DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
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REPLY TO ATTENTION OF

MCMR-RCQ 30 November 2001

HSRRB Policy Memorandum 01-01, Version 01

SUBJECT: Volunteer Data Base Requirements

1. REFERENCES.

a. AR 70-25, *Use of Volunteers as Subjects of Research, 25 January 1990*

b. AR 340-21, *The Army Privacy Program, 5 July 1985*

c. USAMRDC 70-25, *Use of Human Subjects in Research, Development, Training, and Evaluation, 20 April 1990*

2. HISTORY. This is the first version of HSRRB Policy Memorandum 01-01. This version is effective 5 December 2001. Details of the history can be found in Appendix A.

3. PURPOSE. This policy is being written to clarify the Volunteer Data Base requirement and to eliminate the requirement to maintain volunteer information for most extramural research.

4. SCOPE. This policy affects protocols submitted to MCMR-RCQ for review by The Surgeon General's Human Subjects Research Review Board (HSRRB) or submitted with a claim of exemption from HSRRB review.

5. BACKGROUND.

a. AR 70-25 required MACOM commanders and organization heads conducting research, development, test, and evaluation (RDTE) programs involving human subjects to establish a system that permits the identification of volunteers who have participated in research conducted or sponsored by that command or organization. Such a system had to be established in accordance with AR 340-21, *The Army Privacy Program* (AR 70-25, 3-2a(4)). To comply with this AR 70-25 requirement, the USAMRMC established a secure repository for Volunteer Registry Data Sheet (USAMRDC Form 60-R) information. The Volunteer Registry Management System (VRMS) is the current repository established for this purpose in the Office of Regulatory Compliance and Quality (RCQ), Headquarters, U.S. Army Medical Research and Materiel Command (USAMRMC).

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b. There are two reasons stated for establishing such a system (AR 70-25, 3-2h, Appendix H, H-1; USAMRDC 70-25, Appendix L).

(1) It enables commanders to meet their "duty to warn." Commanders have an obligation to ensure that research volunteers are adequately informed concerning the risks involved with their participation in research and to provide research volunteers 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 research.

(2) It enables commanders to readily answer questions concerning an individual's participation in research.

c. The USAMRMC has historically maintained Volunteer Data Base information for both intramural and extramural research. However, it has become difficult to collect the necessary Volunteer Data Base information for extramural research. Extramural research institutions (including foreign institutions) and their Institutional Review Boards or Independent Ethics Committees are increasingly objecting to the requirement to collect the Volunteer Data Base information, generally citing privacy concerns.

d. Although the 1990 version of AR 70-25 recognized the existence of extramural research, it was written at that time primarily for the intramural research program. The extramural research program has grown tremendously since AR 70-25 was first implemented. The extent of the expansion of the extramural research program was not anticipated. AR 70-25 is undergoing revision to address these and other changes to human subjects research that have occurred within the last decade.

e. The Volunteer Data Base requirement is unique to the Department of the Army. There is no analogous DOD requirement, nor is there any volunteer database requirement in the Federal Common Rule.

6. POLICY.

a. For the reasons stated above, the Volunteer Data Base requirement will be modified as follows:

(1) Volunteer Data Base information will be maintained for greater than minimal risk <u>intramural</u> RDT&E research (research conducted within the U.S. Army Medical Research and Materiel Command (USAMRMC)).

(2) Volunteer Data Base information generally will not be maintained for extramural research (research not conducted within the USAMRMC, but supported by DOD funding through contract, grant, cooperative agreement, or other arrangement).

(3) Volunteer Data Base information will be maintained for extramural research that uses an FDA regulated product for which The Surgeon General is the sponsor. The HSRRB will recommend that Volunteer Data Base information be maintained for other extramural research studies as needed.

(4) Volunteer Data Base information will generally not be maintained for any research that is no more than minimal risk. The HSRRB will recommend that Volunteer Data Base information be maintained for specific no more than minimal risk research studies as needed.

(5) For research that began prior to implementation of this policy, Volunteer Data Base information will be maintained if indicated in the informed consent form, even if the research is extramural. This is required because subjects of such research have signed informed consent forms stating that the Volunteer Data Base information is intended to allow the USAMRMC to adequately inform them of risks and to provide any new information.

b. The HSRRB will, upon written request, recommend whether the Volunteer Data Base requirement may be waived under certain exceptional circumstances.

c. Information will be collected for inclusion in the Volunteer Data Base as described in AR 70-25.

(1) The following information will be collected from subjects for inclusion in the Volunteer Data Base: name, social security number, military status at the time of the research, military rank and unit (if applicable), gender, date of birth, address and phone number (local and permanent). Not all of the specified Volunteer Data Base information is available for research conducted outside of the United States; therefore, collection of some of the data elements, such as the social security number, may need to be waived.

(2) Other Volunteer Data Base elements include protocol title, name of principal investigator (PI), name of research laboratory, address and phone number of research laboratory, date of research, test article/drug/device (including manufacturer and lot number), IND or IDE number, occurrence and follow-up of serious or unexpected adverse incidents, and date the volunteer completed or was withdrawn from the study.

d. The process for collecting information and inputting Volunteer Data Base information into a secure automated system is as follows:

(1) Required Volunteer Data Base information will be collected by the PI (or designated member of research staff) on a Volunteer Registry Data Sheet (USAMRDC Form 60-R) or similar or successor form.

(2) The information may be forwarded to USAMRMC, Office of Regulatory Compliance and Quality (RCQ) upon completion of the research study. The information will be stored in the VRMS with appropriate security protections for a minimum of 75 years (USAMRDC 70-25, Appendix L).

(3) If the Volunteer Registry Data Sheet information is not kept in the VRMS at RCQ, it may be maintained at a USAMRMC Major Subordinate Command. The system on which this information is maintained must have adequate security protections, must be readily accessible when needed, and must be kept for a minimum of 75 years.

(4) The Volunteer Registry Data Sheets will be destroyed after the information is entered into an automated Volunteer Data Base.

e. Informed consent documents will inform subjects that they will be contacted, if necessary, using their personal information. It is recognized that a subject's address and telephone number are likely to change over time. Therefore, the social security number or equivalent identification information will be used to update perishable data (e.g., name, address and phone number) as needed (see AR 70-25, Appendix H, H-3).

Julie K. Zadinsky

Encl

JULIE K. ZADINSKY
Colonel, AN
Acting Chair, Human Subjects
Research Review Board

MCMR-RCQ
SUBJECT: HSRRB Policy Memorandum 01-01, Volunteer Data Base Requirements

RECOMMEND APPROVAL/~~DISAPPROVAL~~

JP

DATE: 3 Dec 01

JOHN S. PARKER
Major General, MC
Chair, Human Subjects
Research Review Board

APPROVED/~~DISAPPROVED~~

FOR THE SURGEON GENERAL:

DATE: 5 Dec 01

PATRICK D. SCULLEY
Major General
Deputy Surgeon General

APPENDIX A
HSRRB Policy Memorandum History

Version Number: 01

Version Date: 28 November 2001

Effective Date:

Reason for Revisions: This is the initial policy.

Detailed List of Changes: N/A