

PNL-9182

UNIVERSITY OF CALIFORNIA
LOS ALAMOS SCIENTIFIC LABORATORY
(CONTRACT W-7405-ENG-36)
P. O. Box 1663
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712574

IN REPLY
REFER TO: H

July 16, 1973

Mr. Kenneth Swinth
Laboratory of Nuclear Medicine
and Radiation Biology
900 Veterans Avenue
Los Angeles, CA 90024

REPOSITORY PNL
COLLECTION Intraesophageal
BOX No. 2947
FOLDER HSC-73-5

Dear Ken:

I have enclosed the minutes of the meeting of the LASL Human Studies Review Committee which approved the proposal to use the esophageal probe in human volunteers. I have also included a copy of the proposed consent form to be used in accordance with the AEC and University of California requirements.

I would appreciate any comments that you may have following the review by the Battelle Northwest committee. In the meantime I will try to arrange a couple of volunteers for the experiments.

Sincerely yours,



George L. Voelz, M.D.
Health Division Leader

GLV/mjt

Encls. as stated

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CONSENT TO ACT AS HUMAN SUBJECT

Subject's name _____

Date: _____

1. I hereby authorize _____

(name of person(s) who will perform the
and/or such assistants as may

procedure(s) and/or investigation(s))

be selected by him to perform the following procedure(s) and/or investigation(s):

A probe similar in dimensions and flexibility to a gastroscope is to be passed part way down the esophagus and kept in place for about forty minutes. Surface anesthesia to the throat may be desired to cut down on the gag reflex. It will be necessary to use x-rays to localize the position of the tip of the probe. There are no electrical connections to the probe.

on _____

(Subject)

2. The procedure(s) and/or investigation(s) listed in Paragraph 1 has

(have) been explained to me by _____

(Name)

3. I understand that the procedure(s) and/or investigation(s) described

in Paragraph 1 involves (involve) the following possible risks and discomforts:

Keeping an esophageal probe 8 mm in diameter in position for an extended period is inherently uncomfortable, but is not painful.

There is a remote possibility when instruments are passed into any body orifice that damage to the structures (e.g., perforation) may be caused. One has to rely implicitly on the skill and care of the operator.

There are rare individuals who develop a sensitivity (allergic) reaction to local anesthetics, which may be helpful to use for insertion of the probe.

The exposure to diagnostic x-rays will be similar to a conventional examination of the esophagus and will be limited to the chest region.

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and that the possible benefits of the procedure(s) and/or investigation(s) are as follows:

This study will help determine if an esophageal counter probe will allow a more precise determination of amounts of long-lived alpha-active radionuclides deposited in tracheo-bronchial lymph nodes, and will be helpful in correlations with external counting measurements. The purpose is to find an improved method of determining internal radiation exposures to workers.

4. I understand that _____
(Name of person(s) who will perform procedure(s)
and/or investigation(s)) _____ and/or such assistants as may be selected
by him will answer any inquiries I may have at any time concerning the procedure(s) and/or investigation(s).

5. I understand that I may terminate my participation in the study at any time, and that, owing to the scientific nature of the study, the investigator may in his absolute discretion terminate my participation at any time. In the event that I am being compensated for my participation and my participation is terminated by me or by the investigator I understand that I will be entitled to payment of a sum based upon the scientific value to the study of the information obtained from my participation; provided, however, that in no event shall I receive less than _____ percent of the agreed compensation if I continue to participate beyond the _____
(Describe the applicable time period)
of the study.

SUBJECT'S SIGNATURE _____

WITNESS _____

(If subject is a minor, or otherwise unable to sign, complete the following):

Subject is a minor (age _____), or is unable to sign because

Father

Guardian

Mother

Other person and relationship

MINUTES OF MEETING OF THE HUMAN STUDIES REVIEW COMMITTEE

JUNE 16, 1973

Committee members present:

Harry O. Whipple, M.D., Chairman
Paul L. Flynn, M.D.
Rosemary H. Griffith
David Law, M.D., UNM Medical School
Harry F. Schulte, Secretary

Others present:

George L. Voelz, M.D., Division Leader
Phillip N. Dean

Committee member absent:

Donald F. Petersen

The Committee met to consider a proposal by Kenneth Swinth, M.D. of the University of California at Los Angeles. A copy of the proposal is available to all Committee members. Dr. Law explained that the proposed procedure should not be too uncomfortable. Considerable discussion was devoted to the "informed consent" form to be used. There have been differences between the AEC and the University of California about the proper type of form to be used. Ms. Griffith will look into this.

By telephone, Dr. Petersen questioned the use of a topical anesthetic as unnecessary and carrying the possibility of a specific reaction. The Committee felt that such a reaction seemed very unlikely but that actual statistics on the degree of risk could be obtained.

The matter of x-ray exposure in the procedure was discussed and questions were raised of whether an image intensifier would be used to minimize exposure. Also, is the fluoroscopy necessary and, if so, how much? It should be kept to a minimum. It was suggested that a swallow of barium should be observed to make certain that the esophagus is normal.

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It was also recommended that the procedure say that ethylene oxide sterilization will be done. It would be preferable to perform the procedure in the steel room in HRL building but there is no fluoroscopy equipment there. The tube could be inserted at the Medical Center and the patient moved to HRL.

Dr. Law said that the proposal seems reasonable and acceptable. The Committee expressed unanimous agreement if the suggestions noted above are included.