

*Human
volunteers***Draft Army Regulation - "Use of Human Volunteers in
Research Programs to Obtain Psychological and/or Biological
Data"**

SA T... R & D

General Counsel

26 June 1961

A. Naimon/ar1/65988

1. Reference is made to your informal request of 20 June 1961 for comment on subject draft regulation.

2. The following comments are offered in connection with subject draft:

a. The scope of application of proposed AR is not clearly set forth either in paragraph 1 or elsewhere in subject draft. Thus, it is unclear whether the draft applies to Army-sponsored research programs as well as to Army "in house" research programs, and as a subsidiary question to the above, whether it applies to research projects supported by Army grants, as well as to research projects supported by Army contracts. Further, it is not clear whether proposed AR applies to research programs where the human subject is already ill, but is deliberately exposed to potentially hazardous drugs or other treatment of an experimental nature, but which might effect a cure or other benefit.

b. The phrase, "or other military duties", in the last sentence of proposed paragraph 1 is unclear.

c. It is recommended that the requirement that the consent of the human subject be in writing be qualified and made subject to some officer's discretion, e.g. Chief of Technical Service, especially in view of the unclear scope of application of the AR as a whole.

d. The phrase "may not be delegated to another with impunity", in paragraph 2 (a), is ambiguous; thus it is unclear whether the responsibility involved may or may not be delegated.

e. It is recommended that the phrase "give promise of yielding" be substituted for the phrase "to yield" in paragraph 2 (b).

f. The right of the test subject to bring the experiment to an end, set forth in paragraph 2 (j) should be unqualified.

g. It is recommended that the word "duty" be substituted for the word "authority" in the last sentence of paragraph 3 (a).

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26 June 1961

SUBJECT: Draft Army Regulation - "Use of Human Volunteers in Research Programs to Obtain Psychological and/or Biological Data"

h. It is recommended that paragraph 3(c) be coordinated with Director, Plans, Supply, & Operations, inasmuch as this office has previously recommended to Director, Plans, Supply, & Operations, inclusion of research test subjects as a category eligible for care in Army medical treatment facilities (AR 40-108) (so far unsuccessfully). Thus, there may be strong policy reasons for not making such human test subjects eligible for such care.

i. It is recommended that the material in the Appendix, devoted to Legal Implications, concerning voluntary service, set forth in paragraph 3 and 6 (a) thereof, be coordinated with OJAG to assure the currency of the opinions therein expressed.

ALEXANDER HAYMON
Acting General Counsel

CC: D, P, S, & O

Draft Army Regulation - "Use of Human Volunteers in Research Programs to Obtain Psychological and/or Biological

FROM C/MAD

22 May 1961

ONCE YOU HAVE
DETERMINED

26 APR 1961

Colonel
Major General

Enclosure 1 is a draft AR, subject as above. The increasing use of human volunteers in research programs make it essential that proper safe guards be taken in order to insure proper safe guards.

Your comment or indication of concurrence on the inclosed draft AR is the event you recommend against publication substantially in the event you have specific objections and provide suggested modifications.

Your comment is also desired on the classification required, if any.

RECOMMENDATION OF THE CHIEF OF RESEARCH AND DEVELOPMENT:

TYSON E. SUMNER
Colonel, GS
Chief, Life Sciences Division

THIS IS THE END OF THE MESSAGE

END OF MESSAGE

YOUR COMMENT IS DESIRED ON THE CLASSIFICATION REQUIRED, IF ANY.

TYSON E. SUMNER
Major General, GS
Commanding

24 May 1961

"Use of Human Volunteers in Research Programs
to Obtain Psychological and/or Biological Data"

1. Purpose. The purpose of this regulation is to prescribe policies and procedures governing the use of volunteers in research programs in which personnel are deliberately exposed to unusual or potentially hazardous conditions to obtain human psychological and/or biological data. It is not intended to affect those research and non-research programs, tasks, and tests which may involve matters of occupational health or exposure of personnel to potentially hazardous situations encountered normally as part of training or other normal duties, e.g., flight training, jump training, marksmanship training, range training, fire drills, gas drills, and handling of explosives. That portion of Human Factors Research which involves normal training or other military duties as part of an experiment is likewise exempt.

