SOP 1.3.9 Department of Defense Research

Introduction

Research involving the Department of Defense (DOD) requires additional compliance activities, documentation, and subject protections to meet the regulations under 32 CFR 219. The DOD follows the DHHS and FDA regulations on human subjects research but also applies DOD Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD Supported Research.

Responsibility for meeting and upholding DOD requirements for human subjects research is shared between researchers, the IRB office, and DOD. The requirements for DOD research are presented in this guidance.

General Information

Research involves the DOD when any of the following apply:

- The research is funded by a component of DOD
- The research involves cooperation, collaboration, or another type of agreement with a component of DOD.
- The research uses facilities or property of a component of DOD.
- The subject population purposely includes personnel (military or civilian) from a component of DOD. [1]

DOD components include, but may not be limited to:

- Department of Defense
- Navy
- Office of Naval Research
- Naval Academy
- U.S. Naval Observatory
- Army
-Army Research Institute
- U.S. Army Corps of Engineers
- Military Academy (West Point)
- Air Force
- Air Force Academy
- Marines
- Coast Guard
- Coast Guard Academy
- National Guard
- Missile Defense Agency
- Defense Advanced Research Projects Agency (DARPA)
- Pentagon Force Protection Agency

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[1] *DOD policies and requirements do not apply when DOD personnel incidentally participate as subjects in research that is not supported by DOD, and DOD personnel are not an intended population of the research.*

- Defense Intelligence Agency
- National Geospatial-Intelligence Agency
- National Security Agency
- National War College
- Other DOD facilities

George Mason University maintains an active Navy and Air Force Addendum to its Federalwide Assurance (FWA), confirming that the University will apply all applicable DOD human subject regulations and policies when conducting, reviewing, approving, overseeing, or managing human subject research involving the DOD.

DOD regulations

The DOD follows the DHHS and FDA regulations on human subjects research, but also applies DOD Directive (DODD) 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research." Research sponsored or funded by the DOD must be reviewed by the IRB under all applicable sets of federal regulations.

Unique DOD Requirements

Waiver of Consent

Sections 219.116(c) and (d) of 219 CFR 32 prohibit the IRB from waiving informed consent for DOD-conducted and DOD-supported research involving human subjects. When the research meets the Glossary definition of research involving a human being as an experimental subject, informed consent must be obtained in advance from the experimental subject or the subject's legal representative if the subject cannot consent for him/herself. If consent is to be obtained from the experimental subject's legal representative, the research must intend to benefit the individual subject. The determination that research is intended to be beneficial to the individual experimental subject must be made by an IRB. DOD regulations also prohibit an exception from informed consent in emergency medicine research.

Research related injury

The PI is responsible for informing IRB staff of the DOD Component's requirements for the provision of care in the case of a research-related injury. If the DOD Component has unique requirements for compensation of research-related injuries, permission must first be obtained from university council. The PI should include all appropriate provisions in the informed consent form, which the IRB will review and approve per standard operating procedures.

Compensation to Human Subjects for Participation in Research

A. On-duty federal personnel: Federal personnel participating as human subjects in DOD-conducted (and non-DOD conducted) research while on duty may only be compensated for blood draws[2] and may not otherwise be compensated for general research participation (even if the research is not Federally funded or conducted).

[2] *DODI 3216.02, November 8, 2011 describes compensation for blood draws. Please see this guidance for more information.*

B. Off-duty federal personnel: Federal personnel while off-duty may be compensated for research participation other than blood draws in the same way as human subjects who are not Federal personnel. However, payment to off-duty Federal personnel for research participation other than blood draws must not be directly from a Federal source.
C. Non-federal personnel: Non-federal personnel may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB. Payment for general research participation may come directly from a Federal or non-Federal source.

Submitting DOD Research to the IRB

1. Communicate with the DOD component. Due to the nature of DOD research and the unique regulatory requirements, PIs and research teams should communicate closely with the DOD component prior to submission of an IRB proposal.

