will do no harm or injustice” to patients.\(^\text{15}\) Despite this commitment, historically new medicines and vaccines were often tested on improperly informed and vulnerable people. In the nineteenth century, scientists dealing with research on humans and animals thought that any research that had some potential to benefit human beings was acceptable.\(^\text{16}\) Little attention was paid to the issues that are now important, including the quality and scientific merit of the research protocol.\(^\text{17}\) Modern research ethics developed in response to these issues.

The Nuremberg Code was adopted in 1947, after Nazi doctors were put to trial. The code was devised to prevent the circumstances under which medical experiments on thousands of concentration camp prisoners during the Second World War were performed.\(^\text{18}\) The code stated that the voluntary consent of the human participant was essential in medical research, and the benefits should outweigh the risks. The Nuremberg Code influenced the Declaration of Geneva by the World Medical Association (WMA) in 1948.\(^\text{19}\) This statement of physicians’ ethical duties was seen as a modern version of the Hippocratic Oath.\(^\text{20}\) It was followed by the Declaration of Helsinki in 1964, in which the WMA established ethical principles for human


\(^{17}\) Ibid.


experimentation.\textsuperscript{21} The document and its revisions are considered as an international standard for good clinical practices, prescribe the priority of the well-being of subjects over the interests of science and society, and protect the health and rights of participants. Although the Declaration of Helsinki is not a legally binding instrument, it is a cornerstone document on human research ethics.

More specific ethics principles and guidelines for the protection of persons in research were documented in the Belmont Report (1974) by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.\textsuperscript{22} The three core principles contained in the report are:

1. Respect for Persons
2. Beneficence
3. Justice

With these principles, human participants in research are protected. Respect for persons requires research participants to be treated as individuals capable of making and acting on their own decisions, and that participants with “diminished autonomy” (such as children and vulnerable people) should be protected against harm.\textsuperscript{23} All participants need to be treated with courtesy and respect. Informed consent is an important method of respecting the autonomy of participants by allowing them to decide for themselves whether or not to participate. Researchers have to be truthful towards the participants, and if deception is necessary as a part of a psychological study, the participants must be informed of the truth as soon as possible. Beneficence is the obligation not to cause harm to participants and to minimise the risks participants are exposed to while maximising the potential benefits of conducting the research.\textsuperscript{24} Justice requires researchers to attempt to distribute benefits and burdens fairly among participants and populations.\textsuperscript{25} Vulnerable persons and groups should not be unfairly targeted as research participants. To ensure justice, reasonable, non-exploitative, well-considered and fair procedures must be established, and participants must be treated equally. Although the Belmont Report as such is a historical document, the three principles provide a moral framework for the protection of persons in research. Applying these principles requires careful consideration of informed consent, risks and benefits of the research, and justice in the selection of participants.

The main principles in the Belmont Report can be compared with the framework of moral principles created by Beauchamp and Childress, who identify the four currently most influential clusters of moral principles within the medical and life sciences.\textsuperscript{26} The clusters function as an analytical framework that expresses the general values underlying common

\begin{itemize}
\item \textsuperscript{21} World Medical Association, “Declaration of Helsinki”.
\item \textsuperscript{22} US Department of Health & Human Services, “The Belmont Report”.
http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
\item \textsuperscript{23} Ibid.
\item \textsuperscript{24} Ibid.
\item \textsuperscript{25} Ibid.
\end{itemize}
Ethics assessment in medical and life sciences

moral rules. This four principles approach to biomedical ethics is also called principlism.\(^{27}\) It is based on the following principles:

1. Respect for autonomy – respect for the decision making capacities of an autonomous person
2. Non-maleficence – avoid causing harm
3. Beneficence – providing benefits and balancing benefits against risks and costs
4. Justice – norms for fair distribution of benefits, risks, and costs\(^{28}\)

These principles roughly correspond to the three principles of the Belmont Report, although the Belmont Report’s duty of beneficence is divided into the separate principles of non-maleficence (‘do no harm’) and beneficence (‘minimise risk and maximise benefit’) here.

Principlism is a popular framework for thinking about medical and life sciences ethics which it aims to provide a general moral framework for those working with bioethical problems. The four principles aim to be universal values shared by many people and cultures. Although most individuals and societies would accept the values of principlism, this approach to medical ethics has its critics. Clouser and Gert raise several objections: the principles do not have an underlying theory to support them, there is no clear method for determining how each principle should be weighted compared to the others, and principlism does not provide a procedure for choosing between the principles when they conflict.\(^{29}\) There are other shared moral values that could be important for medical decision making, such as community (for example, what respect is owed to animals (and which animals) and to the dead).\(^{30}\) Despite these concerns, principlism remains an influential framework for research ethics.

2.2 Health Technology Assessment (HTA)

Health Technology Assessment (HTA) is a methodology of testing the effectiveness of new medical technologies was developed by the US Office of Technology Assessment in 1976.\(^{31}\) The HTA process seeks to establish the significant properties of medical technologies, such as cost, effectiveness, safety, and the potential social, economic, and ethical implications of using the technology.\(^{32}\) HTA spread beyond the US in the 1980s with the help of the World Bank and the WHO. The approach gives guidance towards discussions about the rightness or wrongness of particular practices and technologies within the medical domain, which can be used for evaluation before or during research.\(^{33}\)

\(^{27}\) Ibid., p 23.

\(^{28}\) Ibid., pp. 12-15.


