DEPARTMENT OF THE ARMY
UNITED STATES ARMY INTELLIGENCE AND SECURITY COMMAND
Arlington Hall Station
Arlington, Virginia 22212

USAINSCOM Regulation 15-3 — 24 February 1984

Boards, Commissions and Committees
HIGH PERFORMANCE REVIEW PROCEDURES

During 1982 and 1983, in keeping with the US Army Intelligence and Security Command (INSCOM) goal of "extraordinary performance," and seeking to move the command to a level which exceeds commonly defined parameters of performance, the INSCOM conducted a study of high performing organizations and programs in the public and private sectors. Several technologies, management techniques, training experiences and programs were identified for further evaluation with respect to their potential to contribute to the development of extraordinary individual and unit performance within the Command. This regulation contains INSCOM policies and guidance for that evaluation, establishes procedures for the use of INSCOM personnel as volunteers in evaluating and implementing high performing human systems and provides guidance for commanders and supervisors in further implementing and evaluating those high performing human systems. Supplementation of this regulation is permitted only after prior approval has been obtained from this Headquarters, ATTN: IASJA.

Chapter 1

GENERAL INFORMATION

1-1. Purpose. This regulation contains INSCOM policies and guidance for the evaluation and implementation of high performing human systems within the command. It --

a. Promulgates procedures and guidance for the use of INSCOM personnel as volunteers in the evaluation of high performing human systems;

b. Establishes and implements a review process which is consistent with AR 70-25;

c. Insures the continued evaluation of INSCOM activities to assure that the provisions of AR 70-25 are being followed;

d. Establishes procedures to obtain a health hazard assessment prior to approving an INSCOM protocol issued as required herein; and

e. Promulgates INSCOM policies and procedures to assure that INSCOM components do not engage in or contract for experimentation on human subjects in violation of Procedure 13, AR 381-10.

1-2. Applicability. This regulation applies to all elements of the INSCOM.

1-3. References.

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

b. AR 381-10, US Army Intelligence Activities.

c. AR 70-31, Standards for Technical Reporting.

1-4. Scope.

a. Nothing in this regulation is intended to supersede requirements for health hazard or other safety reviews required by any other regulations or directives.

b. The procedures, policies and guidance contained in this regulation pertain to the following:

(1) Behavioral studies, research and/or testing involving human subjects, regardless of whether conducted by INSCOM, a contractor, or other agency utilizing INSCOM funds.

(2) Inclusion of human subjects, whether as the direct or indirect object of research, regardless of the level or risk involved, in the development, testing or study of matters associated with the missions and functions of

the INSCOM, or the application of non-traditional ideas and technologies in achieving high performance of human resources.

(3) The investigation of programs and technologies to enhance organizational and individual excellence where such investigation involves the inclusion of human subjects as their object.

1-5. Exemptions.

a. Research, testing and studies in which human subjects are involved in one or more of the following categories are exempt from this regulation.

(1) Bonafide activities under the sponsorship of another Department of the Army component and involving surveys or interviews where all of the following conditions exist:

(a) Responses are recorded in such a way that subjects cannot be identified directly or indirectly.

(b) The subject's responses, if they become known, would not place the subject at risk of criminal or civil liability or damage the subject's financial or social standing or employability.

(c) The activity does not deal with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(2) Research which involves the use of educational tests, provided the data is recorded in such a way that the subjects cannot be identified directly or indirectly.

(3) Research in non-INSCOM educational settings which involve normal educational practices, such as --

(a) Regular and special educational strategies.

(b) The effectiveness or the comparison among techniques of instruction, curricula, or classroom methods.

(4) Follow-up debriefings, interviews, tests, or evaluations to determine how well participants have learned the information or skills transmitted by training or instructional activities previously attended by the subject thereof.

b. Exemptions of other activities from this regulation, even where such activities may be exempted from other similar regulations or directives, shall not be considered valid for INSCOM purposes unless and until confirmed by the INSCOM Human Technology Review Board as prescribed elsewhere in this regulation.

1-6. Explanation of terms and abbreviations. The explanation of terms and abbreviations used in this regulation is contained in appendix A.

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Chapter 2

RESPONSIBILITIES

2-1. Approving officials. The Commanding General, the Deputy Commander, Intelligence, and the Deputy Commander, Support, are the designated INSCOM approving officials. Only these officials may approve the use of human subjects in research.

2-2. Commanders and Staff Element Heads. Commanders at all levels within the INSCOM, heads of Headquarters staff elements, office chiefs and program directors (hereinafter referred to only as commanders and staff element heads) are responsible within their respective functional areas for --

a. Insuring that the provisions of this regulation are institutionalized into their organizational procedures and practices.

b. Insuring that no persons engage in or contract for experimentation involving human subjects without the express approval of an INSCOM approving official.

