

415 Department of Defense Requirements

Standard Operating Procedure 415: Department of Defense Requirements

I. Scope

When human subjects research is sponsored or initiated by the Department of Defense (DoD) or any of its entities, the provisions in this Standard Operating Procedure apply. Investigators must ensure that their projects are designed to comply with the DoD's requirements related to human subjects research. The best way to ensure this is to obtain approval from a DoD IRB. Utah State University's IRB will engage in a Reliance Agreement to rely on a DoD IRB review for DoD-sponsored projects when feasible. Otherwise, the USU IRB will ensure compliance with these requirements during the review process. No DoD-sponsored work shall be approved unless these requirements are met. [DoD Instruction 3216.02.13](#) and its associated Enclosures govern non-exempt, classified work sponsored by the DoD, and investigators are encouraged to review this information prior to submission of a proposal to DoD agencies that includes human subjects research. Civilian investigators are strongly encouraged to seek collaboration with a military researcher who is familiar with service-specific requirements when seeking military participants to aid in ensuring that all DoD requirements are reflected in the design of the study.

II. Applicability & Initial Steps

1. Education regarding DoD Requirements

When the USU IRB is notified by Sponsored Programs that a proposal to the Department of Defense involves human research participants, the PI will be contacted about the additional ethical and regulatory review requirements that attach to DoD-supported human subjects research.

2. Experimental Subjects

In addition to the information contained in SOP 403 regarding defining "research" with "human subjects," the DoD further defines "research involving an experimental subject" as 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. Investigators should note that this is a broader standard than the general definitions provided by DHHS and represented in SOP 403.

3. DoD Component Review

Human subjects research funded by the DoD must first be reviewed by the DoD Component before it is reviewed by the USU IRB. This administrative review process ensures compliance with all applicable regulations and policies, including any applicable laws and requirements and cultural sensitivities of the local site (when the research is conducted in a country other than the United States). Evidence of completion of this review must be provided in Other Approvals and Documentation in the Quali Protocols submission. In rare cases, the USU IRB will conduct its review first, but will grant only preliminary approval (i.e. no research involving human participants may begin) until this administrative review process is complete.

4. Applicability of Subparts of the Common Rule

Research that involves pregnant women, prisoners, and children are subject to the Subparts of the Common Rule that apply to those populations. Below are some minor differences in their application to DoD projects:

a. Subpart B: Pregnant Women

This subpart applies to pregnant women **when the research is more than minimal risk and involves interventions or invasive procedures to the woman**. As a reminder, USU does not permit research to be conducted on fetuses or neonates.

For all parts of Subpart B referencing “biomedical knowledge,” when applying DoD standards, IRB members and researchers should instead substitute “generalizable knowledge.”

b. Subpart C: Prisoners

In addition to the categories of allowable research contained in Subpart C, when DoD standards apply, epidemiological research is **also** allowable when the research describes the prevalence or incidence of a disease by identifying all cases of studies potential risk factor association for a disease; when the research presents no more than minimal risk; and when the research presents no more than an inconvenience to the participant.

When preparing a submission for the IRB, if the research involves classified information and is reviewed by a non-DoD IRB, such as the USU IRB, the following classified aspects of the research are permitted to be disclosed to the IRB for review (and the information provided to the IRB may be limited to the list below):

- Information needed for IRB approval and oversight of the research;
- Information needed to inform the human participants during the informed consent process; and
- Information provided by human participants during the course of the research.

III. Additional Requirements to Gain Approval

The approval criteria contained in SOPs 404 through 406 apply to all DoD-sponsored research, unless a DoD requirement conflicts with those criteria. In addition to those, in order to gain approval for a protocol that describes DoD-sponsored human subjects research, the following items must be addressed and adhered to:

1. When following DoD requirements, the definition of minimal risk (specifically the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests”) shall not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants 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, constant pain, treatments).
2. When experimental subjects (defined in Section II, above) are involved in the research and informed consent will be obtained from their legally authorized representatives, the research must hold the prospect of direct benefit to the experimental subjects.
3. When experimental subjects (defined in Section II, above) are involved in the research, no waiver or alteration of informed consent will be sought in the submitted protocol, unless a waiver has already been obtained from the Assistant Secretary of Defense for Research and Engineering. The Assistant Secretary of Defense for Research and Engineering may grant a waiver when:
 - 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; and
 - c. The research is conducted in compliance with all other applicable laws and regulations, including the general waiver and alteration standards that apply and are outlined in the 500 Series of these SOPs.

When no experimental subjects are involved, the investigator may request a waiver or alteration under the standards outlined in Series 500 of these SOPs.

