

Policy
2/2/52

MEDICAL BOARD DOCUMENT NO. 1

Organization, Functions and Authority of
the Medical Board of the Clinical Center

1. FUNCTION

The Medical Board is responsible for developing policies governing standards of medical care in the Clinical Center.

2. AUTHORITY OF THE MEDICAL BOARD

All actions of the Medical Board are advisory to the Director of the National Institutes of Health. When approved by the Director of the National Institutes of Health, policies developed by the Board are operating policies of the Clinical Center.

Findings and actions of the Medical Board are reported to the Director of the National Institutes of Health by the Director of the Clinical Center. The Chairman of the Medical Board may discuss directly with the Director of the National Institutes of Health any matter relating to the Board and its activities.

3. MEMBERSHIP AND OFFICERS OF THE MEDICAL BOARD

(a) Membership

The Director of the National Institutes of Health names the members of the Medical Board, who are selected as follows:

1. A representative of each Institute nominated by the Institute Director.
2. The Director of the Clinical Center.
3. The Chief of Professional Services of the Clinical Center.
4. Three members selected from a panel nominated by the Institute representatives on the Board.
5. Three members selected from a panel nominated by the Director of the Clinical Center.

All of the members of the Board except the Director of the Clinical Center shall be entitled to vote.

November 17, 1953

GROUP CONSIDERATION OF CLINICAL RESEARCH
PROCEDURES DEVIATING FROM ACCEPTED
MEDICAL PRACTICE OR INVOLVING UNUSUAL HAZARD*

It is the policy of the National Institutes of Health to place primary responsibility for the formulation and conduct of clinical research and medical care on the principal investigators designated by each Institute Director, in conformity with standards and principles of legal, ethical and administrative propriety established by the Director of the National Institutes of Health.

In order to assist the principal investigator in making determinations with respect to research projects and medical procedures which may involve deviation from accepted medical practice or potential hazard to the life or well-being of the patient or subject admitted to the Clinical Center, the following statement of responsibility is provided as guidance, and methods for obtaining group consideration and advice are established.

It will not be necessary to present each project for evaluation of its medical, scientific and ethical propriety to any single central group, but any unestablished, nonstandard or unusually hazardous procedure shall receive appropriate group consideration before it is undertaken.

I. Basic Responsibility

1. Patient Care Responsibility

Only properly qualified physicians or dentists may assume responsibility for clinical diagnosis, investigation and care. All others associated with the project are subject to the authority of the responsible physician or dentist, and the physician or dentist assumes responsibility for such personnel.

2. Project Formulation

It is recognized that every medical procedure is modified or adapted to accommodate the individual patient. It also contains some element of risk. Determination as to which medical procedures shall be considered as not being established or as involving unusual hazard shall be on an individual basis, in the light of total experience developed in well recognized institutions accepted by the profession for the excellence of

*Approved by Director, NIH

their staff in conduction medical care and research. Published reports of techniques or procedures used elsewhere in clinical investigation without known deleterious effect to the subject will not, of themselves, relieve the investigator from responsibility for submitting for group consideration his plans to use the same or similar methods.

Two distinct types of hazard are recognized: (a) jeopardy to the life or relative state of well-being of the research subject, either a person suffering from disease whether considered curable or incurable, or a normal volunteer subject; (b) jeopardy to the subject's chances for cure of his illness or alleviation of his symptoms, occaisioned by withholding or delaying the application of established therapeutic procedures.

In the development of any clinical study involving procedures deviating from accepted medical practice or involving unusual hazard, the principal investigator shall indicate, as prescribed by the Director of his Institute, such contemplated procedures, referring to the literature and his own and others' experience. He shall indicate the necessity and basis for his proposed research, noting pertinent laboratory, animal and other human research and, insofar as possible, the potential hazard to the patient or subject.

3. Public Health Service Personnel

Self-experimentation and use of Public Health Service personnel as subjects in clinical investigation are prohibited, unless prior written consent is granted by the Director of the National Institutes of Health.

