1. POLICY

Research supported by the Department of Defense (DoD) and involving a human being as an experimental participant, as defined in SOP IV, Glossary, is subject to the Federal Policy for the protection of human participants in research, the Common Rule in Subpart A of 45 CFR 46 under 32 CFR 219. The University shall apply additional requirements outlined in DoD Directive 3216.02 when human research is conducted or supported by a DoD component (an organizational entity within the DoD).

The DoD applies the provisions in 45 CFR Part 46, Subparts B, C, and D, for the protection of vulnerable classes of participants with the following specifications:

- For purposes of applying Subpart B, the phrase “biomedical knowledge” is replaced with ‘generalizable knowledge.”
- The applicability of Subpart B is limited to research involving pregnant women as participants 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 participants.
- Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

Non-exempt classified research must be conducted following the requirement of Department of Defense Instruction 3216.02. 13. Classified research involving human participants cannot be approved by the VA IRB or performed at a VA facility, including space leased to and used by the VA.

The University’s Federalwide Assurance (FWA) with the Department of Health and Human Services (DHHS), Office of Human Research Protection (OHRP) meets the DoD requirement that the University maintain a federal assurance of compliance. The University shall complete a DoD addendum to its FWA when human participant research is conducted or funded by the DoD. The DoD addendum outlines the unique DoD component requirements that are not specifically included in the FWA.

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 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).

Specific Policies

1.1 Multi-Site Research
When conducting multi-site research, a formal agreement between institutions is required and must specify the roles and responsibilities of each party.

1.2 Survey Research

Survey research involving DoD personnel, including U.S. military personnel, typically requires DoD approval. The IRB must approve the research project prior to DoD approval.

1.3 Department of Defense Addendum

The Senior Vice President and Provosts or designee for each campus have signatory authority for the DoD addendum to the University’s FWA when human participant research is conducted or funded by the DoD.

1.4 Education

For research sponsored by the DoD, initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human participant research.

In accordance with SOP 102B: Key Study Personnel Education, all KSP involved in research must complete initial and continuing IRB education requirements regarding human participant research protection issues.

There may be specific DoD educational requirements or certification required of KSP involved in DoD-sponsored research. These requirements will be dictated by the specific sponsoring DoD component involved. The DoD component may evaluate the HRPP education program to ensure KSP are qualified to perform the research, based on the complexity and risk of the research.

DoD education requirements pertain to IRB staff, IRB Chairs and Vice-Chairs, and IRB members. The IRB will identify the required education for the sponsoring DoD component involved and conduct education sessions appropriate for these individuals.

1.5 Records

DoD-sponsored research may require submitting records to the DoD for archiving. The investigator shall submit the relevant IRB records to the DoD component sponsoring or supporting the research. As appropriate, the HRPP Director or designee shall provide additional information pertinent to IRB review to the DoD.

1.6 Research Monitor

Appointment of a research monitor is required for research projects involving greater than minimal risk, although the IRB may also require appointment of a research monitor for a portion of the project or for studies involving no more than minimal risk. There may be more than one required if additional skills or experience are needed.

- The independent research monitor shall be appointed by name. The research monitor may be the ombudsman or a member of a data and safety monitoring board.
- The research monitor has the authority to stop a research project in progress, remove individuals from the research project, and take any steps to protect
the safety and well being of participants until the IRB can make an assessment.

1.7 Research Involving Prisoners

1.7.1 Research with prisoners of war (POW) is prohibited for DoD-sponsored research. See SOP IV, Glossary, for the definition of POW.

1.7.2 Research involving prisoners cannot be reviewed by expedited review procedures.

1.7.3 In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:
   o The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
   o The research presents no more than minimal risk.
   o The research presents no more than an inconvenience to the participant.

1.7.4 When 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 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 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 participant 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 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.

1.7.5 Research involving a detainee as a human participants is prohibited. 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.

1.8 Research Involving International Populations

For DoD-sponsored research involving international populations, the following additional safeguards are required:

- The organization or investigator has permission to conduct research in that country by certification or local ethics review.
- The investigator follows all applicable local laws, regulations, customs, and practices.

Additional safeguards may not be applicable to social-behavioral research involving no more than minimal risk.

1.9 Research Involving U.S. Military Personnel

For DoD-sponsored research involving U.S. military personnel, the IRB shall require the investigator to provide a plan for recruitment that incorporates additional protections.

1.9.1 The following additional protections for military research participants shall be applied to minimize undue influence:

- Officers shall not influence the decision of their subordinates to participate in the research.
- Officers and senior non-commissioned officers shall not be present at the time of recruitment into the research.
- Officers and senior non-commissioned officers must have a separate opportunity to participate in the research.
- When recruitment involves a percentage of a unit, an independent ombudsman shall be present during the recruitment.

