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May 23, 1972

David S. Alberts, M.D.  
Department of Medicine  
1278 M

Dear Dr. Alberts:

The Committee on Human Experimentation reviewed your application, "Combined Radiotherapy-Chemotherapy in the Treatment of Hodgkin's Disease" during their meeting on May 18, 1972. It was decided to send this protocol for additional review and in the meantime to ask you for revision of the informed consent form.

The consent form must be in the first person. That subject will then sign to attest his reading and understanding of the information.

Paragraph 3 of the consent form is misleading in that it states that, "You will then be placed into a treatment group depending upon the extent of your disease . . ." Section 4.01 of your protocol states that, "Patients will be presented to and staged and randomized to treatment groups . . ." The subject should be informed that the assignment to a treatment group is random. The ramifications of this fact must also be explained.

When four copies of the revised consent form and the reviews of the outside reviewers are received, your protocol will again be discussed.

Sincerely,

Leslie E. Bennett, M.D.  
Chairman  
Committee on Human Experimentation

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