Policy on Department of Defense Funded Research

Effective date: 9/20/2019

I. Background
This policy outlines the additional IRB review requirements for Department of Defense (DOD) funded research that must be followed in addition to 45 CFR 46 regulations.

II. Definitions
a. Prisoner of War: Individuals under the custody and/or control of the Department of Defense as defined in the Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949, Articles 4 and 5. In particular, one who, while engaged in combat under orders of his government, is captured by the armed forces of the enemy. Note: Research involving a detainee (as defined in DOD Directive 2310.01E) as a human subject is prohibited.

b. Research Involving a Human Being as an Experimental Subject: 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. Note: This definition applies only to activities that are considered to be research involving human subjects and does not include activities that meet the exemption criteria at 32 CFR 219 (Common Rule) or research involving the collection or study of existing data, documents, records, or specimens from living individuals. Research involving a human being as an experimental subject is a subset of research involving human subjects; used only when 10 USC 980 (Limitation on Use of Humans as Experimental Subjects) applies.

c. Specific Component (DOD): Any one of the military branches or organizational entities within the Department of Defense, including the Army, Navy, Air Force, Coast Guard, or Marine Corps.

III. DOD Requirements for Human Research
a. All personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing DOD-supported research must complete initial and ongoing research ethics and human subjects protections training appropriate to the individual’s involvement, duties, and responsibilities. The DOD-specific component supporting the research (e.g., Department of Navy) may evaluate human subjects research training to ensure that an investigator is qualified to perform the research, based its complexity and risk. Note: DOD may require additional education or professional certification, depending on the research.
b. The definition of “minimal risk,” which includes the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” should not be interpreted to include inherent risks certain classes of humans face in their everyday lives. For example, risks in research focused on special populations should not be considered in the context of the inherent risks of their work environments (e.g., emergency responders, pilots, or soldiers in a combat zone) or of having a medical condition (e.g., by having frequent medical tests or constant pain).

c. Surveys performed on DOD personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol has been reviewed and approved by the IRB.

d. An independent research monitor is required for research involving greater than minimal risk and for some minimal risk studies, when appropriate to provide additional protections for research participants, as described below:
   1. A research monitor must be appointed by name and independent of the research team; the monitor may be an ombudsman or member of a data and safety monitoring board
   2. There may be more than one research monitor (e.g., if different skills or experience are needed) for a study; the duties of the monitor(s) will be based on the risks or specific concerns about the research
   3. The IRB must approve a written summary of the research monitor(s)’ duties, authorities, and responsibilities
   4. The IRB Chair or Institutional Official will communicate with the research monitor(s) to confirm monitor(s)’ duties, authorities, and responsibilities
   5. Research monitors may perform oversight functions (e.g., observe recruitment, enrollment procedures, and/or the consent process; oversee study interventions or interactions; review monitoring plans and/or unanticipated problems involving risks to subjects or others; oversee data matching, collection, and analysis)
   6. Research monitors may discuss the study with researchers, interview research participants, and consult with others outside the study
   7. Research monitors may report observations and findings to the IRB or to a designated university official
   8. Research monitors have the authority to stop a study in progress, remove individuals from study, and/or take any steps necessary to protect the safety and well-being of participants until the IRB can assess the situation.

e. Investigators and the IRBs will ensure that consent disclosures for research-related injury follow the requirements of the DOD-specific component.

f. For “research involving a human being as an experimental subject” (see “Definitions” above), informed consent must be obtained from the subject, with the following exceptions:
1. Consent may be provided by the experimental subject’s legal representative if the research intends to benefit the individual subject. Note: The determination that research is intended to be beneficial to the individual subject must be made by the IRB.