1.9.2 The limitations on dual compensation are as follows:

- Prohibit an individual from receiving pay of compensation for research during duty hours.
- An individual may be compensated for research if the participant is involved in the research when not on duty.
- Federal employees while on duty and nonfederal persons may be compensated for blood draws for research up to $50 for each blood draw.
- Non-federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

1.10 Provisions for Research-Related Injuries

For DoD-sponsored research, DoD components may have stricter requirements than the Common Rule requirements for research-related injuries. The IRB shall apply the stricter requirements for research-related injuries as outlined by the DoD component conducting or supporting the research.
1.11 Consent Requirements

When following Department of Defense (DoD) requirements:

1. If consent is to be obtained from the experimental participants’ 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 participant must be made by an IRB.

1.12 Waiver of Consent Requirements

If the research participant meets the definition of “Experimental Subject,” waiver of consent is prohibited unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) under the following conditions:

- The research is necessary to advance the development of a medical product for the Military Services.
- The research may directly benefit the individual experimental subject.
- The research is conducted in compliance with all other applicable laws and regulations.

If the research participant does not meet the definition of Experimental Subject, the IRB may waive consent.

For classified research, waivers of consent are prohibited.

2. Scope

This SOP applies to all research involving human participants conducted or supported by the DoD.

3. Responsibility

3.1 The investigator is responsible for the initial submission that must include the supplementary DoD research project information and the contact information for the DoD liaison. The DoD liaison is responsible for communicating to the IRB information about specific requirements of the DoD component and whether a DoD addendum will be required.

3.2 The HRPP Director or designee shall review the requirements of the DoD addendum when human research is conducted or supported by a DoD component. The HRPP Director is responsible for providing the DoD addendum to the Senior Vice President and Provost or designee for review and signature.

3.3 The Senior Vice President and Provost or designee shall review and sign the DoD addendum when human participants research is conducted or funded by the DoD.

3.4 The HRPP Education Coordinator is responsible for identifying the required education for the sponsoring DoD component involved and for conducting education sessions appropriate for KSP, IRB staff, IRB Chairs and Vice-Chairs, and IRB members.

3.5 Department of Defense (DoD) Reporting Requirements

For DoD supported research, the following must be promptly reported (no more than within 30 days) reported to the DoD human research protection officer by the investigator:
3.5.1 IRB approval of significant changes to the research protocol.
3.5.2 The results of the IRB continuing review.
3.5.3 A change of the reviewing IRB.
3.5.4 Notification by any Federal department, agency or national organization that any part of an HRPP is under investigation for cause involving a DoD-supported research project.
3.5.5 Any determinations of serious or continuing non-compliance of DoD supported research.
3.5.6 Any suspension or termination of DoD-supported research.

4. Applicable Regulations and Guidelines

Department of Defense Directive, Number 3216.02, March 25, 2002, Certified Current as of April 24, 2007
Office of the Under Secretary of Defense (Personnel and Readiness) and Department of Defense Requirements, Version 22, March 2007
Department of the Navy, SECNAVINST 3900.39D, 6 November 2006
Army Regulation 70-25, 25 January 1990
10 USC 980
32 CFR 19
45 CFR 46, Subpart A
45 CFR 46, Subparts B, C, and D

5. References to Other Applicable SOPS

SOP IV: Glossary
SOP 102B: Key Study Personnel Education
SOP 304: Documentation, Document, and Data Management

6. Attachments

SOP 203-K, Reviewer Checklist

7. Process Overview

At the time of submission to the IRB, the investigator shall identify on the IRB submission that the research is funded by the specific DoD component and provide contact information for the DoD liaison and supplementary DoD information concerning the research project.

7.1 Multi-Site Research

In order to ensure consistent protection of participants under DoD requirements, an investigator conducting DoD-sponsored multi-site research shall submit information to the IRB on the FWA(s) held by collaborating institutions, including the existence of any DoD addendum.

IRB staff shall be responsible for making sure that a formal agreement between collaborating institutions is completed that specifies the roles and responsibilities of each party.
7.2 Survey Research

Survey research projects conducted or supported by the DoD typically require DoD approval. The investigator, with assistance from IRB staff, shall identify any requirements for an additional level of DoD review of the research for DoD-sponsored survey research or survey research that involves DoD personnel, including U.S. military personnel.

The investigator shall submit surveys and all required documentation relevant to survey research review to the IRB for approval prior to submitting the survey to the DoD component for approval.

7.3 Department of Defense Addendum

After the investigator submits an research project to a DoD component, the University may receive notice from the DoD component that the sponsored research award includes a DoD addendum to the existing FWA.

The HRPP Director or designee shall review the requirements of the DoD addendum and shall provide the DoD addendum to the Senior Vice President and Provost or designee and the appropriate IRB Chair for review and signature. The HRPP Director shall also review and sign the DoD addendum.

