

PNL-10616-027

Date May 22, 1978
To E. B. Harkins, Vice Chairman
Human Subjects Committee
From Bob Robinson *Bob Robinson*
Subject HSC 78-2: Translocation of Yellowcake from the
Human Respiratory Tract (300A01198)

729549

TW Ambrose
LG Faust
KR Heid
RL Roswell
Contract Services
File
LB

In response to your memo of May 2, 1978, and our telecon of May 11, 1978, the additional information on how human subjects would be involved in Phase I is given below and a revised consent form for Phase II is attached.

Phase I of the study will be involved with confirming analytical results of unidentified urine samples being submitted as part of an already established surveillance program. In as much as Phase I is involved only with confirming analytical results and there will be no contact with human subjects, there would apparently be no need for a consent form for Phase I.

For Phase II, employees will be selected following an unplanned incident from incident reports based on the magnitude of the exposure and chemical form of yellowcake involved. There will be no pre-selection of either mill site or participants.

The consent form for Phase II (attached) has been revised to include the number of measurements to be made and to state that consent is being given after an incident of yellowcake exposure. Also, the "technical" language in the consent form has been simplified, i.e., excreta samples has been changed to read urine and fecal samples.

If you have questions or I can be of further assistance, please advise.

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attachment

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REPOSITORY PNL
COLLECTION Yellowcake
BOX No. 3161
FOLDER DHSC 81-8

HUMAN SUBJ.

MAY 23 1978

COMMITTEE

INFORMED CONSENT FOR YELLOWCAKE STUDY

After being involved in an incident in which I was exposed to yellowcake on _____, I, _____, am volun-
(date) (name)
teering to participate in the Battelle-Northwest (BNW) study sponsored by the U.S. Nuclear Regulatory Commission to better understand the behavior of uranium in the human body following the inhalation of yellowcake. I understand that following an unplanned inhalation of yellowcake during my working day I will be asked to go and stay in Richland, Washington for a period of approximately two weeks. The purpose is to assure a period of contamination-free environment and ready accessibility to the BNW whole body counting facility. At the counting facility BNW will make three one-hour measurements per day on my lungs and other organs by placing radiation detectors outside of my body. Also, I am to provide daily urine samples and no more than ten fecal samples for analysis of uranium content.

At the end of two weeks, I am to return home for a two-week period, but will not go back to work. I will then return to Richland, Washington for another two to three days for more measurements in the whole body counting facility and to submit daily urine samples. At the end of this period, I may return to my home and work.

I understand that the data is to be coded and used in a statistical sense and my identity is not to be used in any of the research reports. My identity, however, may be used between BNW and my employer for necessary accounting, travel, and such non-research related purposes.

BNW is to make necessary arrangements with my employer so that all travel and reasonable living expenses will be reimbursed and my pay, benefits, etc. remain exactly as if I were present on the job. In addition, I am free to withdraw from the study at any time with no penalties, reimbursements, or effects on my job.

I have had the opportunity to ask questions and receive answers regarding the details of the program. The physical risks involved are not expected to exceed the ordinary risks associated with my travel to and from Richland, Washington.

(name)

(date)