

Policies and Procedures

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1. PURPOSE

This policy outlines the laws, regulations, and guidance with which the Creighton University Institutional Review Board shall comply when conducting, reviewing, approving, overseeing, supporting, or managing Department of Defense (DoD) research with human subjects. In most cases, protocols covered by the Department of the Navy requirements will also have review, approval, and oversight by the Department of Navy's Human Research Protections Program. Creighton University shall review and approve research protocols prior to DoD approval.

2. APPLICABILITY AND SCOPE

This policy applies to all biomedical and social-behavioral research involving human subjects conducted by Department of Defense activities or personnel, involving military personnel and 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 military property, facilities, or assets. The guidelines/regulations listed below shall be followed for research conducted under the auspices of the DoD:

- 2.1. The Belmont Report
- 2.2. Title 32 Code of Federal Regulations Part 219 (32 CFR 219), Department of Defense Regulations, "Protection of Human Subjects" (DoD adoption of the "Common Role")
- 2.3. Title 45 Code of Federal Regulations Part 46, (45 CFR 46) Department of Health and Human Services Regulations, "Protection of Human Subjects," Subparts B, C, and D as made applicable by DODD 3216.02
- 2.4. Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- 2.5. DoD Directive (DoDD) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research"
- 2.6. Title 10 United States Code Section 980 (10 USC 980), "Limitation on Use of Humans as Experimental Subjects"

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2.7. DoDD 3210.7, "Research Integrity and Misconduct"

2.8. DoDD 6200.2, "Use of Investigational New Drugs in Force Health Protection"

2.9. Department of the Navy (DoN)

2.9.1. SECNAVINST 3900.39D of 6 November 2006

2.9.2. SECNAVINST 5720.44B of 1 November 2005

2.9.3. SECNAV M-5210.1 of 1 December 2005

2.9.4. OPNAVINST 5300.8B of 23 April 1997

3. RESEARCH INVOLVING A HUMAN BEING AS AN EXPERIMENTAL SUBJECT

Research involving a human being as an experimental subject is defined as an activity, for research purposes, for which there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose. This does not include:

3.1. Activities carried out for purposes of diagnosis, treatment, or prevention of injury and disease in members of the Armed Forces and other mission essential personnel under Force Health Protection programs of the Department of Defense.

3.2. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions.

3.3. Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance reviews.

3.4. Activities exempt under 32 CFR Part 219 (reference (c)).

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If a research participant meets the definition of an experimental subject, the consent process shall not be waived unless such a waiver is obtained from the Secretary of Defense. If the research participant does not meet the definition of an experimental subject, the IRB may waive the consent process.

4. SPECIFIC CITATIONS FOR KEY ADDITIONAL REQUIREMENTS NOT COVERED BY TITLE 45 CFR 46, SUBPARTS B, C AND D; 21 CFR 50, 56, 312, AND 812; AND THE CU IRB WRITTEN POLICIES AND PROCEDURES (WPP)

4.1. Appointment of a medical monitor - [DoDD 3216.2, para.4.43]

- 4.1.1. For research involving more than minimal risk to subjects, an independent medical monitor shall be appointed by name. Medical monitors shall be physicians, dentists, psychologists, nurses, or other health care providers capable of overseeing the progress of research protocols, especially issues of individual subject/patient management and safety. Medical monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate.

4.2. 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)]

- 4.2.1. For purposes of this paragraph, actions authorizing or requiring any action by an official of the Department of Health and Human Services (HHS) shall be under the authority of the Director, Defense Research and Engineering.

4.3. Additional safeguards for research conducted with international populations - [DoD] 3216.2 para, 4.9; SECNAVINST 3900.39D, para 6i]

- 4.3.1. Research involving human subjects who are not U.S. citizens or DoD personnel, conducted outside the United States and its territories and possessions, requires permission of the host country. The laws, customs, and practices of the host country and those required by this instruction will be followed. An ethics review by the host country, or local Naval IRB with host country representation, is required.

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4.4. Limitation of waivers and exceptions from informed consent - [DoDD 3216.2, para. 4.2; SECNAVINST 3900.39D, para. 6a(3) and 7a(1); 10 U.S.C. 980]

- 4.4.1. Waivers of the requirement for informed consent and exceptions from informed consent requirements for emergency research must be approved by the Secretary of the Navy.
- 4.4.2. **Note:** The IRB shall not waive the requirement for informed consent or grant an exception from informed consent for emergency research unless it has documentation that the Secretary of the Navy has approved it.

