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COMMITTEE ON HUMAN EXPERIMENTATION RECORDS	
ACCESSION NO.	AR 86-23
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FOLDER NAME	Comm. Human Experiment: Reports, corresp., memos,
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January 11, 1965

MEMORANDUM #65-1

TO: All Deans of United States and Canadian Medical Schools

FROM: Dr. George A. Wolf, Jr.

SUBJECT: Draft for an AAMC Code of Ethics on Human Experimentation

Enclosed for your consideration is the draft of an AAMC Code of Ethics on Human Experimentation as developed by the Executive Council.

This document will be presented to the Institutional Membership for discussion and possible adoption at the next meeting, February 6, 1965.

Encl. Draft

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GUIDELINES FOR EXPERIMENTS INVOLVING HUMAN SUBJECTS

The Executive Council of the Association of American Medical Colleges has prepared the following statement to be discussed by every member institution, looking forward to the possible development of a formal policy statement.

These "Guidelines" are presented as one approach to a group of difficult problems which can be resolved only in each individual instance. However, the institutional members of the AAMC are properly concerned that the ethics relating to human experimentation be examined and that appropriate principles guide the conduct of such experiments. It is hoped that such a set of "Guidelines" may allow the parent institution to aid the individual investigator more effectively in properly discharging what must ultimately be a personal responsibility. By doing so, the merits of well conducted human experiments will continue to be available through widespread understanding of the issues involved in the use of humans in an experimental setting.

* * * *

The maintenance of health and the prevention, diagnosis and treatment of disease are based on knowledge of the interaction between that complex living system called man and the total environment of which he is a part. This knowledge is presently grossly inadequate to meet human health needs, although it is rapidly increasing. In order to be able to continue to improve the health of man, it is necessary both to teach effectively our existing knowledge and to extend knowledge through continuing research.

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There are characteristics that define man as distinct from all other species. Because of these differences, man's reaction to his internal and external environment is unique to him. Where these human reactions are to be studied definitively, they must be studied ultimately in man himself.

Research and teaching in human biology and in medicine require the observation of man's reaction to changes in his external and internal environment. Where these changes are either initiated or guided for the purposes of the scientific observer, or where the nature of the observation requires added stress or trauma to the subject, the effort may be said to be experimental.

Experiments have outcomes of widely varying and erratic degrees of certainty. The less certain the outcome or the more threatening the experimental procedure, the greater is the ethical responsibility of the scientific investigator to justify the participation of a human subject. The following principles are fundamental to the fulfillment of this ethical responsibility:

1. The nature and degree of risk or stress to the human subject must be defined as accurately as possible and the experiment designed to minimize the possible risks to the subject.
2. The investigator must provide in advance for the over-all care of any foreseeable adverse reactions of the subject to the experiment, both during the procedure and following it. This requires the participation of professionals competent to care for the health of humans and the availability of facilities necessary for them to render their services.

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3. The decision to utilize a human subject in an experiment must be based on the necessity for observing the unique reactions of the human species. The fullest practicable knowledge of the reactions of suitable animals to the experiment is a prerequisite to making such a decision.

4. The conduct of an experiment utilizing a human subject solely for the purposes of education must be planned without any foreseeable harm to the subject and under circumstances where the subject himself may terminate the experiment at will.

5. The conduct of an experiment utilizing a human subject for the purposes of research is appropriate under the following conditions:

a. The knowledge to be gained is of potential benefit to human health.

b. The subject has sufficient understanding of the nature of the experiment -- its purposes and its probable risks to him -- to allow a reasoned choice on his part as to whether or not he chooses to participate. If because of age or mental state or other circumstances the subject should not or legally cannot make a free and reasoned choice to participate in an experiment, then the investigator is responsible for obtaining written permission from the person, agency and/or court authorized to act for such a subject.

Beyond this, it is the responsibility of the investigator to determine that the subject's choice is truly voluntary and

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c. Neither death nor any permanent disability of the human subject may be a foreseeable outcome of the experimental design. In those rare circumstances where the potential benefit to human health justifies such a hazardous experiment, a volunteer may be allowed to accept the experimental risk only if he has a complete knowledge and full understanding of the risk and has freely and without any persuasion or coercion determined that he wishes to expose himself to that risk.

d. The scientific investigator shall be an experienced and competent professional working in an environment which allows the systematic collection of accurate data from the experiment that will have a high scientific validity.

e. All decisions to utilize human subjects in experiments as well as the experimental design itself should be reviewed by two or more scientific peers of the investigator as well as the responsible administrator of the unit in which the experiment is undertaken. These scientific peers should not be directly involved in the experiment themselves but should be expert in the problems of experimentation using human subjects.

The traditional obligation of the physician to the welfare of his patient is unaltered by their meeting in an experimental setting.

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