Research Funded or Supported by the Department of Defense

Introduction

Research sponsored by the Department of Defense (DoD), involving collaboration with DoD, or involving DoD facilities or personnel (military or civilian) is subject to special requirements for human subjects protections. These requirements are summarized in this guidance.

Investigators must be aware of these special requirements when planning a research project as they may add a significant amount of time to the human subjects review and approval process; and they add requirements relating to the actual conduct of the research.

For DoD-sponsored research, information regarding the specific requirements of the DoD Component should be obtained from the granting agency.

What is Department of Defense Research?

Research is considered to involve the Department of Defense when:

- The research is funded by a DoD Component (see the list below);
- The research involves cooperation, collaboration, or other type of agreement with a DoD Component;
- The research uses property, facilities, or assets of a DoD Component;
- The subject population will intentionally include personnel (military and/or civilian) from a DoD Component. *Note that the DF/HCC does not target DoD personnel as research subjects.*

DoD requirements do NOT apply when DoD personnel incidentally participate as research subjects. That is, the DoD personnel are not the intended research population or where the project is not DoD-supported.

DoD Components include but are not limited to:

- Department of the Navy
- Office of Naval Research
- U.S. Naval Observatory
- Naval Academy
- Department of the Army
- U.S. Army Corps of Engineers
- Military Academy (West Point)
- Department of the Air Force
- Air Force Academy
- Marines
- Coast Guard
- National Guard

- Missile Defense Agency
- Defense Advances Research Projects Agency (DARPA)
- Pentagon Force Protection Agency
- Defense Intelligence Agency
- National Geospatial-Intelligence Agency
- National Security Agency
- Under Secretary of Defense (Personnel and Readiness)

Special Requirements for IRB Review of DoD Research

Most of the DoD requirements are included in this guidance, but investigators are responsible for checking with their project coordinator within the specific DoD Component about any additional requirements.

1. **Training Requirements**
   DoD requires that all individuals involved in the "design, conduct, or approval of human subjects research" complete human subjects research training. CITI training, renewed every three years, meets the training requirements for many DoD Components. However, some DoD Components require additional training. For instance, the DON requires completion of additional CITI modules, and the Secretary of Defense (Personnel and Readiness) requires annual training. Investigators are responsible for ensuring that all study team members engaged in the conduct of human subjects research complete the required training.

2. **Department of Defense Supplement Form**
   All non-exempt research submitted for review to the DFCI IRB which involves a DoD Component must be accompanied by a Department of Defense Supplement Form. OHRS staff will route the protocol for the appropriate SRC, IRB, and departmental review.

3. **Independent Research Monitor**
   For research involving more than minimal risk, an independent research monitor must be appointed and approved by the IRB by name, unless the study team obtains a waiver of this requirement from the head of the DoD Component involved in the research. For research determined to be no greater than minimal risk, the IRB may, in its discretion, require a monitor. The Medical Research Officer may serve as the Research Monitor on a DoD funded study where the IRB has determined a Research Monitor is necessary.

   The monitor is independent of the study team and is responsible for promptly reporting any problems in the research to the IRB. They may stop the research in progress, remove individual subjects from the research, and take necessary steps to protect the safety and wellbeing of subjects until the IRB can assess the monitor's report. The monitor may discuss the research with the investigators, interview subjects, and consult with others outside of the study regarding the research.

Depending on the nature of the research, the monitor may be assigned to assess one or more research activities, such as subject recruitment and consent, study interventions, confidentiality, adverse events, data and specimen collection, data analysis, etc.

Study teams may propose a research monitor for IRB consideration by identifying the individual on the Department of Defense Supplement Form.

4. **Waiver of Consent:**
   For "research involving a human being as an experimental subject," the requirement to obtain prospective consent may only be waived by the head of the DoD Component involved in the research. This includes any research activity 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.
   For research not meeting this definition, the IRB may waive consent as described in 45 CFR 46116(d).

5. **Scientific Review:**
   DoD Components, such as the DON and Army, require the IRB to have documentation of independent review and approval for scientific merit or scholarship (including a summary of scientific issues raised and addressed during the review). OHRS will route the protocol for SRC review prior to IRB review in order to obtain this documentation.

6. **Research-Related Injury:**
   DoD Components may have stricter requirements regarding research-related injury than otherwise required by DF/HCC and federal regulations. For instance, the DON requires all research involving greater than minimal risk to include an arrangement for emergency treatment and necessary follow-up of any research-related injury.

7. **Participant Compensation:**
   The DoD imposes extensive restrictions regarding payments to participants when the research is DoD-funded. Permissible compensation depends on whether the participant is on-duty federal personnel, off-duty federal personnel, or non-federal personnel.

<u>Reporting Requirements for DoD Research</u>

For research involving any DoD Component, the following events must be promptly reported to the DoD Human Research Protection Officer:

- When significant changes to the research protocol are approved by the IRB
- The results of the IRB continuing review
- Change of the reviewing IRB (i.e. if an IRB other than the DFCI IRB assumes oversight)
- When the institution is notified by any federal department, agency, or national organization that any part of the Human Research Protection Program is under investigation for cause involving a DoD-supported research protocol
- All unanticipated problems involving risks to subjects or others
- Serious or continuing noncompliance
- Any suspension or termination of the research

Additionally, DoD Components may impose further Component-specific reporting requirements. For instance, in addition to the above reportable events, the DON requires that the following be reported:

- The initiation and results of investigations of alleged non-compliance with human subject protections
- All audits, investigations, or inspections of DON-supported research protocols
- All audits, investigations, or inspections of the institution's Human Research Protection Program conducted by outside entities (e.g., the FDA or OHRP)
- Significant communication between institutions conducting research and other federal departments and agencies regarding compliance and oversight
- All restrictions, suspensions, or terminations of the institutions' assurances

Department of Defense Addendum to Federal Wide Assurance (FWA)

The DFCI IRB has an approved DoD Addendum to its Federal Wide Assurance (FWA) with the Office for Human Research Protections (OHRP). The DoD Addendum need only be filed with one branch of the military and applies to all DoD Components. The DFCI IRB has chosen to file the DoD Addendum with the Department of the Navy, and it is on file at the following address:

Department of the Navy
Office of Research Protections (MOOR)
Bureau of Medicine and Surgery
2300 E Street, NW
Washington DC 20372

A copy of the DoD Addendum to the FWA is available to research staff by contacting the OHRS Senior Director.