



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedures

Department of Defense/IRB Coordination

Department of Defense/IRB Coordination

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Table of Contents

[Purpose](#)

[Scope](#)

[General Description](#)

[Policy/procedure](#)

[Submission](#)

[Ethics Education Requirements](#)

[Required Monitoring](#)

[Military Personnel as Research Participants](#)

[Consent Process](#)

[Consent in Emergency Medicine](#)

[Multi-Site or Collaborative Research](#)

[Research-related Injury](#)

[Research and Prisoners of War](#)

[Additional DoD Review Required Prior to Initiation of Study](#)

[Scientific Review for Substantive Amendments](#)

[Recordkeeping](#)

[References](#)

1.0 Purpose

To describe policies and procedures at the University of Missouri (UMC) for institutional review and oversight of research supported by the Department of Defense (DoD) that involves human subjects.

2.0 Scope

GENERAL DESCRIPTION

Research supported by the DoD and “involving a human being as an experimental subject” is subject to the Federal Policy for the protection of human subjects in research, i.e., the Common Rule. However, because of the DoD culture, organizational structure, and population, DoD Directive 3216.02 lays out additional requirements that apply as well. These requirements are designed to cover risks unique to DoD employees that differ from civilians both in the conduct of research and in participation in research (e.g., deployability, personal conduct standards, and duty to report certain personnel actions). The procedures outlined in this SOP ensure that UMC research supported by the DoD complies with DoD regulations governing human research.

UMC’s existing Federalwide Assurance (FWA) of compliance approved by the Office of Human Research Protections (OHRP) meets the DoD requirement that the institution hold a federal assurance. The existing FWA was augmented with a DoD Addendum (DoD N-A3388) to inform institutions of additional DoD requirements. In the case of human research sponsored by the Department of the Navy, Secretary of the Navy Instructions (SECNAVINST 3900.39D) apply.

The principal investigator (PI), with assistance from the IRB, submits documentation of Institutional Review Board (IRB) approval, the risk level, and the expiration date of the research to the DoD Component sponsoring or supporting the study. The DoD may also request additional documentation to verify compliance with federal and DoD policies, including minutes related to the research, any exemption determinations, or documentation of continuing approval. The DoD applies the provisions in 45 CFR Part 46, Subparts B, C, and D for the protection of vulnerable classes of subjects but prohibits the use of prisoners of war in DoD-sponsored research. For non-exempt classified research, the IRB will ensure all requirements outlined in 3216.02.13 have been met.

Non-compliance: Issues related to non-compliance with DoD Directive by any DoD Component, subordinate, or supported activity shall be referred initially to the next higher management echelon to take deliberate action to resolve. All findings of serious non-compliance shall be reported to the Director, Defense Research and Engineering.

Additional safeguards apply when the study involves military personnel or international citizen populations as subjects. Research involving greater than minimal risk [as defined in 32 CFR 219.102(i), reference (c)] requires appointment of an independent research monitor. In certain cases, the DoD applies limitations on the waiver of informed consent.

Minimal Risk: 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).

3.0 Policy/Procedure

PROCEDURES

Department of Defense Addendum to the Existing FWA

1. The University of Missouri-Columbia updated the existing Federalwide Assurance with a DoD Addendum, identified as DoD N-A3388. The Institutional Official, the appropriate IRB Chair, and the Director of Human Research Protections reviewed and signed the DoD Addendum.
2. The DoD addendum covers all DoD-sponsored research at UMC; however, various DoD Components may use other processes or have additional requirements. The PI, with assistance from IRB is responsible for identifying additional requirements and conveying those requirements to the IRB, as appropriate.
3. Since the University of Missouri-Columbia occasionally conducts research sponsored or supported by the Department of Defense, the Director of Human Research Protections will continue to renew the addendum prior to the scheduled expiration date.

Submission of DoD Supported Research to the IRB

1. DoD requires scientific review prior to IRB review for all new DoD supported human research. The PI is responsible for obtaining scientific review from his/her Department Chair or designee prior to submission of the application to the IRB. The Department Chair or designee is responsible for conducting the scientific review and signing off on the IRB application.
2. The PI or designee completes an application for IRB review of the protocol and makes the initial determination identifying the research as *supported* by a DoD component (as defined in Department of Defense Directive 3216.02) and submits it to the IRB.
3. The PI is responsible for checking the appropriate DoD-relevant items on the IRB application. The PI indicates in the application whether military personnel or international citizen populations are subjects.

