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Institutional Review Board
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Notes
informational meeting w/Larry Anderson et al.
regarding whole body counter activities involving
human subjects with inhaled radionuclides

Meeting date: Tuesday, January 24 at 1:30 p.m. in B-361, R-1155

Attendees:

Institutional Review Board Members:

Max Creamer
Jim Johnson
Kathleen Noonan
Jack Shearer

Larry Anderson
Tracy Simpson
Debby Kruchten
Tom Crites
Chuck Prevo
Jordan Powell
[redacted], AERE Harwell (subject to be counted)

Dr. [redacted], AERE Harwell, is visiting Larry Anderson. [redacted] is one of the volunteers involved in the niobium measurement study.

Tom Crites asked for this meeting through Larry Anderson. The purpose of the meeting is to discuss where the lung counting program is going. We should consider this meeting an information exchange to provide more information to the IRB.

[redacted] is the fourth subject in the Ni-92m counting program that began in late 1987. The next two people will be [redacted] and [redacted] will visit in mid-February and Larry would like him to meet with the IRB for the same purpose as this meeting. The visits have been approved by a DOE committee coordinating the U.S. effort and involvement in this study.

Jack Shearer gave a list of 7 questions that he either needs answered or provided with better answers. They are:

1. What problem does the proposed experiment address?
2. Is the problem sufficiently important to warrant the use of human beings?
3. Is the protocol (or experiment) designed to provide the desired information? (How many people, what period of time, overall complete protocol)
4. What is the worst thing that could happen to a person involved in this experiment? (death by cancer)
5. What is the probability that one of the human subjects will experience the worst case?
6. Can some or all of the needed information be obtained by a procedure which will reduce or eliminate the need for the use of human subjects?
7. Would we approve of this protocol if LLNL subjects only were involved? (the answer is no)

Jack either doesn't know the answers to these questions, or if he knows the answers, the answers are not favorable.

Pritchard talked about his professional background. He is a physicist, section leader of human health effects of the Human Toxicology Group at Harwell. Don Newton is the section leader in charge of whole body monitoring section, and is the instigator of proposals (niobium and barium studies). Inhalation of particles includes finding information on particle size, breathing patterns, differences in deposition and measurements between men and women, significant smoking habits. Now we can actually measure how much tar people are inhaling.

For 6-7 years, Pritchard has also been the secretary to the Human Ethics Committee at Harwell, but is no longer in that capacity as he proposed protocols for consideration. This committee is an ethics committee, as well as providing peer review for experiments. Pritchard was a coauthor of the new code of practices for this Committee (LLNL IRB has been provided copy of this code). The purview of the committee has been expanded; there are now lay and trade union representatives on this committee. If any work is done involving irradiation of human subjects, the P.I. must be licensed.

Over the past several years, work has been done validating models for ICRB standards. Pritchard has been involved in testing ICRP deposition and clearance models.

The barium study: is a continuation of testing ICRP model. Most data is based on single subject with occupational burden. Ba experiment involves six subject. Newton has detailed information on doses involved. As a part of the study, there were some differences observed from that studied earlier. The reason Battelle and LLNL have been involved in these studies is because they have the state-of-the-art counting equipment and Harwell does not. The equipment to look at distribution of doses at different parts of the body.

Niobium study

History: Started 13-15 years ago with an isotope of palladium to try and estimate what proportion escaped from the lung. Some attempt to correlate chest wall thickness. Palladium gives off high energy x-rays.

In 1982 successful study involving niobium to validate phantom (male phantom). Question: there are a lot of female workers at Aldermaston in England--different chest wall thickness and distribution?

1983-85 study involving women. Women received different particle size, getting much less of niobium returned in deep lung tissue than the study with man. Distribution questions--same for women as men? Smaller particle size used to approximate same distribution.

Battelle studied subject with smaller particle sizes (Pu-238 accidental exposure). 5 microns particle size used in original study. Subsequent studies have shown that smaller particle size is probably more standard (1 micron). It was suggested that volunteer experiment be repeated with 1 micron particle size to more closely represent actual deposition size.

Why measure it at all? Hard to estimate lung burdens. Not practical to use air sampling data. The original niobium study protocol spells out more of justification for experiments than later study protocol.

Numbers of subjects this time: total of 8 subjects, 70 mSv total radiation dose.

Primary objective of study: calibration. Also of interest: look how close particles penetrate as function of particle size. Now, the phantoms show 5 micron particle size is very representative of humans--phantom will have to be modified to show 1 micron particle size is more representative. The smaller particle size (i.e. 0.1 micron) the more susceptible they are to Brownian motion and attenuation.

Creamer asked is there an intent to go beyond the 1 micron particle size? After this study is completed, if differences are of sufficient magnitude, may want to look at smaller particle size.

Different particle sizes used to find out minimum that can be detected and distribution. (1) distribution at this size particle; (2) knowing minimum activity that can be detected with our present measuring techniques.

Pritchard said that by regulation, we are being asked to keep exposure at a level which cannot be measured. Being asked to measure things we cannot measure or in danger of having license revoked. Phantom is an integral item.

Creamer: how many more people is LLNL likely to see? Pritchard says he has no clear idea of what they will do at this point. He has to check with Don Newton.

Take volunteer experiments one step at a time. Possibility, amount of activity needs to be much less.

Shearer asked if there is information on how our system has been improved based on the experiments using phantoms and involving human subjects. Anderson: With 5 micron particle size,a factor of 3-5 off. Based on adjustments made after experiments, phantom was error of 2. With distribution and variability of particle sizes, we are back to a factor of 3.