

VOLUNTEER REGISTRY DATA BASE REQUIREMENTS

PURPOSE: Existing Army Regulation 70-25 requires the Major Army Commander or agency conducting or sponsoring research to establish a registry of volunteers who have participated in research conducted or sponsored by that command. USAMRDC regulation 70-25 requires all laboratories and institutions - both intramural and extramural including those outside the continental United States - to submit volunteer registry data to the archival data base maintained at the United States Army Medical Research and Materiel Command, Office of the Deputy Chief of Staff for Regulatory Compliance and Quality (DCS-RCQ). The purpose of this guidance document is to establish an approach for data collection and submission that creates minimal additional work for laboratories and DCS-RCQ staff and establishes consistency in data collection requirements across the USAMRMC.

POLICY

The Human Subjects Research Review Board will, upon written request, determine if the Volunteer Registry Data Base requirement may be waived. In general, studies involving no more than minimal risk and eligible for the expedited review procedure authorized in 45 CFR 46.110(a) and in USAMRDC Regulation 70-25 may not be subject to VRDB requirements. Under certain exceptional circumstances, the HSRRB may waive the VRDB requirement for studies involving greater than minimal risk to the participants.

The requirement to collect data in paper format on the Volunteer Registry Data Sheet (USAMRDC Form 60-R) may be waived on a case-per-case basis. If the electronic submission is incomplete or unacceptable, the waiver is not binding and DCS-RCQ, USAMRMC may require the standard Form 60-R hard copy submission.

Waivers will be considered on a case-per-case basis. Waivers may be granted for individual protocols submitted for approval to the HSRRB. A request for waiver may be submitted along with the initial submission of the protocol through the USAMRMC-RCQ-HR to the HSRRB. Advance determinations may be granted for like or type protocols or for certain classes of protocols.

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- 1. Excerpts from Army Regulation 70-25, Appendix H, Volunteer Data Base, 26 January 1990
- 2. Excerpts from USAMRDC Regulation 70-25, Appendix L, Volunteer Data Base
- 3. Expedited Review List , 45 CFR 46.110(a)

Originated by: Yvonne Higgins
Date:

Approved by: _____
Date:

Chief, Human Use Review and Regulatory Affairs Division

Approved by: _____
Date:

Deputy Chief of Staff, Regulatory Compliance and Quality

A. Definitions (AR 70-25)

Human Subjects. A living individual about whom an investigator conducting research obtains data through interaction with the individual, including both physical procedures and manipulations of the subject or the subject's environment. The term does not include military or civilian personnel who are qualified to test by assignment to duties that call specifically for qualifications such as test pilots or test engineers.

Human Subjects Research Review Board. The principal body of the Office of the Surgeon General (OTSG) for review of clinical investigation and research activities.

Minimal Risk. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (21 CFR 219)

Research. A systematic investigation that is designed to develop or contribute to generalizable knowledge. The term does not include individual or group training of military personnel such as group training, effectiveness, proficiency, or fitness exercises.

B. Requesting a Waiver from Volunteer Registry Data Base Requirements

1. Prepare a written justification for why the VRDB Requirement should be waived.
2. Submit the written justification and a copy of the protocol to Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Ft. Detrick, MD 21702-5012.

C. Requesting Approval to Submit Electronic Archival Data Without Paper Counterparts to USAMRMC, Office of the Deputy Chief of Staff for Regulatory Compliance and Quality.

1. Prepare a written request for waiver. Include, at a minimum, the following:
 - identification of any key data elements that can not realistically be collected (e.g., the requirement to collect social security numbers of citizens of foreign countries participating in studies conducted at overseas study sites.);
 - a description of the software used for data collection. In brief, data must be submitted as ASCII flat files such as an EXCEL spread sheet. Further guidance may be sought from the Human Use Review and Regulatory Affairs Division.

standard operating procedures pertinent to the use of the system at the study site. At a minimum, SOPs should include: data collection; verification of data entry; data backup and recovery; security.

2. Submit the written justification and a copy of the protocol to Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Ft. Detrick, MD 21702-5012.

EXHIBITS

1. Excerpt from Army Regulation 70-25, Use of Volunteers as Subjects of Research, Appendix H, Volunteer Data Base

The intent of the data base is twofold: first to readily answer questions concerning an individual's participation in research conducted or sponsored by the command; to ensure that the command can exercise its "duty to warn."

2. Excerpt from USAMRDC Regulation 70-25, Use of Human Subjects in Research, Development, Testing and Evaluation, Appendix L, Volunteer Registry Data Base.

The duty to warn is an obligation incurred by Commanders to ensure that research volunteers are adequately informed concerning the risks involved with their participation in research, and to provide them with any newly acquired information that may affect their well-being when that information becomes available. The duty to warn exists even after the individual volunteer has completed his or her participation in the research. To accomplish this, a system must be established which will permit the identification of volunteers who have participated in research conducted or sponsored by the USAMRDC and action must be taken to notify volunteers of newly acquired information.

The data base must contain items of personal information, for example, name, Social Security number, etc., which subjects it to the provision of The Privacy Act of 1974. Within USAMRDC this data base consists of data bases maintained at the laboratory and other research site and the archival data base maintained at USAMRDC Headquarters.

For each human subject enrolled in a research protocol conducted at a USAMRDC laboratory a Volunteer Registry Data Sheet (USAMRDC 60-R) is to be completed. The information from the laboratory data base is exported to the Headquarters archival data base upon completion of a research protocol or annually, whichever occurs first. The information is stored in the Headquarters data base for a minimum

of 75 years.

3. Excerpts from 46 Federal Register 8392, 1 January 1981: Research Activities Which May Be Reviewed Through Expedited Review Procedures

Collection of hair and nail clippings in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

Recording of data from subjects 18 years of age or older using noninvasive procedures employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes procedures such as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the processes accomplished in accordance with accepted prophylactic techniques.

Voice recordings made for research purposes such as investigations of speech defects.

Moderate exercise by healthy volunteers.

The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

Research on individual or group behaviour or characteristics of individuals, such as studies of perception, cognition, game theory or test development, where the investigator does not involve stress to subjects.

Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.