European Deontological Guidelines

Medical Research and Therapeutic Tests

European Council of Medical Orders
Conseil Européen des Ordres des Médecins

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Working Group on Deontological Guidelines

San Remo November 27 2015
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• PLAN

• Ethical texts dealing with this question

• Study on convergence of normative texts on this issue (deontological codes, codes of conduct)

• Deontological recommendation proposal
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I – Ethical texts
A basis for thinking about and elaborating deontological texts

I – The Oviedo Convention (April 4, 1997)

Treaty open to ratification by Member States and Non-Member States whom participated to its elaboration and by the European Union, possible membership by third Non-Member States. Ratified by 29 States.

II – The Helsinki Declaration (June 1964/Last revision in 2013)
111 countries

III – The European Charter of Medical Ethics (Kos June 2011)
17 countries
I – The Oviedo Convention


Article 2 – Primacy of the human being:
The interests and welfare of the human being shall prevail over the sole interest of society or science.

Spain: 59-2: El bien del ser humano que participe en una investigación biomédica, debe prevalecer sobre los intereses de la sociedad y de la ciencia.

Portugal: 76a: O bem do indivíduo deve prevalecer sobre os interesses da ciência e da comunidade;

Switzerland: Human being’s health and well-being prevail over science and society interests (Law on research on the human being, article 4).
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II – WMA Helsinki Declaration – Ethics principles applicable to medical research involving human beings (June 64/Amended in 2013)

Preamble: “… A statement of ethical principles for medical research involving human subjects…”

Integrity of the human being

Respect of legal and regulatory norms

Scientific consensus

Risk assessment

Strong markers

Special protection of underrepresented groups of population

Ethics Committee

Conflict of interests

Consent of the patient

Placebo,

Publication of the results
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II – WMA Helsinki Declaration – Ethics principles applicable to medical research involving human beings (June 64/Amended in 2013)

Germany: (Muster-)Berufsordnung für die in Deutschland tätigen Ärztinnen §15-3

Austria: Ärztlicher Verhaltenskodex (Code of medical conduct) §4

France: Comments in the Code de déontologie Art.15

Ireland: Guide to Professional Conduct and Ethics for Registered Medical Practitioners art.53-1

Czech Republic: The Code of Ethics §2 (last paragraph)

United Kingdom: Good Medical Practice (GMP) → Good practice in research (GPR) §8

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III – European Charter of Medical Ethics (Kos, 10 juin 2011)

Principle 6
The physician uses his professional knowledge to improve or maintain the health of those confiding in him, at their request; he may not act to their detriment under any circumstances.

Principle 9
Health protection goes with constant striving to maintain the person's integrity.

Principle 11
The physician acting as a simple practitioner towards a patient, or as an expert or member of an institution, must ensure the greatest transparency in what might appear to be a conflict of interest and act in full moral and technical independence.
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- Main deontological entries in normative texts of CEOM Member States (codes, guidelines, etc.)

1- Specific article on Research and Testing on Human Beings

2- Respect of the person’s integrity/dignity/Respect of the Human Being

3- Mention of the WMA Helsinki Declaration

4- Research carried out only in the conditions provided by law

5- Ethics Committee

6- Benefits > to estimated risks / No other alternatives

Markers

7- Incapable adult; minor

8- Conflicts of interest

9- Consent

10- Publication of the results
<table>
<thead>
<tr>
<th>Country</th>
<th>1 Article</th>
<th>2 Dignity/Integrity</th>
<th>3 Helsinki</th>
<th>4 Law enforcement</th>
<th>5 Ethics Committee</th>
<th>6 Benefit &gt; Risk</th>
<th>7 Uncapable Adult/Minor</th>
<th>8 Conflicts of interest</th>
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Nbre d'items par Code

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Complementary Remarks : Form

- Only one code out of 16 does not include a specific provision on medical research.
- Texts are either: "all-embracing" and short:
  - Germany, (1 article: n°15)  ➔  Helsinki Declaration
  - Austria, (1 article: n°4)  ➔  Law, Helsinki Declaration
  - France, (1 article: n°15)  ➔  Law, Helsinki Declaration
  - Greece (1 article: n°4)  ➔  Ad hoc legal framework
  - Czech Rep., (last paragraph §2)  ➔  Helsinki Declaration and Nuremberg Code

  either: "detailed":
  - Romania: 1 chapter (art. 40 to 47)
  - Switzerland: 10 articles

  or: "specialized": United Kingdom (Good Practice in Research)
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Complementary remarks: Content

Example: "Incapable adult, minor"

- **Luxembourg: art. 77**: Testing on a healthy subject is permitted if the subject is an adult able to freely give his/her consent.

- **Belgium: art. 90**: Testing on the healthy man is admissible only if the subject is an adult, able to freely give consent, which is not the case of a prisoner, and in medical surveillance conditions likely to face any complication.

- **Portugal : art.78-4**: Testing is forbidden on individuals deprived of freedom.

- **Slovénie : art.49**: In no case is it permissible to use new pedagogical, professional or other methods exclusively with the intention of acquiring scientific data on mentally retarded persons, children, prisoners, dying patients or persons who are in any way subordinate to the researchers.
29. When a person deemed incapable to freely give consent is able to give his/her assent regarding his/her participation in medical research, the doctor must seek that assent in addition to the consent of his/her legal representative. The refusal of a person who may potentially be involved in research should be respected.

- Free and informed consent can be considered as « active » and the result of the person’s autonomy of will.

- « Passive » assent rather indicates « support » to a proposal that has been explained and understood. The person does not oppose it.
Drafting proposals:

1. Refer to approved international texts on this topic.

2. Consider the convergence of existing codes and common items.

3. Capitalize on CEOM works, and refer to already adopted deontological guideline: Informed consent

Deontological guideline being reviewed: Conflict of interest
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Deontological Recommendation Proposal

Given the Oviedo Convention, art. 2
Given the WMA Helsinki Declaration
Given the European Charter of Medical Ethics, principles 6, 9, and 11,
CEOM participants recommend:

The physician involved in medical research must, in compliance with the laws of his/her country, ensure that:

- There is no conflict of interest with the project initiator,

- Research has been the subject of a protocol duly examined by an independent ethics committee protocol,

- There is no other alternative technique to bring into play than research on the Human Being.

- Expected benefits outweigh the risks incurred by the person undergoing research.
Deontological Recommendation Proposal

- Free and informed consent was obtained in the manner of the European Deontological Recommendation on informed consent.

- Medical research involving persons physically or mentally incapable of giving consent can only be conducted in the manner of the Helsinki Declaration.

- The assent of an incapable person must always be sought in addition to the consent of his/her legal representative,

- The physician agrees to publish exhaustively the research results and to make them publicly available.