Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2013-027.0
Policy Title: Additional Requirements – Department of Defense

Purpose

The purpose of this policy is to set forth additional requirements applicable to 1) research supported by the Department of Defense, inclusive of any component of the Department of Defense (DoD) as listed in Appendix A, or2) research intentionally recruiting DoD personnel.

Definitions

See policy 2011-007.0 for definitions of the following terms

Administrative Review	DoD Personnel	Detainee	Experimental Subject
Prisoner of War	Legally Authorized Representative		Risk, Minimal

Policy

It is the policy of the HSPP that all non-exempt human subject research supported by the Department of Defense (DoD) or intentionally recruiting DoD personnel (i.e. on active duty / active employment at the time of study participation), will comply with additional requirements set forth by the DoD. The additional requirements are set forth below to aid investigators and the IRB in meeting these obligations.

DoD Approval

To ensure all required elements are met prior to the start of the research, Principle Investigators must also obtain approval from the DoD Human Research Protection Official (DHRPO) through the Administrative Review that is required to be conducted per DoD. Recruitment and data collection cannot begin until the DHRPO review is complete and notification of approval from the DHRPO has been received by the PI.

Qualifications / Education:

Research personnel and IRB members at UCHC must be in compliance with local training requirements regarding ethics in human subject research. Such education is to be renewed as stated in the education and training policy (Policy #2011-023.0). Proof of such training for all investigators and a listing of roles/responsibilities for all study personnel must be provided to the DHRPO. A curricula vita or bio-sketch for the Principal Investigator must also be provided. If the DoD or component of the DoD impose stricter or additional specific requirements, the investigator(s) must adhere to such. Investigators should contact the project coordinator at DoD to ensure compliance.

Research Monitor:

For research involving greater than minimal risk an independent research monitor must be appointed by name by the investigator and approved by the IRB. A written summary of the monitors duties, authorities and responsibilities must be approved by the IRB. The monitor must be capable of overseeing the progress of the research protocol, including issues of subject safety (e.g. a physician, dentist, psychologist, nurse or other heath care provider). The monitor must be sufficiently qualified through education and experience to act as an advocate for the subjects and cannot be part of the research team. A biographical sketch or c.v. of the research monitor, and proof of human subjects training, must be provided.

The IRB reserves the right to require a monitor for portions of a study and/or for minimal risk studies. The duties of the research monitor may include discussing research progress with the principal investigator, interviewing subjects, consulting with others outside of the study about the research, or evaluating adverse event reports. Monitors are required to report discrepancies, concerns or problems to the IRB and are authorized to stop a study, remove an individual from a study, and/or take any steps to protect the safety and well being of subjects until the IRB can conduct a review.

Research Related Injury:
Investigators should work with the project officer from the relevant DoD component to ensure correct provisions are in place regarding research related injury.

Scientific Review:
New studies and substantive amendments to existing studies must undergo scientific review prior to or at the time of IRB review. Results of scientific reviews conducted prior to the IRB meeting are to be included in the IRB submission.

Modifications:
Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The U.S. Army Medical Research and Material Command (USAMRMC) Office of Research Protections (ORP) Human Research Protection Office (HRPO) defines substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review) or a change that could potentially increase risks to subjects.

Records:
Records maintained that document compliance or non-compliance with DoD regulations will 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. Both the researcher and the IRB are obligated to maintain records.

Reporting Obligations:
Principal Investigators must report to the DHRPO:

- significant changes to the research protocol approved by the IRB
- the results of the IRB continuing review,
- a change of the reviewing IRB,
- knowledge of any notification by any Federal department or agency or national organization that any part of the Human Research Protection program is under investigation for cause involving a DoD-supported research protocol (when related to investigator activity)

The IRB will report to the DHRPO

- unanticipated problems involving risk to subjects or others, suspensions, clinical holds (voluntary or involuntary), or terminations of the research by the IRB, the institution, the sponsor or regulatory agencies, and if not already done so by the investigator,

- knowledge of any notification by any Federal department or agency or national organization that any part of the Human Research Protection program is under investigation for cause involving a DoD-supported research protocol (when related to IRB/oversight activity)

International Research:
Permission to conduct research outside of the U.S. with non-US citizens and/or with DoD personnel must be obtained from the host country. The research must meet approval criteria of the host country as well as the U.S. The research must undergo an ethics review by the host country, or local DoD IRB with representation from the host country. Proof of such review must be submitted to the IRB prior to commencing the research.

