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Radiation Therapy Oncology Group

Radiation Oncology Study Center
American College of Radiology
[illegible] Chestnut Street
Philadelphia, Pennsylvania 19107
(215) 574-3150

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Morton M. Kligerman, M.D.
Director
Cancer Research and Treatment
Center
University of New Mexico
Albuquerque, New Mexico 87131

Dear Klig:

This letter is a follow-up on our recent conversation concerning an appropriate control arm for the proposed pion study of malignant glioma.

I discussed this matter with Dr. David Schoenfeld, the statistician for the existing RTOG glioma study. As I mentioned to you on the phone, the selection of the control arm for the neutron study was a compromise in view of the pilot data on whole brain and mixed beam radiotherapy and the desire to proceed with a study that provided a neutron boost. Since a 1500 rad equivalent neutron boost seemed appropriate following 5000 rad whole brain photon radiation, it was elected to make the control arm in that study identical except for a 1500 rad photon boost. This was an obvious deviation from either of the radiotherapy arms of the existing glioma study, and while undesirable, was an obvious compromise.

Since this is not a consideration for the pion study, Dr. Schoenfeld and I would like to recommend that the control arm be 6000 rad whole brain radiotherapy. While the results of the current study are blinded, none of the arms seems obviously superior in preliminary analysis. Final analysis of the study should occur within the next six months, and if these results are at obvious deviation with the preliminary one, the Committee could obviously reconsider this matter, since the pion study will likely have a small number of cases at that point. The obvious advantage of selecting one of the arms of the existing glioma study is that comparisons with that study may be possible.

I hope this recommendation meets with your approval.

Sincerely yours,

Lawrence W. Davis, M.D.
Associate Chairman

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[illegible] Treatment [illegible] Cancer Institute