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June 22, 1973

Dr. Bruce W. Wachholz
 Division of Biomedical &
 Environmental Research, HQ

STUDIES INVOLVING USE OF HUMAN SUBJECTS

Attached for your information is a copy of Dr. Spickard's notes on a recent meeting of the HSL Committee. Since then, and after discussing the group with you, the Rev. Mr. Barry B. Heath was added as a committee member. A list of the committee members, together with the required Institutional Assurance, was officially forwarded to Dr. Liverman on June 20, 1973.

Original Signed By
 Donald I. Walker

Donald I. Walker, Director
 Health Services Laboratory

Enclosure:

Ltr, Walker fm Spickard, dtd 5/3/73

bcc: J. H. Spickard

REPOSITORY INEL
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ACTIVITY REPORTS
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 FOLDER STUDIES INVOLVING USE OF HUMAN
SUBJECTS

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May 3, 1973

Donald I. Walker, Director
Health Services Laboratory

HUMAN STUDIES COMMITTEE

On May 2, 1973, the first meeting of the Human Studies Committee, including off-site consultants, was held. The purpose of the meeting was to familiarize off-site consultants with the facilities and programs of the Health Services Laboratory. This included a tour of the facilities, a review of the human studies guidelines and a discussion of the current and future protocols. Those in attendance were: Thomas Mitchell, M.D. - Pathologist, LDS Hospital, Idaho Falls; Robert Hahn, M.D. - Radiologist (also Board certified internist), Sacred Heart Hospital, Idaho Falls; Glenn Haluska, M.D. - Radiotherapist, Intermountain Cancer Center, Pocatello, Idaho. Laboratory personnel in attendance: Claude Sill, Chief of Analytical Chemistry Branch; Paul Voillequé, representing the Environmental Sciences Branch; John Spickard, M.D., Medical Department.

These consultants have agreed to participate on the Human Studies Committee. They were in agreement with the guidelines for Human Studies. The following recommendations were made subsequent to the review of the guidelines, the consent form and Dr. Budinger's sample protocol: A statement should be made in the guidelines that no remuneration is provided to the volunteers; a statement should also be made in this document that the individual's exposure for the year has been reviewed and that the guidelines of 5 rem per year will not be exceeded (composite of the "experimental" dose and the occupational dose); a statement should also be made that the dose received in the course of the experiment will be recorded as an occupational exposure. Some minor revisions of the consent form will also be made. This will include addition of the Chief of the Environmental Sciences Branch to the "Review and Approval" section, a statement that the investigator has reviewed the volunteer's occupational exposure for the year to date and also that he has entered the exposure from this experiment.

Any new studies will be reviewed with the consultants. They are in agreement with the program as it is currently being conducted. They did not concur with Dr. Budinger that it is not necessary to give internal, encapsulated radioisotopes for accurate instrument calibration, and feel the current method of study is appropriate.

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May 3, 1973

Donald I. Walker, Director
Health Services Laboratory

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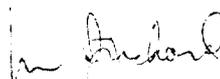
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Donald I. Walker

- 2 -

May 3, 1973

I believe that a copy of the minutes of this meeting should be forwarded to Bruce Wachholz, in addition to the updated guidelines for human study, the revised consent form and perhaps Dr. Budinger's sample protocol. We feel that the consent form contains the critical information provided in the protocol. Paul Voilleque has assured us that the calculations used in our computer programs are consistent with those mentioned in Dr. Budinger's report. These could be recorded separately if required.



John H. Spickard, M. D.
Chairman
Human Studies Committee

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