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DDR&E

Department of Defense Instruction

SUBJECT Investigational Use of Drugs by the Department of Defense

Reference: (a) Drug regulations published by Department of Health, Education and Welfare (21 CFR 130.3)

I. PURPOSE

This Instruction specifies the manner in which the regulations cited in reference (a) will be applied to the investigational use of drugs by the Department of Defense.

II. APPLICABILITY

The provisions of this Instruction apply to all DoD Components and their contractors or grantees engaged in the investigational use of drugs.

III. RESPONSIBILITIES

- A. The Department of Defense assumes full responsibility for the protection of humans involved in research under its sponsorship whether this involves investigational drugs or other hazards.
- B. Each Military Department will establish within the office of its Surgeon General a formal Review Board of professional personnel to consider each research proposal from within that Military Department or from its contractors or grantees which may involve the use of human subjects in the clinical investigation of new drugs. Before a clinical test with an investigational drug may be performed under the sponsorship of a Military Department -
 1. the plan of the test and other pertinent details must be submitted to the appropriate Review Board,
 2. the Board must indicate its approval, and
 3. the approval must be confirmed by the respective Surgeon General.

IV. REPORTS

- A. Clinical investigations that are classified for reasons of national security will not require the filing of a formal "Claim for Exemption" to the Department of Health, Education, and Welfare. Approval of the test by the appropriate Review Board and Surgeon General will automatically exempt the drug being employed from the application of the

new drug section of the Food, Drug, and Cosmetic Act during the investigational study. The Military Departments will report to the Food and Drug Administration (copies to OSD unnecessary) findings associated with such studies which FDA should be aware of in order to make a sound evaluation of non-classified studies proposed on the same or similar drugs. Additionally, the Military Departments will discuss their classified investigations of drugs periodically with FDA personnel who have proper security clearance.

- B. In the case of non-classified security research programs sponsored by the Department of Defense and conducted within its research facilities or for the Department upon contract, copies of the request for approval submitted to the appropriate Review Board, the Review Board's evaluation and approval, and notice of approval by the appropriate Surgeon General will be filed with the FDA as the claim for exemption for the investigational drug.
- C. When the Department of Defense performs clinical tests upon new drugs being sponsored by the pharmaceutical industry, the ordinary claim for exemption (Form 1571 of the Investigational Drug Regulations) will be filed with the FDA.

V. EFFECTIVE DATE AND IMPLEMENTATION

This Instruction is effective immediately. Two copies of implementing instructions shall be forwarded to the Director of Defense Research and Engineering within sixty days.

Harold Brown

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Director of Defense Research and Engineering

Inclosure -1

Memorandum of Understanding