

Checklist: Additional Requirements for Research Supported by the Department of Defense (updated May 30, 2021)

Note: The Department of Defense (DOD) IS a [signatory to the Revised Common Rule](#), which took effect January 21, 2019.

Research sponsored or funded by the U.S. Department of Defense (DOD) must be reviewed by the IRB under and additional set of regulations [32 CFR 219]. Researchers must meet additional DOD requirements prior to initiation of the research. The DOD follows the DHHS and FDA regulations on human subjects research but also applies [DOD Directive 3216.02](#), Protection of Human Subjects and Adherence to Ethical Standards in DOD Supported Research. This document serves as a checklist for additional requirements outlined in [DOD Directive 3216.02](#).

Limitations and Prohibitions

- EXPERIMENTAL SUBJECTS:** DOD defines “research involving human beings as experimental subjects” in [DOD Directive 3216.02](#). The limitations on use of humans as experimental subjects are outlined in the Directive.
- PRISONERS OF WAR:** Research with Prisoners of War (POW) is prohibited. POWs include any person captured, detained, held or otherwise under the control of the DOD personnel (military and civilian or contractor employee). Including; enemy prisoners, civilian internees, retained persons and lawful and unlawful combatants. Such persons do not include DOD personnel being held for law enforcement purposes.
- Research involving a detainee as a human participants is prohibited.
 - This prohibition does not apply to research involving investigational drugs and devises when the same products would be offered to US military personnel in the same location for the same condition.
 - 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.
- CIVILIAN RESEARCHERS** attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements

Informed Consent

- WAIVER OF CONSENT:** When the research meets the DOD definition of “Research Involving a Human Being as an Experimental Subject” or classified research, the IRB may not waive the consent process. The definition may be found in [DODD 3216.02](#), Enclosure 2. Definitions. Paragraph E2.1.3: “An activity, for research purposes, where there is an

intervention or interaction with a human subject for the primary purpose of obtaining the effect of the intervention or interaction (32 CFR 219.102(f)).”)

- A waiver of consent must be obtained from the Assistant Secretary of Defense. The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:
 - The research is necessarily to advance the development of a medical product for the Military Services.
 - The research might directly benefit the individual experimental subject.
 - The research is conducted in compliance with all other applicable laws and regulations.

- INJURY AND ADVERSE EVENTS: Explain to subjects any provisions for medical care for research-related injury. Report unanticipated problems, adverse events, research-related injury and suspensions or terminations of research.

- DODD limits exceptions from informed consent - If the research involves interventions or interactions with subjects the research must not involve a waiver of consent or parental permission unless a waiver is obtained from the Secretary of Defense.

- EMERGENCY MEDICINE RESEARCH: An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

Additional Requirements and Considerations

UCLA Researchers and the UCLA IRB share responsibility for ensuring that the following additional considerations required for DOD supported research are met prior to initiating human research activities.

- EDUCATION: In addition to completing the UCLA OHHRP education requirements, conduct initial and continuing research ethics education for personnel who are engaged in human subject research. This training must be completed by all study team members initially and on a continuing basis every three years.

- SCIENTIFIC MERIT: New research and substantive scientific amendments to approved research shall undergo scientific review and the review is considered by the IRB. In the absence of an external review or an established internal review mechanism, you should make arrangements with your chair or dean for an ad hoc scientific review.

- INTERNATIONAL RESEARCH: Safeguard for research conducted with international populations.

- VULNERABLE POPULATIONS: Protect pregnant women, prisoners and children according to DHHS Subparts B, C, and D. Ensure additional protections for military research subjects to minimize undue influence.
 - For purposes of applying Subpart B, the phrase “biomedical knowledge” shall 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 cannot be reviewed by the expedited procedure.
- **COGNITIVE IMPAIRMENT:** If research involves cognitively impaired adults, there is a direct benefit to the subject
 - **LEGALLY AUTHORIZED REPRESENTATIVE:** Comply with DOD limitations on research where consent by legally authorized representatives is proposed.
 - **SURVEY RESEARCH:** Follow DOD requirements for additional review for DOD-sponsored survey research or survey research within DOD. Research involving the administration of surveys to, or interviews of, DOD personnel (military or civilian) may require DOD approval of the surveys or interview questions. This involves research where DOD personnel and civilian personnel (working with the DOD) are asked to complete surveys; not when researchers funded by the DOD are conducting survey on non-DOD personnel. [DOD Instruction on Surveys of Military Personnel](#) (surveys across branches of the DOD) Survey requirements are different depending on the branch of the DOD.
 - **COMPLIANCE AND MISCONDUCT:** Address and report allegations of non-compliance with human research protections. Address and report allegations of research misconduct. Support oversight by the sponsoring DOD component.
 - **CONFLICT OF INTEREST:** Follow procedures for addressing financial and other conflicts of interest.
 - **COMPENSATION:** Researchers must comply with limitations on dual compensation for U.S. military personnel:
 - Prohibit an individual from receiving pay of compensation for research during duty hours
 - U.S. military personnel 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 participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research
 - **DRUGS, DEVICES AND BIOLOGICS:** Comply with all provisions for research with human subjects using investigational test articles (drugs, device and biologics).
 - **DOCUMENTATION IF EXEMPT:** Document determination by a designated Institutional Official (other than the investigators) whether research meets the criteria for exemption.
 - When research involves U.S. 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
 - May not be present at the time of recruitment
 - Have a separate opportunity to participate

- When recruitment involves a percentage of a unit, an independent ombudsman must be present

Materials for UCLA IRB Review

Researchers conducting DOD supported research must upload the following documents with their webIRB applications:

- EDUCATION: Documentation of DOD-required training for **all** study team members.
- SCIENTIFIC MERIT: Evidence of scientific review.

UCLA IRB/OHRPP Responsibilities

- DOCUMENTATION OF ACTIVITIES:
The DOD may require submission of UCLA IRB/OHRPP records to DOD for archiving.

References

OHRPP Guidance and Procedure: [Research Supported by the Department of Defense](#) includes links to DOD regulations and references

Change history:

2018/7/5: Removed specific OHRPP staff contact information, removed DoD FWA addendum as it is no longer required.

2019/5/9: Added reference to Revised Common Rule.

2020/7/24: Removed medical monitor for greater than minimal risk studies as it is no longer required, and updated links.

2021/05/05: Updated links.

2021/05/30: Added information re: limitations on dual compensation; research involving military personnel, and superiors of service members; information on waiver of consents; vulnerable populations will be reviewed according to HHS subpart, civilian researchers, and research on detainees.