ILLINOIS
Office for the Protection of Research Subjects

Research Guidance Document

DEPARTMENT OF DEFENSE RESEARCH

Definitions

This page provides guidance for researchers and IRBs about special requirements for conducting and reviewing human subjects research involving any component of the Department of Defense (DoD).

Additional Requirements for DoD research

IRB Application
In addition to the standard IRB application, a researcher is required to submit a completed "Department of Defense Supplement Form" found on the OPRS website as part of the IRB submission.

Approvals Required
No research activities may be conducted until all of the following have been met:

a. The IRB has reviewed and approved the research (or granted an exemption).
b. Sponsored Programs Administration (SPA) has provided any materials requested by the DOD funding agency.
c. SPA has been authorized by DoD to activate the award. Note that for DoD-related research that does not involve funding, the researcher must receive approval directly from the DoD contact prior to beginning any research activities.

Training
Training requirements may differ, specifically, as described by DoD, "all personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects must complete initial and ongoing research ethics and human subjects protections training appropriate to each individual's level of involvement, duties, and responsibilities." It is the PI's responsibility to ensure any specific training requirements that exceed the UIUC IRB human subject training requirements are met.

Scientific Merit Review
The Army and the Navy require independent scientific review and approval **prior to IRB review** of new applications and substantive modifications. This requirement does not apply to research involving other components of the DoD.

A scientific review conducted by a funding agency (including DoD) or by an established internal review mechanism in the researcher's school or department will satisfy this requirement. In the absence of such a review, an *ad hoc* scientific review may be provided by the researcher's chair or dean.

DoD refers researchers to the National Naval Medical Center scientific review template and to the Army's description of scientific review criteria in its Human Research Protections Office Policies and Procedures. These are essentially the same as the scientific review conducted by any federal funding agency.

Documentation

Researcher files: Researchers are required by DoD policy to maintain an extensive number of research-related and compliance-related documents in their files. Researchers are responsible for fulfilling these requirements, which typically begin by contacting DoD to learn about the requirements.

DoD documentation requirements: It is the responsibility of the researcher to provide DoD with all documents required by DoD. For example, the sponsoring DoD agency may require the submission of records to the DoD for archiving.

Documentation of exemption: The researcher should document the determination by the IRB whether research meets the research criteria for exemption.

International Research

DoD-related research that involves subjects who are not U.S. citizens or Department of Defense personnel must obtain and provide:

- Permission of the host country.
- Ethics review and approval by the host country or by a local Naval IRB with host country representation.
- Additional safeguards might not be applicable to social-behavioral research involving no more than minimal risk.

Military Research Subjects

DoD requires the following protections for military personnel being recruited for research that involves greater-than-minimal risk.

- 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.
- During recruitment briefings to a unit where part of the unit is being recruited, an independent ombudsman is present.
- Limitations on dual compensation prohibit an individual from receiving pay from more than one position for more than 40 hours of work in one calendar week, which includes temporary, part-time, and intermittent appointments.

Informed consent by legally authorized representative

Per military law and DoD directive, informed consent may be provided by a legally-authorized representatives of subjects if: (1) the subject lacks capacity, due to age, condition, or other reason, to make a decision regarding consent to participate in the research; AND (2) the IRB has determined that the research is intended to be beneficial to the individual subjects.

Waiver of Consent

The requirement to obtain consent cannot be waived for any research involving the DoD, **and** where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction, except under one of the following conditions:

- The research is intended to be beneficial to the subject, the subject lacks the capacity to provide consent, and a legally-authorized representative will provide consent. *Examples:* young minors, cognitively impaired individuals.
- The Head of the DoD component involved in the research may waive the requirement for consent with respect to a specific project, in order to advance the development of a medical product necessary to the Armed Forces, but only if the research may directly benefit the subject and the research is carried out in accord with all other applicable laws and regulations (such as 21 CFR 50.24).
- This prohibition does NOT apply to screening (sometimes called "pre" screening) of records to identify possible subjects. The IRB can grant a waiver of consent for such activities.

Compensation

- Participants may be compensated for research participation as long as the participant is involved in the research when not on duty. Enrolled individuals may not receive payment of compensation for research participation during duty hours.
- Federal employees while on duty and non-Federally employed individuals may be compensated for blood draws for research up to $50 for each blood draw.
- Non-Federally employed individuals may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB.

Survey Research

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.

Ongoing IRB application requirements

- Report unanticipated problems, adverse events, research-related injury and suspensions or terminations of research.
- If the IRB determines that annual continuing review is required for a study, it will be given a 1-year expiration date from the time of IRB approval. If your DOD study requires annual renewal, please submit the following items to the IRB in addition to the standard Continuing Review requirements.
    - **Continuing education:** As described above, DoD requires continuing education related to human subjects for the researchers and appropriate research staff. This requirement may be fulfilled by recertifying CITI training.
    - **Research results:** DoD requires that the researcher provide the IRB with copies of publications, presentations and reports resulting from the research. These should be provided to the IRB with scheduled continuing review information.
- If an amendment involves substantive changes (e.g., new procedures, a new subject population, a new aim), the researcher should upload the documentation of scientific review and approval of the changes in the amendment.

- If the research was not previously DoD-related but the amendment will make the project DoD-related, the researcher must note this in the Amendment Form.
- The researcher is responsible for notifying DoD and the IRB of any audits, investigations, or inspections of DoD-related research.

Classified Research
For all Department of Defense conducted or supported non-exempt human subject research involving classified information (as defined in Executive Order 13526), additional requirements must be applied. Additional requirements are described in the Department of Defense Instruction 3216.02.

Vulnerable Populations
DoD-conducted or supported non-exempt human subject research involving vulnerable populations (DHHS Subparts B, C, and D) may have additional protections required as described in DoD Instruction 3216.02.

Points to Address

New Study Application:	1. Department of Defense Supplement Form must be included with application submission.
Consent Document:	1. Ensure consent document includes DoD and/or appropriate component as an entity who will have access to data.

References & Links

DoD Instruction 3216.02	https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf
Secretary of the Navy SecNav Instruction 3900.39D	https://irp.fas.org/doddir/navy/secnavinst/3900_39d.pdf
Directorate of Human Research Protections	https://rt.cto.mil/ddre-rt/dd-rtl/hsd/hrp/
UIUC OPRS Department of Defense Supplement Form	To be updated