



DEPARTMENT OF THE NAVY  
OFFICE OF THE JUDGE ADVOCATE GENERAL  
200 STOVALL STREET  
ALEXANDRIA, VA 22332

NAV1.941101.023

IN REPLY REFER TO

JAG:131.1:WDC:slb16  
Ser: 13/5676

06 DEC 1983

MEMORANDUM FOR THE ASSISTANT VICE CHIEF OF NAVAL OPERATIONS/DIRECTOR OF  
NAVAL ADMINISTRATION

Subj: Protection of human subjects of Navy research

Ref: (a) Your memo O9BL/58 of 1 Dec 1983  
(b) DoD Dir. 3216.2 of 7 Jan 1983, Protection of Human Subjects in  
DoD-Supported Research [Ref. (a) to enclosure (1)]

Encl: (1) Package containing proposed revision of SECNAVINST 3900.39A

1. In accordance with the request contained in reference (a), draft SECNAVINST 3900.39B has been reviewed and, subject to the modifications recommended hereafter, is considered to be legally unobjectionable.

a. Paragraph 3. It is recommended that the seventh sentence (found on page 2 of the proposed instruction) be changed to read: "Its provisions do not apply to those research activities described in reference (b), section 46.101b [see enclosure (1)] or to epidemiological surveys that are of no more than minimal risk.

Rationale: As currently worded, the draft SECNAVINST would exempt from the scope of the instruction all epidemiological surveys, whether or not such surveys involved risk to human subjects. To comport with the requirement of paragraph B.3 of reference (b), the words "that are of no more than minimal risk" should be added.

b. Paragraph 10. At the end of paragraph 10.a add the following sentence: "Unless deemed impractical by the commanding officer and/or official with approval authority, the Committee shall not be composed of all-male or all-female membership."

Rationale: To comport with the requirement found at paragraph F-2.b.(1) of reference (b).

c. Paragraph 12. Modify paragraph 12.a.(6) to read as follows:

(6) Commanding Officers of Naval Activities.  
Commanding officers of certain naval activities conducting research to whom delegated approval authority is authorized need not submit proposals to the Under Secretary of Defense for Research and Engineering or Assistant Secretary of the Navy if the proposals do not require such approval as defined above. Appropriate review Committees will be established at each activity to assist the commanding officers in accordance with paragraph 10. A commanding officer may not approve

research for which he or she is also a principal or coinvestigator. Such research shall be reviewed and approved at a higher echelon of command. If the review committee recommends safeguards or special conditions to a protocol it is recommending for approval, the commanding officer may not reduce the safeguards or conditions upon approving the protocol. The commanding officer may require additional safeguards, may disapprove the protocol, or may refer it to a higher approving authority and review committee.

Rationale: Paragraphs F.2.d and F.2.f of reference (b) delineate specific DoD requirements which are not otherwise covered in the proposed SECNAVINST. Because the commanding officer most frequently, if not exclusively, will approve projects within the scope of the proposed SECNAVINST, the requirements found at paragraphs F.2.d and F.2.f of reference (b) are incorporated into a new paragraph 12.a.(6) of the proposed SECNAVINST.

2. The following administrative corrections to the proposed SECNAVINST are also recommended:

a. Ref. (b). It is recommended that, for the non-lawyer using the SECNAVINST, the term "(45 Code of Federal Regulations Part 46)" be substituted for the term "(45 CFR 46)". It is further recommended that the term "(NOTAL)" be removed after reference (b) because paragraph 10.b specifically requires review committees to refer to and have access to reference (b).

b. Paragraph 7.e. In the first sentence, correct the term "eg." to read "e.g."

c. Paragraph 10.b. For the purpose of internal consistency, in the last sentence change "Section 111" to read "Section 46.111."

d. Paragraph 12.b.(4). In the last line of paragraph 12.b.(4)(a), reference is made to paragraph 12(b). It is unclear what provision is being referenced because there is no paragraph 12(b).

*H.A. Campbell*  
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OFFICE OF THE CHIEF OF NAVAL OPERATIONS  
WASHINGTON, DC 20350

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1. The proposed instruction at enclosure (1) has significant legal implications for uniformed personnel -- both managers and potential subjects. Therefore, notwithstanding comment in blazer, respectfully request your scrub and chop prior to submission to the VCNO. As usual, considerable pressure to get package to ASN(RE&S) at earliest possible date.

*Respectfully*  
*A. C. Rudy, Jr.*

A. C. RUDY, Jr.  
COMMANDER, JAGC, USN  
Assistant for Legal &  
Legislative Matters

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