

2/30/64 Per conversation with
Capt Fitzgerald (CE)
and OSD must include
in C by OPNAVINST

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DEPARTMENT OF THE NAVY
Bureau of Medicine and Surgery
Washington, D.C. 20372

BUMEDINST 3900.6A
MEDCOM- BUMED-0008- 020
4 February 1982

Research

BUMED INSTRUCTION 3900.6A

From: Chief, Bureau of Medicine and Surgery
To: All Ships and Stations

R) Subj: Protection of human subjects

- Ref:
- (a) SECNAVINST 3900.39A
 - (b) BUMEDINST 3900.3B
 - (c) NAVMATINST 3910.15A
 - (d) BUMEDINST 6710.49D
 - (e) ~~BUMEDINST 6000.4C~~ ^{MANMED 6000.4}
 - (f) MANMED article 20-7
 - (g) SECNAVINST 5212.5B
 - (h) SECNAVINST 5211.5C

- End:
- (1) Suggested Format for Recommendation of Committee for the Protection of Human Subjects
 - (2) Suggested Format for Application to Committee for the Protection of Human Subjects
 - (3) Suggested Format for Privacy Act and Consent Statements
- R)
- R)
- A)

1. Purpose and Scope. To provide guidance and establish procedures for the protection of human subjects in (a) all studies conducted at Navy activities regardless of funding sources, (b) Navy-supported studies conducted in non-Navy Federal activities, and (c) studies conducted by contractors using Navy or Marine Corps personnel or Navy Department employees. It supplements references (a) through (f).

2. Cancellation. BUMEDINST 3900.6.

3. Responsibilities. Reference (a) assigns to the Chief, Bureau of Medicine and Surgery approval authority for all proposed Navy in-house studies involving the use of human subjects and all proposed contract studies using as subjects Navy or Marine Corps personnel or Navy Department employees which do not require approval of the Assistant Secretary of the Navy (Research, Engineering, and Systems) (ASN (RE&S)). Prior to granting approval, the Chief, Bureau of Medicine and Surgery shall ascertain that the provisions of reference (a) relative to consent standards, studies, and safeguards have been met. The BUMED Medical Department Education and Training Division (MED-28) is authorized to approve by direction studies utilizing human subjects which are to be supported by the Navy's Clinical Investigation Program. The Special Assistant for Medical Research and Development (MED-00C8) is authorized to approve by direction all studies using human

subjects which are within the scope of this instruction and which are not intended to be part of the Clinical Investigation Program.

4. Procedures

a. All proposed studies involving the use of human subjects shall be reviewed by the performing activity's Committee for the Protection of Human Subjects (CPHS) as described in reference (a). The CPHS must include at least one Navy enlisted member if any of the subjects utilized in a given study are from the enlisted community.

b. Ongoing studies involving the use of human subjects which have been previously reviewed in accordance with the provisions of reference (a) shall be reviewed by the activity's CPHS and submitted for approval within 90 days following promulgation of this instruction. Those proposals which are approved by the CPHS and do not require approval of ASN (RE&S) are to be forwarded via the chain of command to the Chief, Bureau of Medicine and Surgery (ATTN: MED-28 or MED-00C8) together with completed copies of enclosures (1) and (2). Proposals which require ASN (RE&S) approval shall be submitted via the Chief, Bureau of Medicine and Surgery (ATTN: MED-28 or 00C8), the Deputy Chief of Naval Operations (MPT) (ATTN: Op-01B4) or Commandant of the Marine Corps (ATTN: Chief of Staff for Manpower), and the Chief of Naval Operations (Director, RDT&E).

c. Following review, the Medical Department Education and Training Division (MED-28) or the Special Assistant for Medical Research and Development (MED-00C8) shall: forward information copies of approved proposals not requiring ASN (RE&S) clearance to offices specified in paragraph 12 of reference (a); forward proposals requiring ASN (RE&S) clearance with appropriate endorsement; and notify the performing activity of approval/disapproval recommendations.

5. Maintenance of Records. All records associated with a study involving the use of human subjects shall be retained permanently at the performing activity in accordance with references (a) and (g). Records shall include the names and Social Security numbers of volunteers and shall be maintained in accordance with the provisions of reference (h). In addition a copy of the signed consent statement and privacy act statement (enclosure (3)), shall be filed in the subject's health record, together with sufficient documentation to clearly identify by name or

MANMED 6-134E

BUMEDINST 3900.6A
4 February 1982

code any drugs administered, whether investigational or not, investigational procedures performed, and significant observations, including any adverse effects. The maintenance of such records shall be a matter of primary concern during laboratory and program review or inspection.

- R) **6. Reporting of Complications.** Activities shall notify BUMED (MED-28 or MED-00C8) by message or speed-letter within 24 hours of any accident, untoward drug reaction, appearance of disease or injury which may occur as a result of using human subjects in an experimental study, and the medical or dental treatment, including hospitalization, provided.

7. Action Activities shall take such action as required to implement procedures prescribed by this instruction. (D)

8. Report. Report control symbol MED 3900-3 has been assigned to the Complication in Study Using Human Subjects report required by paragraph 6 of this instruction. This report has been approved by the Chief of Naval Operations for a period of 2 years from the date of this instruction. (A)

J. WILLIAM COX

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