

University of Cincinnati Medical Center
Inter-Office Memo

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To: Dr. Clark West
Dr. Harvey Knowles
Dr. Virginia Donaldson
Dr. Alvin Mauer

From: Evelyn V. Hess, M.D.
Chairman
Faculty Committee
on Research

Date: 9 March 1971

A subcommittee of the Faculty Committee on Research met on K-3 on February 16, 1971. Those present were Drs. Clark West, Harvey Knowles, Evelyn Hess and the special consultant, Dr. Alvin Mauer. Dr. Virginia Donaldson could not be present as she was out of town. Drs. Eugene Saenger and Edward Silberstein were scheduled to attend but at the last moment Dr. Silberstein was unable to attend. All the reviewers were fully conversant with the first proposal, the rewritten proposal and the investigators' replies to the various questions. These were reviewed prior to Dr. Saenger's arrival and it was decided to evaluate the following points with the investigator:

1. More information on which patients get total, partial body irradiation.
2. Whether or not isologous marrow transplant is intended.
3. The estimated number of patients in the various components of the study and whether these would be sufficient to provide data.
4. To obtain more of the result data from the studies undertaken during the previous few years.

When Dr. Saenger arrived, there was a very full and open discussion of all aspects of the proposal. Dr. Saenger was a little unfamiliar with some of the details and these will be supplied in the investigator's written reply. Dr. Saenger made it clear that the data for the study ^{were} essential as there are, in fact, very few ongoing studies of this type of therapy in the United States. It was his impression that the benefits of irradiation were definite and that the original 200 rad dose had given better results than the 100 rad dose. He also stated that it is difficult to estimate the number of patients for the study because there are many other therapeutic trials ^{of} for which these patients ~~are required~~ and they have to "compete" with other groups. Also the patients may have various complications or infections and entry into the study has to be postponed. Many of the results of these studies are in the Annual Report which the department makes to the Defense Atomic Support Agency which funds the radiation study. Dr. Saenger obtained 6 copies of this report and the subcommittee reviewed parts of it at the meeting.

Dr. Saenger agreed that the proposal should not include any references to life islands, in fact these will not be utilized. He also agreed with the committee that the inclusion of other studies and suggestions for future work were not appropriate to the proposal.

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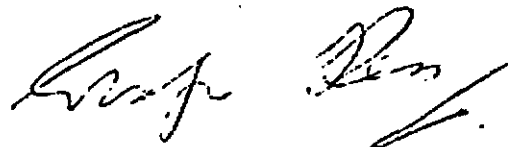
The subcommittee makes the following suggestions to the investigators before making final recommendations to the Dean:

1. To resubmit the proposal excluding references to future work and also excluding the proposed study comparing large field irradiation and 5 fluoruracil for metastatic carcinoma of the large bowel as this is a separate proposal and should be submitted on its own merits.
2. That the proposal make reference to autologous marrow transplant only.
3. That references to life islands be omitted as it is not intended to utilize this facility.
4. That the data available to the investigators be much more cogently reviewed and represented. Their report to the Defense Atomic Support Agency says that 64 patients have been in the program to date but the table submitted with the most recent revision of the proposal lists 27 patients and it is not clear who did and who did not receive marrow transplants, how survival times have been influenced by the treatment, and lastly, what parameters are actually being followed to determine the quality of the response and whether or not it is effective. Data ^{are} ~~is~~ therefore requested on the patients who have been treated to date.
5. It is suggested that the tumor registry data which ^{is} ~~is~~ available for all investigators in Cincinnati might be utilized as a baseline for comparison for treatments. This is particularly appropriate for carcinoma of the colon.
6. It is suggested that data be obtained from the two other centers where total body irradiation is being used for the treatment of Ewing's tumors - Chicago and the University of Toronto Medical Center.

In summary, the committee felt that it required:

- 1. More specific information relating to all the investigations that have been done to date so that this large amount of work can provide good and valuable data.
2. They request clearer guidelines from the investigators as to their method of evaluating the results in these cancer patients with metastatic disease; it is agreed that this is a most difficult area to evaluate and yet philosophically, without evaluation, there really is no data and therefore probably little justification for the great amount of work and effort which goes into a study such as this.

The committee is in complete agreement with the attempts of the Department of Radiotherapy to provide appropriate treatment for patients with metastatic carcinoma, a constantly difficult and challenging area of therapeutic medicine.



Evelyn V. Hess, M.D.
Chairman, Faculty Committee
on Research