

**DISPOSITION FORM**

RCC1.950213.044

2 JUL 1983

For use of this form, see AR 340-15, the proponent agency is TAGO.

S: 22 Aug 83

REFERENCE OR OFFICE SYMBOL

SUBJECT

DRSMC-CLM (A)

DRAFT CRDC SOP 70-25, Use of Human Subjects in Research,  
Development, Testing, and Evaluation.

SEE DISTRIBUTION

FROM C, Hlth &amp; Vet Svcs Ofc DATE 22 July 83

CMT 1

1. The attached DRAFT SOP establishes policy, assigns responsibility and specifies authority for the protection of humans used as subjects of study in RDTE conducted or under contract by CRDC. It is compatible with, but does not supersede, applicable Federal, Army, and State regulations.

2. Request comments or concurrence as appropriate, NLT 22 Aug 83. Comments should be coordinated with this office prior to submission.



SANDERS F. HAWKINS, Ph.D.

COL, MSC

Acting Chief, Hlth &amp; Vet Svcs Ofc

1 Encl

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CRDC SOP 70-25

DEPARTMENT OF THE ARMY  
US ARMY ARMAMENT, MUNITIONS, AND CHEMICAL COMMAND  
CHEMICAL RESEARCH AND DEVELOPMENT CENTER  
ABERDEEN PROVING GROUND, MARYLAND 21010

STANDING OPERATING PROCEDURE  
NO. 70-25

JULY 1983

USE OF HUMAN SUBJECTS IN  
RESEARCH, DEVELOPMENT, TESTING, AND EVALUATION

1. PURPOSE. This Standing Operating Procedure (SOP) establishes policy, assigns responsibility, and specifies authority for the protection of humans used as subjects of study in Research, Development, Test, and Evaluation (RDTE) conducted or under contract by the US Army Chemical Research and Development Center (Chem Rsh & Dv Ctr). In accordance with AR 70-25, it also establishes the Chem Rsh & Dev Ctr Human Use Review Committee. In addition, it is compatible with but does not supersede applicable Federal, Army, and State regulations (Appendix A).
2. SCOPE. This SOP is applicable to Chem Rsh & Dev Ctr and its subordinate elements including, but not limited to, contracts supporting RDTE activities in which human subjects are involved. Nothing in this SOP is intended to supersede requirements for Health Hazard or other safety review required by DA, DARCOM, AMCCOM, or CRDC regulations.

This Standing Operating Procedure supersedes SAREA Regulation No. 70-2, 2 Nov 76

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3. DEFINITIONS.

a. Approving Authority. The DARCOM Command Surgeon is the approving authority for minimal risk RDTE studies in which human subjects are involved. The DA, Surgeon General (TSG) is the approving authority for RDTE studies which involve more than a minimal risk to human subjects, except for all RDTE studies related to nuclear, biological, or chemical (NBC) threat agents. In the case of NBC threat agents, TSG will forward the protocol to the Secretary of Army for approval by under Secretary of Defense for Research and Engineering.

b. Subject consent. The legally effective agreement to participate as a human subject in an RDTE study. This agreement is by a person who has autonomous legal capacity to consent to his or her own participation as a human subject.

c. Human subject. An individual who is or becomes a participant in RDTE, either as a recipient of the test article or a control. Chem Rsh & Dev Ctr will use only active duty military personnel and adult civil service employees as human subjects. Active duty military personnel are regarded as adults when participating in RDTE conducted on federal property. Exceptions to the above will be addressed to the Chem Rsh & Dev Ctr HURC for resolution. The term "human subject" does not apply to individuals participating in epidemiological type studies; to performance of normal accepted military duties by military personnel assigned to provisional or test units executing approved test and evaluation programs; to military personnel participating in approved and accepted force, unit, or crew, or individual combat readiness, effectiveness, proficiency, or fitness exercises; or to civilian or military personnel who are trained to test (e.g. test pilots, test engineers, test chamber operator, etc). and are assigned to duty positions that specifically call for that speciality training. Human subjects are volunteers in the sense that they have a fundamental right to choose as to whether or not to participate as human subjects. This freedom of choice applies also to military personnel and as such they are not subject to prosecution under any provisions of the Uniform Code of Military Justice for choosing not to participate or withdrawing their consent to continue participating in an RTDE study as human subjects.

