COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

MAY 26 1972

B-164031(2)

Dear Mr. Chairman:

Pursuant to your request of December 23, 1971, and discussions with your office, we obtained documents relating to (1) the whole-body irradiation program at the University of Cincinnati Medical Center and (2) the policy of the Department of Defense on the subject of the protection of humans used in medical research projects under contract. The enclosure to this letter identifies the documents obtained by us and made available to your office during our work.

Concerning the policy on the subject of the protection of humans used in medical research projects, an official of the Department advised us that the policy of the Department was set forth in Department of Defense Instruction 5030.29, dated May 12, 1964. The instruction, which is applicable to all components of the Department and to its contractors or grantees, states that:

"The Department of Defense assumes full responsibility for the protection of humans involved in research under its sponsorship whether this involves investigational drugs or other hazards.

"Each Military Department will establish within the office of its Surgeon General a formal Review Board of professional personnel to consider each research proposal from within that Military Department or from its contractors or grantees which may involve the use of human subjects in the clinical investigation of new drugs. Before a clinical test with an investigational drug may be performed under the sponsorship of a Military Department--

"1. the plan of the test and other pertinent details must be submitted to the appropriate Review Board,

"2. the Board must indicate its approval, and

"3. the approval must be confirmed by the respective Surgeon General."

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With the exception of certain reports that were required to be filed with the Food and Drug Administration of the Department of Health, Education, and Welfare in the case of investigational new drugs, no procedures were specified in the instruction with regard to the use of human subjects for other research purposes. The reports to be filed with the Food and Drug Administration were set forth in a Memorandum of Understanding between the Department of Health, Education, and Welfare and the Department of Defense, dated February 1964, which contained the procedures to be followed to ensure that the requirements of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 355), and the regulations issued under the act are fully met.

Although the instruction appeared to be directed primarily toward the investigational use of drugs, an official of the Department of Defense advised us that the instruction applied to all medical research projects. He stated also that each service directed its own research projects without control from the Department.

We contacted officials of the Departments of the Army, Navy, and Air Force and of the Defense Nuclear Agency, formerly known as the Defense Atomic Support Agency (the organizational entity within the Department of Defense that had contracts with the University of Cincinnati relating to the whole-body irradiation program), to determine whether they had any instructions or regulations that were applicable to the use of humans in medical research work under contract. The officials were not aware of any instructions or regulations, other than the instructions and regulations implementing Instruction 5030.29, involving the use of human subjects that would apply to contractors conducting medical research for their organizations.

An official of the Department of the Air Force advised us that the Air Force did not conduct medical research under contract. Officials of the Departments of the Army and Navy stated that, although most medical research had been conducted in-house, some had been performed under contract. They stated also that, when work is to be performed under contract, they must be satisfied that patient consent forms will be used and that human subjects will be adequately protected before a contract is executed.

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An official of the Defense Nuclear Agency advised us that, although the Defense Nuclear Agency did not have any contracts for the use of human subjects for medical research, the following language had been included in all medical contracts after August 1971.

> "The COR [Contracting Officer's Representative] shall be informed in writing of any project plans on the part of the Contractor to employ new, experimental, and investigational drugs or other hazards in research involving human subjects, and such experimentation shall be specifically authorized by the Contracting Officer in writing prior to the prosecution of such research. Without the concurrence and authorization by the Contracting Officer for the specified drug or other hazard involved, such research shall not be performed. (The purpose of this clause is to insure compliance with the Department of Defense Instruction, 5030.29, 1964 May 12, entitled 'Investigational Use of Drugs or Other Hazards by the Department of Defense', a copy of which is furnished to the Contractor with this Contract)."

Concerning the contract with the University of Cincinnati, officials of the Defense Nuclear Agency stated that the cost of radiation treatment and patient care had not been borne by their agency. They stated also that funds of the Defense Nuclear Agency had been used only to pay for supplementary laboratory analyses of patients who had received whole-body irradiation in order for the Defense Nuclear Agency to gain information in areas that were relative to national defense.

We plan to make no further distribution of this report unless copies are specifically requested, and then we shall make distribution only after your agreement has been obtained or public announcement has been made by you concerning the

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contents of the report. We trust these comments will serve the purpose of your inquiry.

Sincerely yours,

Comptroller General
of the United States

Enclosure

The Honorable Edward M. Kennedy
Chairman, Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate