**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](https://hrpp.umich.edu/wp-content/uploads/sites/4/2024/10/dod_guidance.pdf); [U-M HRPP OM Department of Defense](https://research-compliance.umich.edu/operations-manual-contents-page); [ORSP: Working with DoD](http://orsp.umich.edu/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](https://hrpp.umich.edu/wp-content/uploads/sites/4/2024/10/dod_guidance.pdf) |  |  |  |
| 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) *for the sponsoring DoD component* 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** |
| IRB-approved changes to research that involve changes to key investigators or institutions; decreased benefit or increased risk to subjects in greater than minimal risk research as defined in Part 219 of Title 32; addition of vulnerable populations, or DoD-affiliated personnel as 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, if required. |  |  |
| 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. |  |  |
| Change in status when a previously enrolled human subject becomes pregnant, or when the researcher learns that a previously enrolled human subject is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with Subpart B of 45 CFR 46. |  |  |
| Change in status when a previously enrolled human subject becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with Subpart C of 45 CFR 46. |  |  |
| Study closure. |  |  |  |
| **Record Keeping Requirements** | | | |
| **Requirement** | **Yes** | **N/A** | **Documentation** |
| Retain research records per the  U-M [record retention guidelines](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/record-keeping-guidelines). |  |  |  |