The aim of HTA is to provide decision makers with information about the value of practices or technologies. The main focus of HTA is to combine concerns about new technologies, rising costs, and a rise in expectations. Especially the concerns and expectations require ethics assessment, but there is little agreement on the method to integrate ethics into HTA. Although ethical assessments are a part of the HTA process, the major focus in practice is in performing a cost-benefit analysis, and few reports include an ethical analysis. The role of ethics assessment within the HTA should be emphasised rather than considered as something separate to it.

3 Overview of Ethical issues

3.1 General Ethical Issues in Medical and Life Sciences

The ethical issues and principles central in medical and life sciences concern research on persons. The following list of general ethical principles and issues in the medical and life sciences domain is organised according to the principlist approach described by Beauchamp and Childress.

Respect for autonomy

- Informed consent: the researcher discloses appropriate information to a research participant.

Informed consent should include:

- The nature of the study
- An assessment of participant understanding
- The acceptance of the intervention by the participant

The person has the right to know precisely what happens to his or her body and the researcher has a duty to involve the patient in the research process, including care during and after the research.

- Mental competence: a participant should be mentally competent to make a decision. In case of doubt the competence should be assessed, otherwise the participant’s autonomy is balanced against his or her best interests.
- Respect for choices or actions: researchers are obliged to respect the participant’s decisions.

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36 Ibid., p. 427.
• Medical confidentiality: researchers should keep a person’s information private unless he or she gives consent to release that information. The privacy of participants must be respected. Confidentiality is one of the core duties within medical practice, including medical research.\(^{40}\)

• Medical records: data storage should be secure and protected against unauthorised access.

• Trustworthiness of the researchers: creating a trusting environment by respecting and encouraging the participants is very important, and can increase the willingness of a person to seek care or join an experimental set-up.\(^{41}\)

• Effects on identity: this issue is not relevant in all medical and life science, but the effect of a practice or technology on someone’s identity and sense of self should be taken into account during research.

Non-maleficence

• Doing no harm: this includes avoiding potential harm to individuals.

• Reduce the risks of research and new technologies: the use of new technologies and conducting research itself comes with uncertain risks.

• Protecting research participants: persons should not receive treatments that have an unacceptably high risk of causing harm to them.

• Safety concerns: research should be planned and carried out with a concern towards the safety of persons, the reported effects have to be evaluated with special attention towards detecting unexpected ones. Researchers should be competent in the methods and techniques used in the study.

• Human dignity: Every human being has a right to be valued and respected.

The Declaration of Helsinki mentions the protection of dignity as a duty of medical researchers. The European Convention on Human Rights and Biomedicine (the Oviedo Convention) states that “[t]he interests and welfare of the human being shall prevail over the sole interest of society or science.”\(^{42}\)

• Bodily integrity: no one should be a subject of torture or cruelty. Research procedures must be humane. Overall, the inviolability of the body should be respected. Bodily integrity is also one of Martha Nussbaum’s ten principle human capabilities:

  Being able to move freely from place to place; to be secure against violent assault, including sexual assault and domestic violence; having opportunities for sexual satisfaction and for choice in matters of reproduction.\(^{43}\)


\(^{41}\) Ibid.


It can be a part of the respect for autonomy and ensured by informed consent. No one can touch, hit, harm, or conduct testing on human bodies without consent.

- Prevent risks to the researchers.

**Beneficence**

- Contribute to welfare: a treatment can contribute to individual welfare, and research can eventually contribute to the welfare for a larger group.
- Promote good: take positive steps to help others and provide benefits.
- Quality of life: we can place a certain value on life, which can be violated with research or treatment. In medical and life sciences the focus is on the individual’s daily life, with an assessment of the individual’s well-being. The core components of QoL assessment include physical, functional, psychological/emotional, and social/occupational well-being.\(^4\)
- Cost-effectiveness analysis and cost-benefit analysis: evaluation of public policies regarding health, safety, and medical technologies.
- Risk-benefit analysis: proportionality of the risk and benefit, an assessment of the acceptability of risk.
- Protecting against the potential harms of dual use research: research may have harmful alternative uses in addition to its intended benefits. Researchers should consider or predict potentially harmful uses of their research.

**Justice**

- Burden of proof: uncertainty of research can cause unrealistic expectations in society. The transfer of information from the research to society should be protected to prevent misleading expectations.
- Protection against discrimination: everyone should be treated equally, however in research there are inclusion and exclusion criteria for participants. Preventing discrimination is especially important in the case of genetic testing and screening. The Oviedo Convention states that “[a]ny form of discrimination against a person on grounds of his or her genetic heritage is prohibited, and for any other reason.”\(^4\)

### 3.2 Ethical Issues in Specific Fields of Medical and Life Sciences

In addition to the general concerns described above, there are many specific issues raised by particular subfields within the medical and life sciences. Some of these issues are listed below.

**Ethical issues in human stem cell research: embryos and beyond**

- Moral status of the embryo: moral and legal rights of the embryo for both embryonic and adult stem cells. Different views on whether an embryo has the same moral status of a human person or not will give different conclusions about the permissibility of sacrificing embryos to gain stem cells.


• Safety concerns: related to the use of stem cells for medical purposes.
  o Implanting cells into the human body: patients are exposed to risks from cancerous cells or immunoreaction. Full informed consent to the use of these techniques is questionable due to the high uncertainty. One response is to perform more research on animals.
  o Obtaining women’s eggs: concerns about exploiting women to provoke eggs.46
• Justice: social justice and healthcare system, access to new medical procedures.

Nanomedicine
• Diagnostics and medical records; privacy concerning data storage, lab-on-a-chip, and other privacy issues of new medical record-keeping techniques.
• Toxicity – putting patients at risk.
• Treatment:
  o Nano-surgery: toxicity of nanoparticles and drug delivery.
  o Risky new surgical techniques: toxicity and other risks for the body.
  o Distributive justice concerns.