2-3. INSCOM Human Technology Review Board (HTRB). The INSCOM HTRB is responsible for --

a. Observing written procedures for the following:

(1) Initial and continuing review of research, including the reports of findings and actions to the investigator and the approving official.

(2) Determination of those projects which must be --

(a) Reviewed more often than annually.

(b) Verified from sources other than the investigators that no material changes have occurred since the previous HTRB review.

(3) Prompt reporting to the HTRB of proposed changes in the research, and to the HTRB and approving official of unexpected problems involving risks to the subjects or others.

b. Insuring that changes in approved projects (during the period for which approval has already been given) are not initiated without HTRB review, except to eliminate immediate hazards to a subject.

c. Reviewing proposed protocols at meetings attended by a majority of members except when an expedited review is used. For the protocol to be approved, it will receive the approval of a majority of those members present.

d. Reporting to the CG any serious or continuing noncompliance with HTRB requirements and determinations found by investigators.

e. Conducting a continuous review of research studies at intervals proper to the degree of risk, but not less than once per year.

f. Insuring the observation by a third party of the consent process and each investigation, as appropriate.

g. Recommending safeguards or special conditions to a protocol. When such recommendations are made, the approving official may take the following action:

(1) Not reduce the safeguards or conditions, and approve the protocol.

(2) Require additional safeguards.

(3) Disapprove the protocol.

(4) Refer the protocol to a higher echelon approving authority for action and review.

2-4. Chairperson of the HTRB. The DCSPPM is designated Chairperson and a regular member of the HTRB and is responsible for chairing HTRB meetings, keeping the CG informed of HTRB activities, and recommending approval/disapproval of HTRB regular members to the CG.

2-5. Executive Secretary of the HTRB. The DCSPPM will designate a member of his staff to be the Executive Secretary of the HTRB. The Executive Secretary of the HTRB is responsible for --

a. Insuring that the responsibilities of the HTRB prescribed in paragraph 2-3 are carried out.

b. Preparing and distributing the agenda for each meeting to all HTRB members.

c. Insuring that all HTRB members are afforded the opportunity to comment on HTRB actions conducted under expedited review procedures.

2-6. Regular HTRB membership. The INSCOM DCSOPS, DCSPER, DCSSYS, SJA, Command Chaplain and DARCOM LNO, are each responsible for nomination of an individual to serve as a regular member of the HTRB. Nominees may be from their respective staffs, subordinate command functional counterpart staffs, or may be the nominating element head. Nominations will be submitted to the HTRB Chairperson (DCSPPM) for approval/disapproval by the CG. Nominations may be by letter, DF or message, and will contain the information required by paragraph a, below.

a. Nominees will be identified by name, earned degrees, current position and duties, and experience, such as board certifications and licenses. The information in the nomination will be complete enough to describe each member's chief expected contributions to HTRB reviews.

b. Nominees will normally be military officers in the grade of O-5, or above, or civilian employees, GS-13 or above. Nominees will have diverse backgrounds to insure thorough review of research studies involving human volunteers as research subjects. Nominees should be of varied racial and cultural backgrounds. Nominees should have displayed sensitivity to such issues as community attitudes, and respect for advice and counsel and for the rights and welfare of human subjects.

c. Confirmed nominees will serve as HTRB members for an indefinite term, and will be expected to have final authority to speak on behalf of their activity.

2-7. Ex officio HTRB membership. The incumbents of the following positions will serve as ex officio, non-voting members of the HTRB:

a. Chief, CENTEX.

b. Command Psychologist.

c. Chief, Human Technology Office.

d. Chief, Public Affairs Office.

2-8. Ad hoc HTRB membership. The following will serve as ad hoc members of the INSCOM HTRB:

a. The Staff Advisor for Scientific and Cryptologic Affairs.

b. A physician, as approved by an INSCOM approving official (para 2-1). Physician nominees for ad hoc membership will be provided as requested by the Chairperson.

2-9. Principal investigator. The principal investigator for each project covered by this regulation is responsible for --

a. Maintaining adequate records on the following:

(1) Receipt, storage, use and disposition of all investigational materials and devices.

(2) Case histories that record all observations and other data important to the study.

