UNITED STATES ARMY
HUMAN SUBJECTS RESEARCH PROTECTION
MANAGEMENT PLAN

1. Introduction. The United States Army (Army) assures that all of its activities related to research involving human subjects as defined in 32 CFR 219 and supported by DoD Directive 3216.2 will be guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research.*

The Army acknowledges its responsibilities for protecting the rights and welfare of human research subjects; recognizes the principles of respect for persons, beneficence, and justice as stated in the Belmont Report; and will apply these principles in all research involving human subjects to satisfy these responsibilities.

2. Purpose. This Management Plan (the Plan) describes how the Army will implement and comply with 32 CFR 219; 45 CFR 46 subparts B, C, and D; DoD Directive 3216.2; 10 USC 980; Army Regulation (AR) 70-25; AR 40-38; and AR 40-7. The Plan is provided to support the Army's request for the authority to approve DoD assurances and accept other federal assurances for DoD-sponsored research.

3. References.

a. 32 CFR 219, *Protection of Human Subjects,* 1 July 1991

b. DoDD 3216.2, *Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research,* 25 March 2002

c. The Belmont Report, 1979

d. 45 CFR 46 subparts B: *Additional Protections Pertaining to Research, Development and Related Activities Involving Fetuses, Pregnant Women, and Human in Vitro Fertilization*, 14 November 2001; subpart C: *Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects*, 14 November 2001; and subpart D: *Additional Protections for Children Involved as the Subjects of Research*, 14 November 2001

e. 10 USC 980, *Limitations on use of humans as experimental subjects*

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

g. AR 40-38, *Clinical Investigations Program*, 1 September 1989

h. AR 40-7, *Use of Investigational Drugs and Devices and the Use of Schedule I Controlled Drug Substances*, 4 January 1991

i. Designation of Research Approval and Regulatory Oversight Authority (Secretary of the Army to The Army Surgeon General) Documents

j. Delegation of DoD Assurance Approval Authority (The Army Surgeon General to the Assistant Surgeon General, Force Projection)

k. Delegation of Research Approval Authority (The Army Surgeon General to the Commanding General, United States Army Medical Research and Materiel Command)

l. Example of a DoD Multiple Project Assurance

m. United States Army Medical Research and Materiel Command, Office of Research Protections Operational Policies and Procedures

(1) Human Research Protection Office Policies and Procedures

(2) Human Subjects Research Review Board Policies and Procedures

n. US Army Medical Department Center and School, Clinical Investigations Regulatory Office Operational Policies and Procedures

4. Applicability. The Plan applies to all research involving human subjects and all other activities that involve such research even in part, regardless of whether the research is otherwise subject to federal regulation, if the:

a. research is sponsored by the Army, or

b. research is conducted by or under the direction of any employee or agent of the Army in connection with official duties, or

c. research is conducted using any property or facility of the Army, or

d. research involves the use of Army nonpublic information to identify or contact human research subjects or prospective subjects.

Programs under this Plan are not restricted by Budget Activity or program title.

5. Authority and Delegation. The Secretary of the Army, as the head of a DoD Component, delegates the authority in DoD Directive 3216.2, paragraph 5.3.3, to the Army Surgeon General (TSG) (TAB J). TSG has authority to approve DOD assurances and accept other federal assurances for all institutions conducting research on behalf of

the Army. TSG has the authority to develop policy, oversight, and compliance mechanisms for Army institutions.

TSG has delegated the authority to approve DoD assurances and accept other federal assurances to the Assistant Surgeon General for Force Projection (ASG(FP)) (TAB K) effective upon acceptance of this Plan by the Director of Defense Research & Engineering (DDR&E).

TSG has delegated the authority to approve research, development, testing and evaluation protocols involving human subjects to the Commanding General (CG), United States Army Medical Research and Materiel Command (USAMRMC) and places the Human Subjects Research Review Board under the authority of the CG, USAMRMC (TAB L).

6. Policies.

a. Assurance. The ASG(FP) will (1) approve assurances of compliance submitted from institutions only if they have policies and procedures that appropriately implement DoD policies, and (2) accept other federal assurances if they are determined to be appropriate for the DoD-sponsored research, and the institution is aware of the requirement to comply with DoD policies and procedures.

See 32 CFR 219.103 for the DoD policy for approving DoD assurances. An example of an Army Multiple Project Assurance document is attached (TAB M).

Army institutions holding DoD assurances are permitted to accept the approval of another DoD Component's duly-constituted Institutional Review Board (IRB) without the need for the Army institution to modify its assurance to include the other DoD IRB, provided that a Memorandum of Agreement is executed to cover this reciprocal relationship.

b. Component Oversight of Assurance Approval Authority. TSG, on behalf of the Secretary of the Army, ensures DoDD 3216.2 will be appropriately executed throughout the entire Army. The specific execution of DoDD 3216.2 within the Army is described in detail in AR 70-25 and AR 40-38. These regulations will be rewritten as a single Army regulation for research involving human subjects. The USAMRMC Office of Research Protections (ORP) and AMEDDC&S Clinical Investigation Regulatory Office (CIRO) are responsible to TSG for regulatory oversight of all human subjects research conducted or supported by the Army. The USAMRMC, ORP and the HSRRB provide human use oversight assistance to Army Major Commands without human use committees (per AR 70-25).

c. Monitoring the Accountability of the Institution/IRB. The ORP and the CIRO, at the direction of TSG, will monitor and audit the accountability of Army institutions conducting research under a DoD assurance and other institutions having an assurance approved by the Army. The ORP will monitor the accountability of extramural

institutions to ensure compliance with DoD and Army policies when the research is sponsored by the Army and conducted under the institution's assurance approved by another federal department or agency. The Operational Policies and Procedures (TABS N, O) outline how the ORP (Human Research Protection Office and the HSRRB) and the CIRO monitor and audit the accountability of Army institutions or institutions sponsored by the Army.

d. Oversight of Research. The ORP and the CIRO, at the direction of TSG, will provide due diligence in oversight of research (1) conducted by institutions within the Army, (2) conducted by institutions having an assurance approved by the Army, or (3) sponsored by the Army. The Operational Policies and Procedures (TABS N, O) outline how the ORP and the CIRO oversee the research conducted by Army institutions or institutions sponsored by the Army.

e. Training. The ORP and the CIRO, at the direction of TSG, require that all personnel connected with the human subjects research review process, institutional officials, IRB members, administrative staff, investigators, etc., understand and are qualified to meet their obligation to protect the rights and welfare of human subjects. The Operational Policies and Procedures (TABS N, O) outline how the ORP and the CIRO implement appropriate personnel training.

f. Communication. The ORP and the CIRO, at the direction of TSG, ensure that they will keep the DDR&E staff informed of significant issues regarding the safety of human subjects. The Operational Policies and Procedures (TABS N, O) outline how the ORP and the CIRO ensure appropriate communication with DDR&E.

7. Conflicts of Interest. The ORP and the CIRO, at the direction of TSG, ensure that they will provide an environment that identifies and strives to reduce the possibility for conflicts of interest by personnel responsible for protecting human subjects. The Operational Policies and Procedures (TABS N, O) outline how the ORP and the CIRO ensure an environment to minimize conflicts of interest.

8. Duration. This Plan will be reviewed and resubmitted to the DDR&E three years from its approval date or upon any significant changes in the Plan, delegation of authority, policies and procedures, or TSG.

KEVIN C. KILEY, M.D.
Lieutenant General
The Surgeon General