COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No. R (90) 3

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES

CONCERNING MEDICAL RESEARCH ON HUMAN BEINGS[1]

(Adopted by the Committee of Ministers on 6 February 1990 at the 433rd meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.*b* of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members, in particular by the adoption of minimum common rules on matters of common interest;

Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms, in particular its Articles 2.1, 3 and 8; to Article 7 of the United Nations International Covenant on Civil and Political Rights; to the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment; to Recommendation 874 (1979) of the Parliamentary Assembly of the Council of Europe on a European Charter on the Rights of the Child; to Recommendation No. R (83) 2 of the Committee of Ministers concerning the legal protection of persons suffering from mental disorder placed as involuntary patients, and to the Declaration of Helsinki, adopted at the 18th World Medical Assembly (1964) and amended by the 29th Assembly in Tokyo (1975), the 35th Assembly in Venice (1983) and the 41st Assembly in Hong Kong (1989), concerning recommendations guiding physicians in biomedical research involving human subjects;

Being aware of the fact that the advancement of medical science and practice is dependent on knowledge and discovery which necessitate, as a last resort, experimentation on human beings;

Being convinced that medical research should never be carried out contrary to human dignity;

Considering the paramount concern to be the protection of the person undergoing medical research;

Considering that particular protection should be given to certain groups of persons;

Considering that every person has a right to accept or to refuse to undergo medical research and that no one should be forced to undergo it;

Considering that medical research on human beings should take into account ethical principles, and should also be subject to legal provisions;

Realising that in member states existing legal provisions are either divergent or insufficient in this field;

Noting the wish and the need to harmonise legislation,

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1. When this recommendation was adopted, the Representative of the Federal Republic of Germany, in application of Article 10.2.*c* of the Rules of Procedure for the meetings of the Ministers' Deputies, reserved the right of his Government to comply with it or not.

Recommends the governments of member states:

a. to adopt legislation in conformity with the principles appended to this recommendation, or to take any other measures in order to ensure their implementation;

b. to ensure that the provisions so adopted are brought to the knowledge of all persons concerned.

Principles concerning medical research on human beings

Scope and definition

For the purpose of application of these principles, medical research means any trial and experimentation carried out on human beings, the purpose of which or one of the purposes of which is to increase medical knowledge.

Principle 1

Any medical research must be carried out within the framework of a scientific plan and in accordance with the following principles.

Principle 2

1. In medical research the interests and well-being of the person undergoing medical research must always prevail over the interests of science and society.

2. The risks incurred by a person undergoing medical research must be kept to a minimum. The risks should not be disproportionate to the benefits to that person or the importance of the aims pursued by the research.

Principle 3

1. No medical research may be carried out without the informed, free, express and specific consent of the person undergoing it. Such consent may be freely withdrawn at any phase of the research and the person undergoing the research should be informed, before being included in it, of his right to withdraw his consent.

2. The person who is to undergo medical research should be given information on the purpose of the research and the methodology of the experimentation. He should also be informed of the foreseeable risks and inconveniences to him of the proposed research. This information should be sufficiently clear and suitably adapted to enable consent to be given or refused in full knowledge of the relevant facts.

3. The provisions of this principle should apply also to a legal representative and to a legally incapacitated person having the capacity of understanding, in the situations described in Principles 4 and 5.

Principle 4

A legally incapacitated person may only undergo medical research where authorised by Principle 5 and if his legal representative, or an authority or an individual authorised or designated under his national law, consents. If the legally incapacitated person is capable of understanding, his consent is also required and no research may be undertaken if he does not give his consent.

Principle 5

1. A legally incapacitated person may not undergo medical research unless it is expected to produce a direct and significant benefit to his health.

2. However, by way of exception, national law may authorise research involving a legally incapacitated person which is not of direct benefit to his health when that person offers no objection, provided that the research is to the benefit of persons in the same category and that the same scientific results cannot be obtained by research on persons who do not belong to this category.

Principle 6

Pregnant or nursing women may not undergo medical research where their health and/or that of the child would not benefit directly unless this research is aimed at benefiting other women and children who are in the same position and the same scientific results cannot be obtained by research on women who are not pregnant or nursing.

Principle 7

Persons deprived of liberty may not undergo medical research unless it is expected to produce a direct and significant benefit to their health.

Principle 8

In an emergency situation, notwithstanding Principle 3, where a patient is unable to give a prior consent, medical research can be carried out only when the following conditions are fulfilled:

— the research must have been planned to be carried out in the emergency in question;

— the systematic research plan must have been approved by an ethics committee;

— the research must be intended for the direct health benefit of the patient.

Principle 9

Any information of a personal nature obtained during medical research should be treated as confidential.

Principle 10

Medical research may not be carried out unless satisfactory evidence as to its safety for the person undergoing research is furnished.

Principle 11

Medical research that is not in accordance with scientific criteria in its design and cannot answer the questions posed is unacceptable even if the way it is to be carried out poses no risk to the person undergoing research.

Principle 12

1. Medical research must be carried out under the responsibility of a doctor or a person who exercises full clinical responsibility and who possesses appropriate knowledge and qualifications to meet any clinical contingency.

2. The responsible doctor or other person referred to in the preceding paragraph should enjoy full professional independence and should have the power to stop the research at any time.

Principle 13

1. Potential subjects of medical research should not be offered any inducement which compromises free consent. Persons undergoing medical research should not gain any financial benefit. However, expenses and any financial loss may be refunded and in appropriate cases a modest allowance may be given for any inconvenience inherent in the medical research.

2. If the person undergoing research is legally incapacitated, his legal representatives should not receive any form of remuneration whatever, except for the refund of their expenses.

Principle 14

1. Persons undergoing medical research and/or their dependants should be compensated for injury and loss caused by the medical research.

2. Where there is no existing system providing compensation for the persons concerned, states should ensure that sufficient guarantees for such compensation are provided.

3. Terms and conditions which exclude or limit, in advance, compensation to the victim should be considered to be null and void.

Principle 15

All proposed medical research plans should be the subject of an ethical examination by an independent and multidisciplinary committee.

Principle 16

Any medical research which is:

— unplanned, or

— contrary to any of the preceding principles, or

— in any other way contrary to ethics or law, or

— not in accordance with scientific methods in its design and cannot answer the questions posed

should be prohibited or, if it has already begun, stopped or revised, even if it poses no risk to the person(s) undergoing the research.