(3) Volunteer agreement documents.

b. Preparing progress reports, including annual reports, as determined by the approving authority and the INSCOM HTRB.

c. Promptly notifying the approving authority, through the INSCOM HTRB, of any adverse effects caused by the research.

d. Insuring that the research has been approved by the proper authority and the INSCOM HTRB before starting, changing or extending a study.

e. Insuring that all subjects, including those used as controls or their representatives, are fully informed of the nature of the research to include potential risks to the subject.

f. Insuring that investigational materials and devices are administered only to subjects under his or her personal supervision and that of a previously approved associate investigator.

g. Insuring that volunteer recruiting teams are briefed as to the nature of the research and the ethical principles in this and related regulations.

2-10. Members of volunteer recruiting teams. Members of volunteer recruiting teams are responsible for --

a. Establishing volunteer requirements prior to recruitment.

b. Undertaking recruiting in a morally, ethically and legally acceptable manner.

2-11. Medical monitor. The medical monitor of each project is responsible for and is hereby delegated the authority to terminate the effort if --

a. Subjects are at risk of life or limb..

b. It appears the risk is significantly greater than anticipated at the time of review and approval of the project.

Chapter 3

POLICIES

3-1. General. Experimentation involving human technology or human subjects conducted by or on behalf of any INSCOM component may be undertaken only with the informed consent of the subject, and in accordance with guidelines issued by the Department of Health and Human Services (DHHS), setting out conditions that safeguard the welfare of such subjects. The provisions of this regulation constitute INSCOM implementation of those guidelines.

3-2. Approval. INSCOM components may not engage in or contract any research or testing involving human subjects without advance approval through the INSCOM HTRB by an INSCOM approving official, or higher level official, where appropriate. This approval is required regardless of the degree of risk involved.

3-3. Risk determinations. The INSCOM HTRB will render all risk determinations regarding INSCOM research or testing involving human subjects.

3-4. Risk versus benefit. The degree of potential risk involved in any project will never exceed the expected benefits of that effort.

3-5. Moral, ethical and legal concepts. The moral, ethical and legal concepts on the use of human subjects will be followed as outlined in this regulation. Voluntary consent of each human subject is essential. Military personnel are not subject to the Uniform Code of Military Justice (UCMJ) for choosing not to take part as human subjects.

3-6. Fully informed subjects. Only persons who are fully informed and volunteer to take part may be used as human subjects in INSCOM research and testing activities.

3-7. Use of non-US citizens. Research may be conducted outside the US that involves non-US citizens; however, all requirements of this regulation applicable to human subjects shall be equally applicable to non-US citizen human subjects.

3-8. Use of prisoners of war and detainees. The use of prisoners of war and detainees as human research subjects is prohibited.

3-9. Medical care. Volunteers will be authorized all necessary medical care for injury or disease that is the proximate result of taking part in approved INSCOM research or testing activities.

3-10. Stated objectives. Each project will be designed to achieve its stated objectives. The proposed number of subjects will be the minimum needed to insure that statistically significant results are obtained.

3-11. Physical and mental suffering. Each project will be conducted in such a manner as to avoid unnecessary physical and mental suffering. Preparations

will be made and adequate facilities provided to protect the subject and investigators against all foreseeable injuries, disabilities, or death. A project will not be conducted if any reason exists to believe that death or injury will result. The degree of potential risk will never exceed the expected benefits of the project.

3-12. Qualifications of investigators. Only persons judged qualified by the appropriate approving authority will conduct human subject studies. The physician responsible for the health and welfare of the subject may or may not be the principal investigator. The physician is authorized to stop the project at any time he or she believes that injury, disability or death may result.

3-13. Minors. Minors may not be involved as human research subjects without advance approval in each case by the INSCOM HTRB.

3-14. Recruiting of volunteers. Volunteer recuiting will be accomplished by personnel responsible for the conduct of the particular project, or as otherwise specifically approved by the INSCOM HTRB.

3-15. Protocol guidance.

a. Each approved protocol will be reviewed at least annually and on a continuing basis as determined by the INSCOM HTRB. Annually means once each 12-month period.

b. The decision as to whether a research protocol involves more than minimal risk shall be made by the INSCOM HTRB.

c. The research protocol will be prepared in accordance with the instructions contained at appendix B.

Chapter 4

PROCEDURAL GUIDANCE

4-1. Technical reports. Technical reports will be prepared as prescribed in AR 70-31 and follow the format of MIL-STD-847A. When applicable, these reports will contain the following statement:

> For the protection of human subjects, the investigators have adhered to the policies of AR 70-25 concerning the use of volunteers as research subjects.

