

OFFICE MEMORANDUM

712203

TO : Rosemary Griffith, DIR-ADLL ← → DATE: March 1, 1974

FROM : Robert S. Grier, M.D.

SUBJECT : CONSENT FORMS, ESOPHAGEAL PROBE PROJECT

SYMBOL : H-2

210-336...

Attached is a copy of the consent form with description of the information typed in. We have talked with five or six people and have one candidate, as of the moment, and one on the fence who is a possible candidate. The latter was concerned about what his possible medical status would be should we inadvertently perforate the esophagus or if some untoward event occur that we cannot foresee at the present. He would like assurance, in writing, that should some mishap occur the Laboratory would take care of his medical expenses, and for any possible complications in the future. I do not know the answer to this question; I would assume that the Laboratory would do the just thing should something of this sort occur, but naturally I have no authority to make such a commitment. I would appreciate your comments and guidance on this point, and whether such a statement should be part of the consent statement. Mr. Swinth is planning to come out here with the probe the first of next week and we were hoping to try it on one, or possibly two, volunteers on Wednesday afternoon, March 6th, and I'd appreciate your help and guidance.

Robert S. Grier, M.D.

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UNIVERSITY OF CALIFORNIA
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 such assistants as may be selected
and/or investigation(s))
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 _____

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(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

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