II. Group Consideration and Review

1 Institute Committees

Each Institute Director and the Director of the Clinical Center shall establish a committtee or other mechanism to review and make recommendations to him concerning clincial projects proposed by his staff that involve unusual hazard. The review shall include evaluation of the necessity and rationale of any such procedure, all significant questions concerning medical or ethical propriety of the procedure, availability of personnel or facilities to reduce hazard, and other issues requiring experienced group judgment. The committee shall recommend (1) approval with or without modification, (2) disapproval, or (3) referral to the Medical Board.

In general this review is expected to settle such matters without further referral. The principal or senior investigator, who is responsible

for project formulation and eventual conduct of the research, may through channels request his Institute Director to seek further advice or guidance from the Medical Board.

2. Medical Board Committee

The Medical Board shall establish a Clinical Research Committee to serve as an expert review body to advise on problems concerning clinical research involving procedures deviating from accepted medical practice or unusual hazard referred to it by the Director of the National Institutes of Health, institute or clinical directors, or the Director of the Clinical Center. The Committee is authorized to enlist additional assistance on an ad hoc basis from among colleagues, intramural and extramural, consultants and others who may have greater experience and competence in relation to a given problem.

This committee will investigate the scientific and ethical propriety, and provide group consideration, before the institution of any procedure about which such questions have been raised. Recommendations of this Committee will be submitted through the Medical Board to the institute concerned and to the Director, National Institutes of Health, for his information or advice.

3. Public Health Service Policy Committee

A small standing policy committee for the Public Health Service, composed of representatives of the National Institutes of Health and other bureaus, will develop a set of guides and principles relative to human research and serve as a general review body and staff for the Surgeon General. Special problems of major significance which should receive Service-wide consideration or which impinge on general policy may be submitted to this group, by the Director of the National Institutes of Health, institute or clinical directors, or the Director of the Clinical Center.

III. Principals Governing Physician-Patient Relationship

1. Rules of Conduct

Rules of conduct promulgated by the appropriate national professional organization to govern the relationship between the professional man and his patient shall be observed by staff of the National Institutes of Health.

2. Information for Patient

The patient or subject of clinical study shall be considered a member of the research team and shall be afforded an understanding suited to his comprehension of the investigation contemplated, including particularly any potential danger to him.

Each prospective patient will be given an oral explanation in terms suited to his comprehension, supplemented by general written information or other appropriate means, of his role as a patient in the Clinical Center, the nature of the proposed investigation and particularly any potential danger to him.

After admission, the patient shall receive information in keeping with the development of a sound physician-patient relationship.

3. Patient Understanding and Agreement

a. Standard consent or agreement forms shall be used for surgery, anesthesia, photography and other procedures where they are ordinarily required and for permission to disclose clinical findings, records or other personal information.

b. Similarly, standard forms pertaining to post-mortem examination and disposal of body or limbs shall be used to record permission for such procedures given by responsible next of kin or legal representative.

c. Voluntary agreement based on informed understanding shall be obtained from the patient and, when appropriate, from responsible next of kin when the approved investigation includes procedures which deviate from accepted medical practice. In all such cases, a notation shall be made on the patient's chart of the essential points of the explanation and of the agreement obtained, together with any comment or problems raised by the patient. When, in the opinion of the responsible physician or of the advisory groups noted above, a procedure involves an unusual hazard, the proposed procedure shall not be undertaken until the patient has voluntarily signed a statement, entered on the patient's chart or as a separate memorandum, indicating his understanding of the procedure and its purpose, including potential hazards to him, and his willingness to participate.

4. Responsibility

The physician in charge of the patient shall be finally responsible for providing information to the patient, referring physician and next of kin and for obtaining voluntary agreement from the patient, guardian next of kin or others, as required, for the procedures described above.

He shall be responsible for incorporating in the medical record the information given the patient and the nature of the informed consent or agreement accomplished with the patient, including any comments, objections or general reactions made by the patient.