UNIVERSITY OF CINCINNATI
COLLEGE OF MEDICINE

MAILING ADDRESS:
ISOTOPE LABORATORY
CINCINNATI GENERAL HOSPITAL
CINCINNATI, OHIO 45229

February 10, 1972

Mr. Robert Murphy
8112 Federal Building
Cincinnati, Ohio 45202

Dear Mr. Murphy:

The following information concerning informed consent is provided as requested by you in our meeting of February 4, 1972:

Q. What are the NIH and DOD requirements for informed consent?

A. The initial requirements of NIH are those of the National Advisory Health Council of December 3, 1965 as follows:

> "Be it resolved that the National Advisory Health Council believes that Public Health Service support of clinical research and investigation involving human beings should be provided only if the judgment of the investigator is subject to prior review by his institutional associates to assure an independent determination of the protection of the rights and welfare of the individual or individuals involved, of the appropriateness of the methods used to secure informed consent, and of the risks and potential medical benefits of the investigation."

The policy statement of Surgeon General Stewart of February 8, 1966 follows:

> "No new, renewal, or continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application the manner in which the grantee institution will provide prior review of the judgment of the principal investigator or program director by a committee of his institutional associates. This review should assure an independent determination: (1) of the right and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent, and (3) of the risks and potential medical benefits of the investigation. A description of the committee of the associates who will provide the review shall be included in the application."

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page 2 continued:

Also enclosed is a copy of the DHEW pamphlet "Protection of the Individual as a Research Subject." Also DHEW has issued two additional documents which may be of interest: (1) Grants Administration, Chapter 1-40 Protection of Human Subjects, HEW TN 71.6 (4/15/71) and (2) The Institutional Guide to DHEW Policy on Protection of Human Subjects, Revised June 16, 1971. These can probably be obtained from the Division of Research Grants of the National Institutes of Health.

Insofar as we can determine there was no specific DOD policy in regard to informed consent at the time that we began the use of specific informed consent forms in May 1965 thus antedating NIH requirements. (Copies of all of our consent forms are enclosed). It would be necessary to inquire directly of DOD concerning the evolution of policies in this regard over the years. We have regarded compliance with NIH requirements as reasonable fulfillment of DOD requirements for this research. This project was submitted initially to the Faculty Research Committee in March 1966 on the initiative of the investigators since at that time there was no strict requirement of DOD that such review was necessary.

The Faculty Committee on Research of the University of Cincinnati College of Medicine began formulation of guidelines in the autumn of 1964. They made recommendations to the Dean in October 1965 and began functioning as a reviewing committee in 1966. In 1967 a Statement of Principles was made available to the Faculty (copy enclosed).

Please let me know if we can be of further help.

Sincerely,

Eugene L. Saenger, M.D.

ELS/rvl
encls: DHEW Pamphlet
Project Consent Forms
1967 Statement of U.C. Faculty Research Committee

cc: Dr. Edward Gall

bcc CR Berne