Department of Defense/IRB Coordination

Page 4 of 12

4. Upon receipt of the application, IRB staff screen it for completeness and accuracy and make a preliminary determination that the research is DoD-supported. IRB staff also make preliminary determinations of the level of risk, the type of subjects involved (i.e., military personnel or international citizen populations), and the need for a research monitor (see *Research Monitor* below).

5. IRB staff advise the PI and the IRB of DoD-specific requirements in the Addendum. The PI is responsible for identifying DoD component requirements specified in the grant application guidelines and advising the IRB staff and IRB of the requirements.

6. The PI and study personnel are responsible for completing processes specified in the DOD Addendum or DOD guidelines and submitting documentation, as appropriate, to the IRB as an uploaded document to the IRB application.

Department of Defense Ethics Education Requirements

1. The PI and research team members who conduct, review, approve, oversee, support, or manage human participants research must complete all initial and continuing education requirements for human subjects protections in accordance with UMC policy (see Initial Review SOP).

2. The PI is responsible for identifying specific researcher, research members, IRB staff, chair and members educational or certification requirements of the sponsoring DoD Component by consulting the DoD component and conveying those requirements to the IRB. The DoD component may evaluate the education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.

3. IRB staff, with assistance from the PI, determine the need for orientation and/or education of the IRB chair, members, and staff as regards to DoD-specific education requirements.

4. IRB staff assist the PI, study personnel, as identified above, in accessing the necessary human subjects training and certifications required for IRB approval.

5. The PI, study personnel, and IRB members and staff complete DoD-specific research ethics training, as applicable, and the PI submits documentation of training completion to the IRB and to the DoD Component, as appropriate.

6. OSPA staff include relevant certifications, as appropriate, in the sponsored research agreement.

7. The IRB does not approve DoD-supported research until the PI and research team have completed required education and the appropriate certifications are in place.

Research Monitor Required: Greater than Minimal Risk Studies

Department of Defense/IRB Coordination

Page 5 of 12

1. For DoD-sponsored research involving greater than minimal risk to subjects, the DOD requires appointment of an independent research monitor, although the IRB or organizational official can require this for a portion of the research or studies involving no more than minimal risk, if appropriate.
2. The duties and authorities of the research monitor are determined on the basis of specific risks or concerns about the research, such as:
 - a. 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);
 - b. Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study;
 - c. Report observations and findings to the IRB or a designated official. Stop a research study in progress;
 - e. Remove individuals from the study;
 - f. Take any steps to protect the safety and well-being of subjects until the IRB can assess the research monitor's report
3. The PI identifies a candidate for the position of research monitor, taking into account the nature and disciplinary focus of the study and the likely type of medical expertise required.
 - a. The research monitor must be appointed by name and shall be independent of the team conducting the research.
 - b. The monitor may be an ombudsman or a member of the data safety monitoring board.
 - c. There may be more than one research monitor (e.g. if different skills or experience is needed).
 - d. The PI must attach to the IRB application a copy of the monitor's curriculum vitae, a letter from the monitor accepting the role, and a written summary of the monitors' duties, authorities, and responsibilities. The IRB must approve the written summary of the monitors' duties, authorities, and responsibilities.
4. The PI conveys to the monitor relevant DoD-specific orientation/education requirements of the role (see also *Department of Defense Ethics Education* above.) The IRB or organizational official shall communicate with the researcher monitor(s) to confirm their duties, authorities, and responsibilities.
5. The IRB reviews the information regarding the monitor and determines whether the individual designated meets the DoD requirements for educational and professional expertise (see *Definitions* above).

Research Involving International Citizen Populations

1. In the IRB application, the PI provides the necessary information, as appropriate, on the subject populations, the cultural context, and the languages understood by the human subjects. The PI is responsible for identifying local laws, regulations, customs and practices and following them when designing and implementing the research.
2. The PI is responsible for determining whether the sponsoring DoD Component requires an additional ethics review by the host country or a local DoD IRB with host country representation. If applicable, the PI submits to the IRB documentation of permission to conduct research in that country by certification or local ethics review.
3. To ensure the IRB has appropriate knowledge of the local context, the IRB uses an ad hoc or cultural consultant in accord with its standard operating procedures outlined in the Initial Review SOP.
4. Additional safeguards may not be applicable to minimal risk social-behavioral research. The PI and/or IRB staff consults with the sponsoring DoD component, as appropriate.

