SECUR. CLASSIFICATION (If any)

DISPOSITION FORM

FILE NO.	SUBJECT
461 Procurement -2-2 REC	Proposed [illegible] Procurement Instruction re the [illegible] Volunteers in Research [illegible] Development [illegible]

TO	FROM	DATE	COMMENT NO. 1
Executive Officer [illegible] Office	Chief, Procurement Div. [illegible]	6 April 1954 [illegible]Fredericks/5136/eo	

[illegible] Proposed [illegible] Procurement Instruction re the use of volunteers in research and development contracts is returned herewith for further concurrence in view of [illegible] made in proposed directive in accordance with the various suggestions received from divisions of this Headquarters.

1 Incl
Proposed [illegible] PI

[signature]
[illegible] J. [illegible]
Colonel, [illegible]
Chief, Procurement Division

To Chief, Procurement Div.
A few additional suggested changes are indicated in pencil on draft.

[initials]
[illegible] Off.

7 (18)

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DD FORM 1 FEB 50 96 REPLACES NME FORM 96, 1 OCT 48, WHICH MAY BE USED.

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RECOM PROCUREMENT INSTRUCTION NO. -54-

RECOM PI NO. -54-
CML C RESEARCH AND ENGINEERING COMMAND
ARMY CHEMICAL CENTER, MARYLAND
6 April 1954

RESEARCH AND DEVELOPMENT CONTRACTS - USE OF VOLUNTEERS

(To remain in effect until rescinded)

Paragraph

of defense against atomic biological and chemical warfare *

1. Purpose

MAIN

To transmit the policy of the Department of the Army with respect to the
To permit a realistic evaluation and/or development of effective preventive measures
use of volunteers in research by Government contractors and to establish procedures
for effecting same.
and safeguards

2. References

a. Memorandum from the Office of the Chief of Staff, Subject: Use of Volunteers in Research, dated 30 June 1953.

b. Letter from the Office of the Chief Chemical Officer, Subject: Use of Volunteers in Research, dated 24 December 1953, file reference CMLRR-C.

c. Letter from the Office of the Chief Chemical Officer, Subject: Classification of Research Contracts, dated 3 February 1954, file reference CMLRO I.1.

3. Scope

a. This directive shall apply to all contracts involving the use of human subjects in research in defense against atomic, biological, or chemical agents. This is interpreted to encompass the exposure of individuals to the hazards of toxic chemicals, which may be standard or candidate CW agents or standard or candidate therapeutic agents.

* This insert may be necessary here as in ¶ 3 [illegible]

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b. This directive shall not apply to contracts for studies of physiological aspects of protective material, including the protective function of the gas mask, unless such studies involve exposure to toxic chemicals, in which case the policy will apply.

4. Applicability

This instruction will apply to all procurement personnel at installations and activities of the Chemical Corps Research and Engineering Command.

5. Policy

* It is the policy of the Department of the Army to require that the terms of all contracts involving the use of human subjects in research in defense against atomic, biological, or chemical agents shall provide that the contractor will observe the ~~conditions~~ basic principles and safeguards set forth below:

(a) The voluntary consent of the human subject is absolutely essential.

(1) This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

* If "a" is selected, paragraph 2 will read as follows:

(2) The consent of the human subject shall be in writing; his signature shall be affixed to a written instrument setting forth substantially the aforementioned requirements and shall be signed in the presence of at least one (1) witness who shall attest to such signature in writing.

(3) The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

(4) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(5) The number of volunteers used shall be kept at a minimum consistent with item 5 (4) above.

(6) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

(7) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(8) No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur.

(9) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

(10) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

(e) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required, through all stages of the experiment, of those who conduct or engage in the experiment.

(f) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

(g) During the course of the experiment the scientist in charge must 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 a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

(h) Agents used in research must have the following limiting characteristics:

(1) Controllable lethality

(2) No serious chronicity anticipated

(3) Effective therapy available

(4) Adequate background of animal experimentation.

(III) As added protection for volunteers, the following safeguards will be provided:

(1) Direct responsibility for the planning and conduct of the investigations and for the medical care will rest with one adequately-trained physician.

(2) All apparatus and instruments necessary to deal with any emergency situations must be available, e.g., Drinker respirator, Mine Safety Pneophor, oxygen apparatus, etc.

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(3) Medical treatment and hospitalization will be provided for all casualties of the experimentation as required.

(4) The physician in charge will have available to him on short notice throughout the investigation competent consultants representing any of the specialties to be encountered.

6. Procedure

a. All requests for contracts involving the use of human volunteers shall contain a statement to the effect that the approval of the Secretary of the Army has been obtained for the proposed research program.

b. All contracts within the scope of this directive shall comply with the policy set forth above and shall, in addition, provide that the contractor shall obtain the prior approval of the Commanding Officer, Chemical Corps Medical Laboratories, before initiating any research on human volunteers.

c. The Project Officers for contracts involving the use of human volunteers shall maintain close surveillance of such experiments and shall promptly notify the Commanding Officer, Chemical Corps Medical Laboratories, and the Contracting Officer of any failure of a contractor to comply with the policy set forth above or of any untoward incident arising from the use of volunteers.

d. In the preparation of requests for contracts and in the preparation of contracts in subject category, every effort will be made to avoid phraseology which indicates a classified interest by the Corps or which, if made public, would cause embarrassment or adverse publicity. In cases where undesirable phraseology cannot be avoided, the contract and those sections containing such phraseology shall be classified accordingly.

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7. Rescission

All letters and directives previously issued by this Headquarters in conflict with those instructions are rescinded.

BY COMMAND OF BRIGADIER GENERAL CRAIGIE:

EMMER J. COLLINS
Colonel, Cml C
Chief, Procurement Division

DISTRIBUTION:

Procurement Division A, B, and C

PREPARED BY:

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