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# **Does MBES need a Code of Ethics?**

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# What is ethics?

- Most people believe that they know what ethics is and understand its relevance for daily life.
- However, there is only poor common agreement about the real meaning of ethics.
- There is more agreement about what are unethical decisions, actions or judgements.
- However, avoidance of unethical decisions, actions or judgements is not sufficient for justification that this behaviour is ethical (and vice versa).

## Conclusion

The diversity of ethical viewpoints among individual members of a group (team, society) requires harmonization or even standardization in the basic understanding before ethically relevant actions are undertaken.

## Remark

The same statement is true for moral actions!

# Some definitions for ethics

## British (Oxford Concise Dictionary):

- *Moral* principles that govern a person's behaviour or the conducting of an activity.
- The branch of knowledge that deals with *moral* principles.

## British (Cambridge Dictionary)

- A system of accepted beliefs that control behaviour, especially such a system based on *morals*.
- The study of what is *morally* right and what is not.

## American (Merriam-Webster):

- The discipline dealing with what is good and bad and with *moral* duty and obligation.
- The principles of conduct governing an individual or a group.
- A set of *moral* issues or aspects (such as rightness).

## Conclusions

1. Even Dictionaries do not give only one definition. There are no identical definitions.
2. Those definitions underline a close (however unsharp) relation between *ethics* and *morals*.
3. Not mentioned are decisions, judgements, personal responsibility, ethical values etc.
4. Those (unsharp) definitions of ethics are applicable to different types of ethics.

# What is ETHICS and what is MORALS?

- **Ethics** (Greek: éthos) and **Morals** (lat: mos) are both used in the plural (in English language) and often regarded as synonyms, but there is some distinction in how they are used.
- **Ethics** describes the values, objectives and motivations which determine ethical behaviour.
- **Ethics** is not a duty but appeals to the willingness to take over responsibility for the respective decision, action or judgement.
- **Ethics** requires the weighing of different reasons and considerations against each other (in favour and against).
- **Morals** is usually expressed in rules or guidelines which shall be considered for ethical behaviour, sometimes called morals duties.
- **Morals** requires reasoning based on premises that finally should lead to a concluding argument.

## Summary:

Whereas **ethics** is related with values, objectives, motivation, and the willingness to take over responsibility for the outcome, is **morals** determined by rules and guidelines by which responsibility is restricted only to their correct execution, not for the outcome, i.e. **morals** is rather the acceptance of duties than the willingness to take over responsibility.

# What are moral duties?

**Moral duties** are norms that prescribe (more or less precisely) how one should act.

1. **Positive duties:** A duty that requires some form of (positive) action – e.g. the duty to help people in need.
2. **Negative duties:** A duty that just requires to refrain from or even to refuse to do certain actions – e.g. the duty not to inflict harm on others or the duty not to lie. One can fulfil negative duties “without lifting a finger”,  
e.g. by only being passive.
3. **Universal duties:** Duties which are owed to everyone.
4. **Special duties:** Duties that arise as a result of previous acts (e.g. after having signed a contract) or result from special relations to others (e.g. special duties to one’s children, family and friends).

## Some more questions about ethics

Question No. 1: Is there only ONE ethic?

Answer: NO!

Question No. 2: What is the number of different ethics?

Answer: That number is not really limited!

Question No. 3: Are there fundamental differences between those different ethics?

Answer: YES and NO

Question No. 4: Is there a BEST ethics for MBES?

Answer: Good question, but difficult to answer! I will give my answer!

# Some essential features of ethics as a discipline

**A first step to reach common understanding may be that ethics is the discipline that**

- helps to make **good (right)** or **bad (wrong)** decisions, actions or judgements
- is based on **ethical** values (problem: no clear definition, non-limited list)
- underlines the importance of (ethically correct) **decisions, judgements, and actions**
- is controlled by a set of (more or less standardized moral) **rules, duties and obligations**
- may be accepted as principles of **conduct** which are governing an individual or a group



# Ethics for MBES

## General agreement is required that ethics

- may be seen as a discipline that can not be isolated from morals, since it deals with moral acts
- must reflect more than what is demanded by law, customs and public opinion
- is much more than following only the guidelines for correct conduct and for good business practice by professionals
- needs awareness of the ethical dimensions of problems
- includes ethical dimensions that can not only be related to structures, institutions, or organizations
- is determined by ethical dimensions that are related to the individual decision-makers and their personal attitude, to their ethical convictions, and to their sense for responsibility

# Branches of Ethics

Ethics has its origin in philosophy with strong impacts on and interactions with culture, legislation, religion, science and practical life. This origin is still effective!

Five branches are usually identified as the most important derivatives of ethics:

- **Normative Ethics** Systematic investigation of moral standards (norms and values) with the aim to clarify how they are to be understood, justified, interpreted and applied on moral issues.
- **Moral Ethics** This branch is closely related to normative ethics. It questions how individuals develop their morality, why certain aspects of morality differ between cultures and why certain aspects of morality are generally universal. The philosopher Socrates was the first who has searched for universal definitions for moral virtues (more than 2000 years ago).
- **Applied Ethics** Applied ethics is also closely related to normative ethics. However, it focuses on the challenge and application of ethics in particular fields.
- **Descriptive Ethics** This branch is a more scientific approach that focuses on how human beings actually operate in the real world, rather than attempt to theorize about how they should operate.
- **Meta-Ethics** This rather young branch seeks to understand the nature of ethical properties, attitudes, statements and judgements. It discusses the nature of morality and the meaning of moral terms.

**Summary:** These different branches can exist in peaceful coexistence

# **MBES and its multidisciplinary character**

MBES is a multidisciplinary field reaching from basic sciences to many, however different applications.

It integrates physical, mathematical and life sciences and engineering principles both for the study of biology, medicine and health systems as well as for the advancement and application of technology with the aim to improve health and the quality of life.

It creates knowledge from the molecular to organ system levels.

It develops and applies materials, devices, and systems.

