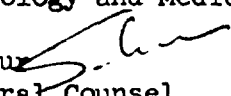


UNITED STATES GOVERNMENT

# Memorandum

TO : Dr. Charles L. Dunham, Director  
Division of Biology and Medicine

FROM : Bertram H. Schur   
Associate General Counsel

DATE: MAY 13 1966

SUBJECT: USE OF HUMAN VOLUNTEERS IN BIOMEDICAL RESEARCH

This is in reference to a proposed memorandum to bring to the attention of the General Manager the contemplated new AEC biomedical research project involving the use of human volunteers. As we understand it, convicts, college students, and other individuals, twenty one years of age or older, will be invited to volunteer, and monetary consideration will be paid for their services. These individuals will ingest or be injected with promethium-147 or plutonium-237. This program will be conducted for AEC by the Hanford Occupational Health Foundation. You have asked for our views.

From the legal standpoint, there are two areas of potential risk which should be considered in the use of human volunteers in experiments:

1. Risk of adverse effects from the radiation experiments properly carried out; for example, the risk that the intended dosage of 0.1 roentgens might cause some pathological condition in certain individuals.
2. Risk of injury from negligent conduct in the course of the experiment; for example, the risk that an experimenter might be negligent in the operation of the radiation source and give dosage of 1.0 rather than 0.1 roentgens causing injury to the volunteer.

It is our opinion that each volunteer should sign a written, witnessed agreement in which he or she states that he or she is in sound mental and physical condition and is participating in the experiment on his or her own volition, that he or she understands that what is being done is for experimental purposes and not for the treatment or diagnosis of the individual, and that he or she understands the nature, procedures, and probable effects of the experiment. In addition, the agreement should set forth the nature and purpose of the experiment, the procedure to be used (including a description of the individual volunteer's participation or use in the experiment), the known possible risks, if any, and the arrangements, if necessary, for possible termination of the experiment or research (e.g. if the volunteer later desires to withdraw from the experiment). It would be advisable if the agreement also negated any inference that the paid volunteers are employees of the contractor for purposes of the experiment. The agreement should be signed only after the volunteer has had an



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opportunity to ask questions. Assuming complete understanding and no unequal bargaining factors (e.g. pressure on prisoners to submit), such an agreement would protect against liability for unauthorized invasion of the person.

The consent form may also contain language absolving the contractor and the AEC from responsibility for injuries to a volunteer resulting from the experiment. This would probably be binding on the volunteer if no negligence occurs. It is doubtful, however, that the clause can be so drawn as to be binding on the volunteer if negligence causes the injury. Not only is the law uncertain on this point, but we cannot be sure as to what law will apply. (Developments in the field of conflicts of law have been such that it is not clear whether the law of the State of Washington would be applied in every case; for example, a volunteer residing in some other state when his injury first becomes apparent might contend that that other state has the most significant contacts with the claim and that its law should be applied.)

Whether or not language absolving the contractor and the AEC from liability - either with or without mentioning negligence - should be incorporated in the consent form is a matter of policy. It may well be that the Commission would prefer not to attempt to add any special provisions designed to eliminate or minimize possible liability. In this regard, it should be borne in mind that the consent agreement itself, without specially added language, would probably be considered as tantamount to a disclaimer of liability for injuries resulting from the experiment properly carried out - that is, where no negligence occurs.

We understand that the contractor has no special view with respect to the obtainment of any special disclaimer agreements, and, also, that liability insurance is available at a reasonable premium; presumably, the contractor and RLOO are exploring the advisability of obtaining such insurance.

cc: Chester G. Brinck, RLOO  
Dr. Wm. T. Doran, Jr., OS

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