Multi-Site Research
The roles and responsibilities of each party at each site involved in the research must be clearly detailed in the DoD Addendum to the IRB application

Contracts and Awards:
Investigators receiving funding from DoD must also comply with applicable contracting requirements and processes required by the Office of Research and Sponsored Programs. Investigators are responsible for working with their assigned Sponsored Programs Specialist.

Department of Defense Personnel:
When research involves DoD personnel who will participate while on duty, including military personnel, the following provisions to minimize undue influence must be addressed:

- Officers cannot influence the decision of the subordinates to participate in research
- Officer and senior non-commissioned officers cannot be present at the time of recruitment
- Officers and senior non-commissioned officers must have a separate opportunity to participate in the research
- When recruitment involves a percentage of a unit, an independent ombudsman must be present during the recruitment

The following limitations on dual compensation for federal employees or military personnel apply:

- An individual may not receive pay from more than one position for more than 40 hours of work in one calendar week. This limitation on dual compensation includes temporary, part-time and intermittent appointments.
- Individuals may receive compensation for research activities if the research activities take place outside of schedule wok hours.
- Payment for participation in research while on duty is limited to blood donation and may not exceed $50 per blood draw. They may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

Survey Review:
Surveys involving DoD personnel, including U.S. Military personnel, typically require DoD Survey Review and Approval. When appropriate, the research is reviewed and approved by the IRB prior to DoD approval.

Waiver of Consent

If research participants do not meet the definition of "experimental subjects" then the IRB may waive the consent process. If research participants of a study funded by the DoD or any of its components do meet the definition of experimental subject then a waiver of consent by the IRB is prohibited unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering (ASDRE). The ASDRE may grant a waiver if all of the following are true:

- 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.
- The research is not classified

Consent from Legally Authorized Representative:

If consent of the experimental subject cannot be obtained in advance, and the research is intended to benefit the subject, a legally authorized representative may provide consent.

Detainee / Prisoners of War

Persons considered detainees, inclusive of prisoners of war, may not be included in research. This prohibition for detainee does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.

Vulnerable Populations:

Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C. and D.

Pregnant Women: For purposes of applying Subpart B, the phrase "biomedical knowledge" is replaced with "generalizable knowledge. Per DoD., the applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants. However, because by internal policy UCHC applies equivalent standards to all research regardless of funding source, and because DHHS does not make such a distinction, UCHC applies Subpart B to all research involving pregnant women.

Fetal Research: Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g which states the following:

(a) Conduct or support by Secretary; restrictions

The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:

- may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
- will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) Risk standard for fetuses intended to be aborted and fetuses intended to be carried to term to be same

In administering the regulations for the protection of human research subjects which:

- apply to research conducted or supported by the Secretary;
- involve living human fetuses in utero; and
- are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations; or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

Prisoners: D.O.D. supported research involving prisoners cannot be reviewed by the expedited procedure. When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum. In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:

- The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
- The research presents no more than minimal risk.
- The research presents no more than an inconvenience to the participant.

For DoD supported research, when a participant becomes a prisoner, if the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB chair must require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol. The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, must promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-participant's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-participant to continue to participate in the research. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants.

Children: The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Emergency Medicine Research

An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

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Procedure

Investigators conducting D.O.D funded research, or recruiting DoD personnel, must complete the Appendix F to the IRB Application. The appendix is designed to capture information regarding DoD requirements.

IRB Analyst will screen submissions, using the checklists as a tool, to ensure required documents have been provided.

IRB Members will be expected to evaluate the addendum to determine whether the relevant DoD requirements have been met such that the research may be approved.