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d. Minimal Risk. The risks anticipated in the proposed study are not greater, considering probability and magnitude, than those encountered in daily life or during the performance of routine medical or physiological examinations or tests.

e. Principle Investigator. The individual, regardless of title or position, who has been designated by the approving authority for the primary responsibility and actual execution of the RDTE study. The Principle Investigator has total technical direction and responsibility for the study throughout its duration.

f. Associate Investigator(s). An individual(s) who may be deeply involved in the execution of the RDTE study but does not have overall primary responsibility.

g. Protocol. The written, detailed plan by which research is to be conducted, and which contains, as a minimum, the objectives of the study, the experimental design, the information to be collected, the means by which it will be collected and analysed, assessment of potential risks to the test subjects and Chem Rsh & Dev Ctr support personnel, health and safety control measures, or other means used to reduce to an acceptable level any risks to the test subjects and Chem Rsh & Dev Ctr support personnel. Appendix B + C contains protocol guidelines.

h. Human Use Review Committee (HURC). The HURC will assess all protocols for scientific validity, safety and health implications, acceptability in terms of regulations, rights and welfare of test subjects, and community acceptance. The committee shall be composed of not less than five employees of the Federal Government with varying backgrounds appointed by the Commander, Chem Rsh & Dev Ctr. The Chairperson, HURC will submit to the Commander those protocols recommended for approval and make disposition to the appropriate approving authority.

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i. Medical Monitor. A physician designated by TSG to be on site during all phases of the study involving human subjects with authority to terminate the study if subjects are at risk or life or limb; or if it appears the risk is significantly greater than anticipated at the time of review and TSG approval of the research.

4. POLICY.

a. In order to provide for the adequate discharge of human subject protection responsibility, it is the policy of Chem Rsh & Dev Ctr that all RDTE studies involving human subjects be documented by a scientific review and recommended for approval by the HURC.

b. The HURC shall determine and document the extent of anticipated risks the test subjects will be subjected to during the study. Assessment of each protocol's risk will be documented in the appropriate HURC's minutes.

c. The study must be such as to contribute significantly to a RDTE Program and have reasonable prospects of yielding militarily important results which are not obtainable by other methods or means of study.

d. The rights, welfare and privacy of each test subject will be adequately protected (Appendix C-G).

e. In RDTE studies where active duty <sup>military</sup> personnel from more than one service are subjects, the approving authority of the service which is exercising primary responsibility for conducting the study will coordinate the protocol with the other services for concurrence.

f. The progress of the study will be reviewed and documented at timely intervals by the Chairperson, HURC. Such reviews will be documented and incorporated into the committee minutes. The HURC can terminate a RDTE study if review indicates unacceptable risks to test subjects or violation of approved protocol procedures.

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g. No Chem Rsh and Dev Ctr contract involving humans as subjects of RDTE shall be awarded unless the contractor has an Institutional Review Board with an approved assurance on file at US Health and Human Services or an Institutional Review Board that complies with the provisions of HHS regulations and submits assurance of such compliance to DA, Surgeon General.

h. The number of test subjects used will be kept at a minimum consistent with the criteria for validity and reliability in the scientific discipline(s) utilized in the research.

i. The research will be conducted so as to avoid all unnecessary physical and mental suffering and injury.

j. No research will be conducted if there is any reason inherent to the nature of the study to believe that death or disabling injury will occur.

k. Proper precautions will be taken and adequate facilities provided to protect the test subjects against all foreseeable possibilities of injury, disability, or death that might be derived from the study. This includes, but is not limited to, adequate on-site emergency apparatus, facilities, and medical treatment as may be required.

l. The RDTE study will be conducted only by a principle investigator whose scientific and professional credentials have been reviewed and approved by the appropriate approving authority.

m. Test subjects will have no physical or mental diseases which will make the proposed RDTE study more hazardous for them than for normal healthy persons. A medical examination and clearance for participation as a test subject may be required as well as additional examinations after completion of the study, if in the opinion of a physician, such examinations are necessary for the health or well being of the test subject.

n. The use of human test subjects in support of RDTE offensive studies is not authorized.