4-2. Advising the Medical Research and Development Command. Two copies of technical reports of study will be forwarded to the Commander, US Army Medical Research and Development Command, ATTN: SGRD-HR, Fort Detrick, Frederick, Maryland 21701. When HQDA approval, or higher, is required, information copies of material forwarded for approval will also be furnished to the office above. These will include as a minimum, two copies of the protocol, a copy of the volunteer agreement and all minutes of INSCOM HTRB meetings reviewing the proposed project.

4-3. Informed consent. Subjects will be given adequate time to review and understand all information before agreeing to take part in a project. The volunteer agreement documents will be written in language that is easily understood by the subject. The documents listed below will be discussed with each subject before his or her acceptance.

a. The Volunteer Agreement (appendix C).

b. The Explanation Portion of the Volunteer Agreement (appendix D).

4-4. Minimum standards. The laws, customs and practices of the country in which the research is conducted will take precedence over procedures required by this regulation, where applicable. The project must meet the same standards of ethics and safety, however, that apply within the US involving US citizens. When standards vary, the more stringent will apply. A minimum age of 18 is required for US citizens taking part in research conducted outside the US, regardless of the laws of the country in which the effort is being undertaken.

4-5. More than minimal risk. When it has been determined that the risk in a human subjects study is more than minimal, then advance approval is required through HQDA (DAMI-CI) by the Secretary or Under Secretary of the Army. In addition, a medical monitor shall be recommended by the INSCOM HTRB and approved by the CG.

4-6. Contractors or vendors. Contractors or vendors holding approved DHHS assurance of compliance shall be considered in compliance with this regulation. In the absence of such an assurance, a special assurance will be negotiated

with the contractor or vendor. In all cases, however, the INSCOM HTRB must approve the INSCOM participation in or utilization of such contractors or vendors.

4-7. Requests for exceptions. Requests for exceptions to this regulation will be submitted to the INSCOM HTRB Chairperson (DCSPPM) with full justification.

4-8. Expedited review categories. Categories which may be processed in the expedited review procedures are as follows:

a. Recording of data from subjects who are 18 years of age or older, using non-invasive procedures routinely employed in clinical practice. This category does not include exposure to electromagnetic radiation outside the visible range (e.g., X-rays, microwaves). It does include --

(1) The use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy.

(2) Such procedures as --

(a) Weighing.

(b) Electrocardiography.

(c) Electroencephalography.

(d) Thermography.

(e) Detection of naturally occurring radioactivity.

(f) Diagnostic echography.

(g) Electroretinography.

b. Voice recordings made for research purposes such as investigations of speech defects, improvement in language utilization, etc.

c. Moderate exercise of healthy volunteers.

d. Study of existing data, documents, records, pathological specimens, or diagnostic specimens.

e. Minor changes in previously approved research during the period for which approval has been authorized.

4-9. Expedited review procedures. Under an expedited review procedure, the HTRB Chairperson, or one or more HTRB reviewers designated by the chairperson, may carry out the review. These reviewers may exercise all of the authorities

of the HTRB except that of disapproval, which may only be exercised as prescribed elsewhere in this regulation.

a. When the expedited review procedure is used, the reviewers will furnish complete copies of all their actions and related materials (e.g., research plan, protocol, etc.) to all other members of the HTRB. The HTRB Chairperson will submit a written report of expedited review actions to the CG within ten working days of approval action.

b. An expedited review procedure may be restricted or suspended to protect the rights or welfare of subjects at any time based upon either direction of an approving official or request by any member of the HTRB.

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Chapter 5

INSCOM HUMAN TECHNOLOGY REVIEW BOARD ACTIVITIES

5-1. Composition of the HTRB. Membership in the INSCOM HTRB will consist of the chairperson; at least six other regular members, appointed by the CG from among the nominations submitted in accordance with paragraph 2-6 and 2-8, above, or from other sources; an executive secretary; and such other ex officio and ad hoc members as prescribed in chapter 2, above. One regular member will be not affiliated with the INSCOM and not part of the immediate family of a person affiliated with the INSCOM.

5-2. General criteria for membership. At least one member of the HTRB will be from a profession/position/activity primarily concerned with the welfare of human persons. At least one member will be non-scientific, such as a lawyer, ethicist or member of the clergy. THE INSCOM HTRB may invite persons with special competence to assist in the review of complex issues that require expertise beyond that available on the HTRB. These persons normally will not vote, unless he or she is serving as the non-INSCOM member of the HTRB.

5-3. General committee activities. Each regular and ad hoc committee member shall have one equal vote, and the entire committee will be vested with the responsibility to determine if a proposed activity is acceptable. Acceptability will be in terms of Army Medical Department (AMEDD) commitments and regulations, applicable law, standards of conduct and practice, and with full consideration for the particularly sensitive nature of the INSCOM's role as an intelligence component.

a. At least five voting members will be required to constitute a quorum at each committee meeting.

b. All actions of the committee will be by majority vote of members present.

5-4. Avoiding possible conflicts of interest.

a. Except to provide information requested by the HTRB, no INSCOM HTRB member may take part in a review of any project which is sponsored by that member's organization or office of employment or assignment, or in which there may otherwise be a conflict or appearance of a conflict of interest.

b. The intended approving official may not be a member of the HTRB. The approving official may not approve research for which he or she is also a principal or associate investigator. A higher echelon of command must review and approve such projects.

5-5. Criteria for INSCOM HTRB approval.

a. In evaluating the risks and benefits for projects under consideration, the INSCOM HTRB should consider only those that may result from that

particular project, unless a clear linkage has been established to other projects.

b. To approve an effort covered by this regulation, the INSCOM HTRB must determine that all of the requirements below are met.

(1) Risks to subjects are minimized by using procedures that are --

(a) Consistent with sound investigation design and do not unnecessarily expose subjects to risk.

(b) Already being used on subjects for diagnosis or treatment, when appropriate.

(2) Risks to subjects are reasonable in relation to --

(a) Anticipated benefits, if any, to the subjects.

(b) The importance of the knowledge that may be expected to result.

(3) In making an assessment for the selection of subjects, the sponsor has adequately considered --

(a) The purpose of the investigation.

(b) The setting in which the research investigation will be conducted.

(4) Informed consent will be secured from each subject.

(5) Informed consent will be properly documented.

(6) The protocol takes adequate provisions for monitoring the data collected to insure the safety of the subjects.

(7) Adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of data when appropriate.

5-6. Special considerations of sensitivity. Some or all of the subjects may be vulnerable to special considerations of sensitivity because of past assignments, affiliations, etc. In such cases, additional safeguards will be included to protect the rights and welfare of these subjects. In no instance will the INSCOM be a party to any research which involves the use of persons with acute or severe physical or mental illness, or those who are economically or educationally disadvantaged.

5-7. Suspension or termination of a project.

a. The INSCOM will suspend or terminate a project that --

(1) Is not being conducted according to the HTRB's requirements.

(2) Has been associated with unexpected harm to the subjects.

b. Suspensions or terminations of a project will include a statement of the reasons for the HTRB's action, and will be reported within 24 hours to the principal investigator and the approving official.

5-8. Records.

a. The HTRB executive secretary will prepare and maintain adequate documents on HTRB activities, including --

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

(2) Minutes of HTRB meetings showing attendance; actions taken by the INSCOM HTRB; the vote of these actions, including the number of members voting for, against, and abstaining a decision; the basis for requiring changes or disapproving a project; 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 HTRB and project investigators.

(5) A current list of HTRB members. 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 HTRB reviews. Any employment or other relationship between members and the INSCOM will be noted.

(6) Written procedures, including agendas, expedited review procedures, etc., for the HTRB.

(7) Statements of significant new findings.

b. The records required by this regulation will be retained permanently under AR 340-18-13. Such records will be reasonably accessible for inspection and copying by authorized DA personnel and representatives of the Federal Food and Drug Administration.

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APPENDIX A

TERMS AND ABBREVIATIONS

Section I - Terms

A-1. Approving official. The INSCOM Commanding General, Deputy Commander, Intelligence, Deputy Commander, Support, or higher level official, who has been delegated authority to approve the use of human subjects in research.

A-2. Associate investigator. A person who may be deeply involved in the execution of research but does not have overall primary responsibility.

A-3. Consent. The legally effective agreement to take part as a human subject. The agreement may pertain to one's own participation or be in behalf of another person. Three terms associated with this meaning that distinguish between the legal validity of such agreements are subject consent, permission, and assent. These terms are defined below.

a. Subject consent. Agreement by an adult person who has autonomous legal capacity to consent to taking part as a human subject. This form of consent pertains only to adults who have not lost their legal capacity to consent.

b. Permission. Agreement by a "legally authorized representative" for taking part as a human subject of another person who does not possess autonomous legal capacity to consent in his or her own behalf. A legally authorized representative is a person or judicial body authorized under applicable law to grant permission (also known as third-party consent).

c. Assent. The affirmative agreement to take part as a human subject by a person not possessing autonomous legal capacity to consent in his or her own behalf, but who is capable of understanding what is proposed and able to express an opinion as to willingness to participate. Assent is concurrence in what is proposed, but is not a substitute for subject consent because, unlike consent, assent has no legal effect.

