

REPOSITORY PNL Eng. Bldg, Sersea 3000
COLLECTION Promethium & Plutonium
BOX No. 3156
FOLDER HS Committee
~~NOVEMBER 22, 1966~~

bcc: RS Paul
CE Newton, Jr.
WJ Bair
PT Santilli

U. S. Atomic Energy Commission
Richland Operations Office
Richland, Washington

Attention: Mr. C. L. Robinson, Acting Director
Research and Development Division

Gentlemen:

**AGREEMENT WITH HUMAN VOLUNTEERS
IN RESEARCH PROGRAMS**
Ref: RSLA

This is in response to Paul Holsted's earlier letter on the above subject asking our comments regarding a draft of a proposed agreement which may be used with human volunteers who agree to take part in experiments on the effects of certain radioisotopes on humans. The Fiscal Year 1967 funding for the program has recently been formalized.

As indicated in the 189 Form covering the Battelle-Northwest portion of the studies involved, entitled "Excretion Rates Versus Lung Burdens in Man", Budget Activity No. 06-01-02, Battelle cannot engage in the practice of medicine or perform research on human subjects. In order to clearly indicate that Battelle is not a party to the practice of medicine, or to the portion of the study involving human subjects, it was stipulated in our proposal that it was necessary to arrange for a separate contract between the party conducting this portion of the study and the Atomic Energy Commission

In line with this concept, and since Battelle is not a party to the proposed human volunteers agreement, we request that the wording be modified to exclude specific reference to Battelle-Northwest. The following changes are requested to accomplish this objective and yet satisfy the need for protection:

*July on
10/26/66 -
The agreement
actually had
reference to
John 189
V. Hol. Vol. Comtee
06-01-02
06-35*

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AUTHOR:	P. T. Santilli	FOR SIGNATURE OF:	S. L. Fawcett
OPERATION			
FOR APPROVAL OF	R. S. Paul		
APPROVED	<i>RS Paul</i>		
DATE	11/23/66		

- (1) The last line on Page 1 and the first line on Page 2 should be revised substantially as follows: "... members of the Foundation, the Hospital staff and other parties as selected by him."
- (2) In the second full paragraph on Page 2, the first sentence should be revised substantially as follows: "For the purposes of these experiments and studies, it is understood that I am not an employee of the Hanford Occupational Health Foundation, the Atomic Energy Commission, or any of the parties performing services or providing materials or equipment for the conduct of the experiments or studies described herein."
- (3) In the third full paragraph on Page 2, the fourth, fifth and sixth lines should be revised to read as follows: "... (as represented by the Atomic Energy Commission), Kadlec Memorial Hospital, all physicians and staff, and all other parties performing services or providing materials or equipment in the conduct of the experiments or studies described herein, from any liability."

Merely as a suggestion for the consideration of the Atomic Energy Commission and not as a party to the agreement, you may wish to consider rewording of the second full paragraph on Page 1 to more accurately define the parameters of the experiments as they become more definite.

We appreciate the opportunity to clarify this relationship of the parties. If we can be of further assistance, please let us know.

Very truly yours,

S. L. Fawcett
Director

SLF/ib

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