

Department of Defense (DoD) Funded Human Subjects Research

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Human Subject Research involves the DoD when any of the following apply:

- The research is funded by a component of the DoD (Navy, Army, Air Force)
- The research involves cooperation, collaboration, or other types of agreements with a component of DoD
- The research uses property, facilities, or assets of a component of DoD
- The subject population will intentionally include personnel (military or civilian) from a component of DoD

- DoD policies and requirements do not apply when DoD personnel incidentally participate as subjects in research that is not supported by DoD, or DoD personnel are not the target population of the research.

- ***New Protocols.*** See the Jefferson Reviewer Checklist for Department of Defense Supported Research for a list of key DoD requirements such as: education and training requirements for the PI; independent scientific review prior to IRB review; medical monitor for greater-than-minimal risk research; and protections for participants who are military personnel.
- ***Amendments.*** Scientific review must be considered for amendments that involve new procedures, a new subject population, or other significant changes.
- ***Continuing Review and Study Closure.*** DoD requires that the IRB receive and maintain copies of publications, presentations or reports based on the research protocol. The IRB should be provided such documents until files can legally be expunged.

Post-Approval Responsibilities

- ***Continuing Education.*** DoD human subjects education requirements exceed Jefferson's requirements (e.g., DoD requires completion of continuing education annually and not every two years).
- ***Reporting Responsibilities.*** Jefferson OHR may be required to notify DoD and any non-DoD sponsor of reports of non-compliance, unanticipated problems involving risk and any actions taken regarding such reports. Jefferson OHR will also notify DoD of any audits, investigations or inspections of DoD-supported research.

IRB Review

- If you are assigned a project supported by the DoD
 - Review OHR Guidance G-620
 - Complete the IRB reviewer checklist in addition to the usual reviewer forms found on the OHR website.
 - Questions should be addressed to The Director or Associate Director, OHR