DECLARATION OF HELSINKI 1989

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WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Recommendations guiding physicians
in biomedical research involving human subjects
Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964
and amended by the
29th World Medical Assembly, Tokyo, Japan, October 1975
35th World Medical Assembly, Venice, Italy, October 1983
41st World Medical Assembly, Hong Kong, September 1989
INTRODUCTION
It is the mission of the physician to safeguard the health of the people. His or her knowledge and
conscience are dedicated to the fulfillment of this mission.
The Declaration of Geneva of the World Medical Association 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 on
patient’s interest when providing
medical care which might have the effect of weakening the physical and mental condition of the
patient.”

The purpose of biomedical research involving human subjects must be to improve diagnostic,
therapeutic and prophylactic procedures and the understanding of the aetiology and
pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve
hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation
involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between
medical research in which the aim is essentially diagnostic or therapeutic for a patient, and
medical research, the essential object of which is purely scientific and without implying direct
diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment,
and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to
further scientific knowledge and to help suffering humanity, the World Medical Association
has prepared the following recommendations as a guide to every physician in biomedical
research involving human subjects. They should be kept under review in the future. It must be
stressed that the standards as drafted are only a guide to physicians all over the world.

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Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of
their own countries.

I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted
scientific principles and should be based on adequately performed laboratory and animal
experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects
should be clearly formulated in an experimental protocol which should be transmitted for
consideration, comment and guidance to a specially appointed committee independent of
the investigator and the sponsor provided that this independent committee is in
conformity with the laws and regulations of the country in which the research experiment
is performed.
3. Biomedical research involving human subjects should be conducted only by scientifically
qualified persons and under the supervision of a clinically competent medical person. The
responsibility for the human subject must always rest with a medically qualified person
and never rest on the subject of the research, even though the subject has given his or her
consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless
the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by
careful assessment of predictable risks in comparison with foreseeable benefits to the
subject or to others. Concern for the interests of the subject must always prevail over the
interests of science and society.
6. The right of the research subject to safeguard his or her integrity must always be
respected. Every precaution should be taken to respect the privacy of the subject and to
minimize the impact of the study on the subject’s physical and

mental integrity and on the
personality of the subject.
7. Physicians should abstain from engaging in research projects involving human subjects
unless they are satisfied that the hazards involved are believed to be predictable.
Physicians should cease any investigation if the hazards are found to outweigh the
potential benefits.
8 In publication of the results of his or her research, the physician is obliged to preserve the
accuracy of the results. Reports of experimentation not in accordance with the principles
laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of
the aims, methods, anticipated benefits and potential hazards of the study and the
discomfort it may entail. He or she should be informed that he or she is at liberty to
abstain from participation in the study and that he or she is free to withdraw his or her
consent to participation at any time. The physician should then obtain the subject's
freely-given informed consent, preferably in writing.
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10. When obtaining informed consent for the research project the physician should be
particularly cautious if the subject is in a dependent relationship to him or her or may
consent under duress. In that case the informed consent should be obtained by a physician
who is not engaged in the investigation and who is completely independent of this official
relationship.
11. In case of legal incompetence, informed consent should be obtained from the legal
guardian in accordance with national legislation. Where physical or mental incapacity
makes it impossible to obtain informed consent, or when the subject is a minor,
permission from the responsible relative replaces that of the subject

in accordance with
national legislation.
Whenever the minor child is in fact able to give a consent, the minor's consent must be
obtained in addition to the consent of the minor's legal guardian.
12. The research protocol should always contain a statement of the ethical considerations
involved and should indicate that the principles enunciated in the present Declaration are
complied with.
II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical Research)
1. In the treatment of the sick person, the physician must be free to use a new diagnostic and
therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing
health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed
against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient – including those of a control group, if any – should be
assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the
physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons
for this proposal should be stated in the experimental protocol for transmission to the
independent committee (I, 2).
6. The physician can combine medical research with professional care, the objective being
the acquisition of new medical knowledge, only to the extent that medical research is
justified by its potential diagnostic or therapeutic value for the patient.
III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-Clinical Biomedical Research)
1. In the purely scientific application of medical research carried out on a human being, it is

the duty of the physician to remain the protector of the life and health of that person on
whom biomedical research is being carried out.
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2. The subjects should be volunteers – either healthy persons or patients for whom the
experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or
their judgment it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over
considerations related to the wellbeing of the subject.
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