

INVESTIGATOR GUIDANCE: Additional DOD Obligations

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1. PURPOSE

- 1.1. This guidance outlines the additional obligations of investigators conducting research supported or conducted by DOD.

2. GUIDANCE

2.1. Training and education

- 2.1.1. All personnel who conduct, review, approve, oversee, support, or manage human subjects research are required to undergo initial and continuing research ethics education.
- 2.1.2. There may be specific DOD educational requirements or certification required.
- 2.1.3. DOD may evaluate the organization's education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.
- 2.1.4. As the investigator, you must be aware of the specific requirements contained in DOD regulations and requirements and educated about these requirements when appropriate.

2.2. Scientific Review

- 2.2.1. The IRB must consider the scientific merit of the research.
- 2.2.2. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

2.3. International Research

- 2.3.1. You or the organization must obtain permission to conduct research in that country by certification or local ethics review.
- 2.3.2. You must follow all local laws, regulations, customs, and practices.

2.4. Reporting: The following findings in DOD-supported research must be reported to the DOD human research protection officer within 30 days:

- 2.4.1. Determinations of <Serious Noncompliance> or <Continuing Noncompliance>
- 2.4.2. Significant changes to the research protocol that are approved by the IRB
- 2.4.3. The results of the IRB continuing review
- 2.4.4. Change of reviewing IRB
- 2.4.5. When the organization is notified by any Federal department, agency or national organization that any part of an HRPP is under investigation for cause requirements
- 2.4.6. <Unanticipated Problems Involving Risk to Subjects or Others>
- 2.4.7. <Suspension of IRB approval>
- 2.4.8. <Termination of IRB approval>

2.5. Survey Approval

- 2.5.1. Surveys performed on DOD personnel must be submitted, reviewed, and approved by the DOD after the research protocol is approved by the IRB.

2.6. Multisite Research

- 2.6.1. When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party.

2.7. Definition of <Minimal Risk>

- 2.7.1. The definition of the minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" must not be interpreted to include the inherent risks certain

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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).

2.7.2. The organization applies this definition to all research regardless of funding.

2.8. Appointment of a Research Monitor:

2.8.1. This is required for research involving greater than minimal risk.

2.8.2. The IRB or institutional official can require a research monitor for a portion of the research or studies involving no more than minimal risk, if appropriate.

2.8.3. The research monitor is appointed by name and must be independent of the team conducting the research.

2.8.4. There may be more than one research monitor (e.g. if different skills or experience are needed).

2.8.5. 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.

2.8.6. The IRB or institutional official must communicate with research monitors to confirm their duties, authorities, and responsibilities.

2.8.7. The duties of the research monitor are determined on the basis of specific risks or concerns about the research.

2.8.7.1. The research monitor may 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 Risk to Subjects or Others>, oversee data matching, data collection and analysis).

2.8.7.2. The research monitor may discuss the research protocol with investigators, interview human subjects, and consult with others outside of the study.

