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THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

MAR 3 1997

**MEMORANDUM FOR:** SECRETARY OF THE ARMY  
SECRETARY OF THE NAVY  
SECRETARY OF THE AIR FORCE

**SUBJECT:** Policy For External Peer Review For Defense Health Program Extramural Medical Research Involving Human Subjects

Section 742 of the National Defense Authorization Act for Fiscal Year 1997 requires the Secretary of Defense to establish a peer review process that will use persons who are not officers or employees of the Government to review the extramural research protocols of medical research projects funded through the Defense Health Program (DHP) account. The authority to establish this process has been delegated to the Assistant Secretary of Defense (Health Affairs). The following process is hereby established:

(1) DHP funds may not be obligated or expended for any extramural medical research project unless the protocol for the project has been approved by the Assistant Secretary of Defense (Health Affairs), a Surgeon General, the President of the Uniformed Services University of the Health Sciences, or an appointed designee of these officials, after a favorable external peer review.

(2) The external peer review must:

(a) perform a review of the scientific merit of the protocol;

(b) ensure that the protocol has been approved by an Institutional Review Board under 32 CFR Part 219, "Protection of Human Subjects;" and

(c) be conducted by a person, group or entity qualified in medical research and independent of the individuals and institutions involved in the protocol.

(3) For the purposes of this memorandum, the term "medical research project" means a research project that:

(a) involves the participation of human subjects;

(b) is conducted solely by a non-Federal entity; and

(c) is funded through the Defense Health Program account.

(4) The peer review requirements are established as of October 1, 1996, and except as provided below, shall apply to all extramural medical research projects proposed or funded on or after that date.

(5) Only the following medical research projects shall be exempt from the peer review requirements:

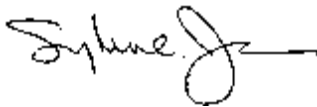
(a) a medical research project that the Assistant Secretary of Defense (Health Affairs) determines has been substantially completed by October 1, 1996;

(b) a medical research project funded pursuant to any provision of law enacted on or after October 1, 1996, if the provision of law specifically refers to the section requiring peer review and specifically states that the peer review requirements do not apply; or

(c) a medical research project exempt under law from section 742 of the National Defense Authorization Act for Fiscal Year 1997.

This memorandum provides interim policy guidance pending the revision of DoD Directive 6000.8, "Funding and Administration of the Clinical Investigation Programs." My point of contact is Salvatore M. Cirone, OASD(HA)/CS, Director of Scientific Activities, who may be reached at

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**HA POLICY 97-033**

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