Department of Defense/IRB Coordination

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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 may, however, be augmented with a DoD Addendum 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.

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.
3.0 Policy/Procedure

**PROCEDURES**

*Department of Defense Addendum to the Existing FWA*

1. After a PI submits an application to a DoD component, OSPA may receive notice from the DoD that the sponsored research agreement for a pending award includes a DoD Addendum to the existing FWA. OSPA staff notify the PI and the IRB of the DoD request.

2. The Director of Human Research Protections or designee reviews the requirements of the DoD Addendum and designates the IRB to review and oversee DoD-sponsored research.

3. The Institutional Official, the appropriate IRB Chair, and the Director Human Research Protections review and sign the DoD Addendum.

4. Once a DoD Addendum is in place, it 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.

*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.

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 complete all initial and continuing mandatory education requirements for human subjects protections in accordance with UMC policy (see Initial Review SOP).

2. The PI, with assistance from IRB staff, is responsible for identifying specific educational or certification requirements of the sponsoring DoD Component and conveying those requirements to the IRB. The PI consults the DoD Component, as appropriate, to identify education requirements.

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**

1. For DoD-sponsored research involving greater than minimal risk to subjects, the DOD requires appointment of an independent research monitor. The research monitor has the authority to:
   - Stop a research study in progress;
   - Remove individuals from the study;
Take any steps to protect the safety and well-being of subjects until the IRB can assess the research monitor’s report.

2. 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. The PI attaches to the IRB application a copy of the monitor’s curriculum vitae and a letter from the monitor accepting the role.

3. The PI conveys to the monitor relevant DoD-specific orientation/education requirements of the role (see also Department of Defense Ethics Education above.)

4. 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). The IRB also ensures that the research monitor is independent of the research team.

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.

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:
   - An individual may not receive pay from more than one position for more than 40 hours of work in one calendar week.
   - 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.

**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.

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 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.
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.

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, which the IRB reviews and approves using standard operating procedures.
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.

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.

**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.

**REFERENCES**

10 United States Code 980
SECONC VINST 3900.39D
24 United States Code 30
45 CFR 46, Subparts B, C, and D (f)