

## 15.0 Research Funded by the Department of Defense

The following considerations apply to human subjects research supported by a Department of Defense component through a contract, grant, or other arrangement.

A Department of Defense component is a military department, defense agency, DOD field activity, or organization within the Office of the Secretary of Defense. DOD components include, but may not be limited to the following: Department of Defense, Army, National Guard, Navy, Air Force, Marines, U.S. Army Corps of Engineers.

### 15.1 Definitions as Defined by DOD

**DOD subjects:** This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person, and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions the purpose of diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees with the detainees' informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and only when the same product would be offered to members of the U.S. Military Services in the same location for the same medical condition and only when consistent with established medical practice involving investigational drugs and devices.

**DOD Research Involving Interventions or Interactions with Subjects:** Research involving a human being as a research 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 a human being as a research subject is a subset of research involving human subjects. This definition does not include exempt research involving human subjects.

**DOD Research Monitor:** The research monitor may be identified by an Investigator or appointed by an IRB or IO for research involving human subjects determined to involve minimal risk. There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. The Heads of the OSD and DOD Components may waive

the requirement to have a research monitor on a case-by-case basis when the inclusion of a research monitor is not necessary to provide additional protections for human subjects. This waiver authority may be delegated to a DOD official, as described in the Component's HRPP management plan, but not at or below the position of the institution's DOD IO.

**DOD Ombudsman:** independent, impartial resource that provides DOD employees worldwide with a safe harbor for informal and confidential dispute resolution.

**DOD Minimal Risk:** Minimal risk is based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests"; minimal risk shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain.)

## 15.2 Policy

### 15.2.1 Criteria for Approval Specific to DOD

- When appropriate, research protocols must be reviewed and approved by the IRB prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
- Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
- There may be specific educational requirements or certification required by DOD above the educational requirements required by the institution. It is the Principal Investigator's responsibility to ensure that research staff has completed all appropriate educational requirements as mandated by DOD policy. The Department of Defense component may evaluate the education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.
- The disclosure regarding provisions for research-related injury follows the requirements of the DOD component. The PI is responsible for informing the IRB, in writing, if there are any additional requirements from the DOD Component regarding the provision of care in the case of a research-related injury.

- When conducting multisite research, a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities.
- Surveys performed on Department of Defense personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB.
- If consent is to be obtained from the research subjects' legal representative, the research must intend to benefit the individual participant.
- The determination that research is intended to be beneficial to the individual research subject must be made by an IRB.
- When Investigators are following ICH-GCP (E6) guidelines, Investigators and research staff must provide all the disclosures and follow the requirements pertaining to consent covered by ICH-GCP(E6).
- The Investigator and research staff are aware of the specific DOD requirements and have been educated about these requirements.
- The research does NOT involve prisoners of war or detainees as subjects.

### **15.2.2 DOD Criteria for Waiver of Consent**

- If the research involves interventions or interactions with subjects, the research does not involve a waiver of consent or permission. The requirement for consent may be waived by the Assistant Secretary of Defense for Research and Engineering ASD(R&E) if the following three conditions are met:
  - The research is necessary to advance the development of a medical product for the Military Services.
  - The research may directly benefit the individual research subject.
  - The research is conducted in compliance with all other applicable laws and regulations. The ASD(R&E) may delegate the waiver authority.

### **15.2.3 DOD Policy Regarding Payment for Research**

- Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.
- Military personnel will not be paid for research conducted while on duty; however, the personnel can be compensated if involved in the research while not on duty.

- Although federal personnel participating as human subjects in DOD-conducted research while on duty may be compensated up to \$50 for each blood draw for scientific and research purposes in connection with the care of any person entitled to treatment at government expense, this IRB allows no such compensation when compensation is otherwise prohibited.
- Military personnel can participate in research off-duty; however, they cannot be paid from federal funds for research conducted while off duty.
- Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

#### **15.2.4 DOD Policy Regarding Recruitment**

- Superiors will not influence the decisions of their subordinates regarding participation in research.
- Superiors will not be present at the time of recruitment and consent. When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.
- 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.
- Research involving minimal risk: The IRB has discussed and determined whether to appoint an ombudsman based in part on the subject population, the consent process, and the recruitment strategy.
- Research involving greater than minimal risk: The IRB has appointed an ombudsman who is unassociated to the research and will be present during the recruitment to monitor that voluntary participation is clearly and adequately stressed and that information provided about the research is clear, adequate, and accurate. The ombudsman may also be the research monitor.