Psychopharmacology, neuroscience and neurosurgery
• Risk of non-beneficial results for the recipients and adverse effects.
• Erasing memories, modulating thought, or enhancing long-term memory.
  o Capacity to take responsibility, holding people morally and legally responsible.
  o Authenticity.
  o Adverse effects.
  o No knowledge about permanent or temporary effects.
• Functional neurosurgery to modulate thought and mood.
• Modulating and enhancing mood.
• Reading minds/controlling can have a risk for someone’s autonomy and privacy. This innovation is particularly in cognitive and social psychology, not in neuroscience.

Regenerative medicine
This includes genetics and molecular biology, materials science, stem cell biology, transplantation, development biology, and tissue engineering.
• Informed consent:
  o Clinical trials, consequences of the experimental therapies are largely unknown
  o Innovative nature questions patient’s ability to consent fully.
  o Potential “dual use” of a therapy, for example to help impaired versus enhance normal functions.
• Procuring donor materials and compensating donors.
• Questions concerning the time of the usage of the donated cells.
• Safety, privacy, and confidentiality for both the recipient and donor.
• Use of xenogenic and human embryonic tissue in tissue engineering.

• Patenting of tissues.

**Innovation in medical care**

- Ethics in innovation: 47
  - Adoption of innovations without adequate supporting evidence.
  - Adoption of innovations without formal scientific testing, e.g. weighting benefits against risks, comparison with other practices.
  - Long term safety concerns and uncertainties.

**Epidemiological research**

- Privacy concerns with the collection and storage of medical information and material.
- Risk of reinforcement of inequities through study design and through the (mis)interpretation of results.
- Consent of future uses of research samples in genetic database research.

**Bio-banking**

- Informed consent, serving the protection of human dignity, autonomy, and privacy.
- Safety of storing human tissue and disease samples.
- Potential harms that are related to human dignity and individual or group discrimination.

**Genetics**

See also many of the other ethical issues here, especially genetic testing and screening, behavioural genetics, human cloning, crossing species boundaries, and artificial cells.

- Shared nature and ownership of genetic information.
- Privacy and discrimination.
- Patenting of genes.
- The unprecedented nature of genetic engineering: innovations, future implications extremely difficult to forecast.
- Burden of proof in genetic engineering – transferred from industry, research institutions etc. to society?
- Forensic DNA databanks.
- Ethical issues in genetic therapy, such as: 48
  - How to distinguish between ‘good’ and ‘bad’ genetic therapy.
  - Which traits are normal and which constitute a disability or disorder.
  - High costs, access to therapy.
  - A less acceptable society for people who are different.
  - Enhance human traits such as height, intelligence, or athletic abilities.

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Genetic testing and screening

- Confidentiality and sharing information. Genetic tests and screenings can give predictive information, or information about relative’s future health. Usage by third parties excluding insurance companies.
- Bio-banks: storage for future testing, associations between genetic factors and health status, difference between public good/health and access to information for individual.
- Genetic testing of embryos.
- The potential for discrimination.
- The (un)desirability of predicting future defects.
- Genetic testing for controversial purposes, e.g., sexing of foetuses, paternity testing without informed consent.

Behavioural genetics

- Risks of discrimination due to identification of individual differences, such as criminality and general intelligence (IQ).
- Drawing line between normality and medicalization
- Eugenics and selective reproduction, designing ‘well-borns’, which brings a risk for autonomy, freedom, dignity, justice, and well-being.

Human cloning and the creating and patenting of new life forms

- Ethical issues in human cloning, such as: 49
  - Depletion of genetic diversity.
  - Uncertainties about risks of harm to future generations.
  - Risks for human autonomy, freedom, dignity, and justice.
- Unfair exploitation of local knowledge on plants by foreign companies patenting useful genetic sequences.

Crossing species boundaries (creating human-animal chimeras and hybrids)

- Species identity: what is their essence? 50

Creating artificial cells

- It is something unnatural; is that also something unethical?
- Commodification of life: is that immoral? 51
  - Playing god arguments.
  - Design of humans or parts of humans.
  - Can we price the products, artificial cells or parts of humans?

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**Synthetic biology, biosecurity, and biosafety**
- Risks for human health and environmental risks; unknown possibilities of “dual-use” of new technologies.
- Risks for scientific personnel due to exposure to hazardous biological agents with which they are working, risks of accidental release of biological agents, and risks to public health and the environment. These risks can/should be lowered with biosafety rules.
- Hostile purposes; biosecurity.

**Human enhancement**
- Naturalness and playing god arguments.\(^5^2\)
- Human dignity and bodily integrity issues.
- Health and psychological risks and effects on identity.
- Implications of prostheses and implants for human dignity and identity.
- Inequality and access issues; distributive justice.
- Ethical issues in germline engineering: similar to the ethical issues related to genetic therapy.
- Ethical issues in cognitive and mood enhancements: similar to the ethical issues concerned with science and neurosurgery.
- Lengthening of the lifespan as a goal of biomedical engineering.

**Pharmaceutics**
- Health risks and side-effects.
- Welfare of humans and animals as test subjects in clinical trials.
- Patents, intellectual property, affordability, and access to drugs.
- Marketing and the creation of new markets by creating new “diseases”.

**Agriculture and Food**
- Farming innovations and animal welfare.
- Agricultural animal biotechnology and animal welfare and dignity:
  - Genetic modification.
  - Transgenic organisms.
  - Cloning.
- Agriculture and the influences on the environment.
- Agricultural innovation, food poverty, equality in access, and justice.
- Food technology; security and health impacts due to additives, pesticides, antibiotics, hormones, infectious agents, and zoonoses.
- Risks concerning genetically modified foods from genetically modified organisms.
- Development of artificial meat: critics of unnaturalness, positive or negative for animal welfare, environment, and consumer attitude.
- Food versus biofuel debate.