Related Policies

2011-006.0 – Additional Protections: General
2011-006.1 – Additional Protections: Pregnant Women, Fetuses, Neonates
2011-006.2 – Additional Protections: Prisoners
2011-006.3 – Additional Protections: Children
2011-006.4 – Additional Protections: Other
2011-007.0 – Definitions Applied to Policies
2011-009.3 - Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board - Review by Convened Board
2011-009.12 – Institutional Review Board – Criteria for Approval
2011-016.0 – Scientific Review
2011-023.0 – Educational Requirements

Basis

45 CFR 46, B, C, D
Department of Defense Directive 3216.02 dated 11/8/2011
10 USC 980(a,b)
SECNAVINST 3900.39D
32 CFR 219

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Reviewed and Approved By:

Richard H. Simon ***15 June 2017***
Richard H. Simon, MD **Date**
Director, Human Subjects Protection Program

APPENDIX A to Policy 2013-027.0
Components of the Department of Defense

Military Departments

- U.S. Department of the Army
    - United States Army Reserve
    - Army National Guard
- U.S. Department of the Navy,
    - Marine Corps
    - Coast Guard (in time of war)
    - Navy Reserve
- U.S. Department of the Air Force
    - Air National Guard
    - Air Force Reserve

Defense Agencies

- Defense Advanced Research Projects Agency (DARPA)
- Defense Logistics Agency (DLA)
- Missile Defense Agency,
- Pentagon Force Protection Agency (PFPA)
- Defense Commissary Agency
- Defense Contract Audit Agency
- Defense Contract Management Agency
- Defense Finance and Accounting Service
- Defense Information Systems Agency
- Defense Legal Services Agency
- Defense Security Cooperation Agency
- Defense Security Service
- Defense Threat Reduction Agency
- Central Security Service

Office of the Inspector General of the DoD

Offices of the Secretary of Defense

- **Acquisition, Technology and Logistics**
    - Department of Defense Test Resource Management Center
    - Defense Technical Information Center
    - Defense Advanced Research Projects Agency
    - Missile Defense Agency
    - Defense Contract Management Agency
    - Defense Logistics Agency
    - Defense Threat Reduction Agency
    - Office of Economic Adjustment
    - Defense Acquisition University
    - Operational Test and Evaluation Directorate
- **Policy**
    - Defense Security Cooperation Agency
    - Defense Policy Board Advisory Committee

    - Defense Prisoner of War/Missing Personnel Office
    - Defense Technology Security Administration
- **Comptroller**
    - Defense Contract Audit Agency
    - Defense Finance and Accounting Service
- **Personnel and Readiness**
    - Principal Deputy Under Secretary of Defense for Personnel and Readiness
        - Department of Defense Education Activity
            - Department of Defense Dependents Schools
    - Assistant Secretary of Defense for Health Affairs
        - Military Health System[11]
            - TRICARE Management Activity[12]
    - Defense Commissary Agency
    - Defense Human Resources Activity
    - Uniformed Services University of the Health Sciences
    - Defense Equal Opportunity Management Institute
    - Office of the Chancellor for Education and Professional Development
- **Intelligence**
    - Defense Intelligence Agency
    - Defense Security Service
    - National Geospatial-Intelligence Agency
    - National Reconnaissance Office
    - National Security Agency
    - Defense Information Systems Agency
- **Other**
    - Assistant Secretary of Defense for Public Affairs
        - Deputy Assistant Secretary of Defense, Internal Communications
        - Defense Media Activity
    - Director of Administration and Management
        - Pentagon Force Protection Agency
        - Washington Headquarters Services
    - Director, Program Analysis and Evaluation
        - Office of Net Assessment
    - General Counsel of the Department of Defense
        - Defense Legal Services Agency

Field Activities

- Defense Media Activity
- Defense Prisoner of War/Missing Personnel Office
- Defense Technical Information Center
- Defense Technology Security Administration
- Department of Defense Education Activity
- Department of Defense Human Resources Activity
- Department of Defense Test Resource Management Center
- Office of Economic Adjustment
- TRICARE Management Activity
- Washington Headquarters Services

Military Service Academies:

- United States Military Academy (West Point NY)
- United States Naval Academy (Annapolis MD)
- United States Air Force Academy (CO)
- United States Coast Guard Academy (New London CT)
- United States Merchant Marine Academy (Kings Point NY)

Source: ***from http://en.wikipedia.org/wiki/Organizational_structure_of_the_United_States_Department_of_Defense***
http://www.defense.gov/faq/pis/20.html