

UNIVERSITY OF CINCINNATI
(INTERDEPARTMENTAL CORRESPONDENCE SHEET)

To Dr. Eugene Saenger

From Dr. Evelyn V. Hess

Date August 23, 1972

Dear Dr. Saenger:

As I told you on the phone, the Faculty Committee on Research has now recommended approval of the protocol to the Deas. They do still have some, I guess you would call them philosophical, comments and I have summarized these which you may find of help, in the enclosure.

If I can be of any help on this final round-up please don't hesitate to let me know.

Evelyn E. Hess, M.D.
Professor of Medicine
Chairman, Faculty Committee on Research

EVH/big

CC: Dr. Silberstein

Encl.

There continue to be some areas of the protocol which need amplification, documentation, or strengthening. Three such areas are as follows:

1. On page 5, the statement is made that hospitalization time for irradiated patients was shortened. No proof for this claim was offered in the text and appendix B to which we were referred was not included. Since no controlled study in similar groups of patients was done for the irradiation study, it is difficult to see how this claim can be made.
2. On page 17 in the development of the rationale, much documentation is needed to support the statements offered. What alteration of the immune system occurs with 200 r whole body or 400 r partial body irradiation? How would the alteration affect the tumor? What evidence do the investigators have that the alteration of immune function would be beneficial?

What metabolic effects on tumor cells are expected to occur with these irradiation doses and how would the alteration affect tumor cell growth or viability?

What documentation can be offered that isolated tumor cells or small clumps of tumor cells are more susceptible to small dose irradiation therapy than large collections of tumor cells?

The investigators do not make clear the advantage of 400 r irradiation to the upper or lower half of the body in a single dose for a tumor located in the abdominal or thoracic cavity over conventional fractionated doses to the cavity involved given to a total greater amount. If they are concerned about distant, unrecognized metastases out of the cavity but seeded in one-half of the body only, do they feel safe in excluding the other half of the body from treatment?

3. On page 26, the statement is made that the proposed subsidiary studies will be of value in providing information about the effects of systemic cancer therapy in various organs. However, the studies chosen are so limited or so uncertain as to their significance that it is not clear what use can be made of the results of all of the studies proposed.