4. In research that involves military personnel, superiors of service members (e.g. unit officers, senior NCOs, and equivalent civilians) are not permitted to influence the decision of their subordinates, and the protocol should have

- a clear plan outlined for how this will be avoided. Additionally, superiors may not be present (in person or virtually, such as being copied on an email) when their subordinates are recruited into the study.
5. In research that involves military personnel, superiors of service members (e.g. unit officers, senior NCOs, and equivalent civilians) must have a separate opportunity to participate, if they meet the inclusion criteria.
 6. During recruitment of military personnel, if the recruitment plan involves a percentage of a unit, an independent ombudsman (as designed by the DoD) must be present, whether in person or virtually.
 7. Compensation must be structured in such a manner that does not permit military personnel from receiving dual pay (from the research and their regular duties) during duty hours. U.S. military personnel may only be compensated for research if the participant is involved with the research while not on duty.
 8. For research involving blood draws, federal on-duty employees and non-federal persons involved in DoD-sponsored research can be compensated up to \$50 for each blood draw. Other procedures that are compensated for non-federal individuals must be reasonable according to local IRB guidelines and the nature of the research.
 9. In DoD-sponsored research, there must be a statement in the informed consent document that the DoD or a DoD Component is funding the study, and that DoD representatives are authorized to review research records. Additionally, each DoD Component has individualized standards for disclosures about research-related injuries that must be included in the informed consent documentation.

IV. Prohibitions

The following bulleted items represent things that are prohibited to be present or take place in DoD-sponsored research at Utah State University:

1. Detainees or Prisoners of War are not permitted to be involved in the project. The Geneva Convention defines a Prisoner of War as a detained person who, while engaged in combat under orders of their government, is captured by the armed forces of the enemy.
2. Utah State University's IRB will not provide review for classified research. If research is classified, the PI should seek review from a DoD IRB, or from a non-DoD IRB equipped to provide a thorough review of classified research. In order to rely on another IRB's review, that IRB or Research Ethics Board must:
 - a. Have a current Federalwide Assurance;
 - b. Determine that the involvement of DoD personnel in the conduct of the research is secondary to that of the non-DoD institution;
 - c. Draft or provide an agreement defining the responsibilities and authorities of each participating organization in complying with all legal requirements; and
 - d. Provide the aforementioned agreement to the appropriate DoD Component for approval prior to engaging in the research

V. Responsibilities of the IRB or Institution

For Department of Defense sponsored research, the IRB or Institution must also ensure that it is communicating promptly and openly with the DoD or its reviewing Component. This includes:

1. Notifying the DoD or appropriate Component, via the appropriate Human Research Protections Officer, within 30 days, of:
 - a. Approval by the IRB of "significant changes" to the research protocol;
 - b. Results of any continuing review conducted by the IRB;
 - c. Any changes in the reviewing IRB; and
 - d. Any notifications that any part of the HRPP is under investigation for cause related to a DoD-supported research protocol.
2. Initiating a re-review of any DoD-supported project that did not initially involve prisoners but later comes to involve a prisoner (referred to here as a prisoner-participant). The IRB Chair must render an immediate determination regarding whether it is in the best interests of the prisoner-participant to remain enrolled in the study until the Convened IRB can review the matter. The re-review by the Convened IRB must be done promptly (i.e. no longer than 30 days from the date the IRB is notified) and the discussion should be led by the IRB Chair and the Prisoner Advocate. The re-review is specific to the individual participant, and does not mean that the protocol is changed

to permit the broad recruitment or entry of prisoners into the study. Specifically, the Convened IRB must render determinations regarding whether:

- a. It is in the best interests of the prisoner-participant(s) to continue with the study;
 - b. Notify the appropriate DoD Component Human Research Protections Officer of a change of status from a participant to a prisoner-participant;
 - c. The rights and wellbeing of the prisoner-participant are not in jeopardy due to their change in status;
 - d. The prisoner-participant can continue to consent to the research procedures;
 - e. The prisoner-participant can continue to meet the requirements of the study;
 - f. The terms of the prisoner-participant's confinement does not inhibit the ethical conduct of the research; and
 - g. That there are no other significant issues preventing the research from continuing as approved with the addition of the prisoner-participant, considering their changed circumstances.
3. Approval by the Institutional Official of a change in a research protocol (once that change has been approved by the IRB) that did not originally involve prisoners but later involves a prisoner-participant.
 4. The IRB must maintain records that document either compliance or noncompliance with DoD requirements. Those records shall be made available for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD Component.
 5. When surveys will be performed on DoD personnel, the IRB must be sure that all DoD Components where the survey will be levied have reviewed and approved those surveys before they are used with DoD participants.
 6. When collaborating with other organizations, including DoD institutions, on DoD sponsored research, ensure that the following requirements are in place in any Reliance scenarios:
 - a. That each participating organization has a current Federalwide Assurance;
 - b. Determine that the involvement of DoD personnel in the conduct of the research is secondary to that of the non-DoD institution;
 - c. Draft or provide an agreement defining the responsibilities and authorities of each participating organization in complying with all legal requirements; and
 - d. Provide the aforementioned agreement to the appropriate DoD Component for approval prior to engaging in the research.