4.5. Limitations on compensation for U.S. military personnel - [Dual Compensation Act and 24 U.S.C. 30]

- 4.5.1. The Dual Compensation Act prohibits an individual from receiving pay from more than one position for more than an aggregate of 40 hours of work in one calendar week. This prohibition applies to employees paid from either appropriated or non-appropriated funds, or a combination thereof, and includes temporary, part-time, and intermittent appointments. This law is not applicable to enlisted off-duty military personnel in relation to their military duty.
- 4.5.2. **Note:** There is the distinct possibility that Navy personnel may be limited in getting compensation as research subjects.

4.6. Navy-wide survey research requires additional review - [SECNAVINST 3900.39D, para 6e; OPNAVINST 5300.8B]

- 4.6.1. A Privacy Act Statement must be displayed prominently on all Navy personnel surveys without exception, regardless of whether personal identifiers are requested. The statement shall identify the authority for survey administration (including OPNAV RCS), advise respondents of the purpose and routine uses of the survey, indicate that the survey is voluntary, explain the intended use(s) of the data, and describe measures used to safeguard confidentiality.

4.7. Requirement for reporting unanticipated problems, adverse events, and research-related injury - [SECNAVINST 3900.39.D, para 8d(2), para., 8e(6), and para. 8g(6)]

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4.7.1. Report the following to the DoN Human Research Protections Program (HRPP) Office and appropriate sponsor(s):

- 4.7.1.1. All suspensions or terminations of previously approved DoN-supported research protocols
- 4.7.1.2. The initiation and results of investigations of alleged non-compliance with human subject protections
- 4.7.1.3. Unanticipated problems involving risks to subjects or others, or serious adverse events in DoN-supported research
- 4.7.1.4. All audits, investigations, or inspections of DoN-supported research protocols
- 4.7.1.5. All audits, investigations, or inspections of the institution's HRPP conducted by outside entities (e.g., the FDA or OHRP)
- 4.7.1.6. Significant communication between institutions conducting research and other federal departments and agencies regarding compliance and oversight
- 4.7.1.7. All restrictions, suspensions, or terminations of institutions' assurances

4.8. Recordkeeping requirements - [DoDD 3216.2, para. 5.3.2; SECNAVINST 3900.39D, para. 8c(18)]

- 4.8.1. Recordkeeping requirements for DON-supported research with human subjects are longer than the Common Rule's requirement. The DON HRPP is developing policy guidance.

4.9. Addressing and reporting allegations of noncompliance with human research protections - [DoDD 3216.2, para. 4.10; SECNAVINST 3900.39D, para. 8d(2) and 6k]

- 4.9.1. Report the initiation of all investigations and report results, regardless of the findings, to the Navy Secretary General and appropriate sponsors.

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4.10. Addressing and reporting allegations of research misconduct - [DoDD 3216.2, para. 4.8; DODD 3210.7; SECNAVINST 3900.39D, 8d(2) para. 6l]

- 4.10.1. All findings of serious research misconduct under this section shall be reported to the Director, Defense Research and Engineering.

4.11. 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]

- 4.11.1. Principal investigators shall not be sponsors for INDs and IDEs.

4.12. Prohibition of research with prisoners of war (POW) and detainees - [DoDD 3216.2, para 4.4.2; SECNAVINST 3900.39D, para. 6a(8)]

- 4.12.1. Research involving any person captured, detained, held or otherwise under the control of DoD personnel (military and civilian, or contractor employee) is prohibited.

4.13. Classified research - [SECNAVINST 3900.39D, para 6j]

- 4.13.1. Classified research must receive prior approval from the Secretary of Defense. It is not eligible for review under expedited review procedures.

4.14. Minimizing undue influence over military research participants

- 4.14.1. Officers shall not influence the decisions of their subordinates
- 4.14.2. Officers and senior non-commissioned officers shall not be present at the time of recruitment of study participants
- 4.14.3. Officers and senior non-commissioned officers shall be given a separate opportunity to participate in the research study
- 4.14.4. When recruitment involves a percentage of a unit, an independent ombudsman shall be present

4.15. Substantive modifications to previously approved research

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4.15.1. For research regulated by the DoD, all substantive modifications to previously approved research shall undergo scientific review prior to IRB review and approval.

4.16. Multi-site research

4.16.1. When conducting multi-site research, a formal agreement shall be required to specify the roles and responsibilities of each party.

5. RESPONSIBILITY

5.16. It is the responsibility of the Principal Investigator to ensure that all additional DoD-DoN requirements for human subject protection are met. This may require submitting records to the DoD for archiving. It also is the responsibility of the IRB to ensure that all additional DoD-DoN requirements for human subject protection have been met before IRB approval of the research project.