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| **Notes:** | |

## Can non-exempt research conducted or supported by DOD be approved?[1,2]

The following General Criteria and all criteria for applicable categories must be met:

1. ☐ General Criteria
   - 1.1. ☐ The investigator and research staff have been trained on DOD regulations and requirements[3]
   - 1.2. ☐ The IRB has considered the scientific merit of the research[4]
2. ☐ Research That Involves Informed Consent
   - 2.1. ☐ The consent document states that the DOD or a DOD organization is funding the study
   - 2.2. ☐ The consent document states that representatives of the DOD are authorized to review research records
   - 2.3. ☐ The disclosure for research-related injury follows the requirements of the DOD component
3. ☐ Multi-Site Research
   - 3.1. ☐ There is a formal agreement between organizations to specify the roles and responsibilities of each party
4. ☐ Research That Involves a Waiver of Consent for "Experimental Subjects"[5]
   - 4.1. ☐ A waiver will be obtained from the Assistant Secretary of DOD for Research and Engineering[6]
5. ☐ Research That Involves LAR Permission for "Experimental Subjects"[5]
   - 5.1. ☐ The research holds out the prospect of direct benefit the individual subject[7]
6. ☐ Research That Involves Pregnant Women, <Fetuses>, or Neonates as Subjects
   - 6.1. ☐ One of the following is true:
     - 6.1.1. ○ The research does not involve interventions or invasive procedures with more than <Minimal Risk> to subjects
     - 6.1.2. ○ The research meets "CHECKLIST: Pregnant Women (HRP-305)"
7. ☐ Research That Involves <Prisoners> as Subjects
   - 7.1. ☐ The research meets the requirements of "CHECKLIST: Prisoners (HRP-308)"
   - 7.2. ☐ The research is reviewed by a convened IRB
   - 7.3. ☐ A prisoner representative is present at the convened meeting
   - 7.4. ☐ The research does not involving prisoners of war or detainees as subjects[8,9]
   - 7.5. ☐ The research was not approved under the category of Epidemiologic studies where prisoners are not a particular focus of the research
8. ☐ Research That Involves <Children> as Subjects[10]
   - 8.1. ☐ The research meets "CHECKLIST: Children (HRP-310)"
9. ☐ Research That Involves Fetal Tissue
   - 9.1. ☐ The research complies with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g
10. ☐ Research Conducted Outside the United States
    - 10.1. ☐ Permission has been obtained to conduct research in each country by certification or local ethics review
    - 10.2. ☐ The investigator will follow all local laws, regulations, customs, and practices
11. ☐ Research That Involves Greater Than <Minimal Risk> to Subjects
    - 11.1. ☐ The IRB has approved an independent research monitor[11]
    - 11.2. ☐ The monitor has been appointed by name
    - 11.3. ☐ The research monitor has expertise consonant with the nature of risks identified within the research protocol
    - 11.4. ☐ The monitor's duties have been determined on the basis of specific risks or concerns about the research[12]
    - 11.5. ☐ The monitor has the authority to discuss the research protocol with the investigators, interview subjects, and consult with others outside of the study about the research

11.6. ☐ The monitor has the authority to stop a research protocol in progress, remove individual subjects from a research protocol, and takewhatever steps are necessary to protect the safety and well-being of subjects until the IRB can assess the monitor's report

11.7. ☐ The monitor will promptly report observations and findings to the IRB

11.8. ☐ The IRB will communicate with the research monitor to confirm duties, authorities, and responsibilities

11.9. ☐ The IRB has approved a written summary of the monitors' duties, authorities, and responsibilities

12. ☐ Research That Involves a Waiver of Consent for Planned Emergency Research

12.1. ☐ A waiver has been obtained from the Secretary of DOD

13. ☐ Research That Involves Service Members as Subjects

13.1. ☐ Superiors of service members will not influence the decisions of their subordinates to take part in research

13.2. ☐ Superiors of service members in the chain of command will not be present at any recruitment sessions or during the consent process in which members of units under their command are recruited to take part in research[13]

13.3. ☐ Service members will not receive payment for research conducted during duty hours[14]

13.4. ☐ One of the following is true:

13.4.1. ◯ The research does not involve surveys administered to service members

13.4.2. ◯ The investigator will obtain DOD approval of surveys administered to service members

