OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #514.0 Revision 0	**TITLE: Research Supported by the Department of Defense**	Effective Date: 7/1/2018
Approved By: OIRB Director	Signature	Date 7/1/2018
Approved By: IRB Chair	Signature	Date 7/1/2018

PURPOSE

To describe requirements to conduct human research supported by the U.S. Department of Defense (DoD)

REVISIONS FROM PREVIOUS VERSION

None

POLICY

Human research supported by the DoD is subject to the Common Rule (32 CFR 219, 45 CFR 46). However, because of the DoD culture, organizational structure, and population, DoD Directive 3216.02 lays out additional requirements that also apply. These requirements are designed to address risks unique to DoD personnel that differ from civilians both in the conduct of research and in participation in research (e.g., deployment, personal conduct standards, and duty to report certain personnel actions). The procedures outlined in this SOP ensure that UNM research supported by the DoD complies with all DoD regulations governing human research.

UNM's existing Federalwide Assurance (FWA) meets the DoD requirement that the institution hold a federal assurance. The existing FWA may be augmented with a DoD Addendum to inform institutions of additional DoD requirements.

The principal investigator (PI) 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 review of the research, determinations that an activity is not human research, any exemption determinations, or documentation of continuing approval.

The DoD applies the provisions in 45 CFR 46, Subparts B, C, and D with modifications for the protection of vulnerable classes of research participants. Additional safeguards apply when the study involves DoD personnel (both military and civilian) or international participants. UNM does not apply DoD policies when U.S. military DoD personnel incidentally participate as participants in a study that is not DoD-sponsored or supported **and** DoD personnel are not the intended target population. Under no circumstances shall the IRB approve research involving *detainees* as defined below. UNM IRB does not review research involving the testing or use of chemical or biological agents.

Research involving greater than minimal risk [as defined in 32 CFR 219.102(i), reference (c)] requires appointment of an independent *research monitor*. The subset of research involving *Human Beings as Experimental Subjects* includes limitations on the waiver of informed consent.

DEFINITIONS

A *DoD Addendum* to an existing FWA is one of several methods that can be used to inform institutions (Institutional Officials and IRB chairs) of DoD research requirements that differ from the OHRP-approved FWA. The DoD Addendum may include designation of the relied-upon IRB(s) and/or an outline of requirements specific to a given DoD Component. The DoD Addendum is effective as long as the FWA is in force.

DoD Components refers collectively to the organizational entities within the DoD that are subject to the DoD Directive 3216.02. These entities include the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD.

DoD Personnel includes DoD civilian employees and members of the military services, unit officers, and noncommissioned officers (NCOs).

Detainee is defined as any person captured, detained, held or otherwise under the control of DoD personnel (military, civilian, or contractor employee). It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power.

Research Involving a Human Being as an Experimental Subject is a subset of human research and is defined as an activity, for research purposes, where 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)]. This definition does not include activities that are not considered research involving human subjects, activities that meet exemption criteria, and research involving the collection or study of existing data, documents, records, or specimens from living individuals. Examples include, but are not limited to, a physical procedure, a drug, a manipulation of the participant or their environment, or the withholding of an intervention that would have been undertaken if not for the research purpose.

Research Monitor refers to an individual designated to oversee a specific protocol that involves more than minimal risk, especially issues of individual research participant management and safety. The research monitor functions independently of the research team and shall possess expertise consistent with the nature of risk(s) identified within the research protocol, in order to protect the safety and well-being of participants.

Support of a study generally means the provision of at least a portion of the funding, personnel, facilities, and all other resources. Under this definition, studies that may be wholly funded internally or by a non-DoD component, such as an agency within the Department of Health and Human Services, but focus, for example, on a health concern prevalent in military populations may still fall under DoD purview.

PROCEDURE

DoD Addendum

1. After a PI submits an application to a DoD component, OSP may receive notice from the DoD that a DoD Addendum to the existing FWA may facilitate the sponsored research agreement for a pending award. OSP staff notify the PI and the OIRB of the DoD request.
2. The Institutional Official (VPR), the IRB Chair, and the OIRB Director review and sign the DoD Addendum.
3. Once a DoD Addendum is in place, it covers all UNM DoD-sponsored research for that Component; however, various DoD Components may use other processes or have additional requirements. The PI, with assistance from the OIRB, is responsible for identifying additional requirements and conveying those requirements to the IRB, as appropriate.