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• Nutrigenomics and health.

**Imaging technologies**

• Informed consent: a patient needs to have the knowledge about all information that can be obtained during imaging.
• Diagnostic imaging techniques that reveal more information than requested.
• Processing the information: a patient needs to adjust to the new information which can have an influence on autonomy and identity.

### 3.3 Professional Ethics

Professional ethics describes the particular duties people possess as a consequence of belonging to a profession. The Declaration of Geneva described earlier defines the professional standards expected of doctors and physicians in treating patients. While the concerns raised by their role as doctors and physicians are described in section 3.1, medical researchers also have ethical issues that arise from their role as scientists. Some of these issues in research ethics are listed below.

**Scientific Integrity**

• Honesty: research findings should be reported accurately in publications. This includes describing the research methodology in sufficient detail to allow other researchers to replicate the research if necessary.
• Objectivity: researchers should not allow individual biases or conflicts of interest to influence the conduct of their research or the presentation of their findings.
• Conflicts of interest: Sources of funding, personal interests and other potential conflicts of interest should be declared.

**Institutional Integrity**

• Misconduct: institutions should respond appropriately to allegations of research conduct and investigate them fairly.
• Conflicts of interest: institutions should prevent outside influences (such as funding providers) from influencing the objectivity of research.

**Collegiality**

• Attribution: work should be accurately credited to those who performed it.
• Sharing: data should be made available to colleagues and other researchers on request if it is legal to do so and there are no privacy and confidentiality concerns that prohibit doing so.
• Peer Review: researchers should be prepared to review other researchers’ work and give unbiased comments and opinions on its quality and findings.
• Respect for colleagues: the work of other researchers should not be unfairly judged or criticised. The work of students and subordinates must be recognised and acknowledged.

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Professional Responsibility

- Plagiarism: the work of others must be properly acknowledged and credited.
- Negligence: researchers should report careless and dangerous conduct to the proper authorities.
- Accurate Reporting: researchers should ensure that their work is represented fairly and accurately to the public.

4 Institutionalisation: EU and International

The most important international institutions are the institutional review boards (IRBs) in the USA and the independent ethics committees in Europe. Significant international standards in the field of medical and life science included the Declaration of Helsinki and the International Ethical Guidelines for Epidemiological Studies of the Council for International Organisation of Medical Sciences (CIOMS) in collaboration with the WHO. The first request for a committee review was made in 1953, when a US Federal Document entitled ‘Group Consideration of Clinical Research Procedures Deviating from Accepted Medical Practice of Involving Unusual Hazard’ was published. These guidelines were only applied to research conducted by the National Institute of Health Clinical Centre.\(^{54}\)

The first federal public statement requiring research institutions to establish research ethics committees (RECs) in the US was made in 1966.\(^{55}\) RECs have since became standard practice in assessing the ethics of research. Often RECs are local bodies within research organisations, but additional to these local RECs, countries may have regional and one or more national RECs. Although most hospitals and universities have (medical) ethics committees, many companies involved in pre-clinical trials do not have these committees. While pre-clinical trials are performed outside clinical settings, they will still require ethical approval. For pharmaceutical research, the pre-clinical studies use *in vitro* experiments, which do not require ethical approval. This changes when the trials evolve into *in vivo* experiments in animals or humans.\(^{56}\) In the follow-up phases of (pharmaceutical) research, there are clinical trials involved with humans which are performed in hospitals. However, it is possible that funding arrangements can constrain research integrity and result in conflicts of norms between companies and hospitals for example.\(^ {57}\) The WHO Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products from 1995 emphasise the importance of research ethics reviews.\(^ {58}\)

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56 Medical research: http://en.wikipedia.org/wiki/Medical_research
4.1 European Legislation, Standards, Frameworks, and Protocols

The main European and international legislation, standards, frameworks, and protocols in the field of medical and life sciences concern clinical trials. The European Commission defines clinical trials as investigations in humans that are intended to discover or verify the effects of one or more investigational medicinal products. A new EU Regulation (Clinical Trials Regulation EU No 536/2014) was adopted on April 16, 2014. This Regulation will enter into force on May 28, 2016 and will replace the current Directive. It aims to create a favourable environment for conduct of clinical trials for all EU Member States, with high standards of patient safety. The main characteristics of the new regulation include a harmonised procedure for assessment, increased transparency regarding clinical trials and their outcomes, and a simplified reporting procedure, while also maintaining the position of RECs. Until the Clinical Trials Regulation enters into force, the requirements of Directive 2001/20/EC remain in use.

There are several other relevant guidelines besides Directive 2001/20/EC and the new Regulation 536/2014. For example, there is Directive 2003/94/EC of October 8, 2003 (the ‘GMP’ or ‘Good Manufacturing Practice’ Directive) that specifies the necessary practices for producing medicines and testing medical products. There is also Directive 2005/28/EC of April 8, 2005 (the ‘GCP’ or ‘Good Clinical Practice’ Directive) that states the requirements for testing medicinal products on people and the requirements for manufacturing and importing such products.

The guidelines by the European Union include the information to be submitted to the competent authorities and to the ethics committees. Besides this, the guidelines include requirements on safety monitoring and the reporting of adverse reactions, requirements on GCP (good clinical practice) including documentation of the clinical trials, requirements regarding the product and the clinical trials itself, and guidance to prepare for inspections. The European Medicines Agency (EMA) also provides guidelines, concerning inspection procedures and guidance of GCP inspections, and requirements related to quality, safety, efficacy, and the specific types of products. The European Commission and EMA are observers of the Clinical Trials Facilitation Group (CTFG). The CTFG is established to discuss on-going technical issues. These guidelines are now revised and updated to be in line with the changes to the Clinical Trials Regulation.

