Research and Development

Use of Volunteers as Subjects of Research

Army review(s) completed.

Headquarters
Department of the Army
Washington, DC

PROCEDURES FOR USE OF HUMANS AS RESEARCH SUBJECTS IN THE EXTRAMURAL RESEARCH PROGRAM

I. Purpose: This is to establish uniform procedures and responsibility for review of the use of humans as research subjects, negotiation of provisions, and administration of research projects in the extramural program. Wherever the term "contractor" appears it shall also mean grantee and other Government agency.

II. References

1. 45 CFR 46 HHS Regulation on Protection of Human Subjects;

2. 10 U.S.C. Section 980 Limitations on Use of Humans as Experimental Subjects;

3. 21 CFR 312 Investigational Drugs and Vaccines;

4. 21 CFR 812 Investigational Medical Devices;

5. 21 CFR 56.111(a)(3) Advertisement Guidelines for the Recruiting of Research Subjects;

6. DOD Directive 6465.2 Organs and Tissues Obtained from Autopsy;

7. DOD Directive 3216.2 Protection of Human Subjects in DOD-Supported Research;

8. Federal Acquisition Regulation (FAR) 52.228-7 Insurance Liability to Third Persons and FAR 31.109 Advance Agreements;

9. USAMRDC Regulation 70-25 Use of Human Subjects in Research, Development, Testing and Evaluation;

10. USAMRDC Broad Agency Announcement (BAA);

11. Army Regulation 340-21 The Army Privacy Program; and

12. Federal Acquisition Regulations (FAR) Part 24 Protection of Privacy and Freedom of Information, 52.224-1 Privacy Act Notification, and 52.224-2 Privacy Act.

III. Objectives:

1. Safeguarding the rights and welfare of human subjects participating in research and development supported by contracts, grants and orders awarded by U.S. Army Medical Research and

Development Command (USAMRDC) is of utmost concern to the Command, and is primarily the responsibility of the contractor or recipient who receives or is accountable to USAMRDC for the funds awarded for the support of the project. However, the sensitivity of such research necessitates that the Command exercise prudence in its oversight responsibilities. The procedures employed shall be flexible and tailored to the requirements of the specific acquisition.

2. It is the policy of USAMRDC that the Department of Health and Human Services (HHS) Regulation on Protection of Human Subjects, Food and Drug Administration Regulations on Investigational Drugs and Vaccines and Investigational Medical Devices, and Advertisement Guidelines for the Recruiting of Research Subjects shall be adhered to by USAMRDC contractors and recipients, with the addition of the following specific DOD/USAMRDC requirements.

a. Informed consent must be obtained in advance from the subject, or in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject must be obtained in advance.

b. Contractors and recipients shall provide all necessary medical care to research subjects for injury or disease which is the proximate result of participation in the research.

c. Anatomical Substances (organs, tissues, or tissue fluids) obtained from autopsy shall not be used for research or investigational purposes without the expressed consent of the next of kin. It should be noted that a general autopsy consent may not, in itself, be sufficient. If autopsy tissue is to be used, the protocol should include a copy of the consent form used to obtain the tissue.

d. Anatomical Substances (organs, tissues, or tissue fluids) obtained from a surgical procedure shall not be used for research or investigational purposes without the expressed consent of the patient or patient's legal representative. It should be noted that a consent to perform surgery may not, in itself, be sufficient. If excised tissue is to be used, the protocol should include a copy of the consent form used to obtain the tissue.

e. Anatomical substances linked by identifiers to a particular person and used for research shall be donated for the purpose of research, and shall be lawfully acquired. The donor shall be the person from whom the substance is removed or, in the event of death or legal disability of the person from whom the substance is removed, the next of kin or legal representative of such person. Donation shall be made by written consent and the donor shall relinquish all ownership and/or rights to the substance. If excised or autopsy tissue is to be used, the protocol should include a copy of the consent form used to obtain the tissue.