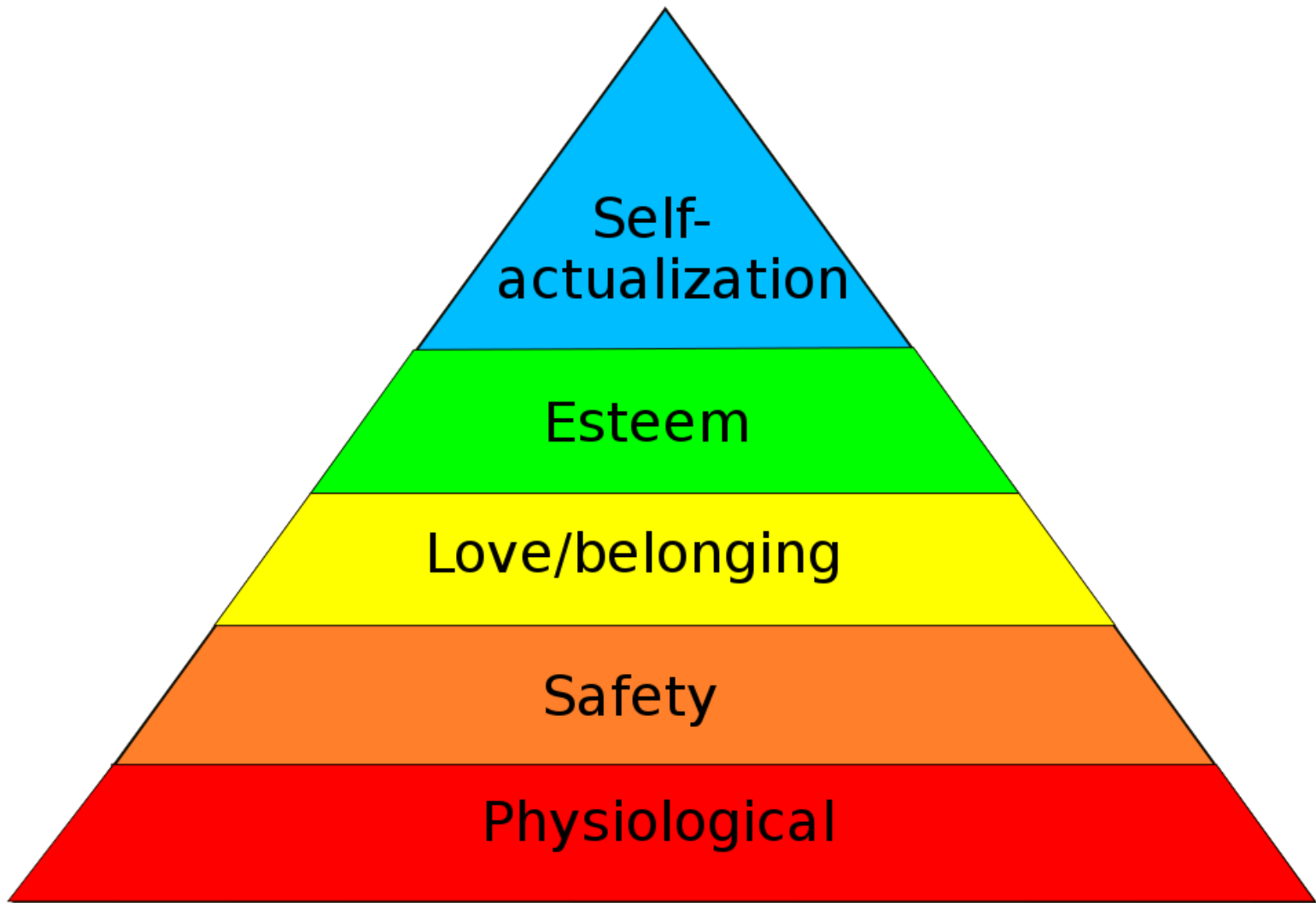
It develops methods for information processing, for health care management, for the evaluation of technology and technical equipment.

It supports medical people in the prevention, diagnosis and treatment of diseases.

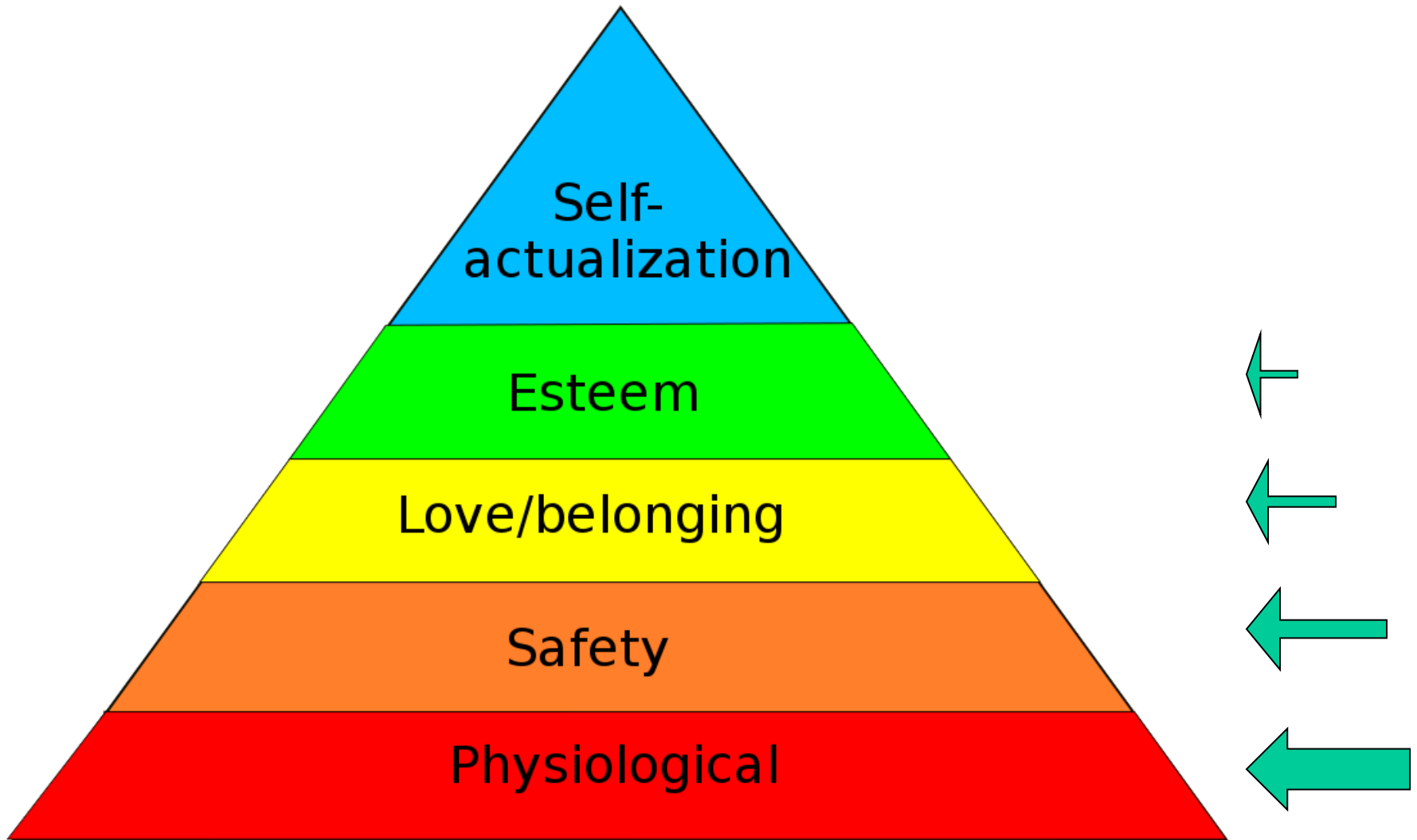
It collaborates with medical people in the provision of health care and rehabilitation.

## **Important**

The interrelation of MBES with human needs is primarily directed to basic needs like survival and safety, with increasing importance of life quality, e.g. love, mobility, social integration. This can be illustrated in the hierarchical presentation of human needs (Maslow 1943).



Maslow's hierarchy of needs, represented as a pyramid with the more basic needs at the bottom  
(proposed by Abraham Maslow in his 1943 paper "A Theory of Human Motivation")



The green arrows illustrate the strength of the interrelation of MBES with the respective need, thereby emphasizing the close relation of MBES with medicine

Maslow's hierarchy of needs, represented as a pyramid with the more basic needs at the bottom (proposed by Abraham Maslow in his 1943 paper "A Theory of Human Motivation")

# MBES ethics – a combination of normative and applied ethics?

Taking these and other aspects into account, a combination of normative and applied ethics seems to be optimal for a MBES ethics:

*Normative ethics* is the study of ethical frameworks. It is the attempt to develop guidelines that do not list ethical actions but may help to judge if an action is ethical according to a given system of principles. The Golden Rule is a classic example of a normative principle: We should do to others what we would want others to do to us.

*Applied ethics* considers the morality of specific actions in such fields as medicine, engineering, business and government. It is frequently seen as the application of normative ethics to particular issues of practical concern. Aspects of those particular issues have to be considered in guidelines for ethical behaviour.

# Types of ethics which are different by their core principles

**Personal ethics** is concerned with the ethical challenges regarding individuals

**Social ethics** is concerned with ethical challenges resulting from living in a society

**Virtue ethics** is derived from Aristotle's and Confucius's philosophical thoughts and based on those virtues which enable an individual to ethical behaviour

**Deontological ethics, duty ethics:** the rightness or wrongness of actions does not depend on their consequences but on whether they fulfill a duty. This duty is defined by Kant in the categorical imperative: **Act only according to that maxim by which you can also will that it would become a universal law.** However, there are slightly different derivatives:

- **categorical ethics** – **the duty must be followed without any exception**
- **imperative ethics** – **if the duty has been followed, the behaviour is ethically justified**

Deontological ethics are not looking for the outcome and the consequences. What about responsibility?

**Teleological ethics, value-based ethics:** An act is morally right if it promotes the good or what has value:

- **utilitarian ethics** is focused on maximising the results rather than on following rules and obligations
- **consequentialistic ethics** is striving to reach the best consequences

**Conclusions:** **Some of these ethics can be inconsistent or even conflicting with others!  
Such conflicts may result in ethical dilemmas!**

# Types of ethics which are focused on objectives

Ethics of conviction

**Ethics of responsibility**

Ethics of behaviour

Situative ethics

Ethics of sustainability

Ethics of future

Ethics of success

**Professional ethics**



# Some ethics that are focused on main disciplines or fields

Animal Ethics

**Bioethics**

**Biotechnoethics**

Business Ethics

Climate Ethics

Computer Ethics

**Engineering Ethics**

Environmental Ethics

Ethics in Psychology

**Ethics in the Natural Sciences**

Intergenerational Ethics

**Medical Ethics**

**Medical Informatics Ethics**

Organizational Ethics

**Technoethics**

Theological Ethics

**Question:** Are essential differences in the ethical principles between them?

## **Relations of MBES to discipline oriented ethics**

In order to avoid conflicting problems, MBES ethics should properly take into account its close relationship with

- Medical Ethics
- Engineering Ethics or Technoethics
- Ethics in the Natural Sciences
- Medical Informatics Ethics
- **Bioethics:** this is of special interest
- Biotechnoethics

# Medical Ethics

## Medical ethics is applied ethics:

- It presents a system of moral principles that apply values to the practice of clinical medicine as well as in scientific research.
- It is based on a set of values to which professionals can refer in case of any confusion or conflict.
- The values of **Medical Ethics** include the respect for autonomy, non-maleficence, beneficence, and justice, dignity, truthfulness, and honesty.
- The term “**Medical ethics**” was introduced by Thomas Percival (1803).

# Technoethics

The term „**Technoethics**“ was first be used in 1977 by the philosopher Mario Bunge who argued that the current state of technological progress was guided by ungrounded practices based both on limited empirical evidence and on trial-and-error learning. He recognized that "the technologist must be held not only technically but also morally responsible for whatever he designs or executes: not only should his artifacts be optimally efficient but, far from being harmful, they should be beneficial, and not only in the short run but also in the long term."

Today, **Technoethics** is applied ethics in relation to advanced technology. It involves the ethical aspects of technology within a society that is shaped by technology. This brings up a series of social and ethical questions regarding new technological advancements and new boundary crossing opportunities.

**Technoethics** provides a holistic umbrella for grounding all sub-areas of applied ethics focused on technology related areas of human activity including business, politics, globalization, health and medicine in research, development and application. It does not consider peculiarities of special fields of technology.

# Bioethics (I)

The term **Bioethics** (correct: **Bio-Ethik**) was introduced by Fritz Jahr (1926). Paraphrasing Immanuel Kant with the categorical imperative, Jahr suggested that all living beings were entitled to respect and should be treated not as means but as ends in themselves. This was called the “**Bio-ethical imperative**”. Jahr argued that a new ethical approach to issues concerning human beings and the environment should be practiced.

The present understanding of **Bioethics**:

**Bioethics** provides a disciplinary framework for the whole array of moral questions and issues surrounding the life sciences concerning human beings, animals, and nature.

**Bioethics** points to many novel complex cases, for example, gene technology, cloning, and human-animal chimeras and facilitates the public awareness for these particular problems.

**Bioethics** also focuses on the study of values in relation to primary care and other branches of medicine. The most important questions arise in the relationships among life sciences, biotechnology, medicine, politics, law and philosophy.

## Bioethics (II) – The Universal Declaration

The UNESCO stated in its “**Universal Declaration on Bioethics and Human Rights**“ (2005):

Convinced that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments.

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

The last paragraph seems to favour teleological ethics!

### **Conclusion:**

**Bioethics** may be the main entrance for MBES into the discussion about a MBES code of ethics!

# Biotechnoethics – a more recent approach to medical sciences and engineering

- Biotechnoethics is concerned with ethical dilemmas originating from the use of biotechnologies in fields including medical research, health care, and industrial applications.
- Topics such as
  - cloning ethics,
  - e-health ethics,
  - telemedicine ethics,
  - genetic ethics,
  - neuroethics,
  - sport and nutrition ethicsfall into this category.
- The debates of problems around such themes like euthanasia and reproductive rights are based on examples of specific relevance, not of general relevance.

# **Bioethics Commissions - National commissions**

Commissions for ethical problems and questions exist at the national level in every EU member state, in some countries already since 1974.

In Austria the Austrian Commission on Bioethics is primarily concerned with Bioethics.

In Germany bioethics is not a main topic for the Deutsche Ethikrat (German Ethics Council).

In Romania the respective institution is the Consiliul Național de Etică.

The Bioethics Commissions are composed mostly of biologists and ethicists. They shall serve to familiarize the public with new advances and to develop guidance on contentious issues like genetic engineering, human cloning and research on humans.

Up to now MBES ethics seems to be no subject of special interest for these national ethics or bioethics commissions.



# **Bioethics Commissions - Regional and local ethical committees in medicine**

The WHO has published guidelines for ethical committees in medicine.

A fundamental component for the work of such commissions is the Declaration of Helsinki.

In some countries regional and/or local commissions have been installed, usually under the name “Ethical Committees”, mainly by universities, medical faculties, hospitals, other clinical organisations like the Red Cross etc.

In different countries the installation of these commissions is regulated by law, e. g. in Austria and in Germany. In Germany the legal basis are the “Arzneimittelgesetz” (Law on medical drugs), and the “Medizinproduktegesetz” (Law on medical devices) in accordance with the respective EU regulation or directive on medical products.

The approval of such a Committee is mandatory not only for clinical studies with humans, but also for animal experiments and some more procedure, e.g. the application of ionizing radiation in until now not standardized and approved procedures or with new equipment.

Usually the membership composition of those committees is defined by the authorities. Experts in informatics must be considered if processing, management and security of medical data are concerned. Obviously, MBES experts are not mandatory even if MBES problems are concerned.

In Austria, several Ethical Committees have launched a forum on voluntary basis with the objective to harmonize the approval procedure. Critical problems are still the responsibility in multicentric studies, collaboration in transnational networks, and the cooperation with industrial companies as partners or sub-partners

# EU and ethics (I)

**1991:** The European Commission created an expert bioethics advisory body, now known as the European Group on Ethics in Science and New Technologies (EGE).

„The European Group on Ethics in Science and New Technologies (EGE) is an independent, multi-disciplinary body which advises on all aspects of Commission policies and legislation where ethical, societal and fundamental rights dimensions intersect with the development of science and new technologies.“

The EGE is situated at the boundary between law, bioethics, and economic policy. It plays an ambiguous role in the EU governance especially with regard to biotechnologies, e.g. the legitimacy of commercial cord blood banking and stem cell research.

