



THE SECRETARY OF DEFENSE
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MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
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UNDER SECRETARIES OF DEFENSE
DIRECTOR, DEFENSE RESEARCH AND ENGINEERING
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ASSISTANTS TO THE SECRETARY OF DEFENSE
DIRECTOR, ADMINISTRATION AND MANAGEMENT
DIRECTORS OF THE DEFENSE AGENCIES
DIRECTORS OF THE DOD FIELD ACTIVITIES

SUBJECT: Interim Policy for Protection of Human Subjects in Classified Research

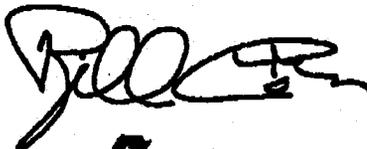
On March 27, 1997, the President directed agencies jointly to modify regulations for the protection of human subjects in research to strengthen protections in classified research. Under the direction of the Office of Science Technology Policy and the Office for Protection from Research Risks of the Department of Health and Human Services, the attached amendment to the government-wide "common rule" for the protection of human subjects in research has been developed and will be promulgated soon. I have approved it as an amendment to DoD's promulgation of the common rule (at 32 CFR Part 219) and direct that all DoD components conform to it, effective immediately. The following additional requirements are established.

1. **Approval process.** All classified research protocols involving human subjects must receive prior approval from the Secretary of Defense. The approval process is submission to the Secretary of Defense by the senior component head responsible of a proposed research project, together with the research protocol approved by the Institutional Review Board (IRB), the IRB minutes documenting compliance with 32 CFR Part 219, and any other appropriate supporting information. The request must be coordinated with the Director, Defense Research and Engineering (DDR&E), the General Counsel, and any other principal with responsibility for the program involved.

2. **DDR&E responsibilities.** The Director, Defense Research and Engineering is responsible for coordinating implementation of this policy. The DDR&E shall be responsible for record keeping and reporting requirements established by the common rule amendment. DDR&E shall also propose appropriate revisions to DoD Directive 3216.2, "Protection of Human Subjects in DoD-Supported Research," January 7, 1983, and is authorized to issue instructions implementing this policy.

3. **Applicability.** For purposes of the applicability of this policy, classified research is that for which the research protocol or other information required by the Institutional Review Board for review of the project includes classified information.

Attachment




U18226-99

32 CFR PART 219 – PROTECTION OF HUMAN SUBJECTS

Section ____ .125 is added to read as follows:

____.125 Additional protections pertaining to classified research

(a) **Applicability.** This section applies only to research which is classified, involves human subjects, and is not otherwise exempted from the Federal Policy for the Protection of Human Subjects as promulgated on June 18, 1991 (56 FR 28003) and as it may be amended. These requirements are in addition to those imposed under the other sections of this part. No agency shall conduct or support classified research involving human subjects unless it has promulgated and complied with the Federal Policy and this section.

(b) **Definitions.** As used in this section:

Classified human research means research involving "classified national security information" as defined in Executive Order 12958, sec. 1.1 (3 CFR, 1995 Comp., p. 333) and set out in this paragraph (b).

Classified national security information (hereinafter "classified information") means information that has been determined pursuant to Executive Order 12958 or any predecessor order to require protection against unauthorized disclosure and is marked to indicate its classified status when in documentary form.

Control means the authority of the agency that originates information, or its successor in function, to regulate access to the information.

Information means any knowledge that can be communicated or documentary material, regardless of its physical form or characteristics, that is owned by, produced by or for, or is under the control of the United States Government.

(c) **Composition of institutional review board.** The nonaffiliated member identified in ____ .107(d) shall not be an employee or officer of the Federal Government (other than for purposes of membership on the IRB) and shall be required to obtain any necessary security clearances.

(d) **Informed consent.** For classified research only:

(1) Human subjects must be provided with:

- (i) a disclosure that the project involves classified research and information sufficient to explain the nature of the classified research; and
- (ii) a disclosure of the identity of the sponsoring agency, unless the head of the sponsoring agency makes a written determination, after consultation with the Director of Central Intelligence and the Assistant to the President for National Security Affairs, that providing this information could compromise intelligence sources or methods and, after consultation with the Director of the White House Office of Science and Technology Policy (OSTP), makes a written determination that the research involves no more than minimal risk to subjects.

- (2) An IRB may require disclosure to the subjects of the research any classified information that the IRB determines is necessary for the subjects to provide a valid informed consent.
- (3) An IRB may not approve a consent procedure which alters or omits any of the consent requirements in ____ .116 and may not waive the requirement that the investigator obtain informed consent and a signed consent form for any classified research.
- (e) Expedited review. An IRB shall not allow use of the expedited review process set forth in ____ .110 for any classified research.
- (f) Approval by agency head. Within 30 days of the IRB approval of a classified research project that has not been appealed under paragraph (g) of this section, the head of the Department or Agency sponsoring the classified research, and not the agency head's designee or delegate, shall review and issue a written approval or disapproval of that project.
- (g) Appeals from IRB approvals of classified research. Any IRB approval of a classified research project shall be subject to appeal by an individual member or members of the IRB.
- (1) Appeals of any IRB approval shall initially be submitted to the head of the Department or Agency sponsoring the classified research within 20 days of the IRB approval. The Department or Agency head must render a written decision within 60 days of the date the appeal is submitted. The decision of the Department or Agency head may affirm the IRB approval, reverse the IRB approval, or remand the matter for further clarification from the IRB.
- (2) The IRB member or members may appeal a decision of the head of the Department or Agency sponsoring the classified research that upholds the IRB approval to the Director of OSTIP who shall review the IRB's decision and the decision of the head of the Department or Agency sponsoring classified research and approve or disapprove the project, or, at the Director's discretion, convene an IRB made up of individuals who are not employees or officers of the Federal Government (other than for purposes of membership on the IRB) each with the appropriate security clearances, to recommend approval or disapproval of the project. The Director of OSPT must issue a written decision on the appeal within 60 days of the date the appeal is submitted.
- (h) Reporting requirements. The head of each Department or Agency sponsoring classified research within the previous 12-month period shall, no later than September 30th of each year, report to the Director of OSTIP the number of ongoing classified research projects involving human subjects and the number of classified research projects completed in the previous 12-month period. Each report required by this paragraph shall include the number of human subjects in each project and shall include information accurate as of the date the report is filed.
- (i) Recordkeeping requirements. The head of each Department or Agency sponsoring classified research shall maintain permanent records of the deliberations of the IRB and the consent documents as well as any other related documents generated in connection with the decision to approve or disapprove a classified research project involving human subjects.
- (j) Responsibilities of OSTIP. The Director of OSTIP shall report the total number of classified research projects and participating subjects to the President and shall then report to the congressional armed services and intelligence committees and further shall publish the numbers in the Federal Register.