MCW Office of Research
Standard Operating Procedure

RESEARCH INVOLVING DEPARTMENT OF DEFENSE FUNDING AND/OR MILITARY PARTICIPANTS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
Research under the review of the Medical College of Wisconsin (MCW) Institutional Review Board (IRB) and sponsored by the Department of Defense (DoD), or involving collaboration with the DoD, or DoD facilities or personnel both military and civilian must meet additional requirements including special protections for research subjects, as well as additional review and reporting requirements.

This procedure outlines the general requirements for projects funded by a DoD component, cooperation, collaboration, or other agreement with the DoD, using property, facilities, or assets of a DoD component, or involving military or civilian personnel from a DoD component which are required in addition to MCW IRB's policies and procedures.

This procedure does not apply to non–DoD research projects where US military personnel are only incidentally enrolled as subjects.

DEFINITIONS:
DoD Component: A component involves one or more of the following agencies or offices: Office of the Secretary of Defense (OSD), the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities.

> This also includes all other organizational entities within the Department of Defense including but not limited to: Air Force, Air Force Academy, Army, Army Corps of Engineers, Coast Guard, Coast Guard Academy, Defense Advanced Research Projects Agency (DARPA), Defense Intelligence Agency, Military Academy (West Point), Missile Defense Agency, National Geospatial-Intelligence Agency, National Guard, National Security Agency, National War College, Navy, Naval Academy, Office of Naval Research, Pentagon Force Protection Agency, Tricare Health System, U.S. Naval Observatory.

Substantive Modifications: MCW HRPP defines a substantive modification as a change in principle investigator, change or addition of an institution, elimination or alteration of the consent process, change to the project population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in project design warranting additional scientific review, or a change that could potentially increase risks to subjects.

Detainee: Any individual captured by, or transferred to the custody or control of, DoD personnel pursuant to the law of war. This does not include persons being held solely for law enforcement purposes, except where the United States is the occupying power. Detainees who are U.S. citizens or U.S. resident aliens will continue to enjoy all applicable rights and privileges under U.S. law and DoD regulations.

Classified Research: Federally sponsored research in which all or some portion of the project, or knowledge of the procedures or results of which, are restricted or require security clearance as dictated by the U.S. Government.

Experimental Subject: Subjects included in an activity for research purposes where

provided by the funding agency, by an established internal review mechanism within the investigator's academic unit, or through an ad hoc scientific review by the investigator's chair or dean. Evaluation of scientific merit conducted by the IRB as part of its review may be sufficient in some cases, as well.

2. Scientific review should include the name and qualifications of the reviewer(s) and must demonstrate that the research uses procedures consistent with sound research design and is likely to yield the expected results. Additionally, the scientific review must include an assessment of the following elements:
   Significance of the research question.
   Scientific approach;
   Research team qualifications;
   Facilities and resources available;

3. Amendments not meeting the criteria to be considered a substantive modification should include documentation that additional scientific review is not needed.

Surveys and Interviews:

1. Research involving surveys or interviews with DoD military or civilian personnel, or their families may require additional DoD approval.
2. Documentation from the DoD component should be provided regarding any additional review requirements along with the timing of the review.

IND/IDE Restrictions:

1. Investigators conducting research involving the Navy may not be designated as sponsors of an Investigational New Drug (IND) or Investigational Device Exemptions (IDE).
   a. Only the Surgeon General, Commanders, and Commanding Officers may act as sponsors of an IND or IDE.

International Research:

1. For DoD research conducted outside of the United States, the Investigator and IRB must consider the laws and requirements of the host country as well as the cultural context of the research. In conduct of such research, the laws, customs, and practices of the country in which the research takes place or those required by the regulations at 32 CFR § 219.101, whichever are more stringent, will take precedence.
2. The research must meet the same standards of ethics and safety that apply to research conducted within the Unites States involving U.S. citizens, and will be conducted in accordance with applicable international agreements.
   a. This may be documented via an in-country or IRB/ethics review and/or a review by a consultant with expertise in that country as described in IRB SOP: International Research.
3. For Navy research involving subjects who are not US citizens or DoD personnel, the investigator must provide documentation of permission from the host country and an ethics review and approval by the host country or local Naval IRB with host country representation.

Collaboration:

1. Collaborating institutions in multi-site research must have a Federal Wide Assurance (FWA) with Office of Human Research Protections (OHRP). Investigators must provide documentation of IRB approval or establish an IRB Authorization Agreement for collaborators. Investigators who would like to establish an IRB authorization should review and follow IRB SOP: Reliance Agreements for Multi-Site Projects.

inappropriate with the purpose of the research, or inappropriate under such other circumstances as the Secretary of Defense may designate.

status of any research team members obtaining consent must be documented in the project application in order for the IRB to assess this requirement.

a. For research considered more than minimal risk and where recruiting is

REFERENCES:

Department of Defense Instruction 3216.02, Protection of Human Subjects and