

**Summary of Key Changes to WU IRB
Policies and Procedures
Policy Date: June 15, 2022**

| Section | Topic | Change | Rationale |
|------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| VIII.I.1.a | Department of Defense supported or conducted research | Updated definition of minimal risk. | Revised to be consistent with DOD INSTRUCTION 3216.02, April 15, 2020. |
| VIII.I.3 | Department of Defense supported or conducted research | Removed, “The DoD component may evaluate the education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.” | Revised to be consistent with DOD INSTRUCTION 3216.02, April 15, 2020. |
| VIII.I.5 | Department of Defense supported or conducted research | Removed, “When research is conducted with international populations, documentation of the permission to conduct the research in that country by certification or local ethics review is required prior to IRB approval. The research will also be required to follow all local laws, regulations, customs, and practices.” | Revised to be consistent with DOD INSTRUCTION 3216.02, April 15, 2020. Equivalent protections for international research are still required per WU IRB policies. |
| VIII.I.12 | Department of Defense supported or conducted research | Removed information regarding the IRB’s review of Research Monitor appointments. | Revised to be consistent with DOD INSTRUCTION 3216.02, April 15, 2020. |
| IX.A.5 | PI Qualifications | Removed language stating that the WU IRB does not permit individuals who are not WU faculty, staff, or students to serve as the PI of a study. | Revised for consistency as the WU IRB oversees research at non-WU/BJH/SLCH facilities. |
| IX.Q | Record Retention | Updated the record retention requirement to reflect six years rather than seven years beyond study closure with the IRB. | Alignment with record retention requirements across the University. |
| IX.U | | Newly added section. | Added to clarify who may serve as a PI. |

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| XI.F.6 | IRB function in relation to other WU committees | Added Center for Gene and Cellular Immunotherapy (CGCI). | Revised to reflect CGCI review requirements as they relate to the IRB review process. |