Summary of Changes:

CIRB Forms and SOP

DATE: January 22, 2024

OVERVIEW: This is a summary of changes that were made to VA Central IRB (CIRB) submission forms, VAIRRS Wizard, and SOP. Please note this update only pertains to projects under the oversight of the VA CIRB.

If there are any questions regarding these changes or if assistance is needed while compiling a submission, please contact the CIRB Manager responsible for your project, a CIRB Administrator or the CIRB general mailbox at VACentralIRB@va.gov for support.

FORM CHANGES
Release Date: 01/22/2024

Form Name	Summary of Significant Changes
100 Protocol Template V1.1	Added new instructions to provide requirements when a project requests to use an existing external/sponsor Protocol (e.g., protocol document from a non-VA CIRB research collaborator or study sponsor), in lieu of or in combination with the CIRB Protocol.
101 Protocol Template – Data/Specimen Only V1.1	Added new instructions to provide requirements when a project requests to use an existing external/sponsor Protocol (e.g., protocol document from a non-VA CIRB research collaborator or study sponsor), in lieu of or in combination with the CIRB Protocol.
112a Waiver or Alteration of Informed Consent V2	To align with recent changes made by the VAIRRS Change Control Board, Form 112a was revised to remove Section 6, the reviewer checklist and signature. The CIRB will now document approval of the waiver in the Determination Letter.
112b Waiver of Documentation of Informed Consent V2	To align with recent changes made by the VAIRRS Change Control Board, Form 112b was revised to remove Section 6, the reviewer checklist and signature. The CIRB will now document approval of the waiver in the Determination Letter.
116 Amendment Request V2.2	Section 2 was updated with the following: (1) Replaced references to Project Cover Sheet Wizard with the new Study Team Tracking Wizard; (2) Updated guidance under Key Study Personnel; and (3) Minor administrative edits.

WIZARD CHANGES

Wizard Name	Summary of Changes

Study Team Tracking Wizard	As it pertains to CIRB Projects:
	• The Study Team Tracking (STT) wizard is a required form for all new CIRB projects and any time there are changes to key personnel or an Investigator. Please note the following:
	  ○ Staff can no longer be updated in the Project Cover Sheet Wizard.
	  ○ For guidance on when key personnel changes are required to be submitted to the CIRB as an amendment, please refer to ORD Guidance titled "GUIDANCE ON IRB APPROVAL OF CHANGES IN STUDY TEAM MEMBERS" which can be found here: Human Research (va.gov).
	  ○ For clarification on what the CIRB considers as an "Investigator" please refer to the definitions in VHA Directive 1200.05.
	• The STT wizard is a site-specific form. This means only staff from that site should be listed in the STT wizard. The only exception is if there is a Co-PI from a different VA facility. Then the Co-PI must be listed on the lead Co-PI site's STT.
	
	Please refer to the instructions and guidance within the new STT wizard as well as the VAIRRS Monthly Webinar: End of Year Updates including New Wizards for additional information regarding these changes.

SOP CHANGES
Release Date: 01/17/2024

SOP	Summary of Significant Changes
CIRB SOP V10.3	• 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). • 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." • 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. • Additional minor changes for clarity.