

October 8, 1984

To: IRB File on P. Meyer Project

From: Fred Hatch, Chair, IRB

Subject: Update on review of project

*F.T. Hatch, M.D.*

Our concern about this project, specifically the elective administration of somewhat less than 0.5 rem of radiation, has been discussed extensively with IRB members George Lawton and Sam Cole, Legal Office attorney Max Creamer, and with CDR L. Yaffee, Chair of the IRB at the NMRI. In addition a state-of-the-art risk estimate for lung cancer has been made by Lynn Anspaugh of ENV Division. This risk estimate lies between 1 per 10E5 and 1 per 10E4. The risk is not negligible by some people's interpretation; and Dr. Anspaugh (also Art Toy of H.C.) question whether LLNL should go through with this experiment.

On the basis of the above discussions, I have drawn the following conclusions. 1) NIH guidelines will be complied with provided the consent form (revision attached) sets forth the risk clearly; 2) The ethical concern is largely removed by following NIH guidelines, by having in hand the approval by the IRB at NMRI, and by assuring ample discussion of the procedures and attendant risk at a briefing session before the experiments take place; 3) The institutional risk to LLNL and the University cannot be mitigated, but is considered acceptable to the Legal Office provided a very thorough file on the experiments, including all dosimetric data, is maintained in the IRB Office (in a form that will be usable many years hence when any consequent litigation may occur).

Based on discussions and literature provided by P. Meyer, I can state that there is significant potential benefit from this project to the diving profession, both in the military and in civilian activities. The results obtained in previous work on this project have been published in scientific journals and presented at various meetings, so they are made freely available to the public.

The draft approval memorandum from V. Shepherd to P. Meyer dated 27 Aug., 1984 will be revised to include the above admonition regarding complete file preparation and submission to the IRB, use of both NMRI and LLNL (revised) consent forms, and brought to current date.

Paragraph 3 of the LLNL consent form shall be revised to read as follows:

"I understand that the following risks and discomfort may result from the procedures:

a. discomfort from breathing through a mouthpiece for up to 2 hours.

b. Any exposure to ionizing radiation carries a small risk of causing cancer--in this case potentially of the lung or trachea where most of the dose is delivered. The best estimate of the risk of this procedure lies between 1 chance in 100,000 and 1 chance in 10,000. The radiation exposure in this procedure will be less than 0.4 rem. This amount is slightly below the Federal exposure limit for annual exposure of the general

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population; is one-tenth of the permissible annual exposure of radiation workers; and is approximately twice the natural background radiation received in most geographical areas of the United States."

Paragraph 6 of the LLNL consent form shall have the following sentence added at the end.

"The findings will be of significant benefit to the diving profession in the future, and will be made available as soon as the studies are completed."