60 Ibid.
61 Ibid.
65 Ibid.
All on-going and complete clinical trials fall within the scope of the Directive and the Regulation and are stored in a European database (EudraCT). The aim of this database is to give all authorities of the Member States, the EMA, and the European Commission the necessary information to communicate and to maintain oversight of clinical trials. This means that results for any trial that is registered in EudraCT is saved in the database, and parts of these results are available to the public in the European Union Clinical Trials Register. A summary of the clinical trial provides information on the objectives, the design, and main results and conclusion.66

Once the Clinical Trials Regulation enters into force, the EMA will be responsible for the establishment of an EU Portal and database. The EU Portal should be a single entry for submission of data and information related to clinical trials. The information submitted via the portal will be stored in the database. The two systems together will form the backbone of the new regime for clinical trials in Europe. The information in the database will be accessible for the public. The confidentiality of the information has to be justified on the basis of protection of commercially confidential information, protection of personal data, protection of confidential communication, and ensuring effective supervision of the conduct of clinical trials by the Member States.67

Another difference, introduced with the Regulation, which can provide the aim to create a favourable environment for conducting clinical trials for all EU Member States based on identical rules, is safety reporting. The Directive provides rules for reporting directly to the national competent authority. The protocol will be simplified and not all adverse events have to be recorded in the report. The Regulation obliges Member States to collaborate in assessing the annual safety reports and report suspected unexpected serious adverse reactions.68

Beyond clinical trials, the Oviedo Convention on Human Rights and Biomedicine regulates medical and biological research involving human participants and the treatment of patients in medical care.69 It states that “[t]he interests and welfare of the human being shall prevail over the sole interest of society or science.”70 The Convention also states biological and medical research should be performed freely, provided that it meets the requirements of the Convention and other applicable laws and regulations.71 While the Convention states that informed consent is generally necessary for medical treatment and intervention, it provides guidelines for the proper treatment of patients and research participants who are unable to give consent. It also prohibits creating human embryos for research purposes.

The rules relating to safety and performance of medical devices were harmonised in the EU in 1990s. Medical devices are defined as “any instrument, apparatus, appliance, software,

68 Ibid.
70 Ibid., chapter I, article 2.
71 Ibid., chapter V, article 15.
material or other article, whether used alone or in combination, […] intended by the manufacturer to be used for human beings […]”. 72 This legal framework consists of three directives: One directive regarding the active implantable medical devices (Directive 90/385/EEC), one regarding medical devices (Directive 93/42/EEC), and one regarding in vitro diagnostic medical devices (Directive 98/79/EC). 73

Another group of European and international legislation in the field of medical and life sciences is within the agricultural research and food safety sector. The Directorate General for Development and Cooperation (DEVCO) has set guidelines for supporting agricultural research for development (AR4D or sometimes ARD). 74 The purpose of DEVCO is to apply agricultural research to address problems of poverty and hunger, and to the global food supply more robust and sustainable. 75 The broad research themes for AR4D are defined as:

- Sustainable inclusive agriculture for growth
- Nutrition, with particular attention to children and women
- Resilience to food security crises 76

DEVCO’s work is distinct from but complimentary to that of the Research and Innovation Directorate General which focuses on fostering and supporting excellence in European research generally. 77

DEVCO’s focus on promoting food security is also shared by CGIAR, formerly known as the Consultative Group for International Agricultural Research. CGIAR is a global partnership of governments and non-government organisations that perform agricultural research. This research focuses on reducing poverty, hunger, and environmental degradation. 78

Apart from the research part of the agricultural sector, there are other guidelines that describe the principles, requirements, and procedures to provide food security. In 2002, the European Parliament and the Council adopted Regulation (EC) No 178/2002 (General Food Law Regulation) and laid down the general principles and requirements of food law. 79 This regulation established the European Food Safety Authority (EFSA) and laid down procedures in matters of food safety. This Regulation provides the basis for a high level of protection of human health and consumer interests in relation to food. The Regulation establishes common principles and responsibilities, such as the precautionary principle and the methods of

75 Ibid.
76 Ibid., p. 10.
77 Ibid, p. 7.
analysing risk.\textsuperscript{80} It provides a strong scientific base, efficient organisational arrangements, and procedures for decision-making in matters of food and livestock feed safety.\textsuperscript{81}

The EFSA assesses and communicates all risks associated with the food chain. Their decisions have the purpose to serve as an advice for policies and decisions of risk managers. Most of the EFSA’s work is based on requests for scientific advice and assessment from the European Commission, European Parliament, and EU Member States. They also undertake scientific work on their own initiative.\textsuperscript{82}

4.2 International Legislation, Standards, Frameworks, and Protocols

Apart from the European regulations, there are also international standards developed by the International Organisation for Standardisation (ISO). Examples for the field of medical and life sciences are clinical investigations. A clinical investigation is “any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of medical devices.”\textsuperscript{83} The aim is to evaluate medical devices and assess their safety and clinical performance to see whether they are or are not suitable for the purpose and population intended.\textsuperscript{84}

Clinical investigations should take scientific principles into account together the accepted ethical standards surrounding the use of human participants, and the objectives and design of the investigation should be documented in the clinical investigation plan.\textsuperscript{85} The ISO 14155-1:2009 describes the general requirements for the conduct of clinical investigations and ISO 14155-2:2009 includes information about the procedure and content of a clinical investigation plan. Good clinical practice for the design, conduct, recording, and reporting of clinical investigations is addressed by ISO 14155:2011. In vitro diagnostic medical devices do not fall into this category and other International Standards are developed for the measurement of quantities in biological samples ISO 17511:2003, ISO 18153:2003, ISO 15193:2009, or ISO 15194:2009. There are many other International Standards within the field of medical and life sciences.

