

24 June 1970

John R. Totter, Ph. D.  
 Director  
 Division of Biology and Medicine  
 U. S. Atomic Energy Commission  
 Washington, D. C. 20545

Dear Dr. Totter:

I am responding to your 15 May letter to Dr. Goldhaber requesting assurance that the Medical Department, Brookhaven National Laboratory adheres to "Protection of the Individual as a Research Subject."

For all studies involving human beings, a proposal is submitted to our Clinical Investigation and Uses of Radioisotopes Committee, which makes recommendations to the Chairman of the Medical Department. When the clinical proposals are approved by the Chairman, there is a continuing surveillance of the study by the Head of the Hospital, the Committee intermittently and the Department Chairman. Whenever there are any questions, the investigator is requested to meet with the Committee and all problems are openly discussed with him. Anytime there is a change in the design of the experiment, it must be submitted in writing and discussed with the Committee. In every instance final action requires approval by the Chairman of the Medical Department.

Enclosed are the Hospital forms for: a) Consent on admission to Hospital, b) Application for participation in a Clinical Research Program, c) Proposal for Clinical Investigation, d) FY 1971 Committees listing, e) Bulletin of the Medical Department, f) Patient's Information Booklet and g) a signed statement on "Institutional assurance on investigations involving human subjects, including clinical research."

We are modifying our clinical research forms to include a statement that the investigator is aware of, has read, and understands, the brochure "Protection of the Individual as a Research Subject" issued by the U. S. Department of Health, Education and Welfare.

Sincerely yours,

Eugene P. Cronkite, M. D.  
 Chairman

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cc: Dr. Bond

Mr. Jackson

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Dr. Goldhaber's office

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to be done

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