A-4. Experimentation. Any research or testing activity involving human subjects that may expose such subjects to the possibility of permanent or temporary injury (including physical or psychological damage and damage to the reputation of such persons) beyond the risks of injury to which such subjects are ordinarily exposed in their daily lives.

A-5. Expedited review procedures. Those procedures used in research involving no more than minimal risk and those used for minor changes in approved investigations. These procedures minimize time required for review.

A-6. Health care practitioner. An individual trained to interact with patients to provide diagnostic or treatment procedures within established professional standards.

A-7. Human subject. Any person, whether or not such person is a US citizen, about whom an investigator conducting research, testing or studies obtains data through interaction with that person. Both physical procedures and manipulations of the subject or the subject's environment are included. Human subjects may be thought of as direct objects when the research is to determine the effects of a new system on man (for example, the psychological effects of a particular interrogation technique on an individual) or as indirect objects when a test is conducted to determine how man affects the ultimate performance of a system (doctrine, concepts, training programs).

A-8. Human Technology Review Board (HTRB). A body set up to provide initial and continuing review of research involving the use of human subjects. HTRB fulfills all the functions of a human use committee as described in AR 70-25. It is fundamentally similar to an Institutional Review Board (IRB) discussed in guidelines issued by the DHHS for human research, but has somewhat different authority as compared to an IRB. Within DOD, authority to approve the use of human subjects in research is vested in commanders. In the INSCOM it is vested in the CG, and has been delegated to the DCG-I and DCG-S for matters under their respective functional control. Approving officials act on recommendations of validly constituted HTRBs. Outside DOD, IRBs tend to be vested with this authority.

A-9. Legally authorized representative. A person or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject taking part in the procedures involved in the research.

A-10. Medical monitor. This person is a military or Department of the Army civilian physician who is responsible for observing human subjects during the conduct of research.

A-11. Minimal risk. When used in the context of this regulation, this means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

A-12. Principal investigator. A person, regardless of title, who is primarily responsible for the actual execution of the research.

A-13. Protocol. The written, detailed plan by which research is to be conducted. The plan contains, as a minimum, discussion of --

a. The objectives of the project.

b. The information to be collected.

c. The means by which it will be collected and evaluated.

d. An assessment of potential risks and benefits to subjects.

e. Safety measures.

f. Other means to be used to reduce the risks to subjects.

A-14. Research. A systematic investigation designed to develop or contribute to general knowledge concerning military or intelligence problems. The term does not include individual or group training of personnel such as combat readiness, effectiveness, proficiency or fitness exercises. This definition is unique to this regulation and is not intended to identify an effort for funding under appropriations intended for Research, Development, Test and Evaluation (RDTE). "Research" in the sense applied in this regulation will be funded according to the project, effort, etc., to which it applies.

A-15. Research and development. Any scientific inquiry, investigation, or validation performed or directed to test hypotheses or develop concepts concerning physical or biological principals or laws. Research is a major exploration of the unknown and contains unpredictable elements. Development usually is confined to the qualification or elaboration of known principals.

A-16. Systematic investigation. A formal inquiry generally described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives. The term includes clinical investigations, but does not include post-training or post-therapeutic inquiries intended only to evaluate individual progress or responsiveness to training or therapy.

A-17. Test and evaluation. An effort or assessment to validate proposed or existing standards or concepts of performance, either of humans or of material.

A-18. Test participants. Humans directly involved in test and evaluations, but who are not themselves the direct object of such activities. Generally, test participants are not regarded as receiving any direct benefits as a result of their participation in the test (for example, a new doctrine or training concept).

Section II - Abbreviations

ACSI	Department of the Army Assistant Chief of Staff, Intelligence
AMED	Army Medical Department
ARI	US Army Research Institute for the Behavioral and Social Sciences
CENTEX	The INSCOM Center for Excellence
CFR	Code of Federal Regulations
DA	Department of the Army
DARCOM	US Army Materiel Development and Research Command
DCSPER	The INSCOM Deputy Chief of Staff for Personnel
DCSPPM	The INSCOM Deputy Chief of Staff for Plans, Programs and Modernization
DCSOPS	The INSCOM Deputy Chief of Staff for Operations
DHHS	Department of Health and Human Services
HPTF	The INSCOM High Performance Task Force (no longer constituted)
HTRB	The INSCOM Human Technology Review Board
INSCOM	US Army Intelligence and Security Command
MACOM	Major Army command
SJA	The INSCOM Staff Judge Advocate
TSG	The Surgeon General of the Army
US	United States

APPENDIX B

FORMAT FOR PREPARATION OF A RESEARCH PROTOCOL

Section I

GENERAL INFORMATION

1. Project title. (Enter complete project title - if this is an amendment to an existing project, identify by indicating "Amendment No.____to" immediately preceding the title).

