Department of Defense (DOD) Supported

Research: Investigator Responsibilities

Investigators who conduct research supported by the Department of Defense (DOD), including collaboration with DOD, or involving DOD facilities or personnel (military or civilian), must follow additional regulatory requirements.

This checklist can be used as a resource to ensure investigators complete these additional DoD requirements. Please review at the time of initial IRB approval and annually until the research has concluded. For further information contact IRB staff at 570-271-8663 or irb@geisinger.edu.

STUDY INFORMATION	
Geisinger IRB #	
Study Title	
PI Name	

Before IRB Approval			
Requirement	**Yes**	**N/A**	**Documentation**
Review GIRB Policy - DOD Research Requirements	☐		
Check with the Program officer/ Scientific Contact at sponsoring DOD component about any additional requirements.	☐		

After IRB Approval			
Requirement	**Yes**	**N/A**	**Documentation**
Submit protocol and other required information to the *sponsoring DoD component Human Research Protections Office (HRPO)* for administrative review before beginning research activities.	☐		DOD HRPO Approval. **Note:** DOD HRPO Approval should be submitted to GIRB via Study Submission Response as part of the Pending Approval Process

During Conduct of Study			
Submit to the HRPO:	**Yes**	**N/A**	**Documentation**
Substantive amendments approved by the IRB. Examples: • PI change • Change or addition of an institution • Elimination or alteration of the consent process • Change to the study population that has regulatory implications • Significant change to study design, or changes that increase risk to subjects.	☐	☐	Communications with HRPO. Documentation of HRPO approval/acknowledgement Note: Communications, acknowledgements, and/or approvals from the DOD should be submitted to GIRB via Amendment/Modification Submission Response
Results of the IRB continuing review, on an annual basis	☐	☐	
If the IRB of record changes to a different IRB	☐	☐	
Determinations of serious or continuing non-compliance.	☐	☐	
All Unanticipated Problems Involving Risk to Subjects or Others/Unanticipated Problems (UaP)	☐	☐	
Suspensions or terminations	☐	☐	
When the research is the subject of any federal department or agency audit, inspection, or investigation.	☐	☐	

If the study has a research monitor assigned, ensure that monitoring occurs as outlined in the protocol. Note: A research monitor is required for greater than minimal risk research.	☐	☐	Documentation of what was reviewed, when it was reviewed, who conducted the monitoring, and any findings or observations and their corrective actions. **Note:** Monitoring reports should be submitted to GIRB via Amendment/Modification submission and should include PI response to any observations or corrective actions.
Record Keeping Requirements			
Requirement	**Yes**	**N/A**	**Documentation**
Retain research records per Geisinger record retention guidelines.	☐		