726115

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

REPOSITORY Records Holding Area, Bldg. 494
COLLECTION Meetings/Minutes/Agendas
BOX No. 2
FOLDER Governing Body, 1971-1974

DATE: November 30, 1971

TO: Members of Clinical Staff, Courtesy Staff, and Scientific Supporting Staff

FROM: R.A.Love, K.D.Knudsen, W.A.Finn

SUBJECT: Ad hoc Committee to incorporate changes by CIRC Committee: Recommendations

Article V, Section 3

1. The CIRC is a standing committee, charged with the review and evaluation of any clinical investigation sponsored within the Medical Department involving the participation of a human subject. The Committee shall advise the President of Staff, who as Department Chairman has approval authority, on the ethical propriety, possible danger, and conformance with established policy of each proposal involving the participation of a human subject.

2. The purpose of each review and evaluation is to assure the maximum safeguards for both patient and investigator. Before recommending approval, the Committee shall determine that the rights and welfare of each subject are adequately protected; that the risks are outweighed by the potential benefits to the individual subjects or by the importance of the knowledge to be gained; and that an informed consent is obtained from each participant. The Committee also shall assure that each proposal is consonant with the policies of the Atomic Energy Commission and the Department of Health, Education and Welfare on protection of human subjects involved in research.

1181320

3. The CIRC shall be composed of seven members, including a Chairman, appointed by the Director, Brookhaven National Laboratory. The membership shall include at least two physicians with tenure appointments to the BNL Scientific Staff, a non-physician member of the Medical Department, and others selected to assure adequate review of the research proposal and to judge its acceptability in terms of institutional regulations, relevant laws, standards of professional practice and community acceptance. An alternate shall be appointed to sit for any member who is involved with the conduct of a proposal that comes before the Committee for evaluation. Additional alternates may be appointed to assure availability of a quorum.

The quorum for a meeting shall be four of the seven members, at least three of which are from the Scientific Staff of the Medical Department.

4. Each proposal of clinical investigation requires a sponsoring physician, licensed to practice in the United States; appointed to the full-time regular staff of the Medical Department with the rank of Scientist or Senior Scientist; and appointed to the Clinical Staff of the Medical Staff of the Hospital of the Medical Research Center.

Regardless of the extent to which the sponsoring physician may share the scientific direction of the program, he will bear final moral, ethical and medical responsibility for the participating human subjects. Following approval by the Chairman of the Medical Department of a proposal for clinical investigation, all subsequent decisions relating to patient participation in that program are the responsibility of the sponsoring physician.

1181321

5. For each new study, the Sponsoring Physician, and Principal Investigator if other than the Sponsoring Physician, shall submit a protocol to the Chairman of the Medical Department including the forms and information determined by the CIRC, and a copy of the investigational consent form, when applicable. After review, the Department Chairman will forward the proposal to the CIRC for review, evaluation and recommended action, or return it to the Sponsoring Physician/Principal Investigator for appropriate disposition. Upon receipt of the Committee's recommendation the Department Chairman will approve the protocol with or without limiting conditions or reject the proposal giving reasons for the rejection. No clinical investigation may be initiated without the recommendation for approval by the Committee.

Modifications in procedures and significant changes in the protocol shall be presented in the same manner for evaluation and approval prior to being put into effect.

6. The CIRC will reevaluate protocols as requested by the Chairman of the Medical Department, as the Committee deems desirable, or requested by the Sponsoring Physician/Principal Investigator. Each protocol shall be reevaluated annually. Additional information may be solicited by the Committee as desired.