

**DOCUMENTATION OF IRB REVIEW AND APPROVAL:  
DEPARTMENT OF DEFENSE SPONSORED RESEARCH**

IRB #: Principal Investigator

Title:

The IRB reviewed the aforementioned research protocol, which is sponsored by the Department of defense (U.S. Army, Navy, Air Force or Marine Corps) OR involves Department of Defense (DoD) personnel

**SCIENTIFIC REVIEW**

- Departmental Scientific Review is always required for DOD-funded research

**RESEARCHMONITOR**

- Not required:** the study does not involve greater than minimal risk. (Skip to page2)
- Not required:** The OSD and DOD have waived the requirement for a research monitor
  
- Name, contact information and responsibilities of a **research monitor** who is independent of the investigative team included in Section 5.13 of the OSIRIS application.

The IRB has determined that the **research monitor** be assigned to assess one or more of the following phases of a research project: (check all that apply)

- Subject recruitment
- Subject enrollment
- Data collection
- Data Storage
- Data analysis
- Not applicable

The IRB finds that the research monitor is to be assigned to the following tasks:

- Discuss research progress with the Principal Investigator
- Interview subjects
- Consult on individual cases, or
- Evaluate adverse event reports
- Report any discrepancies or problems promptly to the IRB
- Not applicable
  
- 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

- Not required:** the study does not involve greater than minimal risk
- DoD required language present in the consent document.

## INTERNATIONAL

- Not applicable
- 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 (OSIRIS section 2.19)
  - Principal Investigator has obtained permission from the host country
  - Laws, customs, regulations and practices of the host country & Pitt will be followed.
  - Certification of ethics review by the host country, or local DoD IRB with host country representation has been submitted.

## INVOLVEMENT OF DoD PERSONNEL (OSIRIS 4.12)

- Not applicable: the study does not involve greater than minimal risk
- Not applicable: the study does not involve DoD personnel
- Additional protections are in place to minimize undue influence of DoD personnel
  - Officers cannot influence the decision of their subordinates to participate in the research.
  - Officers and senior non-commissioned officers not present at the time of recruitment into the research.
  - Officers and senior non-commissioned officers have a separate opportunity to participate in the research.
  - When recruitment involves a percentage of a unit, an ombudsman, who is independent of both the proposed research as well as the unit, must be present to monitor that the voluntary nature of the individual participants is adequately stressed and that the information provided about the research is adequate and correct.

## **COMPENSATION (OSIRIS 6.0)**

- Not applicable: the study does not involve DoD personnel
- Not applicable: the study does not include compensation
- DoD personnel may receive compensation for research activities if the research activities take place outside of scheduled work hours.
- Blood draw compensation to Federal employees while on duty and non-Federal persons does not exceed \$50

## **VULNERABLE POPULATIONS (OSIRIS CS6.0; AND 3.5 – 3.8)**

- Not applicable – Vulnerable populations not included.
  - Research supported or conducted by the Department of Defense that affects vulnerable classes of subjects shall meet the additional protections of 45 CFR Part 46, Subparts B, C, and D.
  - Determinations authorizing or requiring any action by an official of DHHS shall be under the authority of the Director, Defense Research and Engineering.

## **PRISONERS OF WAR**

- Persons considered prisoners of war (POW) are not included in the research.

## **WAIVER OF CONSENT**

- A waiver of consent (including an exception from consent in emergency medicine research) for research involving “experimental subjects” is permissible since the waiver was obtained from the Secretary of Defense.
- The research subject does not meet the definition of “experimental subject,” therefore the IRB may waive the consent process
- This research is classified, a waiver is not permitted.

## **SURVEY RESEARCH**

Surveys involving DOD personnel must be submitted, reviewed and approved by DOD after IRB approval. Any requested DOD changes must be submitted to the IRB via Modification.