

Informed Consent

The valid use of Informed Consent in the total body irradiation/partial body irradiation project has been of particular interest due to the charges and assumptions that information was kept from the patients. When and how was Informed Consent applied? How could Informed Consent be documented? These questions can be answered in two ways - first, the actual experience with patients from 1960 through 1971 and second, a brief discussion of the background of directives by government and academia then.

1. The use of Informed Consent at Cincinnati General Hospital in the Radiation Project between 1960 and 1971.

a) How were patients recommended for total body irradiation/partial body irradiation?

Patients were recommended for total body irradiation/partial body irradiation by several experienced radiation oncologists and medical oncologists who would evaluate each patient individually and make a recommendation as to treatment. This recommendation was made solely on clinical grounds. If total body irradiation/partial body irradiation was agreed to, the patient was placed on a protocol that was completed in 1-2 weeks prior to the actual treatment. Not all patients entered in the study were irradiated. There were 115 patients entered and 88 were treated with total body irradiation/partial body irradiation.

b) Lack of formal advice from DOD regarding Informed Consent

At the time of negotiation of the contract between DOD (DASA) and UC, no advice, specific statement or caution was given by DOD personnel to the principal investigator, E.L. Saenger, M.D., concerning Informed Consent and, during the life of the contract, no official statement of DOD policy was provided or sent to UC.

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c) Informed Consent for total body irradiation/partial body irradiation at UC prior to April 1965

At the outset of the project, it was agreed by the UC physicians that each patient was to be advised of the treatment, its goals and risks in relation to the stage and progress of the cancer. During the period from 1960 to 1965, there was no requirement of Cincinnati General Hospital concerning written Informed Consent. It was the policy of the physicians on this project to inform the patient orally (Informed Consent). The several physicians differed somewhat in methodology but their written statements indicate that Informed Consent was carried out for each patient.

The University of Cincinnati had no specific policies at that point; the then "IRB" committee was evaluating the situation but did not make any specific recommendations until 1966. At that time these recommendations were made primarily for projects supported by the NIH.

d) Use of written Informed Consent beginning in April 1965

In 1964, Dr. Saenger received a copy of the May 12, 1964 DOD Instruction: Subject: Investigational Use of Drugs by the DOD⁴, which detailed the steps to be taken for research with drugs to be in compliance with the Federal Food, Drug and Cosmetic Act⁵. Although total body irradiation/partial body irradiation had been used clinically and was not considered an "investigational drug", nevertheless Dr. Saenger considered that total body irradiation/partial body irradiation could be so considered. Therefore he drafted a written consent form dated April 1965 and used thereafter. This written Informed Consent preceded any F.D.A. requirement by approximately two years. This form underwent several modifications in the next several years on the advice of the UC IRB and its predecessors.

2. Documents of Informed Consent of the DOD

A recent review of DOD policy regarding Informed Consent revealed that on 26 February, 1953, The Secretary of DOD issued a memorandum marked Top Secret concerning Informed Consent and

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the rights of subjects of experimentation¹. This document was released to the public on 22 August, 1975, well after the completion of the UC project. The Department of the Army issued regulations for written Informed Consent on the use of volunteers as subjects of research - AR 70-25, 26 March 1962³; this regulation was not sent to UC.

All Informed Consent at the UC Medical Center was in conformity with the Declaration of Helsinki, derived from the Nuremburg Code.

In order to clarify the various rulings of the Federal Government attached are the major regulations of DHEW and DOD concerning Informed Consent.

References

1. Memorandum for the Secretary of the Army, Secretary of the Navy, Secretary of the Air Force, 26 February 1953. Downgraded to Unclassified 22 August 1975.
3. Use of Volunteers as Subjects of Research, AR 70-25, Department of the Army, USA, 1962.
4. May 12, 1964 - Department of Defense Instruction: Subject: - Investigational Use of Drugs by the Department of Defense; Reference: (a) Drug regulations published by Department of Health, Education and Welfare (21 CFR 130.3).
5. Drug Amendments Act of 1962

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