UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: Research Supported by the Department of Defense (updated May 30, 2021)

Background

In 2006, the Department of Defense (DOD) enhanced its human subjects protection requirements, including the application of those requirements to extramural performers. The information in this guidance is for those members of the UCLA research community involved in human subjects research supported by or in collaboration with DOD.

Responsibility for upholding DOD requirements is shared between researchers and their teams, the University administration, and DOD. Each branch of the DOD may have their own specific requirements for reviewing research protocols that they support, and these requirements must be followed. For specific branch requirements see below or contact your program officer.

Scope - What Qualifies as DOD Research?

The UCLA IRB applies Department of Defense (DOD) and DON "regulations and policies for the protection of human research participants when conducting, reviewing, approving, overseeing, supporting or managing Department of the Navy supported research with human subjects." Department of Defense Directive 3216.02, E2.1.4 defines "support" as generally meaning "the provision of funding, personnel, facilities, and all other resources."

Human Subject Research involves the DOD when any of the following apply:

- The research is funded by a component of the DOD (e.g.; Navy, Army, Air Force)
- The research involves cooperation, collaboration, or other type of agreement with a component of DOD
- The research uses property, facilities, or assets of a component of DOD
- The subject population will intentionally include personnel (military or civilian) from a component of DOD

Important Note: DOD policies and requirements do not apply when DOD personnel incidentally participate as subjects in research that is not supported by DOD, and DOD personnel are not an intended population of the research.

UCLA IRB Review Process

Initial Review. The UCLA Office for the Human Research Protection Program (OHRPP) has incorporated DOD requirements into the IRB review process. When submitting a study that is conducted by or in collaboration with the DOD, researchers should complete the DOD-related branch of the webIRB application.

See the OHRPP Checklist for Additional Requirements for Department of Defense Supported Research for a list of key DOD requirements such as: education and training requirements for the PI; independent scientific review prior to IRB review; and protections for participants who are military personnel.

Risk Assessment. In accordance with DoD Instruction 3216.02 6.b., the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" shall 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).

Modifications. When submitting modifications to previously approved research (amendments) to the IRB, review your webIRB application to ensure that it still accurately reflects the research. If an amendment involves substantive changes (e.g., new procedures, a new subject population), then the IRB must receive documentation of scientific review and approval of the changes.

Continuing Review. When reviewing study materials in preparation for continuing review, review your webIRB application as well to ensure that it still accurately reflects the research. Submit an amendment application (and any additional documentation) if necessary. DOD requires that the IRB receive and maintain copies of publications, presentations or reports based on the research protocol. Please include such items (if any) when submitting an application for continuing review.

Study Closure. DOD requires that the IRB receive and maintain copies of publications, presentations or reports based on the research protocol. Please include such items (if any) when closing a study. You should also continue to submit such items after closure of the study via PAR application.

Post-Approval Responsibilities

Continuing Education. DOD human subjects education requirements may exceed UCLA requirements (e.g., requiring completion of annual continuing education.) **Contact your Program Officer to ensure compliance with DOD continuing education requirements.**

Reporting Responsibilities. You should be familiar with the following UCLA policies for reporting events to the UCLA OHRPP/IRB. The UCLA OHRPP/IRB may be required to notify DOD and the sponsor (if there is a non-DOD sponsor) about such reports and any actions taken regarding the reports.

- Guidance and Procedure: Post-Approval Reporting Requirements (PAR) for Investigators: Reporting of Unanticipated Problems, Including Adverse Events as well as Protocol Violations, Deviations and Incidents and the Reporting of Updated Study Safety Information

- Policy: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research

DOD must also be notified of any audits, investigations or inspections of DOD-supported research. You should always report such inspections to DOD. The UCLA OHRPP/IRB will report such inspections to DOD only when the OHRPP/IRB received notice of audits, investigations, or inspections via webIRB submission.

The following must be promptly (within 30 days) reported, by the Principal Investigator, to the DoD human research protection officer:

- Significant changes to the research protocol approved by the IRB
- Results of the continuing review
- Change of reviewing IRB

Regulations & References

US Department of Defense (DOD)

- The Common Rule - 32 CFR 219, Protection of Human Subjects
- Protection of Human Subjects and Adherence to Ethical Standards in DOD Supported Research, DOD Directive 3216.02
- Surveys of DOD Personnel, DOD Instruction 1100.13
- Guidance on Protecting Personally Identifiable Information (PII), DOD Memoranda
- Privacy Act Program, DOD Directive 5400.11.R

US Department of the Navy (DON)

- Human Research Protection Program, DON SecNav Instruction 3900.39D
- DON HRPP Documentation requirements
- Survey Policy, OPNav Instruction 5300.8C
- DON HRPP Education & Training Guidance
- Step by Step - Instructions on How to Access the DON Training Requirements
- Bureau of Medicine and Surgery (BUMED) HRPP website
- Office of Naval Research (ONR) HRPP website

US Department of the Army

- Use of Volunteers as Subjects of Research, US Army Regulation 70-25
- USMA HRPP website

US Air Force (USAF)

- Clinical Investigation and Human Use in Medical Research, USAF Directive 40-4
- Protection of Human Subjects in Biomedical and Behavioral Research, USAF Instruction 40-402

US Office of the Under Secretary of Defense (OUSD) Personnel Protection & Readiness (P&R)

- OUSD (P&R) HRPP website
- P&R HRPP Requirements
- DOD & OUSD (P&R) Specific and Unique Requirements

Change history:
8/9/2016: Clarification of interpretation of definition of minimal risk; weblink updated.

7/5/2018: Removed reference & link to DoN Addendum to FWA, edited education requirements, removed specific OHRPP staff contact information.
7/24/2020: Removed information on medical monitors and updated links.
5/13/2021: Updated links.
05/30/2021: Added information re: reporting to the DOD within 30 days.