



DEPARTMENT OF THE ARMY  
EDGEWOOD ARSENAL  
ABERDEEN PROVING GROUND, MARYLAND 21010

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SAREA-TD

1 8 JUL 1976

SUBJECT: Testing Involving Humans

THRU: Commander  
US Army Armament Command  
Rock Island, IL 61201

Commander  
US Army Materiel Development and Readiness Command  
5001 Eisenhower Avenue  
Alexandria, VA 22333

TO: HQDA (DASG-RDZ-A)  
WASH DC 20314

1. In spite of considerable interpretive information which has been forthcoming from OTSG since the publication of AR 70-25, there still remains the need to exercise sound judgment at the operational level as to when a particular involvement of humans in testing requires the processing of a formal protocol for TSG approval. This point was discussed between Assistant Surgeon General for Research and Development and the undersigned, and the following procedure was established:

a. When the use of humans as test subjects in work in hazardous studies (as defined in AR 70-25) is needed, required protocols will be forwarded to TSG for approval. The protocols will be reviewed by the EWA Medical Review Committee and by the EWA Human Use Committee. Upon their approval the protocols will be forwarded to Assistant Surgeon General for Research and Development for further processing. If the work requires testing involving chemical agents, the protocols will be forwarded to TSG regardless of the degree of hazard or risk involved.

b. When the use of humans as test subjects in work not involving chemicals is needed (e.g., obtaining anthropometric measurements for mask sizing or testing fit of masks without exposure to agents), the



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requirement will be reviewed by the EWA Medical Review Committee to ascertain whether a hazard or risk exists which would require formal OTSG approval. The Medical Review Committee will also decide whether the protocol warrants further review and approval by the EWA Human Use Committee. If the judgment is made that no significant risk warranting TSG review is involved, the EWA Medical Review Committee will approve locally. Each such action will be documented stating the particulars of the test program and the rationale for local approval. A copy of this documentation will be furnished to OTSG.

c. Individuals whose normal work duties involve risk of exposure, such as technical personnel in the laboratory or conducting field tests, are not considered as test subjects.

2. Your earliest comments and/or concurrence is requested.

FOR THE COMMANDER:

B. L. HARRIS  
Technical Director

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