

DEPARTMENT OF THE NAVY
Bureau of Medicine and Surgery
Washington, D.C. 20390

BUMED 6710.49
BUMED:3113:apl
5 February 1964

BUMED INSTRUCTION 6710.49

From: Chief, Bureau of Medicine and Surgery
To: Naval Hospitals

Subj: Investigational drugs; guidelines for handling

Ref: (a) MANMED arts. 1-11 and 1-12

1. Purpose. To provide guidelines for the safe handling of investigational drugs, and to minimize the chance for misadventure in their use.

2. Definition. Investigational drugs are those new drugs, including vaccines and biologicals, not released for general use and not cleared for sale in interstate commerce by the Federal Food and Drug Administration.

3. Statement of Principles. Following is a resume of a Statement of Principles Involved in the Handling of Investigational Drugs. The Statement was approved by the American Hospital Association, the American Society of Hospital Pharmacists, and the American Nurses Association.

a. Since hospitals are the primary centers for clinical investigation of new drugs, the hospitals and the medical staffs have an obligation to their patients to see that proper usage procedures are established.

b. Investigational drugs should be used only under the direct supervision of the principle staff investigator, who should assume the burden of securing the necessary consent and assuring that such investigations are performed in strict compliance with Part 130.3 of the New Drug Regulation under the Federal Food Drug and Cosmetic Act. Consent of the patient will be required also to release the name or other privileged information to any other agency or to any sponsor and use of case numbers or other coding is preferable. Chapter 23, MMD is applicable. (In all cases, BUMED approval for the use of investigational drugs must be obtained as provided by reference (a). In urgent cases, BUMED authorization may be obtained by telephone or wire, ATTN: Director, Professional Division, Area Code 202, Oxford 6-1280, during normal working hours or BUMED Duty Officer, Area Code 202, Oxford 6-2063, outside normal working hours.

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c. The hospital should do all in its power to foster research consistent with adequate safeguard for the patient.

d. Nurses who administer investigational drugs should be provided with such basic information as dosage forms, strengths available actions and uses, side effects, and symptoms of toxicity.

e. The hospital should establish a central location to maintain and make available essential information on the drugs.

f. The pharmacy service should store the drugs and provide for their proper labeling and dispensing in accord with the investigator's written orders.

4. Guideline Procedures. The following procedures should be adopted for the control and use of investigational drugs, with any modifications necessary to meet the individual needs of the hospital:

a. Requests for use of the drugs shall be approved by a pharmacy and therapeutics committee or a clinical research committee prior to submission to BUMED for final approval.

b. The drugs shall be shipped directly from the manufacturer, in the name of the investigator, to the pharmacy, to assure safe-keeping under proper storage and for record procedures.

c. Upon receipt, the pharmacy staff, with the assistance of the investigator, shall prepare a NAVMED 1448, Investigational Drug Data Record.

d. The pharmacy shall attach to each container a distinctive label (color or shape) containing the statement "Investigational Drug - Not for General Use" and the name of the drug (or if a code number is used, then the pharmacological classification; for example "Analgesic Drug" or "Antihistaminic Drug").

e. The pharmacy shall allocate a separate locked area for the exclusive storage of the drugs.

f. The principal investigator, or any authorized doctor designated by him, shall request the drug from the pharmacy by means of a prescription form.

g. The prescriptions shall be kept in a separate file, numbered consecutively, and the number prefixed by "ID".

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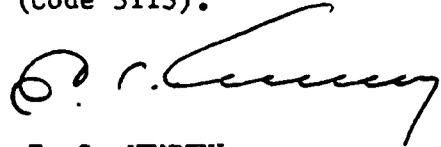
h. A separate NAVMED 1449, Investigational Drug Inventory and Prescription Record, shall be maintained in the pharmacy for each drug. This provides a perpetual pharmacy inventory and serves as a ready reference of all patients receiving the drug.

i. When the drug is delivered to the ward, a completed copy of the NAVMED 1448, Investigational Drug Data Record, and a NAVMED 1398, Narcotic and Controlled Drug Data Record, shall be delivered to the ward nurse and a receipt shall be obtained. This will assure strict accountability and a perpetual inventory for all drugs on the wards. Nursing personnel shall be responsible for returning unused drugs and the completed NAVMED 1398 to the pharmacy and for initiating requests for additional supplies of the drug from the pharmacy.

j. The pharmacy shall dispose of (by return to the manufacturer or by destruction, as most feasible) all drugs no longer in use or for which future use is not anticipated.

k. If "double blind" studies are utilized, the place for the code shall be in the pharmacy.

5. Availability of Forms. An initial supply of NAVMED forms 1448 and 1449 will be provided under separate cover. Additional copies, when required, may be obtained from BUMED (Code 3113).



E. C. KENNEY

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may be obtained from:
Supply Dept., NAVSTA (WASH. NAVYD ANNEX,
Code 514.25)
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