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TO: Dr. Evelyn V. Hess
Chairman,
Faculty Committee on Research

FROM: Dr. Noble O. Fowler
Director,
Division of Cardiology

Subject: Protocol entitled "Evaluation of the Therapeutic Effectiveness of Wide-Field Radiotherapy as Compared to Chemotherapy in Humans with Carcinoma of the Lung or Colon" (Drs. Saenger/Silberstein)

Dear Dr. Hess:

Draft #4 of the Saenger proposal appears to be an improvement, but there remain a number of unanswered questions. I should like to have it clearly spelled out as to the procedure in the event of bone marrow depression-specific cell counts, hospitalization, antibiotics, transfusions, steroids, hematology consultations, etc.

There are a number of additional concerns which are detailed below:

It should be stated why there are no untreated controls.

Pages 2-4 might be summarized as not having a control group, except Horwitz.

Page 5 -- Access period of patients into the study is not clear.

Page 6 -- Since those with liver involvement probably have a worse prognosis, I doubt the usefulness of this comparison.

Tables -- It would be helpful if those from the U.C. study would be appropriately labeled.

Table 5 indicates possibly 10% death rate from radiation. The consent forms appear to deny any serious risk. Is the planned radiation dosage or the procedure (Page 27) different? If so, this should be clarified.

Page 18 -- The method of patient selection appears to offer an improvement in the randomization procedure from the previous draft.

Will patients with carcinoma of the lung have biopsy proof?

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Page 20 -- Statistical calculations are needed to verify the adequacy of sample size in relation to assumed therapeutic results.

The duration of the study is hinted at here and on Page 24, but periods of access and follow-up are not clear. How will patients from other hospitals be selected and how will their randomization be effected?

Pages 23 & 24 -- Will these measurements be made by an investigator blind to the form of therapy?

Consent Forms -- Do the depressed blood counts always return to normal when these drugs are stopped? Is transfusion always successful in treating platelet depression?

NOF:mfr
enclos. (Drafts #3 and #4)

Noble O. Fowler
Noble O. Fowler, M.D.