2. A waiver of consent may be approved by the Assistant Secretary of Defense (ASD) for Research and Engineering (R&E) only for research meeting all of the following conditions: The research is necessary to advance the development of a medical product for the U.S. Military Services, the research may directly benefit the individual experimental subject, and the research is conducted in compliance with all other applicable laws and regulations. Note: The ASD(R&E) may delegate the waiver authority described above to the Heads of the Office of the Secretary of Defense and DOD Components (e.g., Secretary of the Navy) if they have appropriate policies and procedures in their management plans. This authority is further delegable only to a DOD Component official who is a Presidential Appointee with Senate Confirmation.

g. Exceptions from the requirements for informed consent in planned emergency research are prohibited unless a waiver is obtained from the Secretary of Defense or his/her delegate (e.g., Secretary of the Navy).

h. For research involving pregnant women, fetuses, or neonates, or prisoners, additional requirements (including those described in DHHS Subparts B and C, respectively) apply: When applying Subpart B, the phrase “biomedical knowledge” should be replaced throughout with “generalizable knowledge”, the applicability of Subpart B is limited to research involving pregnant women that is greater than minimal risk and that includes interventions or invasive procedures for the woman or the fetus, or to research involving fetuses or neonates, fetal research must comply with 42 USC 289G-1, Research on Transplantation of Fetal Tissue.

i. For research involving prisoners, the following additional requirements apply: DOD-supported research involving prisoners cannot be reviewed by the expedited procedure. When a previously-enrolled research participant becomes a prisoner all of the following are required: The convened IRB, upon being notified that a research participant has become a prisoner, will promptly re-review the study to ensure that the rights and well-being of the now prisoner-participant are not in jeopardy, the convened IRB may only approve a change to the research to allow the prisoner-participant to continue in the study if the participant can continue to provide consent, he/she is capable of meeting the study requirements, the terms of confinement do not inhibit the ethical conduct of the research, and there are no other significant issues preventing the study from continuing as approved, IRB approval is limited to allowing the specific prisoner-participant to continue in the study and does not allow recruitment of additional prisoners, and the Institutional Official and
DOD-specific Component office must review and concur with the convened IRB’s approval to change the research to include the prisoner-participant.

j. When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party, including the following: Statement of work and brief description of the research, responsibility for scientific and IRB review, role of sites in subject recruitment, procedures for obtaining informed consent, provisions for oversight and ongoing monitoring, reporting requirements, document retention, assurance of compliance with all relevant human subjects protection requirements at each site, and for collaborating institutions relying on another institution’s IRB, assurance that such reliance does not compromise any standards or requirements.

k. For international research, the investigator must obtain permission to conduct research in the host country by local IRB or ethics review. All local laws, customs, and practices must be followed.

l. For research involving U.S. military personnel, additional requirements apply: Superiors (e.g., military and civilian supervisors, unit officers, and noncommissioned officers) are not permitted to influence the decisions of their subordinates (e.g., junior enlisted personnel and equivalent civilians), superiors may not be present at the time of recruitment or during the consent process for members of units under their command, superiors will have a separate opportunity to participate in the research, and an independent ombudsman will be present when recruitment involves a percentage of a unit. The following limitations on compensation for military research participants are required: Federal personnel may not be paid by any source other than their regular salaries while on duty, including compensation for research participation, except for compensation for blood drawing (up to $50 per blood draw), and federal personnel may be compensated for research participation when not on duty, in a reasonable amount as approved by the IRB, according to local prevailing rates and the nature of the research.

m. Research involving detainees (as defined in DOD Directive 2310.01E), including prisoners of war, is prohibited. Note: This prohibition does not apply to research involving investigational drugs and devices when used for diagnosis or treatment of a medical condition and when the same products would be offered to members of the U.S. Military Services, in the same location for the same condition, and when consistent with established medical practice (and FDA requirements) involving investigational drugs and devices.

n. The following must be promptly reported to the DOD-specific component’s human research protection official or office: When significant changes to the research are approved by the IRB, results of continuing IRB review, change(s) in reviewing IRB, notification by any federal department, agency, or national organization that any part of the HRPP is under a “for-cause”
investigation involving DOD-supported research, serious and/or continuing noncompliance, any unanticipated problem involving risks to subjects or others for DOD-supported research, and any suspension or termination of DOD-supported research.

o. Records documenting compliance (or noncompliance) with DOD regulations will be made accessible for inspection and copying by DOD representatives at reasonable times and in a reasonable manner.

IV. References

a. DoD Instruction Number 3216.02
b. Human Research Protection Office (HRPO) - USAMRMC - Army.mil
c. Department of the Navy Human Research Protection Program