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o. Whenever feasible, RDTE studies involving human subjects will be unclassified.

## 5. RESPONSIBILITIES

### a. Commander, Chem Rsch & Dev Ctr

(1) Establish and appoint members to the HURC for a two year length of service. Removal from the Committee will be at the discretion of the Commander, termination of employment, or transfer.

(2) Review minutes and recommendations of the HURC, and forward protocols to the appropriate approving authority.

### b. Chief, Divisions or Support Elements

(1) Review protocols for scientific validity and ascertain the necessity for the use of human test subjects.

(2) Evaluate the military relevance of the study and determine if the protocol has a reasonable prospect of yielding militarily important results which are not obtainable by other methods or means of study.

(3) Insure adequate facilities, equipment, and safeguards are provided to protect the test subjects and Chem Rsch & Dev Ctr support personnel against all foreseeable possibilities of injury, disability or death.

(4) To promptly report any change of principle investigator or associate investigators to the Chairperson, HURC.

### c. Chief, Safety Office.

(1) Evaluate protocols for safety and health risks to the test subjects and Chem Rsch & Dev Ctr support personnel and recommend controls as appropriate.

(2) Determine if a Chem Rsch & Dev Ctr Hazardous Safety SOP is required prior to the start of the test and coordinate its approval with the Principle Investigator.

(3) Obtain a Health Hazard Assessment prior to recommending approval of a protocol involving human subjects in the operation of military materiel.

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(4) Recommend approval of protocols.

d. Chief, Health & Veterinary Services

(1) Provide technical support and consultation to principle investigators concerning the scientific validity, health implications, and acceptability of the study design.

(2) Operate as point of contact for obtaining medical information from US Army Medical Research and Development Command, US Army Health Services Command, and DA, Office of the Surgeon General in support of the study.

(3) Provide secretarial/administrative support to the Chem Rsch & Dev Ctr, HURC, maintain records of HURC proceedings, maintain current references, regulations, and public laws governing the use of humans as test subjects.

(4) Serves as Chairperson, CRDC Human Use Review Committee.

e. Commander, KUSAHC

(1) Conduct medical evaluations on subjects prior to entry, during and following a RDTE study as appropriate.

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(2) Terminate subject's participation in an RDTE study, if in the opinion of a physician, the subject's medical condition presents an unacceptable risk or increases the possibilities of illness, injury or disability.

(3) Provide on-site medical personnel to include any specialized medical expertise and equipment as required by the approving authority.

(4) Provide emergency medical support and evacuation as required.

(5) Provide a physician as a voting member to the Chem Rsch & Dev Ctr HURC.

f. Commander, AEHA

(1) Determine medical evaluation criteria for selection of subjects for participation and continuation in a RDTE study.

(2) Provide a physician as a voting member to the Chem Rsch & Dev Ctr HURC.

g. Commander, APG

Provide a Chaplain as a voting member to the Chem Rsh and Dev Ctr HURC.

h. Principle Investigator

(1) Professionally qualified to conduct tests involving human subjects by submitting to the HURC: position, occupation, earned degrees, board certification, or other such pertinent indications of experience to demonstrate competency in the area of anticipated study. Submit documents to HURC prior to submitting protocol for review.

(2) Coordinate the conceptual test design with Chief, Health and Veterinary Services Office and obtain necessary information for preparation of a protocol. These consultations should be early and frequent as needed to obtain timely, economical, and efficient support.

(3) Report immediately any adverse effects which occur to any test subject or Chem Rsh & Dev Ctr personnel to the Chairperson, HURC and Chief, Safety Office.

(4) Promptly report changes or unanticipated problems within any test to the Chairperson, HURC. Changes to an approved protocol will not be initiated without consent of the approving authority, except where necessary to eliminate apparent hazards to the test subjects or others.

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(5) Terminate a test at any stage if there is probable cause to believe, in the exercise of good faith, superior skill, and careful judgement that continuation is likely to result in injury, disability or death to any test subject or Chem Rsh & Dev Ctr support personnel.

(6) Responsible for ascertaining the quality of the test subject's consent.

The Principle Investigator shall seek consent only under circumstances that provide the prospective test subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the test subject shall be in language understandable to the subject (Appendix A-F). This is a personal responsibility of the Principle Investigator and will not be delegated.

(7) When reasonable, provisions will be made for a post-participation debriefing of test subjects to include any significant new findings developed during the course of the study.

(8) Submission of twelve (12) copies of the protocol through the appropriate Div Chief to the HURC at least ten (10) working days prior to a Committee meeting.

Supporting documents such as Code of Federal Regulations or other explanatory documents need only be provided in one (1) copy for the HURC Record File. The Principle Investigator will be present at the HURC meeting to answer any questions pertaining to the protocol.

(9) Responsible for transferring all records of the test to include laboratory notebooks(s), approved Protocol, Volunteer Agreement Affidavits, Volunteer Agreement Explanation, Privacy Act Statements, and copies of HURC minutes to the Chem Rsh & Dev Ctr Technical Library for secure storage for a minimum of 40 years.

## 6. HURC

a. General. The HURC will have nine (9) voting members, with varying backgrounds to promote complete and adequate review of protocols. In addition to possessing the professional competence necessary to review protocols, the HURC shall ascertain the acceptability of proposed protocols in terms of military relevance; Federal, DoD, DA, and State Laws and Regulations; and standards of professional conduct and community acceptance. The HURC shall be composed entirely of employees of the Federal Government.

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The HURC shall not have a voting member participate in initial or continuing review of any RDTE study in which the member has a conflicting interest, except to provide information requested by the HURC. Voting members will be identified by name, earned degrees, representative capacity, and experience such as board certifications and licenses. The information will be complete enough to describe each member's chief expected contributions to the HURC. The HURC may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the HURC. These individuals may not vote with the HURC.

b. Voting Members. The HURC will consist of the following voting members appointed for a period of 2 years by the Commander, Chem Rsh & Dev Ctr:

- (1) Chief, Health and Veterinary Services Office (Chairperson)
- (2) Safety Office (Safety and Health Issues)
- (3) AMCCOM Legal Office (A) (Legal issues)
- (4) Systems Development Division (Military Relevance)
- (5) Systems Development Division (Statistician or Systems Analyst)
- (6) Headquarters & Headquarters Company (an enlisted member, Grade E6 or above,

in a nonscientific area)

- (7) Chaplain Office, APG (Ethnical and morale considerations)
- (8) Kirk US Army Health Clinic (Medical Support & Evaluation of Volunteers)
- (9) US Army Environmental Hygiene Agency (Medical Evaluation Criteria)

c. Non-Voting Member.

- (1) Secretary, Health and Veterinary Services Office (Recorder)
- (2) Commander or appointed Representative of Unit from which military volunteers

are acquired.

d. Quorum. A HURC recommendation will be based upon a convened quorum consisting of a least five noting members. In addition, an opinion from the AMCCOM Legal Office Representative will be required before a formal recommendation is made to forward a

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protocol to the approving authority. A simple majority vote will be required for recommending approval, disapproval or deferring action on a protocol or other appropriate HURC actions.

e. Criteria for HURC recommending approval of an RDTE Protocol. The HURC shall determine as a minimum that all of the following requirements are satisfied:

(1) Scientific and professional qualifications of the Principle Investigator and Associate Investigator(s), are acceptable for conduct of the proposed RDTE study.

(2) Risks to subjects and Chem Rsh & Dev Ctr support personnel are minimized to acceptable levels.

(3) Risks to subjects are reasonable in relation to anticipated benefits and importance of the knowledge that may reasonably be expected to result.

(4) Selection of subjects is equitable.

(5) Informed consent without coercion or undue influence is obtained from each prospective subject and appropriately documented.

