

**Department of the Navy
Human Research Protection Program**

DoD-Navy Addendum to Federalwide Assurance (FWA) of Protection for Human Subjects

**Citations for Department of the Navy (DON) Additional Requirements
For Institutions Conducting or Collaborating in DON-supported Human Subject Research**

Background

The DON supports research with human subjects conducted by DON commands; by extramural performers through contracts, grants, cooperative agreements, or other arrangement; and by collaborators with the DON. The DON implements human research protection requirements through the Common Rule (32 CFR 219), Department of Defense (DoD) policies (DoDI 3216.02), and DON policies (SECNAVINST 3900.39D.)

The DoD and DON mandate additional requirements for research with human subjects. Key additional requirements and the corresponding information are listed below.

Applicability and Scope

[DoDI 3216.02; SECNAVINST 3900.39D para 4a(1) and 6g]

DoDI 3216.02

Applies to research involving human subjects, as defined herein, conducted by a DoD Component (i.e., intramural) and other research that is supported by a DoD Component (i.e., extramural) through a contract, grant, cooperative agreement, or other arrangement.

The Department of Defense has joined with other Federal Agencies to adopt the "Common Rule" Federal policy for protection of human subjects in research. 32 CFR 219 is the Department of Defense's implementation of the Common Rule. All DoD-supported and -conducted research shall comply with 32 CFR 219 and this Directive.

SECNAVINST 3900.39D, para 4a(1) and 6g

4a(1): This instruction applies to: All biomedical and social-behavioral research involving human subjects conducted by Navy and Marine Corps activities or personnel, involving naval military personnel and DON employees as research subjects, or supported by naval activities through any agreement (e.g., contract, grant, cooperative agreement, or other arrangement), regardless of the source of funding, funding appropriation, nature of support, performance site, or security classification. It also applies to human subject research using DON property, facilities, or assets.

6g: DON supports research with human subjects conducted at non-federal institutions. Any research grants, contracts, cooperative agreements, Cooperative Research and Development Agreements (CRADAs), or other transactions must include the additional DOD and DON requirements for human subject protections.

Additional Requirements

1. Initial and continuing research ethics training for all personnel who conduct, review, approve, oversee, support, or manage human subject research
[DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(2)]
2. Written determination by a designated official (other than investigators) whether research meets criteria for exemption
[SECNAVINST 3900.39D, para. 6c]
3. New research protocols must undergo scientific approval prior to ethics (IRB) review
[DoDI 3216.02]
4. Conflicts of interest
[SECNAVINST 3900.39D, para. 6b]
5. Appointment of Research Monitor for greater than minimal risk research
[DoDI 3216.02]
6. Provisions for research-related injury
[DoDI 3216.02; SECNAVINST 3900.39D, para 6a(5)]
7. Additional protections for military research subjects to minimize undue influence
[DoDI 3216.02; SECNAVINST 3900.39D, para 6a(6)]
8. Additional protections for pregnant women, prisoners, and children (Subparts B, C, and D of 45 CFR 46)
[DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(6)]
9. Additional safeguards for research conducted with international populations
[DoDI 3216.02; SECNAVINST 3900.39D, para. 6i]
10. Consent by legally authorized representatives
[DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(3); 10 USC 980]
11. Limitation on exceptions from informed consent in emergency medicine research
[DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(3)and 7a(1); 10 USC 980]
12. Limitations on compensation for U. S. military personnel
[Dual Compensation Act and 24 USC 30]
13. U. S. Navy-wide survey research may require additional review
[SECNAVINST 3900.39D, para. 6e; OPNAVINST 5300.8B]
14. Reporting suspensions, allegations of non-compliance, unanticipated problems, etc.

[SECNAVINST 3900.39D, para 8d(2)]

15. Oversight by the DON HRPP through headquarters-level review of research protocols after local institutional approval

[DoDI 3216.02; SECNAVINST 3900.39D, para. 8b, and 8d]

16. Addressing and reporting allegations of research misconduct

[DoDI 3216.02]

17. Research with human subjects using investigational test articles (drugs, device, and biologics)

[DoDI 3216.02; DoDI 6200.02; SECNAVINST 3900.39D, para. 6h]

18. Prohibition of research with prisoners of war (POW) and detainees

[DoDI 3216.02; SECNAVINST 3900.39D, para. 6a(8)]

19. Classified Research

[SECNAVINST 3900.39D, para 6j]