It is frequently criticized that bioethics advisory groups, such as the EGE, may play a significant part in advising on the direction, value, and legitimacy of developments in science and technology. This is sometimes called „influencing by soft governance“.

## EU and ethics (II)

**2005:** Study: „Main Challenges in the Field of Ethics and Integrity in the EU Member States“. Result: This study provided a wealth of information on the state of public-service ethics.

The Ethics Framework for the Public Sector is a voluntary, non-legally binding European Code of Ethics. It reflects the basic common values and standards of conduct, which are considered important for the proper functioning of the public service. It helps to structure the discussion and can be used as a checklist or a general guideline in the development of national code(s) of ethics.

**2008:** The normative ethics of the European Union is criticized as an attempt how the EU's principles, actions and impact may be judged by using three major approaches to procedural normative ethics: virtue ethics, deontological ethics and consequentialistic ethics.

**2009:** „Ethics“ is discussed as a regulatory tool which can be used to determine what is right and wrong, good and bad, about the scientific developments and technological deployments of biomedicine.

It is emphasized that subsidiarity implies that ethical matters are reserved to the Member States, and the European Union cannot end up in a situation in which one of them can impose its ethical convictions on another; and it is not Europe's role to legislate on ethics.

**2014 – 2020 (Horizon 2020):** For all activities funded by the European Union, ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence.

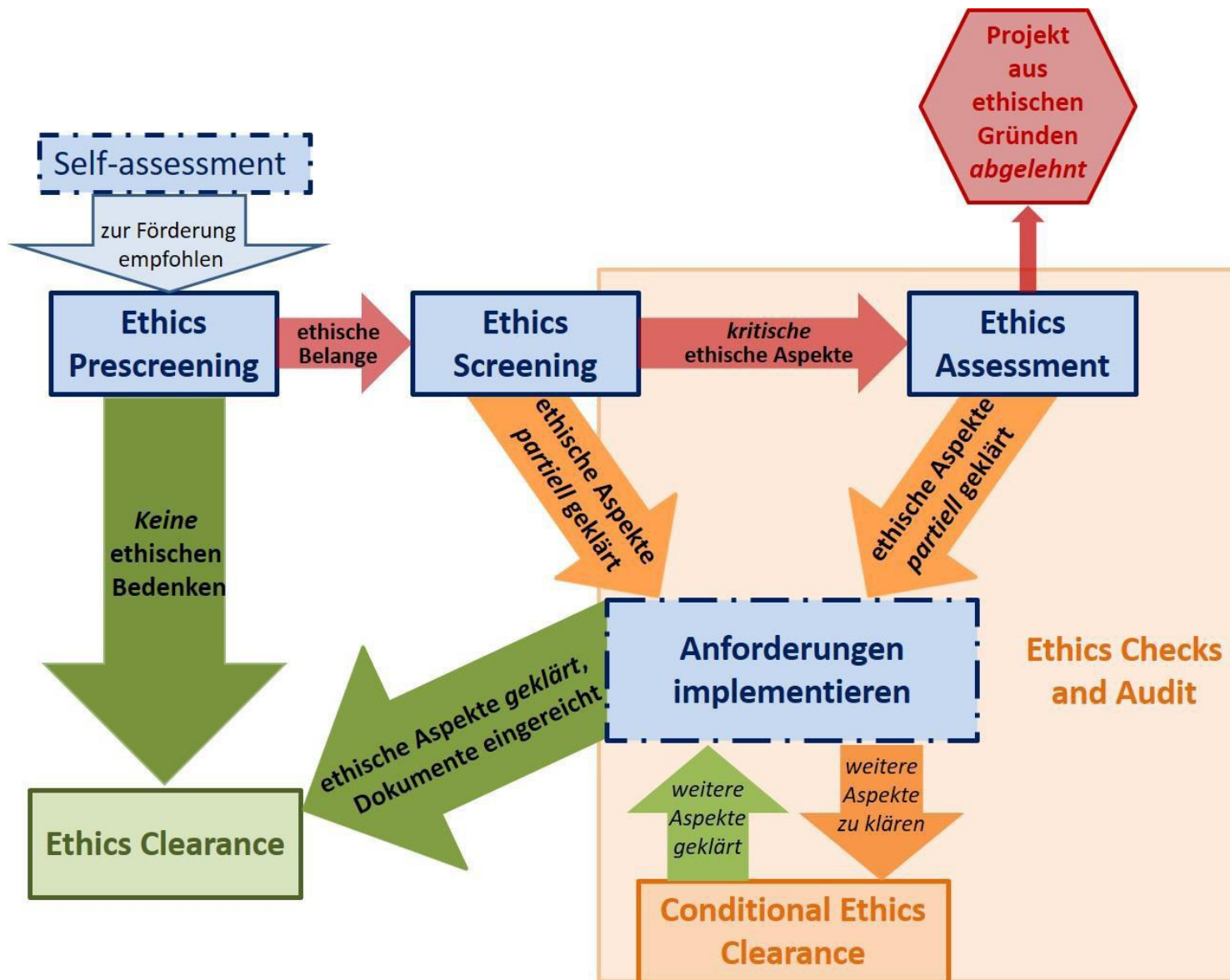
Ethics is given the highest priority in EU funded research: all the activities carried out under Horizon 2020 must comply with ethical principles and relevant national, EU and international legislation, for example the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights.

# EU and ethics – Main ethical principles

1. **Respecting human dignity and integrity**
2. **Ensuring honesty and transparency** towards research subjects and, notably, getting free and informed consent (as well as assent whenever relevant)
3. **Protecting vulnerable persons**
4. **Ensuring privacy and confidentiality**
5. **Promoting justice and inclusiveness**
6. **Minimising harm and maximising benefit**
7. **Sharing the benefits** with disadvantaged populations, especially if the research is being carried out in developing countries
8. **Maximising animal welfare**, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
9. **Respecting and protecting the environment and future generations**
10. **Following the highest standards of research integrity** (i.e. avoiding any kind of fabrication, falsification, plagiarism, unjustified double funding or other type of research misconduct)

## Ethics assessment procedure of projects under H2020

1. **Ethics Self-assessment** (by scientists upon application submission)
2. **Ethics Review** (prior to the finalisation of the Grant Agreement initiated by the EU Commission)
  - a. Ethics Pre-screening
  - b. Ethics Screening
  - c. Ethics Assessment
3. **Ethics Check and Ethics Audit**



nach Isidoros Karatzas, Vortrag 17. März 2016, Berlin

Ethics assessment – decision-making processes within the Grant Commission  
**Guidelines for ensuring compliance with ethical principles in Horizon 2020 – from proposal to Grant Agreement**

prepared by Working Group of European Research Administrators at German Universities (2017)

# UNESCO and bioethics

**1993:** The UNESCO Bioethics Programme was created.

This Bioethics Programme belongs to UNESCO's ethics of science and technology programme.

UNESCO claims a leading role in bioethics at the international level.

**1997:** The General Conference endorsed the Universal Declaration on the Human Genome and Human Rights. This is the only international instrument in the field of bioethics, which was endorsed by the United Nations General Assembly in 1998.

**2005:** The Universal Declaration on Bioethics and Human Rights was adopted by the General Conference.

UNESCO has installed two Bioethics Committees:

- the International Bioethics Committee, composed of 36 independent experts,
- the Intergovernmental Bioethics Committee, composed of representatives of 36 Member States.

UNESCO intends to foster both the national and the international debate on the major ethical issues arising from recent developments in the life sciences and their applications in order to work out ethical guidelines for the international community and Member States.

UNESCO supports national and regional capacity building by facilitating the establishment of networks of institutions and specialists concerned with bioethics, and encourages the establishment or strengthening of regional bioethics information and documentation centres.

