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DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
Washington, DC 20310

OTSG Regulation
No. 15-2

1 March 1976

Boards, Commissions and Committees
HUMAN SUBJECTS RESEARCH REVIEW BOARD

1. REFERENCES.

a. DOD Instruction 5030.29, 12 May 1964, "Investigational Use of Drugs by the Department of Defense."

b. DOD Instruction 6000.4, 7 April 1971, "Clinical Investigation Program."

c. Army Regulation 70-25, 31 July 1974, "Use of Volunteers as Subjects of Research."

d. US Army Medical Research and Development Command Regulation 70-25, 8 October 1975, "Use of Human Subjects in Research, Development, Test and Evaluation."

e. Army Regulation 40-7, 4 April 1975, "Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Substances."

f. Army Regulation 40-38, 23 February 1973, "Clinical Investigation Program."

g. DA Message, 151530Z July 1975, "Interim Change to AR 40-38."

h. DA Message, 122044Z September 1975, "Interim Change to AR 40-38."

2. PURPOSE. This regulation establishes the Human Subjects Research Review Board (herein called the "Board") as required by paragraph 7, AR 40-38 (reference 1g) and establishes procedures to be followed upon receipt of requests for approval of The Surgeon General for the participation of human subjects in biomedical and behavioral research, development, test or evaluation activities, including hospital clinical investigation projects, conducted within or funded by the Department of the Army.

*This regulation supersedes OTSG Regulation 70-4, 7 December 1972, and OTSG Memorandum 15-4, 2 April 1974.

3. BOARD RESPONSIBILITIES. The Board is the principal body of the Office of The Surgeon General (OTSG) for assessment of practices and procedures by which the US Army employs human subjects in research, development, test and evaluation activities, including but not limited to clinical investigation activities. The Board will consider and recommend policy to The Surgeon General to maintain the quality of practices consistent with contemporary moral, ethical and legal standards. The Board will consider the following types of research protocols involving human subjects and make recommendations on them for approval/disapproval to The Surgeon General.

a. The Board will act as the Army Investigational Drug Review Board on investigational drug proposals submitted under provisions of AR 40-7 and DOD Instruction 5030.29 (reference 1a and 1e).

b. The Board will review hospital clinical investigation protocols requiring Board review under provisions of AR 40-38.

c. The Board will review protocols submitted under provisions of AR 70-25 (reference 1c) at the request of the Assistant Surgeon General for Research and Development.

4. BOARD MEMBERSHIP. The Board will consist of the following members appointed by The Surgeon General:

a. Voting Members.

(1) The Assistant Surgeon General for Research and Development (ASG/R&D) or his designee as Chairman.

(2) Chief, Human Use Review Office, Office of The Surgeon General.

(3) At least three other members who are physicians and qualified to evaluate research proposals. At least one of these members should be a Board certified specialist in surgery and another in internal medicine.

(4) The Pharmacy Consultant, Directorate of Health Care Operations.

(5) Two members professionally qualified in the behavioral or allied medical sciences.

(6) A Chaplain or other member of the Clergy.

(7) Judge Advocate, US Army Medical Research and Development Command.

(8) Another member qualified to evaluate the acceptability of research proposals in terms of community attitudes.

b. Non-voting Members.

(1) Investigational Drug Review Officer, Army Investigational Drug Review Board or another officer of the Human Use Review Office who acts as recorder.

(2) Principal Investigator(s) may be invited to attend meetings of the Board at the discretion of the Chairman.

c. Alternates. Two alternates will be designated for each member to insure adequate representation at Board meetings if the voting members are unable to attend. Voting members will nominate their alternates for approval by the Board Chairman. Alternates will be encouraged to attend Board meetings along with the permanent members to gain familiarity with Board policies and procedures.

d. Consultants. The Chairman or the Chief of the Human Use Review Office may request verbal or written consultation on medical-scientific or ethical-legal matters from qualified military or civilian specialists.

e. Ad Hoc Subcommittees. The Chairman may appoint subcommittees of the Board to consider special issues or special types of research protocols and make recommendations to the entire Board. Subcommittees may consist of permanent or alternate members but at least one member of each subcommittee must be a permanent voting Board member.

