

1 Dec 75

RCC2.950224.087

- 1. ~~COL Stahl~~ 11 Dec
- 2. ~~COL Dall~~ B.D. 1/12/75
- 3. ~~Dr. Harris~~
- 4. COL McClure - ACTION

*Please get clearance
get clearance
copy immediately
Plan (AHP)
Thanks -
Key
11 Dec*

RMY
AMENT COMMAND
01

24 NOV 1975

*Dir, B1:
WHAT ABOUT
B.O DEF?*

B.D. 1/12/75

B.D. 1/12/75

Research and Testing

bml

1. Correspondence inclosed (Incl 1) is forwarded for immediate implementation.

2. All proposals will be submitted through HQ, ARMCOM, ATTN: AMSAR-RDM; through HQ, AMC, ATTN: AMCMM; to HQ, DA (DASG-ZA), Washington, DC 20310.

HQA-MR

FOR THE COMMANDER:

Raymond P. Thomas
RAYMOND P. THOMAS
Colonel, GS
Chief of Staff

1 Incl
as

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DEPARTMENT OF THE ARMY
 HEADQUARTERS, UNITED STATES ARMY ARMAMENT COMMAND
 ROCK ISLAND, ILLINOIS 61201

REPLY TO
 ATTENTION OF:

24 NOV 1975

AMSAR-RD

SUBJECT: Use of Volunteers and Human Subjects in Research and Testing

SEE DISTRIBUTION

1. Correspondence inclosed (Incl 1) is forwarded for immediate implementation.
2. All proposals will be submitted through HQ, ARMCOM, ATTN: AMSAR-RDM; through HQ, AMC, ATTN: AMCMM; to HQ, ~~DA~~ (DASG-ZA), Washington, DC 20310.

HQDA-MR

FOR THE COMMANDER:

RAYMOND P. THOMAS
 Colonel, GS
 Chief of Staff

1 Incl
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AMCMM (1 Oct 75) 1st Ind
SUBJECT: Use of Volunteers and Human Subjects in Research and Testing
HQ, US Army Materiel Command, 5001 Eisenhower Ave., Alex., VA 22333

TO: SEE DISTRIBUTION

84 OCT 1975

1. Reference is made to:

a. Telephone conversation between BG Dirks, Commander, US Army Medical Research and Development Command, and Colonel Hernandez, Surgeon, USAMC, on 24 October 1975.

b. Letter, AMCMM, 9 September 1975, subject: Use of Volunteers in Research.

2. Basic letter is forwarded for immediate action.

3. Basic letter represents a significant change in the interpretation by TSG of the scope of coverage of AR 70-25. IAW paragraph 5, basic letter, all research, development, test and evaluation experimental protocols involving human subjects will be submitted to TSG for review and evaluation, regardless of risk of exposure.

4. Written proposals will be submitted through this headquarters, ATTN: AMCMM, to HQDA (DASG-ZA), Washington, DC 20310, IAW paragraph 6, AR 70-25.

FOR THE COMMANDER:

wd all incl



ROBERT L. KIRWAN
Brigadier General, USA
Chief of Staff

DISTRIBUTION:
A, B, C

CF:
HQDA (DASG-ZA)
Cdr, USAHSC, ATTN: HSZA

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DEPARTMENT OF THE ARMY
OFFICE OF THE ADJUTANT GENERAL
WASHINGTON, D.C. 20310

IN REPLY REFER TO

DAAG-PAP-A (M) DASG-ZA

1 October 1975

**SUBJECT: Use of Volunteers and Human Subjects in Research
and Testing**

Commander, US Army Materiel Command, 5001 Eisenhower Avenue,
Alexandria, Virginia 22333
Assistant Chief of Staff for Intelligence, Department of the
Army, Washington, DC 20310
Deputy Chief of Staff for Personnel, Department of the Army,
Washington, DC 20310

1. Reference is made to:

a. Memorandum, CS:385, 30 June 1953, subject: Use of
Volunteers in Research (Incl 1).

b. AR 70-25, 31 July 1974, which superseded original
regulation of 26 March 1962 (Incl 2).

c. FDA-MOU 75-3, 24 October 1974, Memorandum of Under-
standing Between the Food and Drug Administration and the
Department of Defense Concerning Investigational Use of Drugs
by the Department of Defense (Incl 3).

d. AR 40-7, 4 April 1975 (Incl 4).

2. Reference 1a prescribes policies and procedures governing
the use of volunteers in research in defense against atomic,
biological and chemical warfare.

3. Reference 1b continues the implementation of the policies
defined in reference 1a and provides that all proposals for
research in volunteers will be submitted to The Surgeon General (TSG)
in writing. Proposals for research with human subjects involving
nuclear and chemical warfare agents will be forwarded by TSG with
his recommendations on medical aspects to the Secretary of the
Army (SA) for approval. TSG has final approval authority for all
other research using volunteers.

4. Reference 1c establishes policy to insure that the require-
ments of the Federal Food, Drug, and Cosmetic Act and the
investigational drug regulations issued under that Act are met

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**SUBJECT: Use of Volunteers and Human Subjects in Research
and Testing**

without jeopardizing the requirements of national security or the requirements of Federal laws and regulations relating to such use of drugs. In keeping with this agreement, TSG established the Army Investigational Drug Review Board (AR 40-7) which considers each research proposal involving the use of volunteers in the clinical investigation of new drugs and assists TSG in exercising his responsibility under this agreement. TSG will decide which substances are drugs.

5. It is mandatory that every research, development, test, and evaluation experimental protocol sponsored by the Army involving the use of volunteers or human subjects, inservice or under contract or grant, regardless of the source of funds, be submitted to TSG for review and action as defined in paragraph 3 above. All prior approvals, either written, implied or assumed, of protocols, classes of protocols, or classes of test compounds involving the use of human subjects in relation to chemical agents and potential antidotes are hereby revoked.

6. Experimental work involving human subjects will not be initiated until these requirements have been satisfied in writing.

7. The use of chemical agents or drugs in tests, experiments, and operations related to intelligence interrogation is prohibited.

BY ORDER OF THE SECRETARY OF THE ARMY:



PAUL T. SMITH
Major General, United States Army
The Adjutant General

4 Incl
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