The ISO collaborates with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardisation. The ISO together with the IEC published a guide to help standards writers address safety aspect in medical devices. ISO/IEC Guide 63:2012 is designed for all ISO and IEC bodies involved in the development of medical device safety standards, to improve the interface between the developing of standards and the stakeholders they serve, and to make optimal use of resources by the development of devices for which

\textsuperscript{80} Ibid.
\textsuperscript{81} Ibid.
there is a market.\textsuperscript{86} Another example is ISO 15189:2012, based upon ISO/IEC 17025:2005 and ISO 9001:2008, which specifies requirements for competence and quality that are particular to medical laboratories. Medical laboratories have to meet the needs of all participants and clinical personnel responsible for care, including examination request, patient preparation and identification, collection of samples, transportation, storage, processing, and examination of clinical samples. In addition to these needs, the consideration of safety and ethics in laboratory work are included.\textsuperscript{87}

5 Institutionalisation: National

All of the countries considered by the SATORI project have an extensive range of professional organisations that are concerned with research and innovation in medicine and the life sciences. These organisations often set the standards expected of those working in the field they represent, and can impose penalties upon those who fail to live up to these standards. Given the breadth of both medical research and life science research, only a few of the most significant organisations in the European countries featured and China and the US can be mentioned here. The organisations mentioned here are described further in the relevant SATORI Country Reports.

Professional organisations for doctors, physicians, and other health care providers exist within all of the countries examined. These organisations publish codes of ethics that their members are expected to uphold in their work. The British Psychological Society, the Serbian Psychiatric Association, and the American Psychological Association are just a few examples. Often these professional organisations have their own group dedicated to bioethics. For example, the Polish Chamber of Physicians and Dentists has a Bioethics Centre, and the German Medical Association has a Department for Science, Research and Ethics. Outside of Europe, the Chinese Medical Association also has a branch dedicated to medical ethics (the Chinese Society of Medical Ethics) that has published a code of ethics for medical researchers and health care workers.

Professional organisations for practitioners of the life sciences are also common. Within the US has the American Veterinary Medical Association (AVMA) and the American Society for Biochemistry and Molecular Biology (ASBMB). Another example is the China Society for Environmental Sciences. Like their counterparts for doctors and health care workers, these organisations often produce codes of ethics and ethical guidelines for their members to follow. In Europe, such guidelines are often produced by independent organisations that have government support, such as the Dutch Central Committee on Animal Experimentation and the Animals in Science Committee in the UK. France has the Inter-professional Group of Research Reflection and Communication (GIRCOR) that includes representatives from organisations that conduct animal experimentation.


More generally, there are organisations for researchers in science and technology, both within Europe and in the US and China. Some examples are the National Association of Research and Technology in France, the Rathenau Instituut in the Netherlands and the China Association for Science and Technology (CAST).

National associations dedicated to bioethics are common within the countries examined. Examples include the Dutch Society for Bioethics, the Bioethical Society of Serbia, the Polish Bioethics Society, and the Public Responsibility in Medicine and Research (PRIM&R) organisation in the US. The UK also has the Scottish Council on Human Bioethics.

There are national organisations for institutional review boards and local ethics committees. Some examples are the Netherlands Association of Medical Ethical Reviewing Committees, the National Association of Research Ethics Committees in Spain, the Forum of the Austrian Ethics Committees, the National Conference for the Committees for the Protection of Persons in France, the Permanent Working Party of Research Ethics Committees in Germany, and the Association for Research Ethics (AiRE) in the UK. Outside of Europe, the China Association for Ethical Studies (CAES) is comprised of ethics researchers and practitioners. The US has several organisations devoted to training ethics assessors, such as the Health Care Compliance Association (HCCA) and the Society of Corporate Compliance and Ethics (SCCE).

Some of the organisations concerned with ethical assessment have international links with similar groups to foster collaboration between them. For example, technology assessment groups in Germany and Austria (along with Switzerland) are connected via the Technology Assessment (TA) Network of German-speaking countries. The 5TU group of universities that research the ethics of technology in China also has strong links with the similar 3TU group of universities in the Netherlands.

6 Evaluation

The ethical principles, issues and values within the field of medical and life sciences described in this report are broad and cover the whole field. Most of the issues are specific for this field or for experiments with human and animal test subjects, with the main focus being on physical and less on psychological harm. There are many other ethical issues that have particular significance within specific subfields. For example, discrimination is an issue in all fields, but in the case of genetic testing, it becomes particularly and can bring the risk of stigmatisation of ‘different’ people. Professional ethical values for research with human participants are similar to other fields.

There are multiple ethics committees, international, national, and regional, which evaluate and discuss the proposals for clinical trials that involve human participants. These committees will take ethics into account and give an advice about the proposed research. There are many international directives, regulations, guidelines, rules, standards, and laws for clinical trials within the field of medical and life sciences. Institutionalisation within the field of medical and life sciences is covered in all areas. The international or EU institutionalisation is the basis of national institutionalisations. Each country not only has its own RECs, but also their own specific guidelines and laws. The EU has taken a step forward in harmonising these
regulations this is taken in the EU with the Clinical Trials Regulation, which aims to ensure that the rules for conducting clinical trials are identical throughout the EU.

