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.

The University of Connecticut Health Center does not allow research involving chemical or biological agents, including research for prophylactic, protective, or other peaceful purposes involving chemical or biological agents.

The University of Connecticut Health Center does not conduct classified research.

DoD Approval

To ensure all required elements are met prior to the start of the research, Principal 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 can not 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 UConn Health 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: The DoD no longer requires an independent research monitor for studies greater than minimal risk. Investigators of existing open studies with a independent research monitor may request removal of the requirement for a monitor through a modification request to the IRB.

Confidentiality of Data:
Data or information acquired by the DoD component under a pledge of confidentiality for exclusively statistical purposes must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent.
All studies involving large scale genomic data collected on/from DoD-affiliated personnel will apply a DHHS Certificate of Confidentiality.

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. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

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:
The investigator is responsible for adhering to the following reporting requirements:

1. To report the following to the DoD human research protection officer (DHRPO) within 30 days:
    - Determinations of serious or continuing noncompliance
    - 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)

- 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.

2. To report the following to the Component Office of Human Research Protections within 30 days:
    - Reports of audits of DoD-conducted or DoD-supported human subject research by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government.
    - Allegations of serious or continuing noncompliance related to research involving human subjects that are substantiated by investigation, and subsequent actions taken based on the findings.
    - Unanticipated problems involving risks to subjects or others and any subsequent actions taken based on the findings.

3. To report substantiated allegations related to classified human subject research immediately.

The IRB will report the following to the DHRPO and/or COHRP within 30 days:

- 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)

<u>International Research:</u>
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. Investigators must obtain confirmation of approval from the appropriate DoD component prior to research starting when human subjects research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens.

<u>Multi-Site Research</u>
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.

When UConn Health (a non-DoD organization) collaborates on research with DoD organizations, UConn Health IRB will not serve as the reviewing IRB.

When serving as the IRB for DoD-*supported* research, the IRB will report the following to the Component Office for Human Research Protections (COHRP) within 30 days. (DoDI 3216.02 section 3.6):

- When the organization is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that any part of an HRPP is under investigation for cause involving a DoD-supported research protocol.
- Any problems involving risks to subjects or others, suspension, or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD-supported human subject research.
- Closure of a DoD-supported study.
- The PI must report the following to the Component Office for Human Research Protections (COHRP) within 30 days. (DoDI 3216.02 section 3.6): When significant changes to the research protocol are approved by the IRB:
    - Changes to key investigators or institutions.
    - Decreased benefit or increased risk to subjects in greater than minimal risk research.
    - Addition of vulnerable populations as subjects.
    - Addition of DoD-affiliated personnel as subjects.
- Change in status when a previously enrolled subject becomes pregnant, or when the investigator learns that a previously enrolled subject is pregnant, and the protocol was not reviewed and approved by the IRBs in accordance with 45 CFR 46, Subpart B.
- Change in status when a previously enrolled subject becomes a prisoner, and the protocol was not reviewed and approved by the IRBs in accordance with 32 CFR 219, Subpart C.

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

DoD-affiliated personnel, military and civilian supervisors, officers, and others in the chain of command must not be present at any human subject recruitment sessions or during the consent process for DoD-affiliated personnel.

For greater than minimal risk research involving DoD-personnel, when recruitment and consent occurs in a group setting, the IRB will appoint an ombudsperson who:

- Does not have a conflict of interest with the research or is part of the research team.
- Must be present during human subject recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary, and that the information provided about the

research is consistent with the IRB-approved script and materials, including digitally provided materials.
- Should be available to address DoD-affiliated personnel's concerns about participation.

Research involving an "experimental subject" is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving "experimental subjects" is a subset of research involving human subjects. This definition relates only to the application of Section 980 of Title 10, U.S.C; it does not affect the application of 32 CFR 219. If non-exempt research is supported by DoD-appropriated funds and involves experimental subjects as defined in DODI 3216.02, consent must be obtained in advance, in accordance with 10 USC 980.
The IRB may waive or alter some elements of informed consent for research involving human beings as experimental subjects, so long as it preserves the informed consent of the subject (i.e., the consent indicates that participation in the research is voluntary, and the subject/representative is informed of research risks).

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 work hours.
- Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to $50 for each blood draw.
- Non-federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRBs according to local prevailing rates and the nature of the research.

Survey Review:
When conducting surveys on DoD personnel, the PI must submit the surveys for review and approval by the DoD Information Management Control Officer (IMCO) after the research protocol has been reviewed and approved by the IRB. When a survey crosses DoD components, the PI must obtain additional reviews as required.
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
Research involving a detainee or a prisoner of war as a human participant is prohibited.
This prohibition does not apply to activities covered by investigational new drug or investigational device provisions of FDA regulations, when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations, and only when the same product may be available to DoD-affiliated personnel consistent with established medical practices.

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, by internal policy UConn Health applies subpart B to all federally funded or supported non-exempt research, regardless of risk level.

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.

For human subject research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOHRP must be obtained through the COHPR prior to research starting.

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.

When a previously enrolled human subject becomes a prisoner, and the protocol has not been reviewed and approved by the IRB in accordance with Subpart C, the investigator must promptly notify the IRB. For DoD-supported research, the DHSPP/designee will notify the DOHRPO and other federal agencies. All research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) must cease until a request to approve a change in the research protocol is approved by the convened IRB and the DOHRP has concurred with the IRB. 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. The DOHRP must concur with the IRB before the participant can continue to participate while a prisoner.

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.

<u>Emergency Medicine Research</u>
An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense. The PI must obtain approval from the DOHRP on behalf of the Secretary of Defense for a waiver of the advance informed consent provision of 10 USC 980 and include the documentation of approval with the submission to the IRB.

Procedure

Investigators conducting DoD 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 ***11/1/2023***
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