The use of volunteers in research in defense against atomic, biological, and chemical warfare will, in addition to these instructions, continue to be governed by Chief of Staff Memorandum 385 (C), dated 30 June 1953.

2. Basic Principles. Certain basic principles must be observed in order to satisfy moral, ethical and legal concepts. These are:

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

(1) This means that the person involved shall have legal capacity to give consent; shall be so situated as to be able to exercise

choice, without the intervention of any element of force, duress, threats, over-reaching, or other ulterior form of constraint or coercion, and should have sufficient knowledge and comprehension of the nature and extent 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 shall 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.

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

(3) The duty and responsibility for ascertaining the validity of the consent rests upon each individual who initiates, directs or supervises 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, unobtainable by other methods or means of study, and not tedious and unnecessary in nature.

(5) The number of volunteers used shall be kept at a minimum consistent with item 2, above.

The experiment should be so designed that the anticipated results justify the performance of the experiment.

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

No experiment should be conducted where there is a prior knowledge that death or disabling injury will occur.

The degree of risk to be taken should never exceed that justified by the humanitarian importance of the problem to be solved.

Proper preparations should be made and adequate facilities provided to protect the experimental subject against all reasonable possibilities of injury, disability, or death. (Para 3)

The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be exercised through all stages of the experiment of those who conduct or assist in the experiment. See also para 3.

During the course of the experiment the human subject should be allowed to bring the experiment to an end if possible.

Personnel should have no physical or mental diseases.

During the course of the experiment the scientist in charge should be authorized to terminate the experiment at any stage, if he has reasonable grounds to believe, in the exercise of the good faith, superior judgment and discretion of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

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Absolute

The established policy, which prohibits the use of prisoners of war in human experimentation, is continued. Prisoners of war will not be used under any circumstances.

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

a. Direct responsibility for the medical care of Army personnel will rest with one trained physician who will be designated by name and number by the Surgeon General. The physician will have the authority to terminate the experiment at any time that he believes death or injury is likely to result.

b. All apparatus and instruments necessary to deal with likely emergency situations must be available, e.g., Drinker respirator, mine safety respirator, oxygen apparatus, etc.

c. Medical treatment and hospitalization will be provided for the subjects of the experimentation as required.

d. The physician in charge will have available to him on short notice throughout the investigation competent consultants *consultants to whom*

participated

approval by Contract Experiment. It is the responsibility of the Service Chief or other agency chief to make a recommendation on the proposal of these experiments which come within the scope of this directive. This responsibility may not be delegated. The recommendation will be forwarded to The Surgeon General for his approval and then forwarded to the Chief of Research and Development for final approval.

(40-108)

3. Implementing Instructions. Technical Service and agency chiefs will issue necessary implementing instructions to subordinate units.

Local Implications. Appendix #1.

my draft for MB's signature

MEMO-4

12 March 1957

Vice Chancellor
Schools of the Health Professions
University of Pittsburgh
Pittsburgh 13, Pennsylvania

Dear Sir:

This is in reply to letter dated 18 February 1957, from Dr. Paul M. Maurer regarding work to be performed under Contract no. DA 19-07-AM-240.

In connection with your request for a statement concerning the assumption of responsibilities by the Army for liabilities of Contractor incurred in the performance of subject contract, your attention is invited to the provisions of ASIR-7-30.??, Insurance-Liability to Third Persons, copy attached, and particularly to the provisions of the first sentence of paragraph (c), which Article represents the maximum protection which can be afforded contractors under present policy. It is our intention to make this article available to you under this contract, contingent upon your adhering to the following principles, policies, and rules for the use of human volunteers in performing subject medical research contracts.

1. The voluntary consent of the human subject is essential. This means that the person concerned:

- a. Should have legal capacity to give consent.
- b. Should be so situated as to be able to exercise free power of choice, without intervention of force, fraud, deceit, duress, over-reaching, or other form of constraint or coercion.
- c. Should have sufficient knowledge and understanding of the experiment to enable him to make an enlightened decision, on the basis of explanation given to him as specified below.
- d. Should state his consent in writing, signed in the presence of at least one witness who shall attest to such signature in writing.

2. Each individual who initiates, directs or engages in the experiment has a personal duty and responsibility for ascertaining the quality of the volunteer's consent.

3. The established policy, which prohibits the use of prisoners of war in human experimentation, is continued. Prisoners of war will not be used under any circumstances.

