

**University of Cincinnati Human Research Protection Program
Checklist for Department of Defense Research**

Principal Investigator:	
IRB Study #:	
Study Title:	
NOTE:	Research initiated or funded by the Department of Defense (DoD) must be reviewed under an additional set of federal regulations (32 CFR Part 219). Other requirements must be met before study activities begin. The DoD follows DHHS and FDA regulations for human subjects research. It also applies the Directive 3216.02 “Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research” to human research. This checklist is intended to help you ensure these additional requirements are addressed.

1. DoD COMPONENTS AND INVOLVEMENT

What component(s) of the United States Department of Defense (DoD) are involved in this research? Check all that apply.

- Navy
- Army
- US Army Corps of Engineers
- Air Force
- National Guard
- Marines
- Other: _____

What is the role of the DoD in your research?

- A component of the DoD is funding the research
- A component of the DoD will have a collaborative, cooperative, or similar role in the research
- A component of the DoD has property, facilities or assets involved in the research
- The personnel from a component of the DoD (military or civilian) are being recruited as part of the study population and will provide data or specimens

Is the study being reviewed by the DoD IRB?

- Yes NO N/A

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2. AGREEMENTS

Has a copy of the grant, if applicable, been included in the ePas submission with the name of the funding agency/program, title of the grant, award number and name of the lead investigator?

Yes NO N/A

3. RESEARCH REVIEW

The definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” 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 will 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).

The IRB is aware of the definition of “prisoner of war” for the DoD component granting the addendum. Research involving prisoners of war is prohibited.

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.

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.

4. INFORMED CONSENT PROCESS

If the research participant does not meet the definition of “experimental subject,” the IRB is allowed to waive the consent process. When the research meets the DoD definition of “Research Involving a Human Being as an Experimental Subject,” the IRB may not waive the consent process. (The definition may be found in DoDD 3216.02, Enclosure 2. Definitions. Paragraph E2.1.3: “An activity, for research purposes, where there is an intervention or interaction with a human subject for the primary purpose of obtaining the effect of the intervention or interaction (32 CFR 219.102(f).”) This places limitations on research involving deception, Draft 1/16/12 decisionally-impaired individuals, or research being conducted under emergency conditions where the subject may not be able to provide consent.

The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:

- The research is necessarily to advance the development of a medical product for the Military Services.
- The research might directly benefit the individual experimental subject.
- The research is conducted in compliance with all other applicable laws and regulations.

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For classified research, waivers of consent are prohibited.

An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual participant. The determination that research is intended to be beneficial to the individual experimental subject must be made by an IRB.

This statute applies only to certain intervention studies. It does not apply to retrospective research involving analysis of data or specimens, observational studies, blood draws, or tissue collection, and does NOT apply to screening of records to identify possible subjects. The IRB may grant a waiver of consent for such activities.

The Secretary of Defense may waive this consent requirement for a specific project in order to advance the development of a medical product necessary to the Armed Forces, but only if the research may directly benefit the subject and the research is carried out in accord with all other applicable laws and regulations.

Informed consent may be provided by a legally authorized representative (LAR) only if: (1) the subject lacks decision-making capacity; AND (2) the IRB has determined that the research is intended to be beneficial to the individual subjects.

5. VULNERABLE PARTICIPANTS

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

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.

Research involving children cannot be exempt.

Research involving prisoners cannot be and will not be reviewed by the expedited procedure.

When the IRB reviews research involving prisoners, at least one prisoner representative must be and will be present for quorum.

If 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 review 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

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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.

6. STUDY RELATED INJURY

Every project involving greater than minimal risk shall include an arrangement for emergency treatment and necessary follow-up of any research-related injury. Investigators should work with their Program Officer within the DoD component to identify such requirements. Additional language regarding specific requirements by the DoD should be incorporated into the informed consent document as appropriate.

7. PAYMENT TO PARTICIPANTS

When research involves U.S. military personnel, limitations on dual compensation:

- Prohibit an individual from receiving pay of compensation for research during duty hours.
- U.S. military personnel may be compensated for research if the participant is 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 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.

When research involves U.S. military personnel:

- Officers are not permitted to influence the decision of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.

8. APPOINTMENT OF RESEARCH MONITORS (defined in DoDD 3126.02, section 4.4.3)

Medical monitors shall be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual subject/patient management and safety. Medical monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate

For research involving greater than minimal risk, although the IRB or organizational official can require this for a portion of the research or studies involving no more than minimal risk if appropriate:

- The medical monitor is appointed by name and shall be independent of the team conducting the research.
- There may be more than one medical monitor (e.g. if different skills or experience are needed).
- The medical monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the medical monitors' duties, authorities, and responsibilities.
- The IRB or HRPP official shall communication with research monitors to confirm their duties, authorities, and responsibilities.

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The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:

- Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis).
- Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.
- Report observations and findings to the IRB or a designated official.
- The research monitor has the authority to:
 - Stop a research study in progress.
 - Remove individuals from study.
 - Take any steps to protect the safety and well-being of participants until the IRB can assess.

9. REPORTING REQUIREMENTS

For any DoD-supported researcher, the following shall be promptly (no longer than within 30 days) reported to the DoD human research protection officer:

- 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 organizations that any part of an HRPP is under investigation for cause involving a DoD-supported research protocol.

Determinations of serious or continuing non-compliance of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

Any unanticipated problems involving risks to participants or others for any DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

Any suspension or termination of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

10. RECORD RETENTION

Records maintained that document compliance or non-compliance with DoD requirements shall 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.