Research Involving U.S. Military Personnel as Research Participants

1. In cases where the research involves U.S. military personnel as subjects, the PI submits with the IRB application a plan for research subject recruitment that incorporates additional safeguards to minimize undue influence from individuals within a potential subject's chain of command. The PI consults the sponsoring DoD Component, as necessary, for assistance.
2. For research involving greater than minimal risk to subjects *and* involving military personnel, the PI includes procedures in the subject recruitment plan to ensure that officers cannot influence the decision of their subordinates to participate in the research.
3. The PI includes, in the IRB application, procedures in the subject recruitment plan to ensure that officers and senior or other non-commissioned officers cannot be present at the time of recruitment or consent of their subordinates.
4. The PI provides a separate opportunity or recruitment session for officers and senior non-commissioned officers to participate as research subjects.
5. For studies in which subject recruitment involves a percentage of a unit, the PI ensures an independent ombudsman shall be present during the recruitment process to monitor the voluntary nature of participation and that information provided is adequate and accurate.

Department of Defense/IRB Coordination

Page 7 of 12

6. Unless on leave status during research participation, military personnel may not receive compensation for their participation. The IRB reviews the proposed subject compensation to ensure that the PI does not violate DoD policies limiting dual compensation for U.S. military personnel:
- a. Prohibit an individual from receiving pay of compensation for research during duty hours.
 - b. May be compensated for research if the participant is involved in the research when not on duty.
 - c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
 - d. 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.
 - e. An individual may not receive pay from more than one position for more than 40 hours of work in one calendar week.
 - f. Limits address temporary, part-time, and intermittent appointments.
7. UMC does not apply DoD policies when U.S. military personnel incidentally participate as subjects in a study that is not DoD-sponsored or supported and U.S. military personnel are not the intended target population.

Consent Process

1. If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual participant.
2. The determination that research is intended to be beneficial to the individual experimental subject must be made by the IRB.

Waiver of Consent and Exception from Informed Consent in Emergency Medicine

1. If a research subject meets the definition of "experimental subject," DoD regulations prohibit a waiver of consent unless the PI obtains a waiver from the Secretary of Defense. The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all the following are met:
 - a. The research is necessary to advance the development of a medical product for the Military Services.
 - b. The research might directly benefit the individual experimental subject.
 - c. The research is conducted in compliance with all other applicable laws and regulations.
2. The IRB makes the determination as to whether the research subject meets the definition of "experimental subject." The IRB shall not approve a waiver of consent if the research subject meets the definition of "experimental subject" unless the Secretary of

Department of Defense/IRB Coordination

Page 8 of 12

Defense has issued a waiver. The IRB may waive the consent process if the research does not meet the definition of “experimental subject.”

3. DoD regulations prohibit an exception from informed consent in emergency medicine research unless the PI obtains a waiver from the Secretary of Defense.
4. The IRB shall not approve an exception from informed consent in emergency medicine research unless the PI has obtained a waiver from the Secretary of Defense.
5. For classified research, waivers of consent are prohibited.

Multi-Site or Collaborative Research Requirements

1. A PI developing a proposal for DoD funding or other support that involves other collaborating institutions consults the sponsoring DoD Component and IRB staff early in the proposal development process to identify additional requirements for multi-site research.
2. OSPA staff are responsible for negotiating formal agreements with collaborating institutions (see Office of Sponsored Projects Administration/IRB SOP). OSPA staff, in conjunction with the PI, ensure that the formal research agreement between participating institutions includes a statement of work and specifies the roles and responsibilities of each party.
3. For collaborative research involving UMC and DoD researchers, the UMC may choose to rely upon the DoD IRB for review and oversight following the standard operating procedures outlined in the Off-Site Research SOP. For collaborative research involving UMC and non DoD institutions, UMC follows standard operating procedures outlined in the Off-Site SOP. UMC and the collaborating institution sign an IRB authorization agreement which includes a statement of work specifying the roles and responsibilities of the relied upon IRB.
4. In order to ensure consistent protection of subjects under DoD requirements, a PI conducting DoD-sponsored multi-site research submits information to the IRB on the FWA(s) held by collaborating institutions, including the existence of any DoD Addendum or other direct DoD assurance.
5. The PI provides the UMC IRB additional information to ensure ongoing communication among participating IRBs and sites, as indicated in the Off-Site Research SOP.