UNESCO takes part in education and awareness raising of bioethics among specialists (researchers, jurists, journalists, etc.), decision-makers, the general public and specific target groups. At university level, the UNESCO Chairs in Bioethics facilitate regional cooperation between universities and UNESCO in bioethics education.

# Council of Europe and bioethics

Biological and medical research and developments in technology have produced spectacular advances in the health field. However, these advances raise ethical issues that affect the individual and the protection of the individual's rights and dignity (genetics, transplantation, biobanks, emerging technologies, etc).

Bioethics is primarily a multidisciplinary, pluralistic study of sciences and technologies in the biomedical field, which must take account of their constantly changing nature.

## Educational Fact Sheets

### **Making young people aware of bioethical issues through debate**

While scientific and technical developments in biology and medicine have brought progress, they often raise numerous ethical issues.

Central to these issues is the protection of human beings and their fundamental rights and freedoms. It is necessary to be able to distinguish between what is technically feasible and what is morally acceptable, and there are many views on the subject.

Scientific and technical developments are going to influence the future, and the whole of society is concerned. So it is important that young people, as future citizens, should be aware of the ethical issues raised by these developments and be fully involved in discussions on the subject, which form part integral of democratic debate.

# Bioethics in the USA

## US President's Commission

1991 US (President Clinton): The first commission for bioethics as advisory board was installed.

2001 US President's Council on Bioethics (President Bush: Bioethical issues that emerge as a consequence of advances in biomedical science and technology)

**2009** US President's Commission for the Study of Bioethical Issues (President Obama: „As our nation invests in science and innovation and pursues advances in biomedical research and health care, it's imperative that we do so in a responsible manner“.)

This Commission advises the President on bioethical issues that may emerge from advances in biomedicine and related areas of science and technology.

The Commission works with the goal of identifying and promoting policies and practices that ensure **scientific research, health care delivery, and technological innovation are conducted in an ethically responsible manner.**

## It may be taken into account:

**2016** Muzur A. in his „Book Review“ of „The Development of Bioethics in the United States“ by Garrett, J.R., Jotterand, F., Ralston, D.C. (eds.) makes clear:

„ . . . one can immediately observe the mixing up of terminology, so typical for the anglophone bioethical literature, confusing bioethics with medical ethics. In the tradition of European bioethics, bioethics has been viewed as ethics related to any aspect of life“

„ . . . is highly important for understanding the differences between American, European, and other sets of „bioethical“ principles.“

„Thus it is time for the rest of the world to claim its own study on the development of bioethics.“



# What is an ethical dilemma?

- is a situation or problem in which each available and possible course of action breaches some otherwise binding ethical principles so that it is difficult to decide what is ethical and what is unethical.
- can be caused by conflicting requirements from different types or branches of ethics, e.g. individual ethics versus social ethics. Is it unethical to spend a limited amount of money for preventive vaccination of some hundred children instead for the life-saving surgery of a single (and old) heart patient?
- may be what sometimes is called an ethical paradox in moral philosophy. This can occur when a decision has to be made between two possible moral imperatives, neither of which is unambiguously acceptable or preferable.
- may be related with the situation in which there is a choice to be made between two options, neither of which resolves the situation in an ethically acceptable fashion. In such cases, societal and personal ethical guidelines may not really be helpful for the chooser to find a satisfactory outcome.
- if a person has to choose between two options, both of which are morally correct but conflict with each other. Ethics and morals are inseparable since both deal with questions of right and wrong. What constitutes ethical behavior is determined by societal or cultural norms while what constitutes moral behavior is up to the individual to decide between right and wrong based on his own understanding of moral guidelines and moral obligations.

# Two types of ethics with high potential for ethical dilemmas

## Personal ethics versus social ethics

- personal ethics focuses on the rights (and obligations) of individuals

whereas

- social ethics emphasizes the superiority of common interests over the interest of individuals, especially with regard to values like living conditions, self-actualization, sharing of limited resources, and mutual tolerance.

This ethical dilemma will later on be demonstrated by the „ethics of future“ (Jonas).

# Some more ethics with potential for ethical dilemmas

Ethical theories of the normative type with a high potential for ethical dilemmas are:

- Utilitarian Ethics (Bentham, J., Mill, J.S.) is an ethical approach that maximizes the beneficial outcome, primarily for the greatest amount of people.
- Duty Ethics (or Deontological ethics) emphasizes the obligations that an individual has to society. Those obligations are formulated as an universal principle, i.e. the “Categorical Imperative” which was the centre of Kant's ethical theory based on duty. The duty ethics approach focuses on the rightness of actions and does not take into account the consequences or outcome. It only asks for the ethical motivation which causes the individual to act.
- Virtue Ethics highlights the role and virtues that the character of an individual shall contain in order to be able to determine or evaluate ethical behaviour in society. It does neither ask for consequences nor for motivation or obligations. This ethical branch is derived from thoughts of Confucius and of Aristotle. It should be mentioned, however, that the respective virtues have been changing with time.

## Ethical dilemma (example No. 1)

### The numerical relation, e.g. 3 : 1

3 patients are waiting for a live-saving organ transplantation, one for a heart, one for a lung, and one for a liver. Another patient delivered to hospital with a rather harmless problem with his eyes has exactly the tissue specifications which are required for these 3 patients who are waiting for organ transplantation.

If the organs for transplantation are taken from the eye patient, this patient will die, however three lives can be saved.

Is the correct ethical decision to save the live of those 3 patients by sacrificing the live of the 1 patient?

or

Is the correct ethical decision to let die those 3 patients and keep the 1 patient alive?

# Ethical dilemma (example No. 1)

## The 3 : 1 relation

The two questions are:

Is the correct ethical decision to save the lives of those 3 patients by sacrificing the life of the 1 patient?

or

Is the correct ethical decision to let die those 3 patients and keep the 1 patient alive?

The **utilitarian** ethics would answer YES to the first question.

The **consequentialist** ethics would answer YES to the second question.

The **deontological** ethics (**duty** ethics) does not give an answer since it does not take into account the consequences, but only whether a duty (which duty?) has to be fulfilled.

Also the **virtue** ethics does not help to make a correct ethical decision.

Neither the **individual** nor the **social** ethics are helpful for giving an ethically correct answer.

**Most important question, concerning the relevance of the numerical relation:**

**Can an ethical decision be made in dependence on the numerical relation, e.g. for the relation 3 : 1 be different from that for the relation 100 : 1?**

## Ethical dilemma (example No. 2)

### Ethical dilemmas caused by advancing technology

Hans Jonas in his book „Technik, Medizin und Ethik. Zur Praxis des Prinzips Verantwortung“ (1985) „*The imperative of responsibility - In search of ethics for the Technological Age*“ discussed ethical questions specific to the technological age in an effort to advance an ethics of technology. He compares the situation on the globe with that in an over-crowded boat on sea with only limited resources, i.e. food, water. If some people in the boat will have a chance for survival, they have to sacrifice other people, preferably the weakest from their group.

The ethic principle of this new ethics is:

"Act so that the effects of your action are compatible with the permanence of genuine human life"

His conclusion:

Ethics of the future demands

- that medicine does no longer take measures for the reduction of infant mortality and not for the prolongation of life expectancy
- **that medical technology does not develop devices for the reduction of infant mortality and for the prolongation of life expectancy.**

# Ethical dilemma (example No. 3) – The Oppenheimer Problem

## Oppenheimer, Julius Robert (1904 – 1967)

**Scientific director of the Manhattan Project, i.e. the development of the atomic bomb**

His explanation (1965) when asked why he has developed the atomic bomb that killed 1945 in Hiroshima („Little Boy“) and Nagasaki („Fat Man“) directly 126 000 people and another 100 000 people by long-term effects:

„However, it is my judgment in these things that when you see something that is **technically sweet**, you go ahead and do it and you argue about what to do about it only after you have had your technical success. That is the way it was with the atomic bomb.“

Question: **Was his decision an ethical decision?** What is your opinion?

