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UNIVERSITY OF CALIFORNIA  
LOS ALAMOS SCIENTIFIC LABORATORY  
(CONTRACT W-7405-ENG-36)  
P. O. Box 1663  
Los Alamos, New Mexico 87544

IN REPLY  
REFER TO: H

February 19, 1974

Mr. W. J. Bair  
Battelle Pacific Northwest Laboratories  
Battelle Boulevard  
Richland, WA 99352

Dear Bill:

The LASL Human Studies Review Committee has approved the use of the esophageal probe which was the subject of your letter of November 13, 1973. I have enclosed a copy of the action of our Committee as well as a signed confirmation that we have reviewed and approved the use of the probe on volunteers in compliance with the Guidelines for Protection of Human Subjects.

I trust this takes care of that matter and we will proceed now with arrangements for the initial trial of the probe. I talked recently with Ken Swinth and it looks like we should be able to do that in the near future.

Sincerely yours,

Original Signed by  
George L. Voelz, M.D.  
George L. Voelz, M.D.  
Health Division Leader

GLV/mjt

cc: Kenneth Swinth  
R. S. Grier, M.D.

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November 13, 1973



Pacific Northwest Laboratories  
Battelle Boulevard  
Richland, Washington 99352  
Telephone (509)  
Telex 36921

*Copy to Dr. Quinn, H-2  
for action by the  
Comm. This. 1/30*

Dr. George Voelz  
Health Division Leader  
University of California  
Los Alamos Scientific Laboratory  
Los Alamos, NM 87544

Dear Dr. Voelz:

The purpose of this letter is to advise you of actions taken by Battelle's Human Subjects Committee and some of our concerns concerning the testing of the esophageal probe.

Battelle's contribution to the esophageal probe was the development of the sensing source and the instrumentation related thereto. The probe, we understand, was designed by the staff of the UCLA Laboratory of Nuclear Medicine and Radiation Biology. It is apparently intended that your staff will actually perform the testing of the probe by use on human subjects who are, we understand, employees at Los Alamos Scientific Laboratory.

Our Human Subjects Committee has reviewed the portion of the work performed by Battelle and has determined to our satisfaction that in and of itself the sensing capability and related instrumentation present no unusual risk to the human subjects. With respect to the probe itself, which is the responsibility of the UCLA staff, as presenting a potential risk, we have not assessed that part of the experimentation. Additionally, since the testing is to be performed by your staff, we have not reviewed any of the procedures, protocols, or measures to protect the human subjects. Additionally, we have not reviewed the methods of securing consent nor procedures for screening potential participants.

Since the three cooperating institutions are all performing their portion of this activity under U.S. Atomic Energy Commission contracts, we have assumed that each must comply

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Dr. George Voelz  
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with the requirements for protection of human subjects in accordance with AEC requirements. Accordingly, our approval of the experimentation involved in testing the probe on human subjects is conditioned upon the understanding that the other two institutions' Human Subjects Committees have reviewed their portion of the work and have approved it on the basis of compliance with the Guidelines for Protection of Human Subjects, which the AEC requires. We would appreciate your confirming that this has been done and that the experimentation has been approved consistent with those Guidelines. You may do so by signing in the appropriate space below, reflecting that the necessary action by LASL and UCLA Human Subjects Committees has approved the program.

Very truly yours,



W. J. Bair, Chairman  
Human Subjects Committee

CONFIRMED:

By George H. Cook  
Title LASL Health Division Leader  
Date 16 February '74

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OFFICE MEMORANDUM

TO : George L. Voelz, M.D., H-DO

DATE: February 6, 1974

FROM : Robert S. Grier, M.D., Chairman  
Human Use Committee

SUBJECT : ESOPHAGEAL PROBE

SYMBOL : H-2

This is a private communication from the Los Alamos Scientific Laboratory and should not be further distributed or referenced without written permission of LASL.

The Human Use Committee met on January 15, 1974 and again reviewed Battelle's letter concerning the esophageal probe. They had previously given consent on June 16, 1973, and at the meeting on January 15th they saw no objection to signing the approval requested by Battelle. The Committee felt that at the time the probe was used on human subjects the following precautions should be carried out:

1. Long form. The long form consent to be made out and the project explained to the subject.
2. The probe be introduced by Dr. Lee, in the X-Ray Department, under fluoroscopic control, and that it might be well to have a barium swallow on each new subject, if indicated by Dr. Lee.
3. Also, at the time of passing of the probe, one of the surgeons - either Dr. Oakes or Drs. Newman and Jackson - would be present or readily available in the event any difficulties should arise.
4. Sterilization of the probe would be accomplished with the use of ethylene oxide. It is anticipated that one of the physicians of H-2 would be present during the procedures with the esophageal probe, at least until some experience had been gained with the procedure and probably someone uncomfortable was innocuous.

  
Robert S. Grier, M.D.

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