7.4 Education

The HRPP Education Coordinator is responsible for identifying specific required education for the sponsoring DoD component involved. The HRPP Education Coordinator shall conduct the specific required education sessions appropriate for KSP, IRB staff, IRB Chairs and Vice-Chairs, and IRB members.

7.5 Records

7.5.1 IRB staff shall maintain IRB records for DoD-sponsored research in accordance with SOP 304, Documentation, Document, and Data Management. The IRB shall determine, in coordination with the investigator, whether the DoD component requires submission of IRB records to the DoD for archiving.

7.5.2 The investigator shall submit the relevant IRB records to the DoD component sponsoring or supporting the research, as appropriate.

7.5.3 The DoD may also request additional documentation to verify compliance with federal and DoD policies, including IRB meeting minutes related to the research. As appropriate, the HRPP Director or designee shall provide the additional information pertinent to IRB review to the DoD.

7.5.4 The investigator may not initiate the research until the human participants' research protection officer within the sponsoring DoD component reviews and approves the IRB approval and other submitted documentation and notifies the University of such approval.

7.5.5 Records maintained that document compliance or non-compliance 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.

7.6 Research Monitor

7.6.1 The IRB shall require investigators to appoint a research monitor for DoD-
sponsored research projects involving greater than minimal risk. The IRB
may require appointment of a research monitor for a portion of a DoD-
sponsored project or for projects involving no more than minimal risk if
appropriate. The monitor may perform oversight functions such as
observe recruitment, enrollment procedures, 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). The research monitor may
discuss the research protocol with researchers, interview human subjects,
and consult with others outside of the study. The monitor may also report
observations and findings to the IRB or a designated official.

7.6.2 The investigator shall be responsible to appoint the independent research
monitor and to provide the name of the research monitor to the IRB.

7.6.3 The IRB shall approve a summary of the research monitor’s duties,
authorities, and responsibilities. The IRB Chair or Institutional Official will
communicate with the research monitor to confirm these duties,
authorities, and responsibilities.

7.6.4 The investigator shall provide to the IRB reports from the research
monitor at intervals determined by the IRB.

7.6.5 The IRB shall review research monitor reports as provided and assess
the progress of the research project if any further action or changes are
necessary.

7.7 Prisoners of War in Research

The IRB shall review new research project submissions to determine the
proposed research project population involved. Research with POWs is
prohibited for DoD-sponsored research. The IRB shall not approve research with
prisoners of war. See SOP IV: Glossary, for the definition of POW.

7.8 Research Involving International Populations

The IRB shall apply the following safeguards if the proposed research project
involves international populations:

7.8.1 The IRB shall require the investigator to provide to the IRB the local
applicable laws, regulations, customs, and practices for the country where
the proposed research project will occur, along with an outline of how the
investigator will follow those laws, regulations, customs, and practices.

7.8.2 The IRB will require the investigator to provide to the IRB evidence of
permission to conduct research in that country by certification or local
ethics review.

Note: These additional safeguards may not be applicable to social-behavioral
research involving no more than minimal risk to participants as determined by the
IRB.
7.9 Research Involving U.S. Military Personnel

7.9.1 In order to minimize undue influence for DoD-sponsored research involving U.S. military personnel, the IRB shall require the investigator to apply the following additional protections:

- Officers shall not influence the decision of their subordinates to participate in the research.
- Officers and senior non-commissioned officers shall not be present at the time of recruitment into the research.
- Officers and senior non-commissioned officers must have a separate opportunity to participate in the research.
- When recruitment involves a percentage of a unit, an independent ombudsman shall be present during the recruitment.

7.9.2 The IRB shall require the investigator to apply the following limitations on dual compensation for DoD-sponsored research involving U.S. military personnel:

- An individual is prohibited from receiving pay from more than one position for more than 40 hours of work in one calendar week.
- The limitations on dual compensation include temporary, part-time, and intermittent appointments.

7.10 Provisions for Research-Related Injuries

The IRB staff, in coordination with the IRB Chair or IRB designee, shall review the DoD component requirements for research-related injury to determine if the requirements are stricter than the Common Rule requirements. The investigator shall include the stricter provisions in the informed consent documents.

7.11 Consent Requirements

The IRB makes the determination as to whether a research participant meets the definition of Experimental Subject per SOP IV, Glossary.

If a research participant meets the definition of Experimental Subject, DoD regulations prohibit a waiver of consent unless a waiver of consent is obtained from the Secretary of Defense. The IRB shall not approve a waiver of consent unless the IRB has received a waiver issued by the Secretary of Defense.

If the research participant does not meet the definition of Experimental Subject, the IRB may waive consent when appropriate.

The IRB reviewer must also make a determination that research is intended to be beneficial to the individual experimental participant. If consent is to be obtained from the experimental participants’ legal representative, the IRB review must determine that the research is intended to benefit the individual participant.
NEXT ESTABLISHED REVIEW DATE: AUGUST 2016