#### **15.2.5 DOD Research Cognitively Impaired**

- If the research involves interventions or interactions with cognitively impaired subjects, there must be an anticipated direct benefit to the subject.

#### **15.2.6 DOD Research Involving Pregnant Women, Prisoners and Children**

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

### **15.2.6.1 DOD Research – Subpart B – Research with Pregnant Women and Fetuses**

- For purposes of applying Subpart B, the phrase “biomedical knowledge” shall be replaced with “generalizable knowledge.”
- The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.
- Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

### **15.2.6.2 DOD Research – Subpart C – Research with Prisoners**

- 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 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 reviews the IRB’s approval to change the research protocol. Otherwise, the IRB chair shall 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, shall 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.

- Research involving a detainee as a human participant is prohibited.
- This prohibition 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.

#### **15.2.6.3 DOD Research – Subpart D – Research with Children**

- Research involving children cannot be exempt.

### **15.2.7 DOD Research Involving More Than A Minimal Risk**

#### **15.2.7.1 DOD Research – Research Monitor**

- For research involving more than minimal risk, an independent research monitor has been appointed by name who:
  - Has expertise consonant with the nature of risk(s) identified within the research protocol.
  - Is independent of the team conducting the research involving human subjects.
  - Has authority to stop a research in progress, remove individual subjects from research, and take necessary steps to protect the safety and well-being of subjects until the IRB can assess the monitor's report.
- Will promptly report his/her observations and findings to the IRB or other designated official.
- Has an IRB approved written summary of duties, authorities, and responsibilities based on specific risks or concerns about the research. The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor

may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and UPIRTSO reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official. The research monitor may discuss the research protocol with the Investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.

### 15.2.8 DOD Research – Non U.S. Citizens

- If the research involves human subjects who are not U.S. citizens or personnel of the DOD, and is conducted outside the United States, its territories, and its possessions, the IRB will verify:
  - The permission of the host country has been obtained.
  - The laws, customs, and practices of the host country and the United States will be followed.
  - An ethics review by the host country, or local IRB with host country representation, will take place.

### 15.2.9 DOD Research – Classified Research

- See the following additional criteria for Department of Defense (DOD) research involving classified information:
  - Non-exempt classified research must be conducted following the requirements of [3216.02.13](#).
  - The convened IRB approved the research. (Use of an expedited review procedure is prohibited.)
  - The IRB has determined that potential subjects need access to classified information to make a valid, informed consent decision.
  - The IRB has consulted with an expert on classified information.
  - The research does not involve a waiver of informed consent.

- The informed consent process identifies DOD as the supporting institution of the research, unless the research involves no more than minimal risk or the Secretary of Defense has granted an exception.
- The informed consent process includes a statement that the research is classified and an explanation of the impact of the classification.
- Disclosure or use of classified information complies with the federal requirements for access to and protection of classified information.
- Any IRB member who disagrees with a majority decision approving a project will be allowed to appeal the decision to the Secretary of Defense.
- Secretary of Defense approval will be obtained.
- The IRB needs classified information for approval and oversight, subjects must be provided classified information as part of the consent process; or subjects will provide classified information during the course of the research.

### **15.2.10 DOD Research – Non-Compliance**

See the following regarding non-compliance for Department of Defense research:

- Records maintained that document compliance or non-compliance with Department of Defense requirements shall be made accessible for inspection and copying by representatives of the Department of Defense at reasonable times and in a reasonable manner as determined by the supporting DOD component.

### **15.2.11 DOD Research – Additional Reporting Requirements by Investigator to DOD**

- The following shall be promptly reported (within 30 days) to the Department of Defense Human Research Protections Officer by the Investigator:
  - When significant changes to the research protocol are approved by the IRB.
  - The results of the IRB continuing review.
  - Change of reviewing IRB.
  - When the organization is notified by any Federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DOD-supported research protocol.