5. PROCEDURES.

a. Initial Protocol Review. Upon receipt of an application for approval of The Surgeon General to use humans as research subjects, whether or not use of an investigational drug is proposed, the application will be sent to HQDA (DASG-RD-HR) WASH DC 20314. Applications for use of investigational drugs submitted under provisions of AR 40-7 will be reviewed by the Investigational Drug Review Officer, Army Investigational Drug Review Board. Other proposals will be appropriately processed by other Human Use Review Office personnel. Protocols will be sent to consultants for review if this seems appropriate to the Chief, Human Use Review Office or the Board Chairman. The Human Use Review Office will request clarification or comments from protocol authors when they are required for further processing.

b. Board Meetings. When Board review of a protocol is required by Army regulation, the Human Use Review Office will forward copies to Board members for review prior to the meetings. The Chairman will set the time of the meeting, and the Human Use Review Office will make necessary arrangements for them.

c. Voting on Board Recommendations. A Board decision will be based on a simple majority vote of members present. Quorum will consist of nine voting members or alternates of which at least three must be permanent voting members. An opinion from the Judge Advocate or his representative will be required before a formal Board decision can be made. This opinion may be submitted to the Board in writing if the legal representative is unable to attend. Dissenting opinions will be presented along with Board recommendations which will be incorporated into minutes of the meeting for presentation to The Surgeon General.

d. Approval of Board Recommendations. The Surgeon General or his designee will indicate, in writing, his approval, in whole or in part, or his disapproval of the recommendations of the Board as stated in the minutes.

e. OTSG Approval of Low Risk Clinical Investigation Protocols Previously Approved by Medical Center Committees Under Provisions of AR 40-38. Clinical Investigation Protocols involving human subjects in low risk studies, which neither involve investigational drugs nor otherwise require formal Board approval under provisions of AR 40-38, may ordinarily be approved by the Chief, Human Use Review Office under the direction of the Assistant Surgeon General for Research and Development. Examples of low risk studies are those involving the following procedures:

(1) Analysis of hair and nail clippings collected in a nondisfiguring manner and the analysis of deciduous teeth.

(2) Collection and analysis of excreta and external secretions including feces, urine, sweat, saliva, cerumen and tears or swab culture specimens of body orifices.

(3) Recording of data by physical sensors applied either superficially or at a distance and which do not involve significant input of energy into the subject. Such procedures include, but are not necessarily limited to weighing, electrocardiography, electroencephalography, echocardiography, electromyography and detection of naturally occurring radioactivity.

(4) Collection for analysis of blood samples by venipuncture, in amounts not exceeding 450 ml in a six week period, from subjects 18 years of age and over who are not anemic..

(5) Studies involving generally accepted, medically indicated diagnostic or therapeutic procedures or comparisons of two or more generally accepted alternate procedures.

Such studies may be approved only after it has been determined that the protocol contains adequate provisions for obtaining the free, informed, voluntary consent of the subjects and that the protocol has been approved by a properly constituted hospital Clinical Investigation Committee and Human Use Committee.

Protocols which appear not to comply with Army regulations or which involve substantive issues related to OTSG policy on use of human subjects will be presented to the Board for action. At each meeting of the Board, the Chief, Human Use Review Office, will provide the Board with information about protocols approved under provisions of this section.

f. Records Retention. The Human Use Review Office will maintain official files of the actions of the Board and The Surgeon General on proposals for three years after the completion of the project, or rejection of the application. Records will be permanently retired after this three year period to the Washington National Records Center IAW AR 340-18-1. The Investigational Drug Review Officer, Army Investigational Drug Review Board, will maintain the official files on investigational drug projects.

g. Processing Reports. The Human Use Review Office will review clinical investigation reports submitted under provisions of AR 40-38 and reports on investigational drugs submitted under provisions of AR 40-7. The Human Use Review Office will arrange for appropriate expert professional review of such reports and will take appropriate action to have authors correct deficiencies. The Human Use Review Office will present investigational drug reports to the Board along with research proposals if the investigator plans to change the protocol in the coming year. The Human Use Review Office will also bring to the Board's attention any reports which disclose unusual or untoward reactions or any other reports at the discretion of the Board Chairman. Annual reports or other information required by the Food and Drug Administration on Department of the Army Investigational New Drug Applications (IND's) may be released to the Food and Drug Administration on behalf of The Surgeon General by the Board Chairman acting as the Chairman, Army Investigational Drug Review Board.

6. Effective date for implementation of this board is 1 April 1976.

DASG-RD-HR (17 Feb 76)

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