

AR 70-25
DATED 31 Jan 74

ARM1.940713.026

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RESEARCH AND DEVELOPMENT**USE OF VOLUNTEERS AS SUBJECTS OF RESEARCH**

ARMY REGULATIONS

No. 70-25

HEADQUARTERS,
DEPARTMENT OF THE ARMY
WASHINGTON 25, D.C., 28 March 1968

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1. Purpose. These regulations prescribe policies and procedures governing the use of volunteers as subjects in Department of the Army research, including research in nuclear, biological, and chemical warfare, wherein human beings are deliberately exposed to unusual or potentially hazardous conditions. These regulations are applicable worldwide, wherever volunteers are used as subjects in Department of the Army research.

2. Definition. For the purpose of these regulations, unusual and potentially hazardous conditions are those which may be reasonably expected to involve the risk, beyond the normal call of duty, of privation, discomfort, distress, pain, damage to health, bodily harm, physical injury, or death.

3. Exemptions. The following categories of activities and investigative programs are exempt from the provisions of these regulations:

a. Research and nonresearch programs, tasks, and tests which may involve inherent occupational hazards to health or exposure of personnel to potentially hazardous situations encountered as part of training or other normal duties, e.g., flight training, jump training, marksmanship training, ranger training, fire drills, gas drills, and handling of explosives.

b. That portion of human factors research which involves normal training or other military duties as part of an experiment, wherein disclosure of experimental conditions to participating personnel would reveal the artificial nature of such conditions and defeat the purpose of the investigation.

c. Ethical medical and clinical investigations involving the basic disease process or new treatment procedures conducted by the Army Medical Service for the benefit of patients.

4. Basic principles. Certain basic principles must be observed to satisfy moral, ethical, and legal concepts. These are--

a. Voluntary consent is absolutely essential.

(1) The volunteer will have legal capacity to give consent, and must give consent freely without being subjected to any force or duress. He must have sufficient understanding of the implications of his participation to enable him to make an informed decision, so far as such knowledge does not compromise the experiment. He will be told as much of the nature, duration, and purpose of the experiment, the method and means by which it is to be conducted, and the inconvenience and hazards to be expected, as will not invalidate the results. He will be fully informed of the effects upon his health or person which may possibly come from his participation in the experiment.

(2) The consent of the volunteer will be in writing. A document setting forth substantially the above requirements will be signed by the volunteer in the presence of at least one witness not involved in the research study who will attest to such signature in writing.

- (3) The responsibility for ascertaining the quality of the consent rests upon each person who initiates, directs, or conducts the experiment. It is a personal responsibility which may not be delegated.
 - b. The number of volunteers used will be kept at a minimum consistent with c below.
 - c. The experiment must be such as to contribute significantly to approved research and have reasonable prospects of yielding militarily important results essential to an Army research program which are not obtainable by other methods or means of study.
 - d. The experiment will be conducted so as to avoid all unnecessary physical and mental suffering and injury.
 - e. No experiment will be conducted if there is any reason inherent to the nature of the experiment to believe that death or disabling injury will occur.
 - f. The degree of risk to be taken will never exceed that determined to be required by the urgency or importance of the Army program for which the experiment is necessary.
 - g. Proper preparations will be made and adequate facilities provided to protect the volunteer against all foreseeable possibilities of injury, disability, or death.
 - h. The experiment will be conducted only by scientifically qualified persons. The highest degree of skill and care will be required during all stages of the experiment of persons who conduct or engage in the experiment.
 - i. The volunteer will be informed that at any time during the course of the experiment he will have the right to revoke his consent and withdraw from the experiment, without prejudice to himself.
 - j. Volunteers will have no physical or mental diseases which will make the proposed experiment more hazardous for them than for normal healthy persons. This determination will be made by the project leader with, if necessary, competent medical advice.
 - k. The scientist in charge will be prepared to terminate the experiment at any stage if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that continuation is likely to result in injury, disability, or death to the volunteer.

7. Prisoners of war will not be used under any circumstances.

5. Additional safeguards. As added protection for volunteers, the following safeguards will be provided:

- a. A physician approved by The Surgeon General will be responsible for the medical care of volunteers. The physician may or may not be the project leader but will have authority to terminate the experiment at any time that he believes death, injury, or bodily harm is likely to result.

- b. All apparatus and instruments necessary to deal with likely emergency situations will be available.

- c. Required medical treatment and hospitalization will be provided for all casualties.

- d. The physician in charge will have consultants available to him on short notice throughout the experiment who are competent to advise or assist with complications which can be anticipated.

6. Approval to conduct experiment. It is the responsibility of the head of each major command and other agency to submit to The Surgeon General a written proposal for studies which come within the purview of this directive. The proposal will include for each study the name of the person to be in charge, name of the proposed attending physician, and the detailed plan of the experiment. The Surgeon General will review the proposal and forward it with his comments and recommendations on medical aspects to the Chief of Research and Development for approval. When a proposal pertains to research with nuclear, biological, or chemical agents, the Chief of Research and Development will submit the proposal, together with The Surgeon General's review, to the Secretary of the Army for approval. No research with nuclear, biological, or chemical agents using volunteers will be undertaken without the consent of the Secretary of the Army.

7. Civilian employees. When civilian employees of the Department of the Army volunteer under this program, the following instructions will be observed:

- a. Any duty as a volunteer performed during the employee's regularly scheduled tour of duty will be considered as constructive duty for which straight time rates are payable. Time spent in connection with an experiment outside the employee's regularly scheduled tour will be consid-

ered as voluntary overtime for which no payment may be made nor compensatory time granted. The employee will be so informed before acceptance of his volunteer services.

b. Claims submitted to the Bureau of Employees' Compensation, U.S. Department of Labor, because of disability or death resulting from an employee's voluntary participation in experiments, will include a citation to title 10, United States Code, section 4503 as the Department of the Army authority for the use of such volunteer services.

c. All questions concerning hours of duty, pay,

leave, compensation claims, or application of other civilian personnel regulations to volunteer employees will be presented through channels to the Deputy Chief of Staff for Personnel, ATTN: Office of Civilian Personnel.

8. **Implementing instructions.** Heads of major commands and other agencies will issue necessary implementing instructions to subordinate units. Copies of implementing instructions will be furnished to the Chief of Research and Development.