There are many rules for the design and safety of pharmacological experiments or trials of new medical devices, with an emphasis on cost-benefit analysis; much less attention is given to other ethical issues, such as human dignity. The focus in the regulations as well as in the control and inspection of experiments is based on safety and the benefits. This is similar to the HTA methodology used for new technologies in the medical and life sciences, which focuses less on ethical issues and more on cost-effectiveness and cost-benefit.
7 Annex 1 Key publications, journals and conference series

7.1 Key publications


7.2 Journals and book series

  - The leading journal in the field of bioethics, publishing original contributions that explore domestic and global ethical challenges in health care, medicine, public health, and the life sciences.

  - An international journal publishing articles that emphasise living organisms, like plants, animals, and human beings, as well as related considerations like bioethics.

  - American Medical Association’s MEDLINE-indexed ethics publication.

- BMC Medical Ethics - http://www.biomedcentral.com/bmcmedethics
  - Considers articles in relation to the ethical aspects of biomedical research and clinical practice, including professional choices and conduct, medical technologies, healthcare systems and health policies. Deutsches Ärzteblatt International - https://www.aerzteblatt.de/int
  - Official journal of the German Medical Association and the National Association of Statutory Health Insurance Physicians. Publishes peer-reviewed research in clinical medicine.

- Ethics & Medicine - https://www.ethicsandmedicine.com/
o An international journal of bioethics which has tackled difficult issues in bioethics from an international perspective since 1984.

- Indian Journal of Medical Ethics (IJME) - http://www.issuesinmedicalethics.org/index.php/ijme
  o A journal of the forum for medical ethics society since 1993.
  o Has been the flagship scholarly journal in bioethics and the philosophy of medicine. Its’ contributors and focus are international, addressing bioethical concerns across the world.
- Journal of Medical Ethics (JME) - http://jme.bmj.com/
  o A peer-reviewed academic journal in the field of bioethics established in 1975.
  o Aims to publish excellent quality peer-reviewed articles, reports, case notes, and essays in the field of medical law and ethics, since June 2013.
  o An international journal publishing articles that emphasise the molecular, cellular, and functional basis of therapy. The journal emphasises the understanding of mechanism that is relevant to all aspects of human disease and translation to patients.
- Life Sciences, Society, and Policy (LSSP) - http://www.lsspjournal.com/about
  o A peer-reviewed, open access journal devoted to fostering responsible innovation and sustainable development by providing an academic forum for engaged scholarship, interdisciplinary research, critical reflection, and informed discussion concerning the ethical, social, and legal dimensions of the life sciences, resulting in insights, tools and recommendations for civil society, policy, industry, and education.
- Philosophy, Ethics, and Humanities in Medicine (PEHM) - http://www.peh-med.com/
  o Considers articles on the philosophy of medicine and biology, and on ethical aspects of clinical practice and research.

- The Internet Journal of Law, Healthcare, and Ethics (IJLHE) - https://ispub.com/IJLHE
  o A multidisciplinary journal addressing current issues at the intersection of law, healthcare and ethics.
  o A journal of the American society of law, medicine, and ethics.

1.1 Conference series

- The MacLean Center annual interdisciplinary faculty seminar series (33rd in 2014-2015)
The MacLean Center has sponsored an annual seminar series that has examined the ethical aspects of one key health related issue each year, since 1981.

- Dorothy J. MacLean Fellows Conference - http://macleanethics.uchicago.edu/events/
  - The MacLean Center had hosted this conference on topics related to clinical medical ethics since 1989.

  - Provides an ongoing forum for teaching ethical principles and exploring ethical concepts.

- The annual Medical Ethics Conference - http://ethicscenter.nd.edu/programs/mec/
  - To bring together health-care professionals and world-renowned experts in medical ethics to discuss case studies that pose ethical dilemmas in various areas of clinical practice. (30th in 2015)

  - 15th in 2015.

- International Association of Bioethics World Congress - http://www.iab2016.com/
  - 13th in 2016.

- MU Center for Health Ethics October Conference - http://ethics.missouri.edu/

  - The aim of these joint meetings is to promote mutual interest, understanding, and dialogue between biologists, specialists from related disciplines, policy makers and members of the public interested in how modern biology affects society.

- CESAGEN, Cardiff University and Lancaster University - http://www.genomicsnetwork.ac.uk/cesagen/
  - This collaboration constitutes a joint conference series in medical ethics since 2010.

- International Conference on Data Integration in the Life Sciences - http://www.wikicfp.com/cfp/servlet/event.showcfp?eventid=34436&copyownerid=2
  - Aims at fostering discussion, exchange, and innovation in research and development in data integration and management for the life sciences. Researchers and professionals from biology, medicine, computer science and engineering are invited to share their knowledge and experience. Ethical, legal and social issues with biomedical data integration. (10th in 2014)
8 Annex 2 List of organisations

8.1 International and EU Organisations

- Association of Clinical Research Professionals (ACRP) http://www.acrpnnet.org/
  - The mission of ACRP is to provide global leadership to promote integrity and excellence for the clinical research profession. ACRP is the catalyst to bring the team together to educate and certify that clinical research professionals are effectively protecting human subjects and ethically performing clinical trials.

  - AGREE is an international collaboration of researchers and policy makers who work together to improve the quality and effectiveness of clinical practice guidelines by establishing a shared framework for their development, reporting and assessment.

- All European Academies (ALLEA) – EU http://www.aalea.org/Pages/ALL/19/228.bGFuZz1FTkc.html
  - Works on ethical issues in science, policy for science, science for policy, and quality assessment in research.

