

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. RESEARCH IN CONJUNCTION WITH DoD COMPONENT

The appropriate DoD component is responsible for insuring the appropriate administrative review of the research involving human subjects. The DoD Component administrative review must be conducted before the research involving human subjects can begin, to ensure compliance with all applicable regulations and policies, including any applicable laws and requirements and cultural sensitivities of the country when the research is conducted in a country other than the United States.

3. 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:

3.1. The Belmont Report

3.2. 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"

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- 3.3. 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
- 3.4. Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- 3.5. DoD Directive (DoDD) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research"
- 3.6. Title 10 United States Code Section 980 (10 USC 980), "Limitation on Use of Humans as Experimental subjects"
- 3.7. DoDD 3210.7, "Research Integrity and Misconduct"
- 3.8. DoDD 6200.2, "Use of Investigational New Drugs in Force Health Protection"
- 3.9. Department of the Navy (DoN)
 - 3.9.1. SECNAVINST 3900.39D of 6 November 2006
 - 3.9.2. SECNAVINST 5720.44B of 1 November 2005
 - 3.9.3. SECNAV M-5210.1 of 1 December 2005
 - 3.9.4. OPNAVINST 5300.8B of 23 April 1997

4. RESEARCH ETHICS EDUCATION

Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human participants research.

- 4.1. Initial and continuing education and training shall be commensurate with the duties and responsibilities of the DoD personnel
- 4.2. All training and education of DoD personnel shall be documented

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- 4.3. Professional certification in the field of human research protection is encouraged for all DoD personnel involved in review and oversight of research involving human subjects
- 4.4. When assessing whether to support or collaborate with a non-DoD institution for research involving human subjects, the DoD Components should evaluate the non-DoD institution's education and training policies to ensure the personnel are qualified to perform the research. The rigor of the evaluation should be appropriate for the complexity and risk of the research

5. 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:

- 5.1. 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
- 5.2. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions
- 5.3. 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
- 5.4. Activities exempt under 32 CFR Part 219 (reference (c))

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- 5.5. The definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain.)
- 5.6. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements
- 5.7. If a research subject 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 subject does not meet the definition of an experimental subject, the IRB may waive the consent process

6. 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

6.1. Appointment of a research monitor

- 6.1.1. For research involving more than minimal risk to subjects, an independent research monitor shall be appointed by name. Research 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. Research monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate
- 6.1.2. There may be more than one research monitor (e.g. if different skills or experience are needed)
- 6.1.3. The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities
- 6.1.4. The IRB and HRPP official shall communicate with research monitors to confirm the monitors’ duties, authorities, and responsibilities

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6.1.5. The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:

6.1.5.1. Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis)

6.1.5.2. Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study

6.1.5.3. Report observations and finding to the IRB or a designated official

6.1.6. The research monitor has the authority to:

6.1.6.1. Stop a research study in progress

6.1.6.2. Remove individuals from the study

6.1.6.3. Take any steps to protect the safety and well-being of participants until the IRB can assess the situation

6.2. Additional protections for pregnant women, prisoners, and children

Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C, and D

6.2.1. For purposes of applying Subpart B, the phrase “biomedical knowledge” shall be replaced with “generalizable knowledge”

6.2.2. The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman of the fetus or involving fetuses or neonates as participants

6.2.3. Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g

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- 6.2.4. Research involving prisoners cannot be reviewed by the expedited procedure
- 6.2.5. When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum
- 6.2.6. If a participant becomes a prisoner, if the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB Chair may determine that the prisoner-participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB Chair shall require that all research interactions and interventions with the prisoner-participant (including obtaining identifiable private information) cease until the convened IRB can review the request to approve a change in the research protocol. The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, shall promptly (no longer than 30 days) re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB shall consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative
- 6.2.7. If the prisoner-participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-participant's confinement does not inhibit the ethical consult of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-participant to continue to participate in the research.
- 6.2.8. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants
- 6.2.9. Research involving a detainee as a human participant is prohibited
- 6.2.10. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition

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6.2.11. The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed

6.3. Additional safeguards for research conducted with international populations

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

6.4. Consents and Waivers of Consent

Consent documents must include:

- 6.4.1. A statement that the DoD or a DoD organization is funding the study
- 6.4.2. A statement that representatives of the DoD are authorized to review the research records
- 6.4.3. The IRB must determine that the disclosure includes that provisions for research-related injury follow the requirements of the DoD component
- 6.4.4. The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:
 - 6.4.4.1. The research is necessary to advance the development of a medical product for the Military Services
 - 6.4.4.2. The research might directly benefit the individual experimental subject
 - 6.4.4.3. The research is conducted in compliance with all other applicable laws and regulations

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- 6.4.5. If consent is to be obtained from the legal representative of the participant as defined in DoDI 3216.02, the research must intend to benefit each participant enrolled in the study
- 6.4.6. 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
- 6.4.7. **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

6.5. Limitations on compensation for U.S. military personnel

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

- 6.5.1. When research involves U.S. military personnel, limitations on dual compensation:
- 6.5.1.1. Prohibit an individual from receiving pay or compensation for research during duty hours
 - 6.5.1.2. U.S. military personnel may be compensated for research if the participant is involved in the research when not on duty
 - 6.5.1.3. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw
 - 6.5.1.4. Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research
 - 6.5.1.5. **Note:** There is the distinct possibility Navy personnel may be limited in getting compensation as research subjects

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6.6. Navy-wide survey research requires additional review

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

6.7. Requirement for reporting unanticipated problems, adverse events, and research-related injury

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

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

6.8. The following must be promptly (no longer than within 30 days) reported to the DoD human research protocol office:

- 6.8.1. When significant changes to the research protocol are approved by the IRB
- 6.8.2. The results of the IRB continuing review

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6.8.3. Change of reviewing IRB

6.8.4. When the organization is notified by any Federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol.

6.9. Recordkeeping requirements

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

6.10. Addressing and reporting allegations of noncompliance with human research protections

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

6.11 Addressing and reporting allegations of research misconduct

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

6.12. Provisions for research with human subjects using investigational test articles (drugs, device and biologics)

Principal investigators shall not be sponsors for INDs and IDEs

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

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

6.14. Classified research

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

6.15. Minimizing undue influence over military research subjects

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6.15.1. Officers shall not influence the decisions of their subordinates

6.15.2. Officers and senior non-commissioned officers shall not be present at the time of recruitment of study subjects

6.16.3. Officers and senior non-commissioned officers shall be given a separate opportunity to participate in the research study

6.16.4. When recruitment involves a percentage of a unit, an independent ombudsman shall be present

6.16. Substantive modifications to previously approved research

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

6.17. Multi-site research

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

6.17. Research conduct on DoD Personnel

Surveys performed on DoD personnel must be submitted, reviewed and approved by the DoD after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD Components, additional review is required.

7. RESPONSIBILITY

7.1. It is the responsibility of the Principal Investigator to ensure 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 additional DoD-DoN requirements for human subject protection have been met before IRB approval of the research project

7.2. Determinations of serious or continuing non-compliance of DoD supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer

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- 7.3. Any unanticipated problems involving risks to participants or others for any DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer

- 7.4. Any suspension or termination of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer