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SCHOOL OF MEDICINE
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SCHOOL OF DENTISTRY

April 10, 1969

John H. Lawrence, M.D.
Donner Laboratory
University of California
Berkeley 4, California

Dear John:

I have met a very serious and disturbing problem at this institution. For several years we have been doing experiments on prison volunteers from Canon City penitentiary to determine the maximum rate of red cell formation in phlebotomized volunteers who have been given adequate amounts of iron. At present we are trying to determine the survival time and characteristics of red cells formed in these volunteers under two circumstances, first during periods of rapid red cell formation, and second, during periods of severe iron deficiency. In either case we plan on transfusing red cells marked with radio-iron or perhaps DFP_{32} to normal recipients. Our Human Experiment Committee and Radioisotope Committee have adopted an arbitrary and unreasonable rule that no radio-isotope may be given to any human volunteer under any circumstances, regardless of the physical, chemical or biological characteristics of the isotope, or the amount of the isotope. This rule has brought our experiments to a halt.

I am writing to you to find out what the policy is in your own institution and whether you think such a rule is justifiable, that is a blanket denial of the use of isotopes under any or all circumstances in normal volunteers.

Sincerely yours,

Matthew Block, Ph.D., M.D.
Professor of Medicine
Chief, Hematology Division

MB:mg

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Addendum to the "Statement of policy of the Donner Laboratory and Lawrence Radiation Laboratory Committee for Safeguards in Research in Human Subjects."

To insure that all materials administered to human subjects during the course of any experimental protocol are sterile and pyrogen free, the following requirements must be satisfied. The final product must be tested for sterility and pyrogens prior to initial administration of material to human subjects. Subsequent to the initiation of the experimental protocol, the final product must be tested for sterility and pyrogenicity at least once during every four month period. Records must be kept of all such sterility and pyrogen testing by the individual investigator and must be available for perusal by this Committee. Each time the protocol is modified or changed in any way, repeat testing of the final product for sterility and lack of pyrogenicity must be obtained prior to using said product in human subjects. It is recommended that where possible all components utilized in the preparation of the final product and all glassware used in containing these components be purchased certified sterile and pyrogen free.

The final criteria are proposed for limiting the radiation dose received by normal human volunteers receiving radioisotopes as part of any experimental protocol. These limitiations do not apply to the use of radioisotopes in patients with disease processes in whom the data obtained from the study can be useful in evaluating said disease process. (The restrictions below refer to radionuclides decaying by gamma, beta + and beta -, internal conversion and electron capture processes. Evaluation of alpha emitting or neutron emitting radionuclides will be considered individually.)

1. Where the effective half-time of the radioisotope in the body is greater than six months, the maximum dose and dose rate must be less than 1/100 of that recommended by the NCRP for radiation workers (e.g. intergral dose less than 50 mr per year).

2. Where the effective half-time within the body is less than six months but greater than one week, the maximum initial dose rate to any tissue must be less than 1/10th of that recommended by the NCRP for radiation workers (less than 0.5 r per year).

3. For radionuclides with a short effective half-life in the body (less than one week), the maximum dose to bone, bone marrow, lymph nodes, intestinal mucosa and gonads must be less than 1.5 r and the total dose any tissue other than those noted above must be less than 5 r.