# Institutional Review Board Policies and Procedures Manual

## SECTION 17: SPECIAL CONSIDERATIONS FOR DEPARTMENT OF DEFENSE-SPONSORED RESEARCH

## 17.1 INTRODUCTION

In 2006, the Department of the Defense (DoD) enhanced its human subject protection requirements, including the application of those requirements to researchers who are not employees of the DOD. DoD regulations and policies for the protection of human research subjects apply when the Institution is conducting, reviewing, approving, overseeing, supporting or managing DoD supported human subject research. While all units of DoD abide by the Common Rule, including subparts B, C, and 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.

Human Subject Research involves the DoD when any of the following apply:

i. The research is funded (through a contract, grant, cooperative agreement, or other arrangement) by a component of the DoD (e.g. Navy, Army, Air Force).
ii. The research involves cooperation, collaboration, or other type of agreement with a component of the DoD.
iii. The research uses property, facilities, or assets of a component of DoD.
iv. The subject population will intentionally include personnel (military and/or civilian) from a component of the DoD.

DoD policies and requirements do not apply when DoD personnel incidentally participate as subjects in research that is not supported by DoD, and DoD personnel are not an intended population of the research. In addition, research involving human subjects for testing of chemical or biological warfare agents is generally prohibited by section 1520a of title 50, United States Code (U.S.C.) (Reference (f)), subject to possible exceptions for research for prophylactic, protective, or other peaceful purposes.

## 17.2 DEFINTIONS

**Research Involving a Human Being as an Experimental Subject** is defined as 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. Activities exempt under the Common Rule are not included in the definition of research involving a human being as an experimental subject (DoD Directive 3216.02).

**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 (DoDD).

**Research Monitor** refers to 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.

**Minimal Risk** refers to risks ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests. It shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example the

risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain.)

**Prisoner of War** is any person captured, detained, held, or otherwise under the control of DoD personnel (military and civilian, or contractor employee). Under no circumstances shall the IRB approve research involving prisoners of war, as defined by the specific DoD Component.

## 17.3 SPECIAL CONSIDERATIONS FOR DoD SPONSORED RESEARCH

The federal regulations at 32 CFR 219 provide additional requirements for investigators when conducting human subjects research. When the DoD regulations apply, the investigator is responsible for ensuring the research protocol meets the requirements as described below. In addition, when submitting an application in the electronic Cayuse IRB system for human subject research, the PI must identify the research as sponsored or funded by a DoD component (as defined in DoDD 3216.02). It also is the responsibility of the IRB to ensure that all additional DoD and its components' (if applicable) requirements for human subject protection have been met before IRB approval of the research.

### A. Education Requirements

DoD requires initial and continuing ethics education for all personnel who conduct, review, approve, oversee, support, or manage human subjects research. The policy in Section 6: Required Education and Training for Human Subjects Research outlines the Institution's procedures and requirements for investigators and study personnel to follow in order to meet this requirement. In addition, the DoD component may evaluate the education policies to ensure the research personnel are qualified to perform the research, based on the complexity and risk of the research.

### B. Scientific Review

DoD requires scientific review prior to IRB review for new studies subject to DoD regulations. DoD also requires that all substantive modifications to approved DoD research involving human subjects receive scientific review prior to IRB review. The PI is responsible for providing documentation of the scientific review to the IRB when the modification is submitted via the electronic Cayuse IRB Modification application.

### C. Research Monitor

For DoD-sponsored research involving greater than minimal risk to subjects, the DoD requires the 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; and/or 3) Take any steps to protect the safety and well–being of subjects until the IRB can assess the research monitor's report.

The duties of the research monitor are determined on the basis of specific risks or concerns about the research such as:

i. Perform oversite functions such as observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis.

ii. Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.

iii. Report observations and findings to the IRB or a designated official.

The PI is responsible for identifying a candidate for the position of research monitor, taking into account the nature and disciplinary focus of the study and the type of medical expertise required. More than one research monitor may be used if different skills or experience are needed. The PI must then provide the name, contact information, and responsibilities of the monitor to the IRB in the Cayuse IRB application. The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB will ensure the research monitor is independent of the research team, and must communicate with the monitor to confirm and approve a summary of their duties, authorities, and responsibilities.

The IRB may require a monitor for a portion of the research or studies involving no more than minimal risk when appropriate.

**D. Reporting of Non-Compliance and Unanticipated Problems Involving Risks to Subjects**

Serious and continuing non-compliance or unanticipated problems involving risks to subjects or others that occurs in research funded by the DoD will be reported to OHRP and the FDA as outlined in the policy in Section 13: Data Safety Monitoring and Regular Reporting Requirements and to the DoD human research protection officer no longer than within 30 days of notification.

**E. Notifications to the DoD Human Research Protection Officer**

The following shall promptly (no longer than within 30 days) be reported to the DoD human research protection officer:

i. When the Institution is notified by any Federal department, agency or national Organization that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol.

ii. When significant changes to the research protocol are approved by the IRB.

iii. The results of the IRB renewal.

iv. Change of reviewing IRB.

v. Suspension or termination of DoD-supported research.

**F. Provisions for Research-related Injury**

The DoD components may have stricter requirements regarding care and treatment for research-related injury than outlined in the federal regulations at 45 CFR 46. The IRB determines that the informed consent document includes that provisions for research-related injury follow the requirements of the DoD component.

**G. Waiver of Informed Consent**

When research is funded by the DoD**,** or its components**,** and includes "experimental subjects" a waiver of consent by the IRB is prohibited, unless a waiver is first obtained from the Assistant Secretary of Defense for Research and Engineering in the following situations:

i. The research is necessary to advance the development of a medical product for the Military Services.

ii. The research might directly benefit the individual experimental subject.

iii. The research is conducted in compliance with all other applicable laws and regulations.

DoD regulations prohibit an exception from informed consent in emergency medicine research unless a waiver is obtained from the Secretary of Defense. Waivers of consent are also prohibited for classified research. The IRB may waive the requirement of obtaining informed consent if the research subject does not meet the definition of "experimental subject".

**H. Research involving pregnant women and children are subject to the DHHS Subparts B and D**

For purposes of applying Subpart B, the phrase "biomedical knowledge" shall be replaced with "generalizable knowledge." The applicability of Subpart B is limited to research involving pregnant women as subjects in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as subjects. Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g. Research involving children cannot be exempt.