UNLV | Office of RESEARCH INTEGRITY HUMAN SUBJECTS

Guidance - Department of Defense Requirements

General Description

Research that is regulated by federal agencies often times have agency-specific requirements. This guidance is the assist researchers and the IRB in identifying additional regulatory considerations.

When it applies / context

This guidance may be used by members of the UNLV Human Research Protection Program (HRPP), Researchers and the IRB. Researchers should review this guidance when conducting research supported by the Department of Defense (DoD). The IRB should use this guidance to review for agency-specific requirements in research supported by the DoD.

Considerations & Best Practices

Definitions-As Defined in Department of Defense Instruction (DoDI) 3216.02, November 8, 2011

Minimal Risk

- 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. See DoDI 3216.02 for more specific details of applicability.
- 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).

Experimental Subject

- The definition of research involving a human being as an experimental subject is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experiment subject is a subset of research involving human subjects.
- If the research participant does not meet the definition of "experimental subject," the IRB may waive the consent process.
- If the research participant meets the definition of "experimental subject," a waiver of the consent process is prohibited unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering. The Assistant Secretary for Defense for Research and Engineering may waive the requirements for consent when all of the following are met:
    - 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.
- For classified research, waivers of consent are prohibited.

Education

For all personnel who conduct, review, approve, oversee, support, or manage human participants research, initial and continuing research ethics education is required. IRB or EC staff, chair, and members; and Researchers and Research Staff are responsible to become aware of the specific requirements contained in DoD regulations and requirements and educated themselves about these requirements when appropriate.

IRB Considerations

During the review, the IRB should consider the following when evaluating the appointment for a research monitor:

- Required for research involve greater than minimal risk, 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.
- The research monitor is appointed by name and must be independent of the team conducting the research.
- There may be more than one research monitor (e.g. if different skills or experience are needed).
- The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.
- The IRB or HRPP official must communicate with research monitors to confirm their duties, authorities, and responsibilities.
- The duties of the research monitor are determined on the basis of specific risks or concerns about the research.
    - May 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).
    - May discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.
    - Report observations and findings to the IRB or a designated official.
- The research monitor has the authority to:
    - Stop a research study in progress.
    - Remove individuals from study.
    - Take any steps to protect the safety and well- being of participants until the IRB can assess.

For non-exempt research, the IRB must consider the scientific merit of the research. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

The IRB must make a determination regarding the following, as appropriate:

- The disclosure for research-related injury follow the requirements of the DoD component
- If research is intended to be beneficial to the individual experimental subject
    - If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual participant.

Waivers

- For classified research, waivers of consent are prohibited.
- An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

Additional Safeguards for Participants

For research conducted with international populations,

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

When research involves U.S. military personnel, additional protections for military research participants to minimize undue influence include:

- Officers are not permitted to influence the decision of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.
- There are limitations on dual compensation, including:
    - 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 non- federal 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.

Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C. and D.

- For purposes of applying Subpart B,
    - The phrase "biomedical knowledge" must be 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.

- Research Involving Prisoners (Subpart C)
    - Research involving prisoners cannot be reviewed by the expedited procedure.
    - When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.
    - In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:
        - The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
        - The research presents no more than minimal risk.
        - The research presents no more than an inconvenience to the participant.
    - 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.

- Research involving a detainee as a human participants is prohibited. However, 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.
- Research involving prisoners of war is prohibited. The IRB is aware of the definition of "prisoner of war" for the DoD component granting the addendum.

- Research Involving Children (Subpart D),
  - The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Other Considerations

Non-exempt classified research must also be conducted following the requirements of Instruction 3216.02..

The following must be promptly (no longer than within 30 days) reported to the DoD human research protection officer:

- Any determinations of serious or continuing non- compliance of DoD-supported research
- Any unanticipated problems involving risks to participants or others for any DoD-supported research
- Any suspension or termination of DoD- supported research
- When significant changes to the research protocol are approved by the IRB.
- The results of the IRB continuing review.
- Change of reviewing IRB.
- When the organization is notified by any federal department, agency or national organization that any part of an HRPP is under investigation for cause involving a DoD- supported research protocol.

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.

Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB.

When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party.

Resources

Instruction 3216.02 p.13 http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

Instruction 3216.03 Department of Defense Instruction Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

AAHRPP Elements: I.1.A., I.1.E., I.1.F., I.3., I.5.D., II.2.D., II.2.E., II.2.F., II.2.G., II.2.H., II.3.A., II.3.B., II.3.C., II.3.F., II.3.G., II.4.A., II.4.B., II.4.C., II.5.A., II.5.B., III.1.E., III.1.F., III.2.D.