Exempt Human Research

1. When human subject research meets the criteria for exemption at 45 CFR 46.101(b), the PI follows standard procedures in accord with the Exempt Review SOP. The PI sends a copy of the IRB Exemption approval letter to the DoD for review and concurrence. The IRB does not use exempt procedures to review DoD research involving children.

Expedited Human Research

1. The IRB uses expedited review procedures to review minimal risk, non-exempt human research using materials (e.g., data, documents, records, or specimens) that were previously collected for any purpose, provided the materials were not collected for the currently proposed research. The IRB does not use expedited procedures to review DoD classified research or DoD research involving prisoners.

Submission of DoD Supported Research to the IRB

1. DoD requires a scientific review of the protocol. The PI is responsible for obtaining a comprehensive scientific review either from his/her Department Chair or designee prior to submission of the application to the IRB or through the grant peer-review process in accord with SOP 203 Review of Scientific Validity and Merit.
2. The PI or designee completes the IRB protocol, identifies the research as supported by a DoD component (as defined in DoD Directive 3216.02) and submits it to the OIRB.
3. The PI is responsible for ensuring the appropriate DoD-relevant items are included in the IRB protocol. The PI should also indicate in the protocol whether DoD personnel are participants.
4. OIRB staff advise the PI and the IRB of DoD-specific requirements as outlined in SOP and the DoD Reviewer Checklist. The PI is responsible for communicating with the DoD to identify DoD component requirements specified in the grant application guidelines and advising the OIRB and IRB of the requirements.
5. The PI and project team are responsible for completing processes specified in the DoD Addendum or DoD guidelines and submitting documentation, as appropriate, to the OIRB as an attachment to the IRB submission.
6. In addition to the standard mandatory education requirements under UNM IRB policy, the PI 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.

Research Monitor: Required for Greater than Minimal Risk Studies

1. For DoD-sponsored research involving greater than minimal risk to participants, the DoD requires appointment of one or more independent research monitors. The IRB may require a research monitor for a portion of the research or studies involving no more than minimal risk if appropriate. The research monitor has the authority to:
    - Stop a research study in progress;
    - Observe recruitment when conducted in a group setting;
    - Remove individuals from the study; and
    - Take any steps to protect the safety and well-being of participants until the IRB can assess the research monitor's report.
2. The PI identifies candidates for the position of research monitor, taking into account the nature and disciplinary focus of the study and the likely type of expertise required. The PI attaches to the IRB submission curriculum vitas for the proposed monitors and a written summary of the monitors' duties, authorities, and responsibilities.
3. As part of its review, the IRB considers the information regarding the proposed monitor(s) including his/her educational and professional expertise as required by the DoD to provide oversight (see *Definitions* above).
4. The IRB approves the research monitor(s) by name and approves a summary of the monitor's duties, authorities, and responsibilities. The PI then provides the IRB with a letter from the monitor accepting the role and associated responsibilities and conveys to the monitor relevant DoD-specific orientation/education requirements of the role.
5. The research monitor may perform oversight functions and may discuss the research protocol with the researchers, interview study participants, and consult with others outside of the study about the research. The research monitor promptly reports observations or findings to the OIRB.

Research Involving U.S. DoD Personnel as Research Participants

1. For research involving clinical investigations, the PI includes women and minority military personnel, unless the DoD component has waived this requirement.
2. In conducting the review, the IRB takes into consideration the unique risks involved in enrolling DoD personnel as research participants. If the IRB does not have the relevant expertise, the IRB obtains consultation from an ad hoc expert with working knowledge of the risks or from the DoD component.
3. In cases where the research involves U.S. DoD personnel as participants, the PI submits a participant recruitment plan to the IRB that incorporates additional safeguards to minimize undue influence from individuals within a potential participant's chain of command. The PI consults the sponsoring DoD Component, as necessary, for assistance.
4. For research involving greater than minimal risk to participants *and* involving DoD personnel, the PI includes procedures in the recruitment plan to ensure that officers cannot influence the decision of their subordinates to participate in the research.
5. The PI includes, in the IRB protocol, procedures in the recruitment plan to ensure that superiors in the chain of command, officers, and senior or other NCOs cannot be present at the time of recruitment or consent of their subordinates.
6. The PI provides a separate opportunity or recruitment session for supervisors, officers, and senior NCOs to participate in the research.