2. Investigators.

a. Principal investigator. (Enter full name, rank, title, organization and telephone number).

b. Associate investigators. (Identify all associate investigators and area of the project for which each is responsible. Include full name, rank, title, organization and telephone number for each).

3. Location of the project. (Identify all locations at which the project will be carried out and specify which portions will be done at each location and who is the point of contact at each location. Include telephone number for POC).

4. Period covered by the project. (Give month and year of expected start and completion dates).

Section II

INTRODUCTION

5. Synopsis.

a. (Enter a short, one-page or one-paragraph, summary of the proposed project, similar to the abstract of a scientific paper).

b. (Enter a list and brief description of safety measures for human subjects involved in the project).

6. Medical application. (Explain briefly the medical importance, including psychological considerations, and possible usefulness of the project).

7. Objectives. (State briefly but specifically the objectives of the project. Include items below, where applicable).

a. Study design. (Double-blind, crossover, etc.).

b. Technologies to be employed. (List the generic technologies to be employed in the project).

c. Type of population involved. (List the subject population to be observed).

8. Status. (State what has been accomplished or published in the proposed area of study and describe how this project will relate to, differ from and/or advance that which has already been accomplished).

9. Bibliography. (List all references used in preparing the protocol).

10. Authority. (Cite the specific authority for the INSCOM to engage in this project. Indicate date of approval, and if not yet approved, indicate specific approval authority needed for this project. Identify any POC in approval authority's organization with whom coordination has been effected.

Section III

PROTOCOL PLAN

11. General approach.

a. (Outline expected accomplishments in sufficient detail to show a clear course of action).

b. (Include discussion of the technological validity of the proposed research procedures).

c. (List the chronological steps to be taken).

12. Project subjects. (Give as a minimum the information below).

a. Number of subjects. (Indicate the total number of subjects expected to complete the study).

b. Age range.

c. Sex.

d. Inclusion criteria. (State specific and detailed reasons for inclusion of subjects by class, or individually, as appropriate).

e. Diagnostic criteria for entry.

f. Evaluations before entry. (Include any physical or psychological examinations, medical history, etc., which is to be done on each subject before entry into the project).

g. Exclusion criteria. (Include a complete list detailing the subjects, diseases, medications, etc., which constitute the criteria for exclusion from the project).

h. Source of subjects. (Describe briefly where subjects will be obtained).

i. Subject identification. (Describe code system, if any, which will be used in the project).

j. Subject assessment. (Describe the methods used to assign or allocate the object of this research to particular subjects).

k. Risks and benefits. (Discuss the analysis of risks and benefits to subjects and to those conducting the research).

l. Minimization of risks. (Discuss the precautions to be taken to minimize or eliminate risks to subjects and those conducting the research).

m. Corrective actions. (Describe hypothesized adverse reactions and corrective actions expected to be taken if such adverse reactions occur).

n. Special equipment. (Describe any special medical or nursing care or equipment needed for subjects admitted to the project).

13. Project technologies.

a. (State the complete name and description of all technologies to be used, including procedures for their application).

b. (Identify the source of all technologies and related items, devices, etc. List all components and manufacturing and quality control plans/ procedures, where applicable).

c. (Identify the methodology for application, if different from procedures described above).

d. (State the schedule, administration and duration of each aspect of the project).

e. (Describe in detail accompanying devices amd their intended use. Identify whether these are classified as medical devices and whether the medical devices amendment to the Federal Food, Drug and Cosmetic Act applies).

f. (Discuss labeling to medical devices, where applicable).

14. Evaluations made during and following the project. (A project schematic may be included, or the items may be listed as indicated below. In either case, it is important to identify the person who will perform each evaluation).

a. Specimens to be collected.

(1) Schedule of collections.

(2) Evaluations to be made on specimens.

(3) Storage. (If applicable, state where and if special conditions are required.)

(4) Labeling and disposition.

(5) Laboratories performing evaluations.

(6) Special precautions.

b. Clinical/behavioral assessments. (Include how adverse effects are to be recorded).

c. Vital signs. (State when desired and the frequency).

d. Follow-up procedures.

e. Disposition of data. (State location and duration of storage. Include pertinent information regarding Privacy Act and AR 381-10 considerations, if applicable).

f. Methods used for data collection. (State critical measurements used as end points to characterize safety, efficacy or equivalency).

