

VA Central IRB SOP Version 10.3, dated January 17, 2024

Changes to Version 10.3

- Inclusion of FDA required section on written procedures for IRB review of FDA regulated devices (Section 5.9)
- Inclusion of FDA required section on written procedures for IRB review of Investigational drugs and IND requirements or IND exemptions (Section 5.10)
- Reconciliation of SOP with language in the MOUs (Version 07/20/2023) and the Table of Reporting Requirements (V.1 06/27/2023) relating to RCO reports (section 2.12)
- Removal of requirement that the MCD delegate VA CIRB Liaison in writing, and clarification that this designation may come from the research office
- Designation by the Chair when new members are sufficiently experienced to be expedited reviewers is no longer in writing, but occurs in communication with the CIRB Administrator
- The previous CITI training requirement for VA CIRB Members has been removed as ORD policy requires this training only for individuals who are involved in VA human subjects research, and that is monitored by the Member's local Research Office
- Training of VA CIRB members includes training in the Belmont Report, federal regulations for the protection of research subjects, and an orientation to VA CIRB SOPs and IRBNet
- Removal of assent requirement when LAR is giving permission for a Veteran to be enrolled in research (Section 7.4)
- Minor edits to align more closely with VHA Directives 1058.01 and 1200.05
- Addition in glossary of the term "voting status"
- Minor changes for clarity