



DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH CENTER
503 ROBERT GRANT AVENUE
SILVER SPRING, MARYLAND 20910-7500

IN REPLY REFER TO:

NAVMEDRSCHCENINST 3900.6D
025

10 APR 2009

NAVMEDRSCHCENTER INSTRUCTION 3900.6D

From: Commanding Officer, Naval Medical Research Center

Subj: COMMAND HUMAN RESEARCH PROTECTION PROGRAM

Ref: (a) 10 USC 980
(b) 32 CFR Part 219
(c) 21 CFR Parts 50 and 56, 312, and 812
(d) 45 CFR 46 Subparts B, C, and D
(e) DoD Directive 3216.2
(f) SECNAVINST 3900.39D of 6 Nov 06
(g) SECNAVINST 5720.44B of 1 Nov 05
(h) SECNAV M-5210.1 of 1 Dec 05
(i) OPNAVINST 5300.8C of 24 Apr 08
(j) DoD Instruction 3210.7 of 14 May 04
(k) DON HRPP Education and Training Policy for Research Ethics and the Responsible Conduct of research issued 13 November 2006
(l) NAVMEDRSCHCENTERINST 3900.4B

Encl: (1) Institutional Review Board: Policies and Procedures for the Protection of Human Subjects in Research
(2) Research Misconduct: Policies and Procedures for the Protection of Human Subjects in Research
(3) Research Education and Training: Policy and Procedures for Education and Training in Human Subject Protections

1. Purpose. To establish a comprehensive human research protection program. Subordinate activities shall develop procedures that comply with the requirements of this instruction and references (a) through (l) to meet their specific needs.

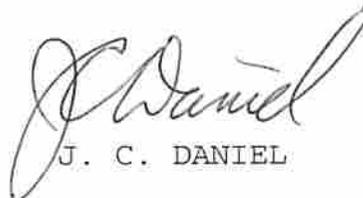
2. Cancellation. NAVMEDRSCHCENINST 3900.6C is hereby cancelled and superseded.

3. Scope. This instruction applies to all research involving human beings, human specimens or human data. Its provisions encompass all biomedical and behavioral research when human subjects are involved. Nothing in this instruction shall supersede requirements for health hazard or other safety reviews required by other regulations.

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4. Policy. Enclosures (1) through (3) establish the mandatory minimum policies for all NMRC personnel for the ethical protection of the rights and welfare of human participants from research risks, including the review and approval of human subject research, responsible conduct of research and education in human subject protections. All investigators are expected to comply with the requirements of this Instruction even if the human research is being conducted at another institution.

5. Administration. The Human Research Protection Program's management is under the Office of Research Administration (ORA). Authority is delegated to ORA for the oversight, administration of and assistance with the development of policies, procedures and forms consistent with the terms of its "DoD-Navy Assurance" and "Federalwide Assurance" requirements, as well as federal and local regulations and requirements. ORA is assigned the responsibility for the ongoing implementation of enclosures (1) through (3).



J. C. DANIEL

Distribution:

List(s) A, B, C and D