SAREA-BL

Proposed SAREA Reg 70-__, Use of Human Subjects in Research, Development, Test and Evaluation Projects

Adjutant | Dir of Biomed Lab | 1 Nov 76

1. The enclosed draft SAREA Regulation is submitted for editing and publication.

2. Justification for this regulation is contained in DF, SAREA-TD, 26 Jun 76, subject: Human Volunteer Testing, copy attached (Encl 2). Publication of a SAREA regulation is appropriate since this directive implements the provision of more than one existing AR (AR 40-7, 4 Apr 75) and AR 70-25, 31 Jul 74).

3. Concurrence was obtained from the Technical Director and the Commander, EWA. No other EWA element concurrence is required.

4. Recommended distribution is A.

2 Encl
as

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SAREA Regulation 70-

USE OF HUMAN SUBJECTS IN RESEARCH, DEVELOPMENT, TEST AND EVALUATION PROJECTS

1. Purpose. The purpose of this regulation is to prescribe policies, responsibilities and procedures for the use of human subjects in research, development, test and evaluation.

2. Scope. This regulation applies to all elements of Edgewood Arsenal, to all activities conducting tests utilizing the resources of Edgewood Arsenal and to all contracts by elements of Edgewood Arsenal.

3. Policy and Responsibilities. The Director of the Biomedical Laboratory (BML), by direction of the Secretary of the Army, has the professional and ethical, civil and military responsibility for planning, controlling and safety of experiments involving volunteers utilized in research studies at or under the control of the Biomedical Laboratory, subject to review by The Surgeon General.

4. Procedures. a. All proposed research, development, test and evaluation as delineated in para 1 above, which would involve human subjects will be submitted to the Director, BML, before any solicitation of volunteers or commencement of work. A determination will be made by the Director, BML, utilizing such consultation as he considers desirable as to whether the proposed use of human subjects involves risk to the subjects. If risk is present, no work will be performed using human subjects until the applicable provisions of references cited below (para 4f) have been complied with.

Regardless of whether risks are involved in work involving human subjects, such work will be under the control of the Director, Biomedical Laboratory.

b. For each approved protocol, the Director, BML, will designate one of the physicians on his staff as the responsible physician. The Director, BML, and the designated responsible physician individually have the authority to terminate or suspend any test in whole or in part when medical reasons so indicate or when such tests deviate from the approved protocol. This authority can be delegated to the on-site medical monitor also.

c. Scheduling of tests involving human subjects can be done only by the Director, Biomedical Laboratory. The principal investigator may propose a schedule.

d. Reports of research, development, test and evaluation utilizing volunteers will be submitted to The Surgeon General for review and inclusion in the official files at not longer than yearly intervals. The report will include the names of volunteers.

e. The Director, BML, will establish a Medical Review Committee for the scientific evaluation of protocols using human subjects and a Human Use Committee for the moral and ethical review of such protocols; the establishment of such committees to be in consonance with the applicable laws, regulations, directives, etc.

f. Any violation of the spirit or principles of AR 470-7, AR 70-25, the Memorandum of Understanding between DARCOM and OTSG (27 Apr 76), or other applicable laws or regulations will be reported immediately and directly to the Commander, Edgewood Arsenal, the Commander, ARMCOM, and to the Assistant Surgeon General for Research and Development by the Director, Biomedical Laboratory.