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

a. Direct responsibility for the medical care of Army personnel will rest with one trained physician who will be designated by name and provided by The Surgeon General. The physician will have the authority to terminate the experiment at any time that he believes death or injury is likely to result.

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b. All apparatus and instruments necessary to deal with likely emergency situations must be available, e.g., Drinker respirator, mine safety pump, oxygen apparatus, etc.

c. Medical treatment and hospitalization will be provided for all participants of the experimentation as required.

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40-108

d. The physician in charge will have available to him on short notice throughout the investigation competent consultants *representative of the specialties which might be anticipated.*

Handwritten note:
Committee to study of

5. Approval to Conduct Experiment. It is the responsibility of the Medical Service Chief or other agency chief to make a recommendation on the protocol of these experiments which come within the scope of this directive. This responsibility may not be delegated. The report and recommendation will be forwarded to The Surgeon General for review and comment and then forwarded to the Chief of Research and Development for final approval.

5. Implementing Instructions. Technical Service and agency chiefs will issue necessary implementing instructions to appropriate units.

6. Local Implications. Appendix #1.

3. Before the acceptance of consent of the volunteer, he must be given adequate explanation. He should be informed of 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.

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

5. The number of volunteers used must be kept at a minimum consistent with the requirement of a fruitful experiment for the good of society.

6. In order that the anticipated results will justify doing the experiment, it (the experiment) should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study.

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 a prior reason to believe that death or disabling injury will occur.

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

10. The experiment should be conducted only by scientifically qualified persons (including an adequately trained physician) who shall be required to exercise the highest degree of skill and care throughout the experiment. Consultant consultants should be available on short notice in this connection.

11. Adequate preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death. This includes hospitalization and medical treatment as may be required.

12. The human volunteer subject should be at liberty to bring the experiment to an end if he feels that it is impossible for him to continue under the test.

13. The scientist or physician in charge must be prepared to terminate the experiment at any stage, if he has previous 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.

14. Established policy prohibits the use of prisoners of war in human experimentation. They will not be used under any circumstances.

15. Agents used in research must have the following limiting characteristics:

- a. Controllable lethality
- b. No serious chronicity anticipated
- c. Effective therapy available
- d. Adequate background of animal experimentation.

Sincerely yours,

cc: Dr. Maurer

MAX H. BROWN
Lt. Colonel, M.C.
Contracting officer

CONCURRENCE:

Chief, Legal Office

Chief, research & Development
Division

PUBLICATION)

12 March 1954

Use of Human Volunteers in Medical Research
 Principles, Policies and Rules of the Office of The Surgeon General
 (To be used as far as applicable as a non-mandatory guide for planning
 and conducting contract research.)

1. The voluntary consent of the human subject is essential. This means that the person concerned:
 - a. Should have legal capacity to give consent.
 - b. Should be so situated as to be able to exercise free power of choice, without intervention of force, fraud, deceit, duress, over-reaching, or other form of constraint or coercion.
 - c. Should have sufficient knowledge and understanding of the experiment to enable him to make an enlightened decision, on the basis of explanation given to him as specified below.
 - d. Should state his consent in writing, signed in the presence of at least one witness who shall attest to such signature in writing.
2. Each individual who initiates, directs or engages in the experiment has a personal duty and responsibility for ascertaining the quality of the volunteer's consent.
3. Before the acceptance of consent of the volunteer, he must be given adequate explanation. He should be informed of 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.
4. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other means of study, and not random and unnecessary in nature.
5. The number of volunteers used must be kept at a minimum consistent with the requirement of a fruitful experiment for the good of society.
6. In order that the anticipated results will justify doing the experiment, it (the experiment) should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study.

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 a prior reason to believe that death or disabling injury will occur.

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

10. The experiment should be conducted only by scientifically qualified persons (including an adequately trained physician) who shall be required to exercise the highest degree of skill and care throughout the experiment. Competent consultants should be available on short notice in this connection.

11. Adequate preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death. This includes hospitalization and medical treatment as may be required.

12. The human volunteer subject should be at liberty to bring the experiment to an end if he feels that it is impossible for him to continue under the test.

13. The scientist or physician 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.

14. Established policy prohibits the use of prisoners of war in human experimentation. They will not be used under any circumstances.

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