(6) The protocol provides provision for monitoring the conduct of each RDTE study by the HURC and evaluation of test results to insure the health and safety of the subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.

f. Records. The Chairperson, HURC will prepare and maintain adequate documents on HURC activities, including:

(1) Copies of all protocols reviewed, scientific evaluations that accompany the protocols, approved sample consent documents, progress reports submitted by investigators, and reports of injuries and adverse reactions.

(2) Minutes of HURC meetings showing attendance; actions taken by the HURC; the vote on these actions, including the number of members voting for, against, and

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abstaining a decision; the basis for recommending changes or disapproving the protocol; and a written summary of the discussion of controverted issues and their resolution.

- (3) Records of continuing review activities.
- (4) Copies of all correspondence between the HURC and the investigators.
- (5) A list of HURC members with summary of academic and professional background.
- (6) Written procedures for the HURC.

(7) Transfer of HURC files one (1) year after completion of the RDTE study to the Chem Rsh and Dev Ctr Technical Library for inclusion with the principle investigator's data which will be maintained for a minimum of 40 years (AR 340-18-13).

7. Approval. The Chairperson, HURC, will notify the Principle Investigator in writing when approval is received from the appropriate approving authority. Approval to start the RDTE study will expire one year after the date approval is granted by the appropriate approving authority. No deviations are permitted from an approved protocol without consent of the Chairperson, HURC, thru the approving authority.

8. Technical Reports.

a. Technical Reports will contain this statement in the preface or introduction paragraph: "For the protection of human subjects, the CRDC investigators have adhered to the policies of AR 70-25 concerning the use of volunteers as research subjects".

b. One copy of the Technical Report will be provided to Chairperson, HURC, for inclusion into the HURC files.

FOR THE COMMANDER:

VAN THORNTON  
CPT, AG  
Chief, Admin Ofc

Distribution:  
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APPENDIX A  
BIBIOGRAPHY

1. AR 70-25, Use of Volunteers as subjects of Research, 31 July 74 (under revision)
2. OTSG Reg 15-2, Human Subjects Research Review Board, 28 Sep 81
3. USAMRDC Reg 70-25, Use of Human Subjects in Research, Development, Testing and Evaluation, 28 Apr 81.
4. DoD Directive Number 3216.2, Protection of Human Subject in DOD-Supported Research, 7 Jan 83.
5. 45 CFR 46, Protection of Human Subject, as revised 26 Jan 81.
6. Protecting Human Subjects, The Adequacy and Uniformity of Federal Rules and Their Implementation, GPO Stock No. 040-000-00452-1, Dec 81.
7. "Self Evaluation Guide for Human Use Committees", Human Use Review Office, US Army Medical Department, 11 May 82.
8. Memorandum for Secretary of the Army, Navy, Air Force, Secretary of Defense, Subject: Use of Human Volunteers in Experimental Research, 26 Feb 53.
9. Memorandum for Chief Chemical Officer and The Surgeon General, Chief of Staff, Subject: Use of Volunteers in Research, 30 June 53.

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APPENDIX B

SAMPLE TITLE PAGE

DEPARTMENT OF THE ARMY

US ARMY MATERIEL DEVELOPMENT AND READINESS COMMAND

US ARMY ARMAMENT, MUNITION, AND CHEMICAL COMMAND

CHEMICAL RESEARCH AND DEVELOPMENT CENTER

ABERDEEN PROVING GROUND, MD 21010

RDTE PROTOCOL TITLE

PREPARED BY:

APPROVED BY:

\_\_\_\_\_  
FULL NAME                      DATE  
PRINCIPLE INVESTIGATOR

\_\_\_\_\_  
TO BE DETERMINED BY PROTOCOL CONTENT

RECOMMEND APPROVAL:

\_\_\_\_\_  
FULL NAME                      DATE  
Chief, Division or Element

\_\_\_\_\_  
FULL NAME                      DATE  
CHAIRPERSON, CRDC HUMAN USE  
REVIEW COMMITTEE

\_\_\_\_\_  
FULL NAME                      DATE  
Chief, Safety Office

\_\_\_\_\_  
FULL NAME                      DATE  
COMMANDER, CRDC

\_\_\_\_\_  
FULL NAME                      DATE  
COMMANDER, AMCCOM

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GUIDELINE FOR WRITTING A CRDC RTDE HUMAN USE PROTOCOL

1. PROJECT TITLE. (Enter complete project title).
2. PRINCIPLE INVESTIGATOR, ASSOCIATE INVESTIGATOR(S), BRANCH, DIVISION; COMMERCIAL AND AUTOMON TELEPHONE NUMBERS
3. LOCATION OF STUDY. (Enter Building and Room Number, APG-EA, MD 21010).
4. TIME REQUIRED TO COMPLETE. (Give month and year of expected start and anticipated completion date.)
5. INTRODUCTION.
  - a. Military Relevance. (Explain briefly the military importance and possible usefulness of the study.)
  - b. Background (What has been accomplished or published in the proposed area of study? In what way will the study relate to or differ from that which has been accomplished?)
  - c. Scientific Objective(s). Brief but specific statement of project objective(s).
6. STUDY DESIGN. (Outline exactly what is proposed to be accomplished in enough detail to show a clear course of action. Scientific validity of procedures and chronological steps should be described.)
7. SELECTION OF SUBJECTS.
  - a. Number of subjects. (The total number of subjects expected to complete the study.)
  - b. Age range. (Normally 18-35 years of age)
  - c. Sex
  - d. Inclusion criteria. (Specific and detailed guides should be presented.)
  - e. Exclusion criteria (A complete list detailing what subjects are ineligible for admission into the study.)
  - f. Source of subjects.
  - g. Subject identification. (Describe system used.)
  - h. Medical evaluation prior to entry, during and following the study. (Medical history, physical examination, x-ray, hematology, etc.)

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8. SAFETY AND HEALTH

- a. Risks to the subject
- b. Precautions to be taken to minimize or eliminate risks.
- c. Requirement for onsite medical personnel and/or specific emergency medical support.
- d. When applicable, Name and Telephone Number of Medical Monitor.
- e. Modification of Protocol. (Describe procedures to be followed if protocol is to be modified).

9. Bibliography. (All references mentioned in the protocol should be listed and referred to.)

10. Copy of Volunteer Agreement Affidavit

11. Copy of Volunteer Agreement Explanation

12. Copy of Privacy Act Statement

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APPENDIX D

EXAMPLE OF A VOLUNTEER AGREEMENT AFFADAVIT  
(MILITARY PERSONNEL)

I, Name: \_\_\_\_\_ Rank: \_\_\_\_\_ SSN: \_\_\_\_\_

having full capacity to consent, do hereby volunteer to participate in a research study entitled \_\_\_\_\_ under the direction of \_\_\_\_\_. The implications of my voluntary participation; the nature, duration and purpose; the method and means by which it is to be conducted; and the inconveniences and hazards which may reasonably be expected, have been explained to me by \_\_\_\_\_, and are set forth in the Volunteer Agreement Explanation which I have signed. I have been given an opportunity to ask questions concerning this study, and any such questions have been answered to my full and complete satisfaction.

I understand that I may, at any time during the course of this study, revoke my consent and withdraw from the study without prejudice; however, I may be required to undergo certain further examination if, in the opinion of a physician, such examinations are necessary for my health or well being.

\_\_\_\_\_  
Signature Date

I was present during the explanation referred to above, as well as the time of the volunteer's opportunity for questions, and hereby witness the volunteer's signature.

\_\_\_\_\_  
Witness Signature Date

\_\_\_\_\_  
Principle Investigator's Signature Date

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APPENDIX E

EXAMPLE OF A VOLUNTEER AGREEMENT AFFIDAVIT  
(DA, Adult, Civilian employee)

I, \_\_\_\_\_, SSN: \_\_\_\_\_, a federal government  
employee at \_\_\_\_\_, currently residing at \_\_\_\_\_  
\_\_\_\_\_ having attained my \_\_\_\_\_  
birthday on \_\_\_\_\_ and otherwise having full capacity to consent,  
do hereby volunteer to participate in a research study entitled: \_\_\_\_\_

\_\_\_\_\_ under the direction of \_\_\_\_\_  
The implications of my voluntary participation; the nature, duration and purpose;  
the methods and means by which it is to be conducted; and the inconvenience and  
hazards which may reasonably be expected have been explained to me by \_\_\_\_\_  
\_\_\_\_\_ and are set forth in the Volunteer Agreement  
Explanation which I have signed. I have been given an opportunity to ask questions  
concerning this research study, and any such questions have been answered to my  
full and complete satisfaction.