Please consider that those killed people had been no soldiers but civil persons.

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Question: **Was his decision an ethical decision?**

What is your opinion? Please consider that those killed people had been no soldiers but civil persons.

**But please consider also that possibly the life of some 10 000 US soldiers and many civil persons could have been saved since those two bombs have enforced immediately the end of the war.**

**Makes this to change your mind?**



# Definition and meaning of „code“

„Code“ has several meanings.

Here the following meaning is used:

British (Cambridge English Dictionary):

- a set of principles that are accepted and used by society or a particular group of people:
  - a moral code
  - a code of ethics
- a set of rules that are accepted as general principles:
  - a code of behaviour
- a set of written rules that say how people in a particular organization should behave:
  - a code of conduct

American (Merriam Webster):

- a system of principles or rules
  - code of ethics
  - moral code
  - code of conduct

# What is a Code of Ethics?

## A Code of Ethics

- provides positive encouragement and awareness for ethical behaviour and practice.
- offers a helpful guidance for ethical decisions, judgements and actions.
- reveals clearly the core values on which it is based. This is important in cases of ethical dilemmas.
- is necessary but not sufficient for the prevention of unethical behaviour and practice.
- must be supported by ethical education, ethical culture and permanent improvement.
- demands the willingness of the respective individual or group to take over the responsibility for all consequences that result from ethical decisions, judgements and actions.
- is more than a code of conduct. A code of conduct is primarily a set of rules or guidelines outlining the social norms, legal aspects, religious rules, professional duties, organizational demands etc. An individual or a group that correctly follows those rules, however, does not take over responsibility for the outcome.

**Caution:** Within a society, different codes of ethics may be accepted by individuals, groups, organizations etc. with the risk for ethical dilemmas!

# Code of professional ethics – some Pros and Contras

## Pros

- codes of professional ethics help the professionals to enhance consciousness for specific ethical challenges by their discipline
- codes of professional ethics can make clear which expressions of ethical considerations are relevant for decision-making although they are no general recipes for decision-making and do not provide solutions to specific ethical problems
- codes of professional ethics should be understood as conventions within a professional community (see: Luegenbiehl, H.: Codes of Ethics and the Moral Education of Engineers (1983): „The adoption of a code is significant for the professionalization of an occupational group, because it is one of the external hallmarks testifying to the claim that the group recognizes an obligation to society that transcends mere economic self-interest.“)

## Contras

- a code of professional ethics may lead to confusion between ethics and law
- implementation of a code of professional ethics may be in conflict with the moral autonomy of individuals that is to be expected
- a code of ethics for professionals with special obligations which is separate from the ethics of ordinary human beings within a moral society is questionable and may create problems

**Question to you: Shall the MBES code of ethics contain components of a professional code?**

**My recommendation: YES, but any conflict with Contras must be avoided!**

# The Ethics Codes Collection (ECC)

- the ECC at the Illinois Institute of Technology is the largest database of codes of ethics and guidelines
- it contains over 2,500 individual codes from around 1,500 different organizations
- it collects both current and historical versions of these documents from around the world
- obviously a considerable number of those codes are rather codes of professional conduct than codes of professional ethics
- it contains only ONE ethics code for MBES: the Biomedical Engineering Society Code of Ethics (2004) from the US Biomedical Engineering Society:

## Preamble:

Biomedical engineering is a learned profession that combines expertise and responsibilities in engineering, science, technology, and medicine. Since public health and welfare are paramount considerations in each of these areas, biomedical engineers must uphold those principles of ethical conduct embodied in this Code in professional practice, research, patient care, and training. This Code reflects voluntary standards of professional and personal practice recommended for biomedical engineers.

# Hippokrates (460 – 370 BCE)

**The Hippocratic Oath is the earliest expression of medical ethics in the Western world, establishing several principles of medical ethics which remain of paramount significance today. These include the principles of medical confidentiality and non-maleficence.**

I swear by Apollo the Healer, by Asclepius, by Hygieia, by Panacea, and by all the gods and goddesses, making them my witnesses, that I will carry out, according to my ability and judgment, this oath and this indenture.

To hold my teacher in this art equal to my own parents; to make him partner in my livelihood; when he is in need of money to share mine with him; to consider his family as my own brothers, and to teach them this art, if they want to learn it, without fee or indenture; to impart precept, oral instruction, and all other instruction to my own sons, the sons of my teacher, and to indentured pupils who have taken the physician's oath, but to nobody else.

I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing. Neither will I administer a poison to anybody when asked to do so, nor will I suggest such a course. Similarly I will not give to a woman a pessary to cause abortion. But I will keep pure and holy both my life and my art. I will not use the knife, not even, verily, on sufferers from stone, but I will give place to such as are craftsmen therein.

Into whatsoever houses I enter, I will enter to help the sick, and I will abstain from all intentional wrong-doing and harm, especially from abusing the bodies of man or woman, bond or free.

And whatsoever I shall see or hear in the course of my profession, as well as outside my profession in my intercourse with men, if it be what should not be published abroad, I will never divulge, holding such things to be holy secrets.

Now if I carry out this oath, and break it not, may I gain for ever reputation among all men for my life and for my art; but if I break it and forswear myself, may the opposite befall me.

**Please pay attention: The dominating formulation is „I will“, and there is no „I shall not“**

# WMA Declaration of Geneva

(last version October 2017)

I solemnly pledge to dedicate my life to the service of humanity;

The health and well-being of my patient will be my first consideration;

I will respect the autonomy and dignity of my patient;

I will maintain the utmost respect for human life;

I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient;

I will respect the secrets that are confided in me, even after the patient has died;

I will practise my profession with conscience and dignity and in accordance with good medical practice;

I will foster the honour and noble traditions of the medical profession;

I will give to my teachers, colleagues, and students the respect and gratitude that is their due;

I will share my medical knowledge for the benefit of the patient and the advancement of healthcare;

I will attend to my own health, well-being, and abilities in order to provide care of the highest standard;

I will not use my medical knowledge to violate human rights and civil liberties, even under threat;

I make these promises solemnly, freely, and upon my honour.

# WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

(last version October 2013)

The Declaration of Geneva of the WMA binds the physician with the words, “**The health of my patient will be my first consideration**”, and the International Code of Medical Ethics declares that, “**A physician shall act in the patient’s best interest when providing medical care**”.

Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights. **While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.**

Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

The research protocol must be submitted for consideration, comment, guidance and approval to the concerned **research ethics committee** before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study’s findings and conclusions.

**Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting.**

# The Ten Commandments

**(The best known version of theological ethics, using both “Thou shalt” (3x) and “Thou shall not” (7x))**

I am the Lord God. Thou shalt have no other Gods before me.

Thou shalt not take the name of the Lord thy God in vain.

Thou shalt remember the sabbath day, to keep it holy.

Thou shalt honor thy father and thy mother.

Thou shalt not kill.

Thou shalt not commit adultery.

Thou shalt not steal.

Thou shalt not bear false witness against thy neighbour.

Thou shalt not covet thy neighbor's house.

Thou shalt not covet thy neighbor's wife, nor his manservant, nor his maidservant, nor his cattle, nor anything that is thy neighbor's.