2.8.7.3. Report observations and findings to the IRB or a designated official.

2.8.8. The research monitor has the authority to:

2.8.8.1. Stop a research study in progress.

2.8.8.2. Remove individuals from study.

2.8.8.3. Take any steps to protect the safety and well-being of subjects until the IRB can assess.

2.8.9. Recruitment of Service Members

2.8.9.1. Officers are not permitted to influence the decision of their subordinates.

2.8.9.2. Officers and senior non-commissioned officers may not be present at the time of recruitment.

2.8.9.3. Officers and senior non-commissioned officers have a separate opportunity to participate.

2.8.9.4. When recruitment involves a percentage of a unit, an independent ombudsman is present.

2.8.10. Compensation of Service Members:

2.8.10.1. Service member may not receive pay or compensation for research during duty hours.

2.8.10.2. A service member may be compensated for research if the subject is involved in the research when not on duty.

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- 2.8.10.3. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
 - 2.8.10.4. Non-Federal persons may be compensated for participating in research involving other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
- 2.9. Consent
- 2.9.1. The disclosure for research-related injury must follow the requirements of the DOD component.
 - 2.9.2. If the subject undergoes interactions or interventions for research purposes, the subject is considered an “experimental subject.” For experimental subjects:
 - 2.9.2.1. A waiver of the consent process is prohibited unless a waiver is obtained from the Assistant Secretary of DOD for Research and Engineering.
 - 2.9.2.2. The Assistant Secretary for DOD for Research and Engineering may waive the requirements for consent when all of the following are met:
 - 2.9.2.2.1. The research is necessary to advance the development of a medical product for the Military Services.
 - 2.9.2.2.2. The research may directly benefit the individual experimental subject.
 - 2.9.2.2.3. The research is conducted in compliance with all other applicable laws and regulations.
 - 2.9.2.3. The IRB may waive the consent process for subjects who are not “experimental subjects.”
 - 2.9.2.4. If consent is to be obtained from the experimental subjects’ legal representative, the research must intend to benefit the individual subject.
 - 2.9.2.4.1. The determination that research is intended to be beneficial to the individual experimental subject must be made by an IRB.
 - 2.9.3. Waivers of consent are prohibited for classified research.
- 2.10. Research on Pregnant Women
- 2.10.1. Research involving pregnant women and fetuses as subjects is subject to HHS Subpart B except:
 - 2.10.1.1. The phrase “biomedical knowledge” is replaced with “generalizable knowledge.”
 - 2.10.1.2. The applicability of Subpart B is limited to research involving pregnant women as subjects in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as subjects.
- 2.11. Research on Prisoners
- 2.11.1. Research involving prisoners is subject to HHS Subparts C.
 - 2.11.2. Research involving prisoners cannot be reviewed by the expedited procedure.
 - 2.11.3. When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.
 - 2.11.4. In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:

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- 2.11.4.1. The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
- 2.11.4.2. The research presents no more than minimal risk.
- 2.11.4.3. The research presents no more than an inconvenience to the subject.
- 2.11.5. When a subject becomes a prisoner, if the investigator asserts to the IRB that it is in the best interest of the prisoner-subject to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-subject may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the institutional official and DOD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB chair must require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol. The convened IRB, upon receipt of notification that a previously enrolled human subject has become a prisoner, must promptly 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 should 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. If the prisoner-subject can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-subject's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human subjects from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-subject to continue to participate in the research. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.
- 2.11.6. Research involving a detainee as a human subjects is prohibited.
 - 2.11.6.1. 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.
- 2.11.7. Research involving prisoners of war is prohibited.
 - 2.11.7.1. "Prisoner of war" includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person, and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power.
 - 2.11.7.2. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions for the purpose of diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees with the detainees' informed consent when the medical products are subject to FDA regulations for investigational new drugs or investigational medical devices, and only when the same product would be offered to members of the U.S. Military Services in the same location for the same medical condition and only when consistent with established medical practice involving investigational drugs and devices.

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- 2.12. Research on Children
 - 2.12.1. Research involving children is subject to the HHS Subpart D.
 - 2.12.2. 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.
- 2.13. Research on Fetal Tissue
 - 2.13.1. Fetal research must comply with US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
- 2.14. Waiver of Informed consent for Planned Emergency Research
 - 2.14.1. An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of DOD.
- 2.15. Records
 - 2.15.1. Records maintained that document compliance or <Noncompliance> with DOD regulations must be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.
- 2.16. Non-exempt Classified Research
 - 2.16.1. The involvement of classified information may be limited to information needed for IRB approval and oversight of the research; information needed to inform the human subjects during the consent process and Information provided by the subjects during the course of the research.
 - 2.16.2. Secretary of DOD approval is required for all classified non-exempt research involving subjects.
 - 2.16.2.1. Submission for approval must be from the Head of the OSD or DOD Component conducting or supporting the non-exempt research involving human subjects. The request must be coordinated with the ASD(R&E) and General Counsel of the Department of DOD after the IRB has approved the research.
 - 2.16.3. Waivers of informed consent are prohibited.
 - 2.16.4. Informed consent procedures must include:
 - 2.16.4.1. Identification of the DOD as the supporting institution of the research, unless the research involves no more than minimal risk. The Secretary of DOD may grant an exception to this requirement on the grounds that providing this information could compromise intelligence sources or methods.
 - 2.16.4.2. A statement that the research involving human subjects is classified and an explanation of the impact of the classification.
 - 2.16.5. IRB approval process must meet the following requirements:
 - 2.16.5.1. IRB review must be conducted using a full board review. Use of an expedited review procedure is prohibited.
 - 2.16.5.2. At least one non-affiliated member must be a non-Federal employee (other than as an individual appointed as an expert or consultant for purposes of service on the IRB).
 - 2.16.5.3. Any IRB member who disagrees with a majority decision approving a project may appeal the decision to the Secretary of DOD. The appeal must be included in the DOD Component's submission to the Secretary of DOD.

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- 2.16.5.4. The IRB must determine whether potential subjects need access to classified information to make a valid, informed consent decision.
- 2.16.6. Disclosure or use of classified information must comply with DOD requirements for access to and protection of classified information.

3. REFERENCES

- 3.1. 10 USC 980
- 3.2. DOD Instruction 3216.02
- 3.3. DOD Instruction 3216.2
- 3.4. OPNAVINST 5300.8B
- 3.5. SECNAVINST 3900.39D