I understand that I may at any time during the course of this study, revoke my  
consent, and withdraw from the study without prejudice; however, I may be request-  
ed to undergo certain further examinations if, in the opinion of the attending  
physician, such examinations are necessary for my health or well-being.

\_\_\_\_\_  
Signature Date

I was present during the explanation referred to above, as well as the volunteer's  
opportunity for questions, and hereby witness the volunteer's signature.

\_\_\_\_\_  
Witness Signature Date

\_\_\_\_\_  
Principle Investigator's Date  
Signature

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APPENDIX F

WORKSHEET FORMAT EXAMPLE OF A MINIMAL RISK VOLUNTEER AGREEMENT EXPLANATION

- NOTES: 1. When feasible, use non-scientific language that is easily understood by the subject.
2. If any subject who understand only (ex. Spanish) have enrolled in a study, a (ex. Spanish) translation of the consent documents should be considered.

TITLE OF STUDY:

INSTITUTION: US Army Materiel Development and Readiness Command  
US Army Armament, Munitions and Chemical Command  
Chemical Research and Development Center  
Aberdeen Proving Ground, MD 21010

ACTUAL LOCATION: Building and Room number or other specific identifier as to location where the study will actually be conducted.

PRINCIPLE INVESTIGATOR: Full Name  
Branch  
Division  
Chemical Research and Development Center  
Autovon  
Commercial

1. PARTICIPATION INFORMATION:

a. This research study does not directly or indirectly expose you, or any study personnel, to any chemical, biological, or nuclear warfare agent. You will be exposed, while wearing .....(Brief sentence on protective clothing to be used, etc)....

to (Name the chemical, physical, and/or biological stresses). These are discussed and explained later within this agreement explanation.)

b. (Principle Investigator's Full Name) is to be contacted for answers to pertinent questions about this research study, subject's rights, and the unlikely possibility of a research related injury.

c. All records of this study, including the names and social security numbers of each subject, will be transferred to the Chemical Research and Development Center Technical Library for secure storage for a minimum of 40 years.

d. There are no hidden experimental procedures within this study.

e. This research project has been reviewed for both scientific and military significance to include ethical concerns. As a volunteer, you will be authorized, under the provisions of Army Regulation 70-25, all necessary medical care for injury or disease which is the proximate result of your participation in this study.

Subject's Initials \_\_\_\_\_

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f. The complete plan of this study is called the protocol. A copy of the protocol will be provided to you upon request.

g. You have been asked to participate in a research study to be conducted by the Chemical Research and Development Center. It is very important that you read and understand the following general principles which apply to all participants in our studies: (a) your participation is entirely voluntary; (b) you may withdraw from participation in this study or any part of the study at any time. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; (c) after you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

h. (Additional information governing broad policy or regulatory aspects for the study.)

2. DURATION OF STUDY:

3. EXPECTED DURATION OF SUBJECTS PARTICIPATION:  
(Number of hours per day for a specified number of days)

4. APPROXIMATE NUMBER OF SUBJECTS INVOLVED IN THE STUDY:

5. REASON FOR STUDY: (Specify military relevance, background and need for the study)

6. OBJECTIVE(S) OF STUDY:

7. DESCRIPTION OF STUDY:

a. How will the study be conducted? (Specify all phases of the study so that prospective subjects have a good understanding of what will be expected)

b. What (if any) test simulant(s) will be used in the study?

8. REASONABLY FORESEEABLE RISKS OR DISCOMFORTS:

a. Describe any foreseeable risks or discomforts to subjects which may reasonably be expected from participating in this research study.

b. The Principle Investigator will personally ensure that the procedures contained within the study are followed and that no changes are permitted from the approved protocol. The Principle Investigator has the responsibility and authority to stop this study at any stage if cause to believe that continuation is likely to result in injury to the test subjects.

