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NOTES	
FOUND BY	PERRY HALL

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June 14, 1972

Dr. Charles B. Wilson
Department of Neurosurgery
704 K

Dear Dr. Wilson:

The Committee on Human Experimentation reviewed the project which you submitted to it, "Protocol for the study of BCG and ⁶⁰Co and Irradiation in the Treatment of Malignant Glioma of the Brain" at the meeting on June 8, 1972. At that meeting the Committee felt it was unable to take any definitive action, either pro or con, and it raised several questions. The Committee recognizes the value of a cooperative study in the treatment of malignant glioma.

It seemed to the Committee that there were some inconsistencies in the research protocol as explained in Section 3.1, which describes the study design. It stated that there be four groups of patients and shows that patients in Group 1 will receive radiation with the group not receiving radiation only chemotherapy. In contrast to this, Section 4.8.3 states that patients "randomized as the protocol" will receive radiation. Did I misread the protocol or is this indeed an internal inconsistency? Has some rationale explanation?

Another inconsistency is found in Sections 4.8.4 and 4.8.5. Section 4.8.4 says "all patients subject to randomization must be treated under the supervision of the senior investigator or his designee." On the other hand, Section 4.8.5 states "for any reason, the participating physician believes that continuation of this protocol is not in the best interests of the patient, he should be removed from the study."

I am sure you agree that the law proposed that whenever a human serves as a research subject, there should be a primary physician responsible for his care as a part of the research team. Does Section 4.8.3 mean that the investigator is a primary physician responsible for the patient's care? The whole research protocol indicates that the individual responsible for the patient's care is also the investigator.

Perhaps the most important reason for the Committee not taking action at this time revolves around the consent form. If I understand the documents which you submitted correctly they originated from the group entitled, "The Brain Tumor Study Group with the National Cancer Institute. The Table of Contents, No. 16, indicates a form "Request for Treatment (Informed Consent)". As an informed consent form for participating as a research subject, this is totally inadequate and is completely out of conformity with the DHQP's own policies with respect to the essential elements of informed consent. I enclose a xerox copy of page 7 of the NIH document entitled "The Institutional Guide of the DHQP on Policy on Protection of Human Subjects". It lists, in the middle of the page, the basic elements of informed consent. I also enclose a copy of the standard

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