

Key Points for investigators –

Additional Requirements for Department of Defense (DoD) Human Subjects Research¹

***It is IMPORTANT to check with the sponsoring DoD Component Program Officer for specific additional requirements related to your research since the DoD Component can waive, alter or add requirements beyond those included in this policy.²**

When do these DoD Special Requirements apply to your Human Subjects Research?

- The research is funded by a DoD Component, and Geisinger receives prime or subaward, or
- The research involves cooperation, collaboration or other type of agreement with a DoD Component, or
- The research uses property, facilities, or assets of a DoD Component, or
- The subject population will intentionally include personnel (military and/or civilian) from a DoD Component. (DoD requirements do not apply when DoD personnel incidentally participate as research subjects where they are not the intended research population or where the project is not DoD-supported).

What DoD requirements are different from those of other federal sponsors?

DoD Human Research Protections Office (HRPO) Administrative Review²

- AFTER Geisinger IRB approval, the PI must submit the information specified by the DoD Component for DoD Administrative Review before the research can begin. GIRB has this included in our “pending approval” process and will grant final approval once DoD signs off.

Scientific Review

- DoD Component might require Scientific Review before IRB review and will specify whether this will be completed by the DoD or if Geisinger SRC can review.

DoD Approval of Surveys/Interviews

- Research involving surveys or interviews with DoD personnel (military or civilian) or their families might require DoD approval.

Use of LAR Consent

- Informed consent may be provided by a legally authorized representative (LAR) **only if the IRB has determined that the research is intended to be beneficial to individual participants.**

Research Monitor for More than Minimal Risk Research

- A research monitor must be appointed for all research that involves more than minimal risk; however, the Institutional Official of the DoD Component may waive this requirement.
- The monitor must be independent of the research team and possess enough expertise to evaluate the risks and conduct of the research.

- The investigator must identify the research monitor by name and have the selection approved by the reviewing IRB.

DoD Personnel (Military & Civilian) as Research Participants

- **Adult Status:** All active duty service members and reserve component members are considered to be adults for the purpose of participating in DoD-conducted or supported research.
- **Command Approval:** Command approval may be required for military personnel to participate as some types of research could impact a soldier's readiness in the field.
- **Protection of Service Members from Undue Influence:** Officers and senior non-commissioned officers may not influence the decision of subordinates to participate in research and may not be present at the time of recruitment. Superior officers must be recruited in a separate session from subordinates.
- **Limitations on Compensation:** Review policy section 5.3

Reporting Requirements²

The following must be reported **within 30 days of the event** to the HRPO of the DOD Component:

- Determinations of serious or continuing noncompliance;
- Unanticipated problems involving risks to subjects or others;
- Study suspensions or terminations;
- Audits, inspections or investigations of DoD research;
- Results of Continuing Review;
- Changes to the reviewing IRB;
- Substantive modifications to the research protocol

Resources:

¹[HRPP Handbook - Requirements for Department of Defense \(DoD\) Human Subjects Research \(p. 219\)](#)

²[Department of Defense \(DoD\) Supported Research: Investigator Responsibilities](#)