7. For greater than minimal risk studies involving military service members in which recruitment occurs in a group setting, the PI ensures an independent research monitor (or ombudsman) is present during the recruitment and informed consent process to monitor the voluntary nature of participation and ensure that information provided is adequate and accurate.
8. For greater than minimal risk studies involving DoD civilian employees in which recruitment occurs in a group setting, the IRB may at its discretion, require an independent research monitor to be in attendance based on the participant population, consent process and recruitment strategy.

Compensation for Participation in Research

1. The IRB reviews the proposed participant compensation plan to ensure that the PI is aware of DoD policies and limitations depending on whether or not participation occurs during on-duty or off-duty status and whether funds used to compensate participants come from a Federal source as follows:
   A. DoD personnel (active duty and civilian):
      - On Duty: compensation limited to blood draws
        - May participate in research during work or duty hours with supervisor approval and no compensation other than $50 per blood draw
        - Compensation can be from Federal or non-Federal source
      - Off Duty:
        - No restrictions as long as the source of compensation is not Federal dollars, but compensation for up to $50 per blood draw can be a from a Federal source

   B. Non DoD personnel:
      - No restrictions and compensation can be from a Federal or non-Federal source.

Waiver of Informed Consent

1. If the research is minimal risk, the IRB may use criteria in (45 CFR 46.116 or 32 CFR 219.116) to approve a waiver of some elements of informed consent.
2. If the research meets the definition of "research involving a human beings as experimental subjects" (as defined in DoD Directive 3216.02), the PI obtains consent from the participant or the participant's legal authorized representative (LAR).
3. The IRB makes the determination as to whether the research meets the definition of "research involving human beings as experimental subjects." The IRB shall not approve a waiver of consent if the research includes participants meeting the definition of "research involving a human being as an experimental subject" unless the DoD has issued a waiver.
4. If consent will potentially be obtained from the participant's LAR the IRB ensures that the research is intended to be beneficial to the experimental participants.

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 OIRB staff early in the proposal development process to identify additional requirements for multi-site research.
2. OSP staff are responsible for negotiating formal agreements with collaborating institutions. OSP 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 UNM and DoD researchers, UNM may choose to rely upon the DoD IRB for review and oversight following procedures outlined in SOP 207 IRB Reliance Process. UNM and the collaborating institution sign an IRB Authorization Agreement (IAA) which specifies the roles and responsibilities of the relying institution and the IRB of record.
4. The PI provides the UNM IRB additional information to ensure ongoing communication among participating IRBs and sites, as indicated in SOP 508 Research at External Sites.

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 of initial and ongoing to verify compliance with federal and DoD policies, including minutes related to the research. As appropriate, OIRB staff will 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, the PI 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 OSP and OIRB staff upon receipt of relevant HRPO authorization and/or DoD Survey Review approval, as appropriate. OSP staff release the award only after receiving certification of final human subjects and survey review and approval from the HRPO or relevant DoD designee.

Reporting and Recordkeeping

1. The PI promptly (within 30 days) notifies the DoD HRPO of:
    - IRB approval of significant changes to the research protocol;
    - results of IRB continuing review;
    - participant complaints;
    - unanticipated problems involving risks to participants or others;
    - instances of serious or continuing noncompliance;
    - suspension or termination of IRB approval;
    - change in reviewing IRB; and
    - any Federal department or agency or national organization for cause investigation involving a DoD-supported human research protocol.
2. OIRB staff will make records accessible for inspection by authorized representatives of the DoD and/or supporting DoD Component.

REFERENCES

DoDD 3216.02
DoDD 2310.01E
32 CFR 219