
Yale University Institutional Review Boards Procedure

100 PR.4 Department of Defense Supported Research

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Overview

Research supported by the Department of Defense (DoD), including its separate components: the Army, Navy, Air Force and Marine Corps, or recruiting DoD personnel requires compliance with additional federal regulations, Directives and Instructions. This procedure applies to human research that is funded by or recruits participants from the DoD or a DoD component through a contract, grant, cooperative agreement or other arrangement.

Definitions

DoD Addendum: An application to the Department of Defense attesting that Yale University will comply with all relevant federal regulations, DoD Instructions and Directives and other relevant documents regarding the protection of human subjects in research. The Addendum applies to research supported by the DoD, Air Force, Navy and Marine Corps. The Army does not use the mechanism of an Addendum. Additional Army requirements are managed through the contracting process.

Research Involving a Human Being as an Experimental Subject: The Department of Defense definition is: An activity, for research purposes, 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 (32CFR.210.102 (f) reference (c)). Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose.

Application Supplement

Investigators conducting DoD supported research must complete and submit the Yale IRB Application Supplement in addition to the protocol materials submitted to the IRB for initial review. The supplement application; Department of Defense (DoD) Supported Protocols, 100 FR 16 can be found at <http://www.yale.edu/hrpp/forms-templates/biomedical.html>; <http://www.yale.edu/hrpp/forms-templates/behavioral.html>).

This supplement aids the investigator and the IRB in ensuring compliance with unique DoD requirements.

Contracts and Awards

In addition to requirements set for the by the funding agency, investigators conducting human research supported by the DoD or its components, (Army, Navy, Air Force Marine Corps) must comply with contracting requirements and processes required of Yale's Office of Grant and Contract Administration and the Award Set Up Unit. See <http://www.yale.edu/grants/>

Education

Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support or manage human research supported by the DoD or its components.

The Yale Human Subject Protection Training policy (HSPT) policy requires initial and continuing education of research personnel and IRB members every three years. Note however, individual DoD components may have stricter or specific educational requirements. Researchers should contact their project coordinator at the DoD, or DoD component, to ensure adherence to any unique requirements. Note that collaborators external to Yale must document initial or continued HSPT and any specific training required by the DoD may..

IRB members and staff can access Department of Defense requirements through the HRPP website, <http://www.yale.edu/hrpp/members/tools.html>. IRB Coordinators assigning reviewers to protocols funded by the DoD will ensure that training requirements are current at the time of review.

International Research

When DoD-sponsored research involves human subjects who are not U.S. citizens or DoD personnel and the research is conducted outside the United States, and its territories, the investigator must obtain the permission of the host country. The laws, customs, regulations and practices of the host country and those required by Yale Policy 450, International Research, will be followed. An ethics review by the host country, or local DoD IRB with host country representation, is required. Evidence of permission to conduct the research in the host country by certification or local ethics review must be submitted to the Yale IRB prior to initiation of the project.

Multi-site Research

When conducting multi-site research, the supplement must clearly detail the roles and responsibilities of each party at each site involved in the research. The Yale IRB can aid the Yale researcher in developing a formal agreement should it be required by the DoD or one of its components.

Prohibition of Research with Prisoners of War

Research involving persons considered prisoners of war (POW) (captured, detained, held under the control of DoD personnel) is prohibited. Refer to the definition of "prisoner of war" for the Department of Defense component granting the addendum. For the Army definition see <http://www.army-technology.com/glossary/prisoner-of-war.html>; for the Navy definition see http://www.med.navy.mil/sites/nmrc/documents/secnavinst_3900_39d.pdf, enclosure 1.

Research Monitor

Appointment of an independent research monitor is required for research involving greater than minimal risk. The monitor must be a physician, dentist, psychologist, nurse, or other healthcare provider capable of overseeing the progress of the research protocol, especially issues of individual subject/patient management and safety. The monitor must be independent of the investigative team and possess sufficient educational and professional experience to serve as the subject/patient advocate. The Principal Investigator is responsible for providing the name, contact information and responsibilities of the Monitor to the IRB in the IRB application. Note however, that the IRB may require a monitor for a portion of the project or for studies involving no more than minimal risk when appropriate.

At the discretion of the IRB, the medical monitor may be assigned to discuss research progress with the principal investigator, interview subjects, consult on individual cases, or evaluate adverse event reports. Medical monitors shall promptly report discrepancies or problems to the IRB.

The research monitor has the authority to stop a research study in progress, remove individuals from a study, and/or take any steps to protect the safety and well being of subjects until the IRB can make an assessment.

Research Related Injury

The Department of Defense components may have stricter requirements regarding research-related injury than those outlined in University policy 200 (Informed Consent) and federal regulations. Investigators should work with their project coordinator within the DoD component to identify such requirements.

Scientific Review

New research and substantive amendments to approved research must undergo scientific review prior to or at the time of ethics (IRB) review.

Studies Involving Department of Defense Personnel

When research involves Department of Defense personnel, including U.S. military personnel, the following requirements will apply.

Additional protections must be in place and articulated in the IRB application to minimize undue influence:

- Officers cannot influence the decision of their subordinates to participate in the research.
- Officer and senior non-commissioned officers cannot be present at the time of recruitment into the research.
- Officers and senior non-commissioned officers must have a separate opportunity to participate in the research.
- When recruitment involves a percentage of a unit, an independent ombudsman must be present during the recruitment.

The following limitations on dual compensation for U.S. military personnel apply:

- An individual may not receive pay from more than one position for more than 40 hours of work in one calendar week. This limitation on dual compensation includes temporary, part-time and intermittent appointments.
- Individuals may receive compensation for research activities if the research activities take place outside of scheduled work hours.
- Surveys involving Department of Defense personnel, including U.S. Military personnel, typically require Department of Defense Survey Review and Approval. When appropriate, the research project is reviewed and approved by the IRB prior to Department of Defense approval.

Wavier of Informed Consent

If the research subject of a study funded by the DoD or its components meets the definition of “experimental subject” (see above) then a waiver of consent by the IRB is prohibited unless a waiver is obtained from the Secretary of Defense. However, if the research subject does not meet the definition of “experimental subject”, then the IRB may waive the consent process.

References:

32 CFR 219

DoD Directive 3216.2

DoD Instruction 3210.7

DoD Instruction 6200.02

AFRL Instruction 40-402

Department of the Navy, HRPP Addendum to FWA Additional Requirement List

U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office (HRPO) Institutional Policies and Procedures

University of Oklahoma, Institutional Review Board, DoD Funded Research Materials