**Please consider the essential difference in the meaning of „Thou shalt . . . „, and „Thou shalt not . . . „.**

**Thou shalt** (3x) is imperative, i.e. there is no other option, whereas **Thou shalt not** (7x) excludes one option, but renders possible (many) other options and thereby stresses the principle of personal responsibility!



# IEEE Code of Ethics

(Version of 2006)

We, the members of the IEEE, in recognition of the importance of our technologies in affecting the quality of life throughout the world, and in accepting a personal obligation to our profession, its members, and the communities we serve, do hereby commit ourselves to the highest ethical and professional conduct and agree:

1. to hold paramount the safety, health, and welfare of the public, to strive to comply with ethical design and sustainable development practices, and to disclose promptly factors that might endanger the public or the environment;
2. to be honest and realistic in stating claims or estimates based on available data;
3. to reject bribery in all its forms;
4. to improve the understanding by individuals and society of the capabilities and societal implications of conventional and emerging technologies, including intelligent systems;
5. to maintain and improve our technical competence and to undertake technological tasks for others only if qualified by training or experience, or after full disclosure of pertinent limitations
6. to seek, accept, and offer honest criticism of technical work, to acknowledge and correct errors, and to credit properly the contributions of others;
7. to treat fairly all persons and to not engage in acts of discrimination based on race, religion, gender, disability, age, national origin, sexual orientation, gender identity, or gender expression;
8. to avoid injuring others, their property, reputation, or employment by false or malicious action;
9. to avoid real or perceived conflicts of interest whenever possible, and to disclose them to affected parties when they do exist;
10. to assist colleagues and co-workers in their professional development and to support them in following this code of ethics.

# Transition of ethics in the last 40 years

## Timetable and milestones for the transition to post-modern ethics

### **Jonas, H.: The imperative of responsibility – taking into account the longterm consequences**

1979 Das Prinzip Verantwortung. Versuch einer Ethik für die technologische Zivilisation

(The Imperative of Responsibility - In Search of an Ethics for the Technological Age)

1985 Technik, Medizin und Ethik. Zur Praxis des Prinzips Verantwortung

(Engineering, Medicine and Ethics. Practical Application of the Imperative of Responsibility)

### **Küng, H.: There can be no new world order without a world ethic!**

1990 Projekt Weltethos (Global Responsibility: In Search of a New World Ethic – 1991)

1993 Towards a Global Ethic: An Initial Declaration (accepted by the Parliament of the World's Religions)

### **Bauman, Z.: Postmodern Ethics**

1993 The author emphasizes that morality conceived of as responsibility (to others) is opposed to the conception of morality as obedience to moral rules. He makes clear that moral responsibility is infinite and cannot be reduced to the fulfilment of a limited set of rules.

### **Croitor, E.: Ethics of responsibility? Some Postmodern Views**

2014 „Postmodern Ethics, . . . , give up discussing the call of ultimate moral principles, replacing the primacy of theoretical ethics with the empire of applied ethics and bioethics mainly.“

„Ethics of care is one of moral theories developed by postmodernity, with the central ethical value - care, and hence responsibility.“

# Hans Küng

## **Author „Global Responsibility. In Search of a New World Ethic” (1990)**

Küng points to the demand of changing ethics in order to follow the change from the modern to the post-modern phase with the new challenges. He presents the need in our post-modern and pluralist world for a minimum of common values, norms and attitudes, and for an ethic of responsibility, in the double sense of accountability and concern for the truly human.

He was one of the authors of a paper accepted by the United Nations: "Universal Declaration of Human Responsibilities", designed to underpin, reinforce and supplement human rights from an ethical angle. (September 1997)

**1998:** Since globalisation of the economy, technology, and the media also means globalisation of problems (from financial and labour markets to the environment and organised crime), also globalisation of ethics is needed: not a uniform ethical system, but a necessary minimum of shared ethical values, basic attitudes and standards.

**In the „Symposium on Global Ethic, Law and Policy“, Washington 2011 it was emphasized**

- that awareness of the ethical dimensions of urgent problems is needed,
- that these ethical dimensions do not only relate to structures and institutions, but also to the individual decision-makers and their personal attitude, ethical convictions and sense for responsibility
- there will be no survival of our globe without a global ethic

# Challenges for MBES ethics in the post-modern time

## General challenges

- globalisation
- digitisation

## Specific challenges

- big-data handling
- pre-natal diagnosis and therapy
- telemedicine
- e-health
- nanotechnology
- 3D-printing technology
- tissue and organ breeding (or engineering)
- personalized medicine
- knowledge-based therapy management
- model-based process control and optimization
- medical robotics
- roboter-assisted surgery
- autonomous (intelligent) devices and systems

# **Preliminary Draft of a code of ethics for MBES**

## **Overview**

### **Preamble**

- 1. Definition of MBES**
- 2. Multidisciplinary Challenge**
- 3. Awareness**
- 4. Risk assessment**
- 5. Technical Standards**
- 6. What shall be taken into account**
- 7. General remark**

### **Competence**

### **Responsibility**

### **Commitments 1 & 2**

### **Commandments**

# **Preamble (1) - Field Definition**

Medical and Biological Engineering and Science (MBES) integrate physical, mathematical and life sciences and engineering principles for the study of biology, medicine and health systems and for the application of technology to improve health and the quality of life.

It creates knowledge from the molecular to organ system levels, develops materials, devices, systems, information approaches, technology and health care management, methods for the evaluation of technology, for the prevention, diagnosis and treatment of disease, for the provision of health care and for patient care and rehabilitation.

## **Preamble (2) - Multidisciplinary Challenge**

MBES is a multidisciplinary field with strong relations to many other fields, especially to engineering disciplines based on different technologies, to medical disciplines including nursing and health care management, to natural sciences from basic research to applications, to mathematical sciences including informatics, and to law.

Effective cooperation with specialists in those fields requires a fundamental understanding of the respective particularities and sufficient knowledge about the considered problem.

## Preamble (3) - Awareness

MBES scientists and engineers must be aware that scientific progress and engineering have the potential to violate human rights and the right of animals, to irreversibly damage the nature, and to disturb social harmony.

They should be familiar with

- the Universal Declaration on Bioethics and Human Rights (first proclaimed by the United Nations in 1948, most recent version from 2005)
- the Declaration of Helsinki (published by the World Medical Association, last version from 2013)
- the Universal Declaration of Animal Rights (UNESCO 1978)
- the Rio Declaration on Environment and Development (United Nations 1992)



## **Preamble (4) - Risk Assessment**

MBES scientists and engineers should recognize the paramount relevance of the precautionary principle first endorsed by the United Nations (1982).

„Where potential adverse effects are not fully understood, the activities should not proceed.“

This statement clearly defines their responsibility.

They should be familiar with technology assessment, risk assessment, and with risk management.

## **Preamble (5) - Technical Standards**

MBES scientists and engineers should know that technical standards (published as formal documents by domestic, national or international bodies) are generally accepted formulations which represent the technical knowledge and expertise available at the time when they had been formulated.

Standards do neither represent the technological progress and the extension of knowledge and expertise which have been reached since that time nor the actual state of science.

The primary aim of standards is to establish uniform engineering or technical criteria, methods, processes and practices.

## **Preamble (6): What shall additionally be taken into account**

For effective cooperation with experts in other fields the respective field-special ethical code should be properly taken into account, e.g.