2. Complete Training Requirements. The PI, with assistance from IRB staff, is responsible for identifying specific educational or certification requirements of the sponsoring DOD component. The PI should consult directly with the DOD component to identify these requirements and convey the necessary information to the IRB. Additionally the PI and research team must complete all mandatory Mason education requirements for human subjects protection in accordance with Mason policy. The IRB will not approve DOD supported research until the PI and the research team have completed all required education/certifications. It is the responsibility of the PI to provide the IRB with documentation of any required continuing education as completed.

3. Obtain Scientific Review. DOD requires scientific review prior to IRB review for all new DOD supported human subject research. The PI is responsible for obtaining scientific review prior to submission of the application to the IRB. A scientific review must be conducted by a funding agency (including DOD) or by an established internal review mechanism in the researcher's school or department (either of these will satisfy this requirement). In the absence of such a review, an ad hoc scientific review may be provided by the researcher's chair or dean. The review must address the following areas: significance, research design, research methods, analysis, researcher qualifications, and research environment. Written documentation of the scientific review that summarizes any scientific issues raised and addressed during the review should be submitted to the IRB. Reviewers should be identified by name and position/affiliation and should not be part of the research team. Reviewers can use the Scientific or Scholarly Review form in the IRBNet library, and the researchers can then include the completed form in their IRB submission in order to meet this requirement.

4. Complete and submit an IRB Application. The PI or research team must complete an application for IRB review. In the application, it must be clear whether the research is supported by a DOD component and all DOD relevant items in the application must be completed (including whether DOD personnel are subjects). The PI and study team are responsible for completing processes specified in the DOD guidelines and submitting documentation, as appropriate, with the IRB application.

5. Designate a Research Monitor[3]. For greater than minimal risk research, DOD requires designation of a Research Monitor. [4] Research monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate. The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities with the IRB protocol.

6. IRB Review. The IRB office/IRB will provide review as detailed in relevant SOPs.

7. Submit IRB approval documentation to DOD. After the IRB completes its review and issues approval, the PI should submit documentation of IRB approval, the risk level and the approval and expiration dates of the research to the DOD component. The PI should not initiate the study until the sponsoring DOD component reviews and accepts the IRB approval and any other submitted documentation. The PI should notify the IRB upon receipt of relevant DOD component authorization as appropriate.

8.. The Mason Office of Sponsored Programs (OSP) will establish a funding account only after receiving certification of final approval from the DOD. Researchers are not permitted to utilize DOD funds for human subjects research until all of the following requirements have been met:

- The IRB has reviewed and approved the research (or granted an exemption).
- Mason researchers have provided any materials requested by the DOD funding agency.
- OSP has been authorized by DOD to activate the award.

8. Recordkeeping. IRB staff must secure and maintain IRB records for DOD-sponsored research in accordance with the provisions of the IRB Recordkeeping SOP. Additionally, the PI should maintain adequate regulatory records as well as determine whether the DOD Component requires submission of IRB records to the DOD for archiving. It is responsibility of the PI, with assistance as necessary from the IRB staff, to submit all relevant records to the DOD.

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[3] Appropriate officials of the DOD Components may waive the requirement to have a research monitor on a case-by-case basis when the inclusion of a research monitor is not necessary to provide additional protections for human subjects. This waiver authority may be delegated to a DoD official, as described in the Component's HRPP management plan, but not at or below the position of the institution's DOD IO. (DODI 3216.02, November 8, 2011)

[4] Additionally, a research monitor may be identified by an investigator or appointed by an IRB or IO for research involving human subjects determined to involve minimal risk. (DODI 3216.02, November 8, 2011)

References

DOD Directive 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research," November 8, 2011
http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

219 of title 32, Code of Federal Regulations

Section 30 of title 24, United States Code

University of Missouri Standard Operating Procedures Department of Defense/IRB Coordination dated June 10, 2010

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Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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