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UNIVERSITY OF WASHINGTON
SEATTLE, WASHINGTON 98105

Office of the Vice President for Research
203 Administration Building

July 16, 1969

AIR MAIL

Dr. John F. Cotter, Director
Division of Biology and Medicine
United States Atomic Energy Commission
Washington, D. C. 20545

Dear Dr. Cotter:

Thank you very much for your prompt response to my request for information concerning the comments of scientists who have reviewed proposals for AEC support of Dr. C. Alvin Paulsen's work during the past several years. This information was very helpful to the members of our Human Subjects Policy Board during their consideration, on July 2 and 3, of Dr. Paulsen's appeal from earlier decisions of University of Washington review committees to deny approval for Dr. Paulsen to carry out his experiments under University auspices.

I am sorry not to have reported to you immediately on the results of our deliberations, but I have spent nine days in Alaska in the meantime and this is my first opportunity.

As Dr. Paulsen may already have informed your office, the Human Subjects Policy Board declined to overrule the earlier decisions to deny approval. Dr. Paulsen was informed of this by telephone on July 7 and by my letter dated July 8 which I quote, in part, as follows:

> I regret to inform you that the Human Subjects Policy Board has declined to overrule the decision of the Biomedical Sciences Review Committee to deny approval for the experiments described in your proposal entitled "Effects of Acute X-ray and Neutron Irradiation on Human Testicular Function." Thus, approval cannot be given for this work to be carried out under University of Washington auspices, and it will not be possible for me, as Vice President for Research, to forward your proposal for continued support of the project to the Atomic Energy Commission in its present form (i.e., in a form which includes provision for neutron irradiation of human subjects).

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> The Board's decision was based upon its assessment of the risks that would be incurred by the participants in the proposed experiments and the potential benefits that might be realized from them. Although some concern was expressed about the risks incurred in the X-ray experiments which have now been under way for several years, . . . the Board addressed itself primarily to the proposed experiments involving neutron irradiation of human subjects, and, on balance, decided that the potential benefits to science and to society do not justify the risks.
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> I recognize that this decision will be a serious disappointment to you and your colleagues. However, I am confident that the issues were fully and thoughtfully aired in the course of the Board's discussions, and I assure you that the Board's decision was based upon the most careful collective judgment that it could make.
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I discussed the matter yesterday with Dr. Paulsen. He is quite naturally very disappointed but is now preparing, I believe, to go ahead with further X-ray experiments. The Department of Institutions of the State of Washington has recently instituted new requirements; these will make it necessary for Dr. Paulsen to submit any proposal for further X-ray work with prisoners to the Research Review Committee of the Department of Institutions for approval. Dr. Paulsen will undertake this and will, at the same time, work again through the University review committees to obtain approval for continuation of his experiments on the effects of X-rays on testicular function. Thus, the proposed neutron work has been rendered unfeasible and the continuation of the X-ray work will require additional clearance.

I regret very much that it was necessary to deny approval for the neutron experiments and that a delay in Dr. Paulsen's other work may result. I do believe, however, that careful and informed judgments have been made by the responsible University review groups, and that the administrative action taken was a necessary consequence of these judgments.

Again, may I express my thanks to you and Dr. Goldstein for your very helpful cooperation.

Sincerely yours,

George W. Farwell
Vice President for Research

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cc: President Charles E. Odegaard

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