

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 with Others on 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 Common Rule (32 CFR 219), Department of Defense (DoD) directives (DoDD 3216.2), and DON instructions (SECNAVINST 3900.39D).

The DoD and DON mandate additional requirements for research with human subjects. The key additional requirements and the corresponding specific citation are listed after "Applicability and Scope."

Applicability and Scope

[DoDD 3216.2, para 2.2 and 4.3.1; SECNAVINST 3900.39D para 4a(1) and 6g]

DoDD 3216.2

2.2: 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.

4.3.1: 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 DoD-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.

Specific Citations for Key Additional Requirements

1. Initial and continuing research ethics training for all personnel who conduct, review, approve, oversee, support, or manage human subject research

[DoDD 3216.2, para. 4.5; 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 and substantive amendments to approved research must undergo scientific approval prior to ethics (IRB) review
[SECNAVINST 3900.39D, para. 8c(6)]
4. Procedures for addressing conflicting and competing interests
[DoDD 3216.2, para. 4.4.4; SECNAVINST 3900.39D, para. 6b]
5. Appointment of Medical Monitor
[DoDD 3216.2, para. 4.4.3]
6. Provisions for research-related injury
[DoDD 3216.2, para. 5.3.4; SECNAVINST 3900.39D, para 6a(5)]
7. Additional protections for military research subjects to minimize undue influence
[DoDD 3216.2, para. 4.4.4; SECNAVINST 3900.39D, para 6a(6)]
8. Additional protections for pregnant women, prisoners, and children (Subparts B, C, and D of 45 CFR 46)
[DoDD 3216.2, para. 4.4.1; SECNAVINST 3900.39D, para. 6a(6)]
9. Additional safeguards for research conducted with international populations
[DoDD 3216.2, para. 4.9; SECNAVINST 3900.39D, para. 6i]
10. Limitations on research where consent by legally authorized representatives is proposed
[DoDD 3216.2, para. 4.2.; SECNAVINST 3900.39D, para. 6a(3);10 U.S.C 980]
11. Limitation on exceptions from informed consent in emergency medicine research
[DoDD 3216.2, para. 4.2; SECNAVINST 3900.39D, para. 6a(3)and 7a(1); 10 U.S.C. 980]
12. Limitations on compensation for U. S. military personnel
[Dual Compensation Act and 24 U.S.C 30]
13. U. S. Navy-wide survey research requires additional review
[SECNAVINST 3900.39D, para. 6e; OPNAVINST 5300.8B]
14. Requirements for reporting unanticipated problems, adverse events, and research-related injury
[SECNAVINST 3900.39D, para 8d(2), para. 8e(6), and para. 8g(6)]
15. Oversight by the DON HRPP through headquarters-level review of research protocols (including relevant IRB meeting minutes) after local institutional approval and site visit of the institution's HRPP
[DoDD 3216.2, para. 5.3.3; SECNAVINST 3900.39D, para. 6g , 8b, and 8d]

16. Recordkeeping requirements
[DoDD 3216.2, para. 5.3.2; SECNAVINST 3900.39D, para. 8c(18)]
Recordkeeping requirements for DON-supported research with human subjects are longer than the Common Rule's requirement. The DON HRPP is developing policy guidance.
17. Addressing and reporting allegations of non-compliance with human research protections
[DoDD 3216.2, para. 4.10; SECNAVINST 3900.39D, para. 8d(2) and 6k;]
18. Addressing and reporting allegations of research misconduct
[DoDD 3216.2, para. 4.8; DoDD 3210.7; SECNAVINST 3900.39D, 8d(2)para. 6l]
19. Provisions for research with human subjects using investigational test articles (drugs, device, and biologics)
[DoDD 3216.2, para. 4.9; DoDD 6200.2; SECNAVINST 3900.39D, para. 6h]
20. Prohibition of research with prisoners of war (POW) and detainees
[DoDD 3216.2, para. 4.4.2; SECNAVINST 3900.39D, para. 6a(8)]
21. Classified Research
[SECNAVINST 3900.39D, para 6j]