*AR 70-25

ARMY REGULATION
No. 70-25

HEADQUARTERS,
DEPARTMENT OF THE ARMY
WASHINGTON, DC, *31 July 1974*

RESEARCH AND DEVELOPMENT

USE OF VOLUNTEERS AS SUBJECTS OF RESEARCH

Effective 15 September 1974

This revision transfers the final approval authority from the Chief of Research and Development to The Surgeon General for all research using volunteers, except research involving nuclear and chemical warfare agents and identifies the requirement for use of active duty military personnel as volunteers and instructs major commanders to provide assistance in their recruitment. Local limited supplementation of this regulation is permitted, but is not required. If supplements are issued, Army Staff agencies and major Army commands will furnish one copy of each to HQDA (DASG-RDZ), Washington, DC 20310. Other commands will furnish one copy each to the next higher headquarters.

1. Purpose. These regulations prescribe policies and procedures governing the use of volunteers as subjects in Department of the Army research 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 inconveniences 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

*This regulation supersedes AR 70-25, 26 March 1962.

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.

l. 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 has final approval authority for all research using volunteers except research with nuclear or chemical warfare agents. Proposals for research with nuclear or chemical warfare agents will be forwarded by The Surgeon General with recommendations on medical aspects to the Secretary of the Army for approval.

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 considered 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,

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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. Recruitment of active duty military volunteers. Some research will require active duty military personnel as volunteers because of the nature of the investigations. Recruiting is best accomplished by research personnel responsible for conduct of the research. Major commanders will provide assistance to recruiting teams. At all times recruiting will be conducted in a morally, ethically, and legally acceptable manner.

APPENDIX

LEGAL IMPLICATIONS

The following opinions of The Judge Advocate General furnish specific guidance for all participants in research using volunteers:

1. Authority. The Secretary of the Army is authorized to conduct research and development programs including the procurement of services that are needed for these programs (10 U.S.C. 4503). The Secretary has the authority to "assign detail and prescribe the duties" of both members of the Army and civilian personnel (10 U.S.C. 3012(e)).

2. Military personnel and Department of the Army civilian employees. Compensation for the disability of death of a civilian employee resulting from personal injury or disease proximately caused by his employment is payable under the Federal Employees Compensation Act (39 Stat. 742 et seq.), as amended (5 U.S.C. 751 et seq.), regardless of whether his employment was of a hazardous nature. The amount and type of disability compensation or other benefits payable by reason of the death or disability of a member of the Army resulting from injury or disease incident to service depends upon the individual status of each member, and is covered by various provisions of law. It may be stated generally that under present laws no additional rights against the Government will result from the death or disability of military and civilian personnel participating in experiments by reason of the hazardous nature of the operations.

3. Private citizens. It is the policy of the United States to prohibit the acceptance of voluntary services particularly when they may provide a basis for a future claim against the Government. (R.S. 3679, as amended; 31 U.S.C. 665(b)).

4. Use of appropriated funds for the purchase of insurance. As the payment of insurance premiums on the life of an officer or employee of the United States is a form of compensation which is not currently authorized, payment of those premiums is prohibited (R.S. 1765; *Commissioner of Internal Revenue* v. *Bonwit,* 87 F 2d 764 (2d Cir. 1937); *Canaday* v. *Guitteau,* 86 F 2d 303 (6th Cir. 1936); 24 Comp Gen. 648 (1945)).

5. Contractor's employees. There appears to be no legal objection to the use of employees of contractors in research and development experiments. It is the responsibility of the contracting officer to determine whether the terms of the contract are sufficiently broad to permit the participation of these employees. Generally, benefits to which private employees may become entitled by reason of death or disability resulting from their employment are payable under State law except persons covered by the survivors insurance provisions of the Social Security Act (49 Stat. 623, as amended (42 U.S.C. 402)). Reimbursement of the employer for additional costs by reason of this liability of his employees will depend upon the terms of each contract. These employees are not disqualified from prosecuting claims against the Government under the Federal Torts Claims Act (28 U.S.C. 2671 et seq., see AR 25-70). In cost reimbursement type research contracts with commercial organizations the cost of maintaining group accident and life insurance may be reimbursed to the contractor (subject to certain exceptions) under ASPR 15-205.16 provided that the approval of the head of the Procuring Activity is obtained (APP 10-551).

6. Irregular or fee-basis employees. Intermittent services of such employees are authorized. (For experts and consultants see Sec. 15, Act of 2 Aug 1946 (60 Stat. 810; 5 U.S.C. 55a); Sec. 501, DoD Appropriation Act, 1961 (74 Stat. 349); note APP 30-204.1, CPR A7; Sec. 710 Defense Production Act of 1960 (64 Stat. 819; 50 U.S.C. App 2160); and for architects, engineers, and other technical and professional personnel on a fee basis, see 10 U.S.C. 4540.). Whether these employees can be detailed or assigned to the proposed experiments will depend upon the statutory authority for employment and the provisions of their employment agreement in each case. The Federal Employees Compensation Act, *supra,* in all probability applies with respect to these irregular and fee-basis employees for any injury or disease resulting from their employment, although a final determination in such cases will have to be made by the Bureau of Employees Compensation, Department of Labor. Subject to such restrictions and limitations as may appear in the statutory authority under which he is employed, it would appear that the Government may legally bear the expense of premiums upon the life of an irregular or fee-basis employee whose rate of compensation is not fixed by law or regulations. In this regard, it may be advisable for the Government to provide an

additional allowance to the employee for financing such private insurance arrangements as he may wish to make rather than to undertake direct negotiations with insurance carriers for the desired coverage.

7. Conclusion. Subject to the above conditions, Armed Forces personnel and/or civilians on duty at installations engaged in research in subject fields will be permitted to actively participate in all phases of the program.

The proponent agency of this regulation is the Office of The Surgeon General. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to HQDA (DASG–RDZ), WASH DC 20310.

By Order of the Secretary of the Army:

CREIGHTON W. ABRAMS
General, United States Army
Chief of Staff

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VERNE L. BOWERS
Major General, United States Army
The Adjutant General

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SUBJECT: HUMAN TESTING

1. AR 70-25 DOES NOT REFLECT THE CURRENT POLICY CONTAINED IN THE DRAFT DOD DIRECTIVE SUBJECT: PROTECTION OF HUMAN SUBJECTS IN DOD RDT&E AND CLINICAL INVESTIGATION ACTIVITIES WHICH IS CURRENTLY BEING STAFFED AND FINALIZED.

2. THE NEW DOD DIRECTIVE IS CONSISTENT WITH HQ DA LTR REFERENCED IN PARAGRAPH 4 AND SHOULD BE PUBLISHED SHORTLY.

3. AR 70-25 IS PRESENTLY BEING REWRITTEN TO REFLECT THE PENDING DOD DIRECTIVE AND SHOULD BE AVAILABLE DURING THE FIRST QUARTER FY82.

4. IN THE MEANTIME, THE ANNOUNCED POLICIES OF HQ DA LTR DTD 16 JUN 80 SUBJECT: HUMAN TESTING REMAIN VALID PENDING PUBLICATION OF REVISED AR 70-25. USE OF VOLUNTEERS AS SUBJECTS OF RESEARCH.

5. DISSEMINATE TO ALL HUMAN TESTING FACILITIES.

6. COORDINATED BY: OSA(GC), OASA(RDA), ODCSOPS, ODCSPER, ODCSRDA, OTJAG, OTEA AND DASG-HOP.

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AR 70-25.