October 15, 1971 402272 cc: Dr. Bond
Mr. Finn
Dr. Aronson

RESEARCH INVOLVING HUMAN SUBJECTS

Any research project, program or experiment which involves human subjects must be approved by a review committee prior to the initiation of the study. This committee will be appointed by the Director of the Laboratory and will evaluate the risks, benefits, and safeguards to the subject's health, safety and right to privacy. The committee shall be so composed that only persons who are independent of the study in question shall sit at a given meeting. The make-up and responsibilities of the committee shall be consistent with the directives of the Federal Food and Drug Administration, the Department of Health Education and Welfare and the Atomic Energy Commission (see: Protection of the Individual as a Research Subject, U. S. Dept. Health, Education, and Welfare, PHS, May 1, 1965; Federal Register, 36, 5037-5040, 1971; HEW Policy Statement on Patient Consent, HEW Grants Administration Manual, 1-40-00 through 1-40-50.)

Informative records of reviews and decisions shall be kept by the Committee and continuing review of the studies shall be made at appropriate intervals not to exceed one year. The principal investigator involved shall initiate Committee review by submission of the experimental design, description and protocol to his or her Department Chairman, who will, after evaluation, either forward the study to the Committee for review or return it to the principal investigator.

Following its review, the Committee will return the proposal to the Department Chairman recommending either approval or rejection, and the Chairman shall either approve the study or reject it. Reasons for rejection of a proposal shall be adequately explained. No project may be put into action without the recommendation of approval by the Committee.

The project director or principal investigator must report to the Committee any problems which arise or significant changes in procedure which occur during the course of the experiment.