Identification of U.S. Department of Defense Sponsored Research

This policy applies to all research involving human subjects supported by the U.S. Department of Defense. While all units of the Department of Defense (DoD) abide by the Common Rule, including subparts B-D (protections for vulnerable populations of pregnant women, prisoners, and children), some components have unique policies and procedures that reflect the characteristics of the agency (e.g., leadership, culture, risk tolerance, mission) for approving institutions and assuring compliance for their sponsored research.

When submitting an application for human subject research to the IRB, the principal investigator (PI) must identify the research as sponsored or funded by a DoD component (as defined in Department of Defense Directive 3216.02). The PI is responsible for identifying DoD component requirements specified in the grant application guidelines and for advising the IRB staff and IRB of the requirements.

Responsibility

It is the responsibility of the PI to ensure that all additional DoD and/or Department of the Navy (DoN) requirements for human subject protection are met. It also is the responsibility of the IRB to ensure that all additional DoD and/or DoN requirements for human subject protection have been met before IRB approval of the research study. When additional review for DOD sponsored survey research or survey research with the DOD is required, surveys typically require DOD survey review and approval. When appropriate, the research protocol is reviewed and approved by the IRB prior to DOD approval.

Definitions

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 [32 CFR 219.102(f), reference (c)]. Examples 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.

DoD Components

Refers collectively to the organizational entities within the DoD that are subject to the human subjects protections laid out in Department of Defense Directive.
Research Monitor
A physician, dentist, psychologist, nurse, or other healthcare provider designated to oversee a specific protocol that involves more than minimal risk, especially issues of individual subject/patient management and safety. The research monitor functions independently of the research team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate.

Prisoner of War
A detained person as defined in Articles 4 and 5 of the Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949. In particular, one who, while engaged in combat under orders of his or her government, is captured by the armed forces of the enemy. As such, he or she is entitled to the combatant's privilege of immunity from the municipal law of the capturing state for warlike acts which do not amount to breaches of the law of armed conflict. For example, a prisoner of war may be, but is not limited to, any person belonging to one of the following categories who has fallen into the power of the enemy: a member of the armed forces, organized militia or volunteer corps; a person who accompanies the armed forces without actually being a member thereof; a member of a merchant marine or civilian aircraft crew not qualifying for more favorable treatment; or individuals who, on the approach of the enemy, spontaneously take up arms to resist the invading forces. Also called POW or PW.

Specific considerations and Procedures for DOD Research

Scientific Review
DoD requires scientific review prior to IRB review for all new DoD supported human research. DoD also requires that all substantive amendments to approved DoD research involving human subjects receive scientific review prior to IRB review. Changes that do not qualify as minor in the Human Research Protection Program (HRPP) Manual 8-6 “Revisions to an Approved Research Study” and are submitted to the full IRB constitute substantial amendments. The PI is responsible for providing documentation of the scientific review to the IRB.

Education Requirements
DOD requires initial and continuing mandatory ethics education requirements for human subjects protections. The HRPP Manual 11-1-A “Education: Investigators and Research Staff” for mandatory and continuing education to meet this requirement.

Research Involving International Citizen Populations
For research conducted internationally the IRB will take into consideration subject populations, the cultural context, the languages understood by the human subjects, identifying and considering local laws, regulations, customs, and practices. In addition determinations are made as to whether the sponsoring DoD Component requires an additional ethics review by the host country to assure the researcher follow all local laws, regulations, customs, and practices. The IRB may require the investigator obtain permission to conduct research in that country by either certification or local ethics
review. These additional safeguards might now be applicable to social/behavioral research involving no more than minimal risk.

**Serious or Continuing Noncompliance Reporting Requirements**
See the following sections from the HRPP Manual: 8-10 “Project Audits,” 9-1 “Unanticipated Problems Involving Risks to Subjects or Others,” 9-2 “Noncompliance.”
All findings of serious noncompliance shall be reported to the DoD. The IRB will report to DoD any of the following for DoD-related research:
- Suspension or termination of the research
- Initiation and results of investigations of alleged noncompliance
- Unanticipated problems involving risks to subjects or others, and/or serious adverse events
- Any audit, investigation or inspection of DoD-supported research
- Any audit, investigation, or inspection of the institution’s HRPP conducted by outside government entities (e.g., U.S. Food and Drug Administration, U.S. Office for Human Research Protections)
- Significant communication between institutions conducting research and other federal departments and agencies regarding compliance and oversight
- Any restriction, suspension or termination of the institutions’ assurance

**Multi-Site or Collaborative Research Requirements**
When conducting multi-site research, formal agreements may be necessary to ensure that participating institutions understand and accept their scope of work specific roles and responsibilities agreed upon by each site engaged in research. See HRPP Manual 6-9-F “Multiple Research Sites.”

**Research Monitor Required: Greater than Minimal Risk Studies**
For DoD-sponsored research involving greater than minimal risk to subjects, the DoD requires appointment of an independent research monitor. The research monitor has the authority to:
- 1) Stop a research study in progress;
- 2) Remove individuals from the study;
- 3) Take any steps to protect the safety and well-being of subjects until the IRB can assess the research monitor’s report.
The PI in coordination with the IRB identifies a candidate for the position of research monitor, taking into account the nature and disciplinary focus of the study and the likely type of medical expertise required. The IRB will ensure that the research monitor is independent of the research team.

**Research Involving U.S. Military Personnel as Research Subjects**
If any research includes U.S. military personnel as subjects the IRB protocol must include a plan for research subject recruitment that incorporates additional safeguards to minimize undue influence from individuals within a potential subject’s chain of command. The PI is required to consult with the sponsoring DoD Component to ensure the IRB the following safeguards are in place:
- 1) Officers are not permitted to influence the decision of their subordinates;
- 2) Officers and senior non-commissioned officers may not be present at the time of recruitment;
- 3) Officers and senior non-commissioned officers have a separate opportunity to participate;
- 4) When recruitment involves a percentage of a unit, an independent ombudsman is present. In addition, unless on
leave status during research participation, military personnel may not receive compensation for their participation.

Provisions for Research-related Injury
The PI is responsible for informing the IRB if there are any requirements from DoD Component’s the provision of care in the case of a research-related injury. If the DoD Component has stricter requirements than the Common Rule or MSU HRPP policies this will need to be discussed and agreed upon by General Counsel and Institutional Official. These requirements will also need to be disclosed in the informed consent document.

Waiver of Consent and Exception from Informed Consent in Emergency Medicine
If a research subject meets the definition of “experimental subject,” DoD regulations prohibit a waiver of consent unless the PI obtains a waiver from the Secretary of Defense. The IRB may waive the consent process if the research does not meet the definition of “experimental subject.” DoD regulations prohibit an exception from informed consent in emergency medicine research unless the PI obtains a waiver from the Secretary of Defense.

Classified Research
Classified research must receive prior approval form the Secretary of Defense. Classified research is not eligible for review under expedited review process.

Prisoner of War
Under no circumstances shall the IRB approve research involving prisoners of war, as defined by the specific DoD Component.