- the Declaration of Geneva (Physician's Oath), adopted by the World Medical Association (WMA)
- the Operational Guidelines for Ethic Committees that review Biomedical Research, adopted by the World Health Organization (WHO)
- international, domestic, and interdisciplinary codes of ethics since until now natural sciences and technology professions do not have global codes of ethics
- the request of the International Council for Science (ICSU) concerning the „scientific responsibility and accountability to society“. Special attention should be paid to sustainable development, and to the protection of human and animal rights.
- codes for professional ethics like the ICN Code of Ethics for Nurses, first adopted in 1953, or the IMIA Code of Ethics for Health Information Professionals (2005)

## **Preamble (7) - General Remark**

This code of ethics for MBES is not a code of conduct, i. e. it is not a set of written guidelines for professionals how to behave in certain situations.

It shall be an aid for making ethics-based decisions between „right“ and „wrong“, but also in cases of ethical dilemmas to recognize „superior right“ against „less right“.

MBES scientists and engineers shall be aware of their personal responsibility for those decisions and their consequences.

# Competence

MBES requires a high level of competence, with special regard to

- professional competence
- methodological competence
- communicative competence
- personal competence
- social competence

# Responsibility

- for making decision, initiating or starting actions, omission of necessary actions or refusal to provide required and possible assistance;
- for receiving the decision-relevant information from other collaborating team members and for providing complete MBES relevant information including warning and risk assessment to other collaborating team members;
- for continuous learning and training taking into account the rapid progress in scientific, medical, technological, methodological, ecological and legal knowledge;
- for considering all relevant technical standards and Good Practice Guidelines, e.g. Guidelines for Quality assurance, and Guidelines for the Quality of Medicine and Healthcare;
- for avoiding conflicting interests that may concern professional ethical or moral principles, especially conflicts with
  - personal interests
  - economic interests
  - scientific interests
  - political interests
- for acknowledging the own responsibility and for taking the necessary consequences and measures if errors have occurred, including the reporting to the appropriate professional bodies and/or – if relevant – to public authorities.

# Commitments (1)

MBES ethics is an individual's ethics as well as a professional's obligations

- to respect
  - the society
  - the public welfare
  - the dignity, safety, health and well-being of all individual human members
  - the vulnerability and multi-diversity of the ecological system
- to be aware that sustainable development is the leading engineering challenge
  - of meeting human needs for natural resources, industrial products, energy, food, transportation
  - of conserving and protecting environmental quality
  - of avoiding waste and demolition of natural resources
  - of providing liveable conditions for coming generations
- to be guided in scientific work
  - by scepticism against unproven hypotheses
  - by rejection of results which are acquired by non-scientific methods
  - by indifferent and fair evaluation of results from competing groups

# Commitments (2)

MBES ethics is an individual's ethics as well as a professional's obligation

- to contribute to research activities
  - by employing morally undisputed methods
  - by thoroughly assessing the potential of advanced, emerging and new technologies
  - by strictly rejecting participation in tests with patients or animals without clear motivation and morally acceptable aim
- to support developmental work
  - by the strongest effort to consider all relevant technical standards and safety aspects
  - by the generation of a design that excludes misuse or non-intended applications
- to apply only equipment that fulfills all relevant requirements and safety conditions
- to make available own knowledge, experience and skills in order
  - to solve urgent problems
  - to reach important results
  - to consider all relevant aspects of sustainability
  - to develop high-quality devices, equipment, and methods



# Commandments

BMES scientists and engineers shall not

- participate in unethical activities or in actions that are not controlled by moral principles
- be affected in their decisions by individual features, e.g. ethnic, national, political, religious or gender aspects
- be motivated by considerations that are not helpful to reach the agreed objectives
- be unable to recognize, articulate, or consider the ethical consequences of their decisions and activities
- allow sympathy, empathy or other personal feelings to gain control over rational arguments
- permit the misuse of their specific knowledge and expertise in collaborative research, development and application
- oppress in conflicting cases deliberations and discussions based on moral justification or refuse to take part in such discussions with experts
- refuse to consider or accept evidence-based conclusions
- reveal confidential information, especially when personal, medical or clinical data or sensitive information about individuals are concerned
- undertake or support actions that damage the reputation of the MBES profession

**With „BMES scientists and engineers shall not“ the fundamental principle of personal responsibility with the possibility to make „positive“ decisions shall be emphasized!**

# Summary and Conclusions

**Does Medical and Biological Engineering need a code of ethics?**

**YES**

**Which branch of ethics shall be used?**

**Applied ethics**

**Shall it be a code of ethics for professionals?**

**Yes, however avoiding any conflicts with the relevant aspects of general ethics, laws and customs.**

**What is the most important aspect of this code?**

**Enhancement of personal responsibility**

**How shall this be reached?**

**By clearly formulated commitments and commandments**

**How shall this code be established?**

**By organisations like EAMBES after thorough discussion**

**Is this an urgent problem?**

**My personal conviction: YES**

**I thank you very much for your kind attention and hope  
for critical and stimulating discussion**

**I am happy to inform that the**

**European Alliance for Medical and Biological  
Engineering and Science (EAMBES)**

**has accepted with date of March 11, 2019  
the submitted proposal for a Code of Ethics as**

**EAMBES Code of Ethics**

<http://eambes.org/Activities/5-Documents>

# List of ancient legal codes in chronological order

(Wikipedia)

- Code of Urukagina (2,380-2,360 BC)
- Cuneiform law (2,350-1,400 BC)
- Code of Ur-Nammu, king of Ur (c. 2050 BC)
- Laws of Eshnunna (c. 1930 BC)
- Codex of Lipit-Ishtar of Isin (c. 1870 BC)
- Babylonian laws / Code of Hammurabi (c. 1790 BC)
- Hittite laws (c. 1650–1100 BC)
- Code of the Nersisim (c. 1650-1500 BC)
- Law of Moses / Torah (10th-6th century BC)
- Assyrian laws / Code of the Assura (c. 1075 BC)
- Draconian constitution (7th century BC)
- Gortyn code (5th century BC)
- Twelve Tables of Roman Law (451 BC)
- Edicts of Ashoka of Buddhist Law (269-236 BC)
- Law of Manu / Hinduism (c. 200 BC)
- Corpus Juris Civilis (Justinian code) (529 to 534 AD)
- Sharia or Islamic Law (c. 570)

Nearly all of the oldest (known) codes are from the Near or Middle Eastern region (Mesopotamia)

# Bioethics at the Council of Europe

Since the end of the Second World War, biomedical research has resulted in major advances in areas such as the transplantation of organs, procreation, genetics and cell therapy.

The Nuremberg Code and the Helsinki Declaration laid the foundations for the principles to be applied to biomedical research. Intense discussions arose in many countries, then at international level, on the ethical principles that should apply to biomedical activities, whether in day-to-day medicine, research or new technologies.

In 1985, with the Parliamentary Assembly providing the impetus, bioethics was included among the Council of Europe's activities. The aim of this new work was to establish a framework for the protection of human beings and to promote scientific progress for the benefit of humankind.

In 1992, the Steering Committee on Bioethics (CDBI) was established. Its mission is to study ethical problems, in particular the challenges for human rights, raised by progress in the biomedical sciences, and to frame legal instruments to deal with such problems.

In 1997, the first international legally binding instrument in the field, the Convention on Human Rights and Biomedicine (Oviedo Convention, ETS No. 164), was adopted. It established a legal framework for the protection of rights applying both to day-to-day medicine and to new technologies in human biology and medicine.

In 2012, the CDBI became the Committee on Bioethics (DH-BIO) and is now directly attached to the Steering Committee for Human Rights (CDDH). Its tasks are still to assess new ethical and legal issues in the ever-changing field of biomedical science and technologies, such as those relating to genetics and biobanks, to develop the principles enshrined in the Convention on Human Rights and Biomedicine in specific fields and to help to raise awareness about its principles and facilitate their implementation.