APPENDIX A AR 70-25

Policy to be followed by the Contractor where the use of human subjects is involved.

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

a. 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 and 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.

b. 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.

c. 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.

2. 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.

3. The number of volunteers used shall be kept at a minimum consistent with item 2 above.

4. 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.

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

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

7. 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.

Superseded by AR 70-25

(Also part of contract 5198 with date 6 April 1954)

(9)

Command Historical Office; CBDCOM
Edgewood Arsenal, MD
Row #2; File Cabinet #78; Drawer #3

APPENDIX A
(Cont'd)

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

9. 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.

10. 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.

11. 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.

12. 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

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

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

b. All apparatus and instruments necessary to deal with any emergency situations must be available, e. g., Drinker Respirator, Mine Safety Pneophore, oxygen apparatus, etc.

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

d. 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.

APPENDIX A 6 April 1954

Policy to be followed by the Contractor where the use of human subjects is involved.

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

a. 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 and 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.

b. The consent of ths 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.

c. 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.

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

3. The number of volunteers used shall be kept at a minimum consistent with item 2 above.

4. 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.

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

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

7. 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.

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

9. 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.

10. 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.

11. 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.

12. 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.

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

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

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

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

d. 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.

Ltr from OCCml0 (C) Fwd CCRPO 1/6/ca to be held for HGF
Use of Enlisted Personnel Under 21 Years of Age as Volunteers in Research — 17 Feb 55

Ltr to CO, Med Labs (C) Fwd CCRPO-1/6/ca to be held for HGF
Use of Volunteers in Research — 14 Mar 55

Policy to be followed ~~by the Contractor~~
When the use of Human Subjects is Involved

Any research under this contract which may involve human subjects shall be governed by, and accomplished in accordance with, the policies and procedures set out in AFP 70-25 dated 26 March 1962. The contractor agrees to comply fully with the conditions of this regulation. The contractor is not to commence experiments with subjects until approvals required by the regulation have been obtained. It should be the responsibility of the Contracting Officer to obtain the required approvals.

Peter to Scott