Re: Total Body Irradiation Project

November 19, 1970

Dr. Edward Silberstein
Associate Director
Radioisotope Laboratory
H Basement

Dear Dr. Silberstein:

Thank you for agreeing to meet with the Faculty Committee on Research on your proposal on Monday, November 30th, approximately 4:45 PM in the K-4 Library. As the committee will be meeting on another proposal earlier, I would appreciate it if you would be available in your department and I will phone you when we are finished with the first proposal so that you do not have to waste time waiting.

The committee does have a number of questions and would appreciate it if you could reply to this in writing before the meeting so that it will be available for study and will, therefore, expedite our session.

1) As you may know, this whole study of Therapeutic Effect of Total Body Irradiation was given only Provisional Approval by the Faculty Committee on Research in 1967. It is for this reason then that I think that it should be completely re-evaluated and a full new proposal submitted. This study has been on-going for a number of years now and we are told that 70 patients have received irradiation and that the clinical course has paralled that of comparable patients treated with other agents. The investigators refer to Protocols A and B in this respect. They also refer to Protocol C in regard to the Immune Studies. However, none of these protocols were with the application. The committee requests a full progress report on the data of the 70 patients treated so far.

2) Exactly how will Palliation be measured? Will this be by peripheral blood counts only?

3) When will the stored bone marrow be administered? Times of blood counts are given in detail as well as certain tests, but it is not clear if marrow will be given to all the patients in the group receiving it immediately after irradiation as is implied in the paragraph at the bottom of page 4 or whether it will be given only prn for a low blood count.

4) It would appear wiser to make a more definite protocol for the experiments related to stored autologous marrow. What are the experimental risks of pulmonary emboli? Are there any psychological risks for patients in life islands? The possibility of using a laminar air flow unit is mentioned -- is this available at this medical center?

5) There is a brief reference to a serum factor which breaks chromosomes. Does the proposal mean that the serum factor may alter the survival of stored marrow to be given to a patient following irradiation? If so, is this a serious detriment to the successful outcome?

6) The details on the voluntary consent statement are inadequate for present-day usage. It is suggested that there should be two (2) consent forms -- one for patients having total body irradiation, and another for those having the bone marrow transplant. On both of these the actual benefits, hazards, etc., should be listed in far more detail and in wording that the patient can fully understand.

7) It is noted that the references are all fairly ancient; it would appear that there must be literature references that are much more up-to-date which would be more appropriate to this 1970 proposal.

If we could have a reply in writing to these questions before the meeting, this will expedite that session. Thank you very much for your cooperation.

Sincerely,

Evelyn V. Hess, M.D.
~~Professor of Medicine~~
~~Director, Div. Immunology~~
Chmn,
Fac. Com.

EVH:js