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# Yale University Institutional Review Boards

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## 100 PR.4 Department of Defense Supported Research

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### Overview

Non-exempt 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 (DoD Instruction 3206.12). 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. This guidance is posted on the HRPP website, so that researchers, research staff, IRB Chairs, members and staff are conversant with DoD requirements.

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### 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.

**DoD Personnel:** DoD civilian employees and members of the military services, unit officers, and noncommissioned officers (NCOs) (DoDI 3206.12).

**Minimal Risk:** Those risks ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests. Minimal risk should not be evaluated against the inherent risks encountered in participants' work environment (e.g., soldier in a combat zone) or having a medical condition (e.g. constant pain).

**Research:** a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. 32 CFR§219.02 (d)

**Research Involving Human Subjects:** Activities (as defined by 32 CFR 219.101(a) and DoDI 3216.02) that includes both a systematic investigation designed to develop or contribute to generalizable

knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information

**Research Involving a Human Being as an Experimental Subject:** 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 (DoD 3206.12; ref 10 U.S.C. 980). 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, or the withholding of an intervention that would have been undertaken if not for the research purpose.

**Research Monitor:** An individual or individuals with expertise consonant with the nature of risk(s) identified within the research protocol, in order to protect the safety and well-being of human subjects. A research monitor may be required to oversee a specific protocol that involves more than minimal risk, especially issues of individual subject/patient management and safety. The research monitor is appointed by name, functions independently of the research team and must be approved by the IRB. (DoD 3206.12)

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## Application Supplement

Investigators conducting DoD supported research must complete and submit the Yale IRB DoD Application Supplement in addition to the protocol materials submitted to the IRB for initial review. The supplement application, entitled 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.

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## Contracts and Awards

In addition to requirements set 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/>

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## 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 (HSPT) policy requires initial and continuing education of research personnel and IRB members every three (3) 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. The DoD component may also evaluate Yale's education policies to ensure that personnel are qualified to perform the research, based on the complexity and risk of the research.

Note that collaborators external to Yale must document initial or continued HSPT and any specific training required by the DoD..

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

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## 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.

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## Multi-site Research

When conducting multi-site research, the application 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.

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## NonCompliance

Any IRB determination of serious or continuing non-compliance must be reported to the DoD human research protection officer.

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## 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](http://www.med.navy.mil/sites/nmrc/documents/secnavinst_3900_39d.pdf), enclosure 1.

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## Records

IRB records regarding both compliance and non-compliance with DoD regulations shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

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## Reporting

The following must be reported to the DoD Human Protections Administrator:

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- Significant changes to the protocol, approved by the IRB
  - Results of IRB continuing review
  - Any change in the reviewing IRB
  - Any unanticipated problems involving risks to participants or others for any DoD-supported research. These must be reported promptly
  - Any suspension or termination of DoD-supported research

- Any notification to the institution by any Federal department, agency or national organization that any part of the institutions' HRPP is under investigation for cause involving a DoD-supported protocol.

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## Research Monitor

Appointment of an independent research monitor is required for research involving greater than minimal risk. The monitor must be independent of the investigative team and possess expertise consonant with the nature of risk(s) identified within the research protocol. A protocol may use more than one Research Monitor, depending on need. The Research Monitor may be identified by the investigator or appointed by the IRB or Institutional Official (IO). The monitor may be an ombudsman or a member of the data safety monitoring board (DSMB).

The IRB shall approve the research monitor(s) by name. The IRB must approve a written summary of the monitor's duties, authorities and responsibilities, and shall communicate with research monitors to confirm their duties, authorities and responsibilities.

Research Monitor duties are determined on the basis of specific risks or concerns about the research. S/He may perform oversight functions (e.g., observe recruitment or the consent process, oversee study interventions, review monitoring plans, etc.) and report their findings to the IRB. The Research Monitor may discuss the protocol with the investigators, may interview subjects and may consult with others outside the study regarding the research.

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 assess the Research Monitor's report. Research Monitors have the responsibility to promptly report their observations and findings to the IRB or other designated official.

Note: the Heads of the Office of the Secretary of Defense (OSD) and the DoD may waive the requirement for a Research Monitor on a case by case basis, when inclusion of such is not necessary to provide additional protections for human subjects.

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## Research Related Injury

The Department of Defense components may have stricter requirements (DoDI 3216.02) 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.

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## Scientific Review

New research and substantive amendments to approved research must undergo scientific review prior to or at the time of ethics (IRB) review. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

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## Studies Involving Department of Defense Personnel

DoD civilian employees follow their organization's policies regarding permission to participate in human subjects research.

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

- Supervisors cannot influence the decision of their subordinates to participate in the research covered by DoDI 3216.02.

- Supervisors cannot be present at any recruitment sessions or during the consent process in which DoD civilians under their supervision are offered the opportunity to participate in human subjects research.
- Supervisors shall have the opportunity to participate in the research, when applicable.
- For research that is greater than minimal risk, involves Service members, and conducts recruitment in a group setting, the IRB shall appoint an ombudsman who is not associated with the research to monitor the voluntary nature of the recruitment and that the recruitment information is clear, adequate and accurate. For group recruitment of civilians the IRB shall discuss, based in part on the subject population, the consent process and the recruitment strategy, appointing an ombudsman.

The DoD has extensive regulations (DoDI 3216.02) regarding payment to subjects. Contact the IRB for information.

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## Surveys

Surveys performed on Department of Defense personnel must be submitted, reviewed and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB/

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## Vulnerable Subjects

Additional protections must be in place for all human subjects in DoD research who may be considered vulnerable as defined by 45 CFR 46 subparts B-D and DoDI 3216.02. Investigators, IOs, DoD component personnel or the reviewing IRB shall consider the need for additional safeguards for other vulnerable populations such as subjects in subordinate relationships to investigators, subjects with decisional impairment, physical disability or other circumstances that may place them in need of additional protections. Qualified individuals may be appointed to perform oversight or assist subjects, as determined appropriate.

DoD regulations concerning vulnerable populations are complex. See DoDI 3216.02, Enclosure 3, Section 7. Contact the IRB if you are or will be conducting DoD research with vulnerable subjects.

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## Waiver 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 Office of the Assistant Secretary of Defense. The Assistant Secretary may waive consent only if the following is found: The research is necessary to advance the development of a medical product for the Military Services; the research may directly benefit the individual experimental subject; the research is conducted in compliance with all other applicable laws and regulations. Note: for all classified research a waiver is not permitted.

If the research subject does not meet the definition of “experimental subject”, then the IRB may waive the consent process.

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## References:

32 CFR 219  
DoD Instruction 3216.2  
DoD Instruction 3210.7

DoD Instruction 6000.08  
DoD Instruction 6025.18  
DoD Instruction 6025.18-R  
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