Summary of Changes:

Post Approval Submission Forms

VA Central IRB
VA Institutional Review Board for Multisite Studies

DATE: June 28, 2023

OVERVIEW: This is a summary of significant changes that were made to VA Central IRB processes and post approval submission forms. The changes stated in this document will take effect June 28, 2023. In addition to the form and process changes detailed below, many VA Central IRB forms have undergone minor formatting and administrative changes. These changes include new headers, new instructions, and improved fillable formatting. For additional guidance and details regarding these changes you may refer to the VAIRRS Webinar from June 27, 2023 titled "CIRB Process and Form Changes."

The new forms and processes will:

- Align VA Central IRB submission forms with required IRBNet Wizards (IRB Information and Project Cover Sheets).
- Provide better usability, improved instructions, and more efficient experience for research teams.
- Eliminate unnecessary submission forms which will in turn reduce inconsistencies across forms and reduce submission errors that often leads to multiple rounds of revisions.
- Reduce duplication of reviews (VA Central IRB and local research reviews) on select content.

SIGNIFICANT PROCESS CHANGES:

Process Changes	Description
Reference Principal Investigator Only	• Removed all references to "Study Chair (SC)" from title of Principal Investigator/Study Chair (PI/SC). • Reference will now be Principal Investigator (PI) only. • Reference to Local Site Investigator (LSI) will not change.
Researcher Training Dates	• The CIRB will no longer verify Human Subjects Research training completion dates for study personnel. • The CIRB will now require a checkbox attestation that training requirements have been met and verified locally prior to submission to CIRB. • Study teams must continue to follow national policy and requirements for completing training.

Investigator COI Documentation	• The CIRB will no longer require COI documentation to be submitted for Investigators unless there is a COI management plan. If there is a COI management plan, it must be submitted.
	• The CIRB will now require a checkbox attestation that COI requirements have been completed and verified locally prior to submission to CIRB.
	  ○ New Projects – COI attestation will be in Form 102 ACOS Review
	  ○ Amendments – COI attestation will be in Form 116
	  ○ Continuing Reviews – COI attestation will be in Forms 115a/115b
	• Study teams must continue to follow national policy and requirements for completing annual COI reviews.

Reportable Events	• The CIRB Table of Reporting Requirements has been updated to reflect current definitions and submission requirements. • Additionally, a new, single Reportable Events Form 124 that captures all types of reporting categories has been created. Contents of Forms 119 UAP/SAE and 129 Protocol Deviation are captured in this new form. Forms 119/129 will be discontinued. • Reportable Events that are submitted to the CIRB, but do not require prompt reporting and are reviewed outside of a Convened Meeting will have a change in their review type. Reviews are changing from an "expedited" review with an "acknowledgement" to an "administrative" review with an "acknowledgement" as these submissions do not qualify as an expedited review procedure. Reportable Events that fall under an administrative review will be reviewed by a designated voting member of the CIRB. This change will be reflected in Review Details and CIRB Determination Letters.

RCO Audit Reports	• The CIRB has collaborated with the ORO to develop a streamlined process for submitting local RCO Audit Reports to the CIRB.
	• The required process of how to submit an RCO Audit Report is detailed in the new CIRB Table of Reporting Requirements which specifies how to submit if you are an Investigator or if you are an RCO.
	• This new process allows for RCOs to submit audit reports with no findings or findings not required to be reported within a specified timeframe under VHA Directive 1058.01 directly to the CIRB utilizing the new IRBNet RCO Audit workspace.
	• RCO Audits with findings of Apparent Serious/Continuing Noncompliance or UPIRTSO must be submitted by the responsible Investigator utilizing our new Reportable Events Form 124 and follow the reporting timelines specified in the CIRB Table of Reporting Requirements. This can be done in 1 of 2 ways:
	  1. RCO provides the responsible Investigator with the audit report and the Investigator will in turn submit the report to the CIRB as part of a Reportable Events Package in IRBNet using Form 124.
	  2. Alternatively, RCO may submit findings by email to the Investigator and the VA Central IRB using vacentralirb@va.gov. In the email, the RCO will clearly indicate that there is a finding of Apparent Serious/Continuing Noncompliance or UPIRTSO and inform the Investigator of the prompt reporting timeframe to submit the findings as a Reportable Event Package in IRBNet with Form 124.

FORM CHANGES
Release Date: 6/28/2023
Must Use By: 8/14/2023

Form Name	Summary of Significant Changes
102 Local ACOS Review	Form 102 will no longer be used for Investigator COI documentation. This form is to be completed by the PIs or LSIs local ACOS when a new project application is submitted to the CIRB. Additionally, when there are Co-PIs from different VA facilities, each Co-PI must have each local facility ACOS complete this form. From 102 now allows for the ACOS to certify that all local training, credentialing and COI review has been completed prior to the new project being submitted to the CIRB.
103 Waiver of HIPAA Authorization	No significant changes.
112a Waiver of Informed Consent	No significant changes.
112b Waiver of Documentation of Informed Consent	No significant changes.
116 Amendment Request	Revised and added new selections for change requests. Revised change request section to include updated listing of documents required for specific change requests. Replaced training, credentials and COI with a checkbox attestation when adding key personnel.
117a PI Project Closure	No significant changes.
117b LSI Local Site Closure	No significant changes.
124 Reportable Events	**NEW FORM:** Created a single Reportable Events form that captures all categories of events that may need to be reported according to the updated CIRB Table of Reporting Requirements (e.g., UPIRTSO, noncompliance, incarceration, etc.). Contents of Forms 119 SAE/UAP and 129 Protocol Deviation are captured in this new form. Forms 119 and 129 will be discontinued.
127 Protocol Exception Request	No significant changes.
130 Annual Status Report	Removed Verification of Staff section. The form will no longer require a listing of all study personnel nor will allow for staff to be removed or added.
131 Administrative Update	**NEW FORM**: The CIRB now requires this form to be submitted for ALL administrative updates and will no longer accept a cover memo to be submitted describing the update. This new form will provide a more formal submission of LSI updates due to PI amendments, LSI site specific changes, and PI administrative updates that do not require an amendment (e.g., update to phone numbers in ICF).
140 CIRB Memo	**NEW FORM:** Generic memo template that can be used when addressing the CIRB in an IRBNet package. The CIRB Memo cannot replace a required form.

DISCONTINUED FORMS
Discontinuation Date: 6/28/2023

Form Name	Where Information Will Be Captured
119 Report of SAE and UAP	New Form 124 Reportable Events
127a COVID-19 Protocol Exception Request	Form 127 Protocol Exception Request
129 Report of Protocol Deviation	New Form 124 Reportable Events
134a Change in PISC	Form 116 Amendment and Protocol Cover Sheet
134b Change in LSI	Form 116 Amendment and Protocol Cover Sheet

WHAT'S NEXT?

June 28, 2023

- New Post Approval Submission Forms will be uploaded to IRBNet Forms and Templates library (VA Central IRB Administration, Washington, DC – Documents for Researchers) and will be available for use.
- Old forms will temporarily remain in the IRBNet Forms and Templates library to accommodate submissions that are in progress.
- If there are any questions or if assistance is needed while compiling a submission during this transition time, please contact the VA Central IRB Manager responsible for your project, a CIRB Administrator or the VA Central IRB general mailbox at VACentralIRB@va.gov for support.

August 14, 2023

- On this date the VA Central IRB will only accept the new forms listed in the table above. Any package submitted with an old form will be returned for the new form to be submitted.