14. ☐ Research That Involves Recruitment in a Group Setting

14.1. ☐ Select the one that is true:

14.1.1. ◯ The research involves service members as subjects

14.1.2. ◯ The research does NOT involve service members as subjects

14.2. ☐ Select the one that is true:

14.2.1. ◯ The research involves greater than <Minimal Risk>

14.2.2. ◯ The research involves NO greater than <Minimal Risk>

14.3. ☐ The IRB has appointed an ombudsman[12] (service members)

14.4. ☐ The IRB has determined whether to appoint an ombudsman[15] (NO services members or <Minimal Risk>)

15. ☐ Classified Research[16]

15.1. ☐ The Secretary of DOD has approved the research[17]

15.2. ☐ The research does not involve a waiver of informed consent

15.3. ☐ One of the following is true:

15.3.1. ◯ The consent document identifies DOD as the supporting institution of the research

15.3.2. ◯ The research involves no more than <Minimal Risk>

15.3.3. ◯ The Secretary of DOD has granted an exception[18]

15.4. ☐ The consent document states that the research involving subjects is classified

15.5. ☐ The consent document explains the impact of the classification

15.6. ☐ Review is conducted using a full board review[19]

15.7. ☐ At least one non-affiliated member is a non-Federal employee and not a DOD consultant

15.8. ☐ Potential subjects need access to classified information to make a valid, informed consent decision

15.9. ☐ The IRB has obtained consultation to ensure that use or disclosure of classified information complies with federal requirements

**Footnotes**

1. DoD Instruction 3216.02 Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
2. In this worksheet, "research" means <Research as Defined by HHS> involving <Human Subjects as Defined by HHS>, and "subject" means <Human Subject as Defined by HHS>.
3. DOD may evaluate the organization's education policies to ensure the personnel are qualified to perform the research, based on complexity and risk, and may require additional training.
4. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

5. "Experimental Subject" means a living individual involved in an activity where, for research purposes, there is an <Intervention> or <Interaction> with that individual for the primary purpose of obtaining data regarding the effect of the <Intervention> or <Interaction>. "Experimental Subject" is a subset of <Human Subjects as defined by HHS>.
6. The Assistant Secretary for DOD for Research and Engineering may waive the requirements for consent when all of the following 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[4]. (3) The research is conducted in compliance with all other applicable laws and regulations. The IRB may waive the consent process for subjects who are not "Experimental Subjects".
7. The determination that research is intended to be beneficial to the individual <Experimental Subject as Defined by DOD> must be made by an IRB.
8. “Prisoner of war” 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.
9. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions for 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.
10. For purposes of legal capacity to participate in DoD-conducted or -supported research involving human subjects, all active duty Service members and all Reserve Component members in a Federal duty status are adults. The participation of such members is not subject to requirements of 45 CFR §46 Subpart D.
11. The research monitor may be identified by an investigator or appointed by an IRB or institutional official for research involving human subjects determined to involve more than <Minimal Risk>. There may be more than one research monitor. The monitor may be an ombudsman or a member of the data safety monitoring board. The Secretary of DOD 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. This waiver authority may be delegated to a DOD official, per the Component’s HRPP plan, but not at or below the position of the institutional official.
12. The research monitor may perform oversight functions and report their observations and findings to the IRB or a designated official.
13. Superiors may have the opportunity to participate as human subjects in a separate recruitment session.
14. An individual may be compensated for research involved in the research when not on duty. 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 participating 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. The ombudsman may also be the research monitor. The decision to require the appointment of an ombudsman should be based in part on the human subject population, the consent process, and the recruitment strategy.
16. The involvement of classified information may be limited to information needed for IRB approval and oversight of the research; information needed to inform the human subjects during the consent process and Information provided by the subjects during the course of the research.
17. Submission for approval must be from the Secretary of DOD or DOD Component conducting or supporting the research. The request must be coordinated with the Assistant Secretary of Defense for Research & Engineering and General Counsel of DOD after the IRB has approved the research.
18. The Secretary of DOD may grant an exception on the grounds that providing this information could compromise intelligence sources or methods.
19. Use of expedited review is prohibited. Any IRB member who disagrees with a majority approval may appeal the decision to the Secretary of DOD.