15. Departure from protocol for individual subjects.

a. When allowed. (Use flexible, but definite criteria. If none is to be allowed, so state).

b. Who will be notified. (Include both those regarding the individual subject, if appropriate, and those elsewhere within the INSCOM. Must notify at least the HTRB).

16. Adverse reactions. (Must correlate with paragraph 12m, above).

a. Definition of subject reactions.

b. Immediate reporting procedures.

c. Routine reporting procedures.

d. Potential post-project adverse reactions.

Section IV

ADMINISTRATION

17. Modification of protocol. (Describe the procedure to be followed to modify, terminate or extend the protocol).

18. Disposition of unused project material. (Give a statement pertaining to disposition of unused project material and devices, if applicable).

19. Publications and reports. (Describe use, including potential restrictions, of information and publications and reports arising from the project).

20. Funding. (Identify source of funds and any special or unusual funding implications).

21. Medical monitor. (State the name and telephone number of medical monitor, when applicable).

22. Protocol review. (Identify the human use committee or institutional review board which will provide initial, continued and annual review of this protocol).

(Signature)_____
(Name, rank and organization of person submitting protocol)

(Signature)_____
(Name, rank and organization of principal investigator)

(Signature)_____
(Name, rank and organization of approving official)

Attachments
A - Proposed Volunteer Agreement
B - Proposed Explanation Portion of the Volunteer Agreement
C - Review of Scientific and Human Research Issues (if applicable)
D - Biographic Sketch of principal and associate investigators

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APPENDIX C

VOLUNTEER AGREEMENT

Part A

I, _____, having attained my eighteenth (18th) birthday, and otherwise having full capacity to consent, do hereby volunteer to participate in an investigation study entitled: _____
_____
_____, and under the direction of _____
_____.

The implications of my voluntary participation; the nature, duration and purpose, and the methods and means by which it is to be conducted; and the inconveniences and hazards to be expected have been thoroughly explained to me by _____, and are set forth in Part B of this Agreement, which I have signed. I have been given the opportunity to ask questions concerning this investigative 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 investigative study revoke my consent, and withdraw from the study without prejudice; however, I may be required to undergo certain further examinations, if, in the opinion of competent authority, such examinations are necessary for my health or well being.

_____ _____
Signature Date

_____ _____
Witness's Signature Date

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APPENDIX D

VOLUNTEER AGREEMENT

Part B

Explanation Portion of the Volunteer Agreement

1. Project title. (The title of the project and the place where it is to be conducted).

2. Principal investigator. (Must agree with the protocol).

3. Discussion. (A statement that the study involves research. An explanation of the purpose of the study and the expected duration of the subject's participation. A description of the procedures to be followed. An identification of any experimental procedures. A statement giving information about prior, similar, or related studies that provide the rationale for this project).

4. Risks or discomforts. (A description of any reasonably foreseeable risks or discomforts to the subject).

5. Benefits. (A description of any benefits to the subject or to others that may reasonably be expected from the study).

6. Alternative procedures. (A disclosure of proper alternative procedures or courses of treatment, if applicable, that might be advantageous to the subject).

7. Confidentiality of records. (A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Also, if more than a minimal risk is involved, a statement that authorities outside the US may inspect the records).

8. Subject's rights. (An explanation of whom to contact for answers to pertinent questions about the study and the subject's rights and whom to contact in the event of study-related injury to the subject).

9. Voluntary participation. (A statement that --

a. Participation is voluntary.

b. Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

c. The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled).

10. Compensation and medical treatment. (For a study involving more than minimal risk, an explanation as to whether any compensation and medical treatment

are available if injury occurs and, if so, what they consist of, or where further information may be obtained).

11. Additional comments. (When appropriate, one or more of the elements of information below will also be given to each subject.

a. A statement that a certain treatment or procedure may involve risks to the subject - or to the embryo or fetus if the subject is or may become pregnant - that are currently unforeseeable.

b. The anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

c. Any additional costs to the subject that may result from participation in the study.

d. The consequences of a subject's decision to withdraw from the study and procedures for the orderly end of the subject's participation.

e. A statement that new findings developed during the course of the study which could affect the subject's willingness to continue will be given to the subject.

f. The approximate number of subjects involved in the study.

g. The precautions to be observed by the subject before and after the study.)

The proponent of this regulation is the Staff Judge Advocate Users are invited to forward comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to this Headquarters, ATTN: IASJA.

FOR THE COMMANDER:

OFFICIAL:

LOUIS D. KIRK
Colonel, GS
Chief of Staff

J. J. KRAYNAK
Administrative Officer

DISTRIBUTION:
A B C (2 cys)
Plus -
Staff Judge Advocate (30 cys)