9. Precautions to be observed before and during this study:

a. A statement that the study may involve risks to the subject (or to the embryo or fetus, if the subject is, or may become pregnant) which are currently unforeseeable.

Subject's Initials \_\_\_\_\_

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(EXAMPLE: If you are pregnant, you are advised not to participate in this study. Should you become pregnant, it is not known whether this drug (or treatment) might harm the unborn child. Therefore, it is important that patients not become pregnant during the course of the study. If you do become pregnant, you should notify the doctor in charge of your care at the earliest possible moment so that you may receive further information concerning the management of the pregnancy and the possibility of discontinuance of this treatment.)

b. Are certain medication, alcohol, or activities (e.g., driving a car) to be avoided before or following the study?

10. BENEFIT OF PARTICIPATING IN THE STUDY: (A description of any benefits the subject will receive from participating in the study)

11. ADDITIONAL COSTS TO SUBJECT THAT MAY RESULT FROM PARTICIPATION IN THE STUDY: (When appropriate)

12. ASSURANCE OF CONFIDENTIALITY OF SUBJECTS' IDENTITY: I have been provided with the attached Privacy Act Statement which has made me aware of the safeguards available to me because of the Privacy Act of 1974. I understand that the information gained from this study may be analyzed and used as part of a scientific publication, but I will in no way be personally identified.

13. CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT:

a. At the discretion of a physician you may be withdrawn at any time for medical reasons.

b. You may be removed, at the discretion of the Principle Investigator, if, in his opinion you have demonstrated disciplinary or motivational problems which interfere with your full participation in the test.

14. COMMENTS FROM SUBJECT:

a. Your safety is our primary concern. Any feedback in the form of questions, comments, and criticism is essential to the success of the test.

b. If there is any portion of this explanation that you Do Not Understand, ask the Principle Investigator Before Signing.

Subject's Initials \_\_\_\_\_

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\_\_\_\_\_  
VOLUNTEER'S SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINTED NAME

\_\_\_\_\_  
PERMANENT ADDRESS

I was present during the explanation referred to above, as well as during the volunteer's opportunity to ask questions. I hereby witness the volunteer's signature.

\_\_\_\_\_  
WITNESS SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINCIPLE INVESTIGATOR'S SIGNATURE

\_\_\_\_\_  
DATE

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APPENDIX G

PRIVACY ACT STATEMENT

1. AUTHORITY.

- a. Section 301, Title 5, United States Code.
- b. Section 3101, Title 44, United States Code
- c. Section 1071-1087, Title 10, United States Code
- d. Executive Order 9397

2. PRINCIPAL PURPOSE. The purpose for requesting personal information is to provide:

- a. Various types of data needed to satisfy the scientific objectives of the study.
- b. Minimum information necessary should you require medical treatment at any future time for a condition proximately resulting from your part in this research study.
- c. Minimum information so that steps can be taken to contact you later should it be in your best interests.

3. ROUTINE USES.

a. This information may be used to:

- (1) Provide data for determining protection required in design of masks, clothing, protective equipment, etc.
- (2) Provide full documentaton of investgative studies.
- (3) Conduct further investigations.
- (4) Teach
- (5) Compile statistical data
- (6) Provide data to develop new policy or docturine concerning decontamination methods, etc.

b. Even though permitted by law, when possible, this personal data will not be released without your consent.

Subject's Initials \_\_\_\_\_

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4. Mandatory or voluntary disclosure and effect on persons not providing information.

a. Disclosure of requested information is voluntary. If the information is not furnished, or is not available from other sources, voluntary participation in this research study may be prevented.

b. I understand that a copy will be retained by the Chemical Research and Development Center Technical Library.

c. I have received, or have declined to accept, a copy of the Privacy Act Statement, Volunteer Agreement Affidavit, and Volunteer Agreement Explanation, which I may keep.

\_\_\_\_\_  
VOLUNTEER'S SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINTED NAME

\_\_\_\_\_  
WITNESS SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINCIPLE INVESTIGATOR'S SIGNATURE

\_\_\_\_\_  
DATE

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