

## 15.0 Research Funded by the Department of Defense

1. 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.
2. 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.
3. 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.
4. Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.
5. There may be specific educational requirements or certification required.
6. See the following additional criteria for approval of research funded by the Department of Defense:
  - 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.<sup>1</sup>
  - Military personnel will not be paid for research conducted while on duty.<sup>2</sup>
  - Military personnel can participate in research off-duty; however, they cannot be paid from federal funds for research conducted while off duty.

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<sup>1</sup> 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 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.

<sup>2</sup> 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.

- If the research involves interventions or interactions with subjects<sup>3</sup>, the research does not involve a waiver of consent or permission.<sup>4</sup>
  - If the research involves interventions or interactions with cognitively impaired subjects, there is anticipated direct benefit to the subject.
  - If the research involves Prisoners, the convened IRB reviewed the research. (Review by the expedited procedure is not allowed.)
  - 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.<sup>5</sup>
  - The disclosure regarding provisions for research-related injury follows the requirements of the DOD component.
  - 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.
  - If the research involves a survey performed on DOD personnel, DOD approval will be obtained before the research commences.
7. For research involving more than minimal risk an independent research monitor has been appointed by name who:<sup>6</sup>
- 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.

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<sup>3</sup> Research involving a human being as 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 a human being as an experimental subject is a subset of research involving human subjects. This definition does not include exempt research involving human subjects.

<sup>4</sup> The requirement for consent may be waived by the ASD(R&E) if the following three conditions are met: (1) The research is necessary to advance the development of a medical product for the Military Services. (2) The research may directly benefit the individual experimental subject. (3) The research is conducted in compliance with all other applicable laws and regulations. The ASD(R&E) may delegate the waiver authority.

<sup>5</sup> When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

<sup>6</sup> 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 HRRP management plan, but not at or below the position of the institution's DOD IO.

- Has an IRB approved written summary of duties, authorities, and responsibilities<sup>7</sup> based on specific risks or concerns about the research.
  - Has confirmed in writing his/her duties, authorities, and responsibilities.
8. If recruitment is in a group setting and the research involves more than a minimal risk:
- Research involves greater than minimal risk: The IRB has appointed an ombudsman<sup>8</sup> 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.
9. If recruitment is in a group setting and the research involves minimal risk:
- Research involves 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.
10. 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 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.
11. See the following additional criteria for Department of Defense (DOD) research involving classified information:<sup>9</sup>
- The convened IRB approved the research. (Use of an expedited review procedure is prohibited.)

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<sup>7</sup> 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.

<sup>8</sup> The ombudsman may also be the research monitor.

<sup>9</sup> 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.

- 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.