

Summary of Significant Changes
SECNAVINST 3900.39C
to
SECNAVINST 3900.39D
22 June 2007

This chart is a summary of significant changes made in SECNAVINST 3900.39D to reflect current regulations and unify the Department of Navy Human Research Protection Program (DON HRPP).

Topic	Paragraph	Description of Change
Subject line	N/A	Changed from “Protection of Human Subjects” to “Human Research Protection Program” to reflect the national standard. Throughout the instruction changed “human use” to “human research” or “research with humans” depending on the context.
Scope: Test pilots and experimental divers	4(a)4	Revised paragraph: Test pilots and experimental divers who become subjects in research (i.e., not their normal assignment) are covered by this instruction.
Scope: Cadaver research	4b(4)	New paragraph: This instruction does not apply to research using cadavers. However, an ethics review by an IRB is required when there is a link to private identifiable information between deceased and living individuals.
Investigational drugs, biologics, and devices – Force Health	4b(5)	New paragraph: This instruction does not apply to use of investigational drugs, biologics, or devices for the purposes of Force Health Protection. Such use is governed by DoDD 6200.2.
Research Ethics Education and Training	6a(2), 6a(4)(b), 8a(2), 8a(3), 8c(1), 8c(2), 8d(1)(f), 8e(2), 8f(1), and 8g(2)	New paragraphs: Delineate research ethics and human subject protections education and training for COs, Institutional Review Board members, investigators, etc.
Research-related Injury	6a(5)	Revised paragraph: Expanded the concept of research-related injury to consider provisions for minimal risk research. Research-related injury provisions may be appropriate for some minimal risk research. In these cases, IRBs should make a determination based on the review of the research itself. For example, written or oral surveys, or interviews on sensitive topics (child abuse, suicide, domestic violence, for example) may trigger severe, unpredictable psychological reaction that may require emergency treatment and follow-up.

Topic	Paragraph	Description of Change
Additional Protections - Active Duty Personnel	6a(6).	New information: Added “deployed active duty personnel” to list of examples of groups warranting additional protection.
Chemical & Biological Testing	6a(7)	New paragraph: Addresses research involving testing chemical or biological agents.
Captured or Detained Personnel	6a(8)	New paragraph: Addresses the prohibition of research involving prisoners of war (POW) and detainees. Added definition of POW to enclosure (1), item #21. .
Expedited Review of Research	6d, 7a(8)(a)-(b), and 7b(2)	New paragraphs: The intent is to ensure consistency within the DON of the review and approval processes for all research involving human subjects, including research eligible for expedited review. In addition, this preserves the historical checks and balances between the review and approval functions.
Survey Research	6e	New paragraph: Addresses survey research that meets the dual requirements of the OPNAV instruction on surveys (OPNAVINST 5300.8B) and human research protections.
Extramural Research	6g	New paragraph: Addresses DON-supported extramural research performed outside the DON and includes areas covered by ONR’s policy (ONRINST 3900.34B) on human research for DON-supported extramural research. DoD-sponsored extramural human subject research must comply with appropriate federal and DOD human research protection regulations and policies.
Investigational Drug/Device Sponsorship	6h	New paragraph: Addresses research involving the use of investigational agents. This paragraph was extracted from BUMEDINST 6710.69 to incorporate the intersection of IND/IDEs with human research protections in a SECNAV level policy statement. The requirements have not changed with regard to COs and investigators; however, the paragraph adds the option that the SG may be the IND/IDE sponsor.
Classified Research	6j	New paragraph: Addresses review of classified research to reflect the SECDEF 1993 memorandum and guidance in the federal regulation.
Public Release of Research Information	6m	New paragraph: Addresses public release of research information.
Research that Requires Approval of Secretary of the Navy	7a(1)	Revised paragraph: Adds the Secretary of the Navy as the approval authority for research, involving: <i>(a) Waivers of the requirement for informed consent under 10 USC 980.</i> <i>(b) Exceptions from informed consent requirements for emergency research under 21 CFR 50.24 and in accordance with the requirements of 10 USC 980.</i> <i>(c) Requests for waiver of requirements of DON policy</i>

Topic	Paragraph	Description of Change
		<i>regarding human research protections.</i>
Research the Under Secretary of the Navy Must Approve	7a(2)	New paragraph: Adds the Under Secretary of the Navy as the approval authority for certain types of research involving human subjects for which, under SECNAVINST 3900.39C, the Assistant Secretary of the Navy for Research, Development and Acquisition served as the approval authority.
Navy Surgeon General	7a(5)	Revised paragraph: Revised the role of the Navy SG. The Navy SG is the single authority for policy development, oversight, compliance, and ongoing monitoring concerning human research protections in the DON
Requirements for SG to Report	8a(14)	New paragraph: Addresses items the SG must report to DDR&E
Chief of Naval Research Role	8b	Revised paragraph: Revised the role of the Chief of Naval Research (CNR). The CNR provides support and expertise to the SG for human research protections in the System Commands, operational forces, training commands, and DON-supported extramural performing institutions.
Commanding Officer Responsibility	8c(21), 8c(22), 8c(23)(c) – (f)	New paragraphs: Address COs' requirement to review and report research misconduct and non-compliance with human research protections to the SG
IRB Members	8e(1)	New paragraph: Limits IRB members to current federal employees, consultants, and "appointed" vs. "detailed" IPAs. Status as a contractor or federal retiree is not sufficient to qualify as a federal employee.
Principal Investigators	8g	New paragraph: Emphasizes the definition of Principal Investigator in enclosure (1) limiting eligibility for Principal Investigators status for DON-supported intramural research to federal employees.