

QUESTIONS ON FACULTY COMMITTEE ON RESEARCH REVIEW (December 20, 1971)1. Question:

Was the total body irradiation project submitted to a review committee concerned with safe-guarding human rights?

Answer:

The proposal was first formally submitted to the University of Cincinnati Medical Center Faculty Committee on Research in March 1966, which was the first year that the committee officially operated (for historical review of Human Rights Committee, see appendix I). A revised and expanded protocol was later resubmitted to the committee and approval was granted in May, 1967, with the proviso that infusion of stored bone marrow constitute a supportive measure, and that parts of the protocol be rewritten, particularly in relation to the plan of investigation (see appendix II). As the chief investigator changed and the protocol was also changed, a revised protocol was submitted to the committee in October 1970. After a number of revisions dealing with a review of the data from 1960 to 1970, a final revision was approved in August of 1971 (see appendix II).

2. Question:

Why was the project not reviewed in 1960 when the work began?

Answer:

The first formal declaration in the United States of the rights of the individual in human experimentation was set forth in the Declaration of Helsinki in 1964. The American Association of Medical Colleges drafted its first code of ethics in 1965. The Surgeon General of United States Public Health Service first recommended review of Department of Health, Education and Welfare grants dealing with human investigation in February, 1966 (see appendix I).

It should be noted that the investigators submitted their proposals as soon as the Medical College machinery for such review was made available. Prior to 1966, the investigators had utilized the general consent forms used at the Cincinnati General Hospital and had always obtained full consent from the patients.

3. Question:

How is the Faculty Committee on Research constituted?

Answer:

The members of the committee are appointed by the Dean of the Medical College and represent senior members of the faculty with experience in research and clinical investigation. The committee originally had eleven members (see page 3 of appendix III). The present committee is composed of thirteen members, with the Dean as an ex-officio member. The members are senior faculty from the Departments of Medicine, Pediatrics, Surgery,

Obstetrics and Gynecology, and Pharmacology. There are two lay members of the committee. The chairman is a Professor of Medicine. A secretary with part salary from the Dean's office is provided for the committee. It is the opinion of the Dean and Faculty Chairman that members serve at least two years to acquire the essential expertise required for this very important task. Only one member of the 1967 committee is still serving on the present committee, and that is as a representative of the General Clinical Research Center of the Cincinnati General Hospital.

4. Question:

How are outside members of the committee selected?

Answer:

Prior to 1971, lay representation was not required for research committees. However, in March 1971, the Food and Drug Administration of the Department of Health, Education, and Welfare enacted into law (Title 21) a requirement that Medical Center Committees have non-medical representation. After much discussion, the University of Cincinnati Medical Center Committee decided to have two representatives, a lawyer interested and knowledgeable in medical matters, and a religious representative interested and knowledgeable in morals and ethics. These members could also represent the potential patient.

5. Question:

What guidelines do the committee follow?

Answer:

The committee is guided by the statement of principles issued by the committee in 1967 (see appendix III) and by the guidelines published as a pamphlet by the U.S. Department of Health, Education and Welfare in May, 1969 (see appendix IV). The DHEW is in the process of revising its guidelines and this committee has contributed to the revision of these guidelines. The new pamphlet will be available sometime in early 1972.

6. Question:

What are the mechanics of the committee review?

Answer:

A faculty member submits a research protocol to his Department Chairman for review and approval. Graduate students, fellows, and housestaff can only submit protocols with an experienced faculty investigator. After departmental review, three copies of the proposal, which must follow the guidelines suggested by the committee and with the accepted type of consent form, are sent to the Faculty Committee Chairman (see appendix V). The chairman selects three members of the committee with expertise relevant to the submitted protocol and each are sent a copy. The sub-committee returns the review copy with their typed comments and questions. If there are such comments and questions, the chairman forwards these to the investigator, who then answers these comments and questions. The investigator replies, the

typed reply is then sent to the three reviewers, and they then indicate by typed letter their approval or disapproval. If there are unanswered questions or disapproval by any one member of the sub-committee, a meeting of the sub-committee with the committee chairman and the investigator is then held. This results in an unanimous decision. Should it not, review by the full committee and outside consultants would follow (this has not been required to date). Following these procedures, the committee chairman writes to the Dean with the committee's recommendations, and the Dean then writes to the investigators. Subsequently, the investigators submit a follow-up report every six months.

A consultant panel for this committee has been appointed by the Dean and appropriate members can be used for their expertise. This panel lists eleven senior members of the faculty with expertise in all areas including Radiotherapy, Biostatistics, Biochemistry, Physiology, Psychiatry, Sociology, Infection Control, etc. The committee is also free to obtain consultation from outside the Medical Center and indeed, outside the city.

It should be pointed out that in the last two years, two proposals have not been approved by the committee, that questions were asked on at least 80% of the proposals, that revisions of the proposals have been requested and obtained in about 25% of the proposals and that sub-committee meetings were held on about 10% of the roughly one hundred thirty proposals submitted each year to the committee.