Department of Defense/IRB Coordination

Page 9 of 12

Provisions for Research-related Injury

1. 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 stricter requirements than the Common Rule or University of Missouri rules, the PI, with assistance from IRB staff, must obtain prior permission from the Institutional Official or designee.
2. The PI includes documentation of the Institutional Official approval of the stricter requirements in the IRB application. The PI includes the appropriate provisions in the informed consent form. The IRB determines the disclosure includes the provisions for research-related injury and follows the requirements of the DoD component.

Prohibition on Involvement of Prisoners of War in Research

1. The definition of "prisoner of war" may vary by DoD Component. The IRB applies the definition in this SOP or the definition for the DoD Component granting the DoD Addendum, as applicable. The PI is responsible for providing the IRB with the applicable definition of "prisoner of war."
2. Under no circumstances shall the IRB approve research involving prisoners of war, as defined by the specific DoD Component granting the DoD Addendum.

Additional DoD Review Required Prior to Initiation of Study

1. After the IRB completes its review and issues approval, the PI submits documentation of IRB approval, the risk level, and the expiration date of the research to the DoD Component sponsoring or supporting the study.
2. The DoD may also request additional documentation to verify compliance with federal and DoD policies, including minutes related to the research. As appropriate, IRB staff provide the PI any additional information pertinent to IRB review, which may not be under a PI's purview. The PI sends requested information to the DoD.
3. The PI may not initiate the study until the human research protection officer (HRPO) within the sponsoring DoD Component reviews and approves the IRB approval and other submitted documentation.
4. If the study is for DoD-sponsored survey research or survey research within the DoD that involves DoD personnel, including military personnel, the PI, with assistance from IRB staff, identifies any requirements for an additional level of DoD review of the study. Surveys typically require DoD Survey Review and approval. The PI submits surveys and all required documentation relevant to survey research review to the requesting DoD Component.

Department of Defense/IRB Coordination

Page 10 of 12

5. The PI notifies OSPA and IRB staff upon receipt of relevant HRPO authorization and/or DoD Survey Review approval, as appropriate. OSPA staff establishes the account only after receiving certification of final human subjects and survey review and approval from the HRPO or relevant DoD designee.

Scientific Review for Substantive Amendments of Approved Protocols: Prior Scientific Review Required

1. DOD requires that all substantive amendments to approved DoD research involving human subjects receive scientific review prior to IRB review.
2. For substantive amendments to the study protocol, the Department Chair or designee conducts a scientific review of the amended protocol.
3. When the PI submits a modification review application, he/she submits a cover memo from the Department Chair. The Department Chair's or designee's signature on the memo attests to this new scientific review and approval of the amended protocol.

Research involving Pregnant Women, Prisoners, and Children

1. Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C, and D.
2. For purposes of applying subpart B, the phrase "biomedical knowledge" shall be replaced with "generalizable knowledge".
3. The applicability of subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.
4. Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
5. Research involving prisoners cannot be reviewed by the expedited procedure.
6. When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.
7. In addition to allowable categories of research on prisoners in subpart C, epidemiological research is allowable when:
 - a. The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
 - b. The research presents no more than minimal risk.
 - c. The research presents no more than an inconvenience to the participant.
8. 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

Department of Defense/IRB Coordination

Page 11 of 12

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 this 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 re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy.

- a. 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-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 conduct 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. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants.
 - i. Research involving a detainee as a human participant is prohibited.
 - ii. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military in the same location for the same condition.
9. Research involving children cannot be exempt.

Recordkeeping

1. IRB staff secure and maintain IRB records for DoD-sponsored research in accord with the provisions of the IRB Recordkeeping SOP. In addition, the PI determines, in conjunction with IRB, whether the DoD Component requires submission of IRB records to the DoD for archiving. The PI submits the relevant IRB records to the DoD, as appropriate with assistance from ORI staff.
2. Records maintained that document compliance or non-compliance with DoD requirements shall 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.

Department of Defense/IRB Coordination

Page **12** of **12**

REFERENCES

Department of Defense Directive, DoD 3216.02, March 25, 2002, Certified Current as of April 24, 2007

10 United States Code 980

SECNA VINST 3900.39D

24 United States Code 30

45 CFR 46, Subparts B, C, and D (f)

[Return to Table of Contents](#)