- Council for International Organisations of Medical Sciences (CIOMS) http://www.cioms.ch/
  - International ethical guidelines for biomedical research involving human subjects established jointly by WHO and UNESCO.

  - The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.

- European Network of Research Ethics Committees (EUREC) http://www.eurecnet.org/index.html
  - Brings together national Research Ethics Committees (REC) associations, networks or comparable initiatives on the European level.

- Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP) http://www.fercap-sidcer.org/
  - The Asian network for developing capacity in ethical review.

- Fogarty International Centre Bioethics Information and Resources http://www.fic.nih.gov/ResearchTopics/Pages/Bioethics.aspx
  - The Fogarty International Centre at the U.S. NIH supports and facilitates global health research conducted by U.S. and international investigators, builds partnerships between health research institutions in the U.S. and abroad, and aids in training the next generation of scientists to address global health needs.

- Global Forum for Bioethics in Research http://gfbroline.com/
  - A global collaborative project promoting discussion on major ethical issues in international research involving human subjects

Ethics assessment in medical and life sciences

- An independent body that examines and reports on ethical issues in biology and medicine.
  - Provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioural research.
- **Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)** [http://www.sidcer.org/](http://www.sidcer.org/)
  - The global network for establishing best practices in ethical review.
  - An inter-governmental organisation dedicated to contributing to peace and security in the world by promoting collaboration among nations through education, science, culture and communication in order to further universal respect for justice, for the rule of law and for the human rights and fundamental freedoms.
  - Consists of several databases including a database of ethics institutions, a database of experts in the field of ethics, a database of ethics teaching programs and a database of legislation, guidelines and regulations relating to ethics. GEObs is made accessible to all Member States of UNESCO as well as to the general public through the UNESCO website free of charge.
  - An inter-governmental organisation whose objective is the attainment by all peoples of the highest possible level of health.
- **WHO Research Ethics Review Committee (ERC)** [http://www.who.int/ethics/review-committee/en/](http://www.who.int/ethics/review-committee/en/)
  - Ensures that WHO only supports research of the highest ethical standards. The ERC reviews all research projects, involving human participants supported either financially or technically by WHO.
  - An independent confederation of Medical Associations from different countries representing physicians from all sectors, medical specialities and regions of the world.

### 8.2 National organisations

  - The Working Party is an association of research ethics committees that seeks to harmonise the work and assessment procedures of its members.
• Odwolawcza Komisja Bioetyczna (Appeal Bioethics Committee (ABC)) – Poland
  http://www.mz.gov.pl/rozwoj-i-inwestycje/nauka/komisje-bioetyczne/odowlawcza-komisje-bioetyczna
  o The ABC handles appeals to decisions issued by local bioethics committees that concern research involving human beings.
• Association for Research Ethics (AfRE) – United Kingdom
  o National association promoting research ethics in human subjects research and representing university research ethics committees.
• Bioetičko društvo Serbije (Bioethics Society of Serbia (BSS)) – Serbia
  http://wwwworld.med.bg.ac.rs/?sid=1363
  o Gathers citizens who are interested in ethical issues in the field of medicine, health care, population politics, animal welfare, food production, etc., to stimulate, help, and develop bioethics, bioethical education, and research.
• Comité de Bioética de España (Spanish Bioethics Committee (CBE/SBC)) – Spain
  http://www.comitedebioetica.es/
  o Collegiate, independent, and consultative professional body, which will develop its responsibilities, with full transparency on material related to the social and ethical implications of biomedicine and health sciences.
• Centrale Commissie Mensgebonden Onderzoek (Central Committee on Research Involving Human Subjects (CCMO)) – Netherlands
  http://www.ccmo.nl/en/review-procedure
  o Protection of subjects taking part in medical research by reviewing the research.
• Comité Consultatif National d’Éthique pour les sciences de la vie et de la santé (National Consultative Ethics Committee for health and life sciences (CCNE)) – France
  www.ccne-ethique.fr/
  o Deliver opinions on ethical and social issues raised by the progress of knowledge in the field of biology, medicine, and health.
• Conférence Nationale des Comités de Protection des Personnes (National Conference for the Committees for the Protection for persons (CNPC)) – France
  http://www.cnpcp.fr/
  o An association of research ethics committees.
• Valtakunnallinen sosiaali- ja terveysalan eettinen neuvottelukunta (National Advisory Board on Social Welfare and Health Care Ethics (ETENE)) – Finland
  http://www.etene.fi/en
  o It evaluates issues in health care and social care from the ethical point of view on principal level.
• Komisija Republike Slovenije za medicinskio etiko (Republic of Slovenia National Medical Ethics Committee (KME/NMEC)) – Slovenia
  http://www.kme-nmec.si/
  o Assessment of research proposals and clinical trials on medical issues related to research involving human beings.
• National Committee for Bioethics of the Republic of Serbia (NCB) – Serbia
  http://www.sanu.ac.rs/English/Bioethics/Bioethics.aspx
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.

- Det Etiske Rad (The Danish Council of Ethics (RAD)) – Denmark
  - The council shall work out of respect for humankind and future generation’s integrity, including respect for life and nature.
9  Annex 3  Case Studies of Subfields

Separate reports of case studies of specific disciplines and subfields in the medical and life sciences are written in the SATORI project. This includes:

- Gerontechnology
- Pharmaceutics
- Public Health
- Genetics
- Neurosciences and Neurotechnologies
- Biobanking

The reports will start with a basic description of each subfield following an elaboration on the more specific ethical issues and principles. Institutionalisation and important organisations for the disciplines will be described and listed with a description of the most important international frameworks and protocols. The reports of these cases studies can be found in the following sections (Annex 3.1-3.6).