



DEPARTMENT OF DEFENSE SPONSORED RESEARCH: INVESTIGATOR RESPONSIBILITIES

Purpose: Investigators who conduct research sponsored 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 is intended as a resource for Investigators to ensure they are meeting the additional DoD requirements and should be reviewed at the time of initial U-M IRB approval and annually until the research has concluded. For further information contact the IRB staff owner for the study.

Additional guidance on Investigator responsibilities when conducting DoD sponsored research can be found on the following U-M websites: [HRPP Guidance: Additional Requirements for Department of Defense \(DoD\) Research](#); [U-M HRPP OM Department of Defense](#) ; [ORSP: Working with DoD](#).

STUDY INFORMATION	
HUM #	
Study Title	
PI Name	
Date Checklist Completed	
Person Completing Checklist	

Before IRB Approval			
Requirement	Yes	N/A	Documentation
Review U-M HRPP Guidance: Additional Requirements for DoD Research			
Check with the Program Manager at sponsoring DoD component about any additional requirements.			

After IRB Approval			
Requirement	Yes	N/A	Documentation
Submit protocol and other required information to the Human Research Protections Office (HRPO) <i>for the sponsoring DoD component</i> for administrative review before beginning research activities.			HRPO Approval. Note: HRPO Approval should be submitted to the U-M IRB as an ORIO Report, specifically as report type, "Report(s) to or from oversight entity". Include "HRPO approval" in the ORIO report title.
During Conduct of Study			
Submit to the HRPO:	Yes	N/A	Documentation
Substantive amendments approved by the IRB. Examples: <ul style="list-style-type: none"> 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 the U-M IRB as an ORIO report, specifically as report type "Report(s) to or from oversight entity". Include the fact that the report is a communication from the DoD in the ORIO report title.
Results of the IRB continuing review, on an annual basis.			
If the IRB used to review and approve the research 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.			

During Conduct of Study			
Submit to the HRPO:	Yes	N/A	Documentation
<p>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.</p>			<p>Documentation of what was reviewed, when it was reviewed, who conducted the monitoring, and any findings or observations and their corrective actions.</p> <p>Note: Monitoring reports should be submitted to the U-M IRB as an ORIO report. An amendment should be submitted as appropriate in response to any observations or corrective actions.</p>
Record Keeping Requirements			
Requirement	Yes	N/A	Documentation
Retain research records per the U-M record retention guidelines .			