

Summary of Changes

PI and LSI Continuing Review



DATE: June 14, 2023

OVERVIEW: This is a summary of significant changes that were made to the Continuing Review Process and Forms. All changes will take effect June 14, 2023. In addition to the form and process changes detailed below, minor formatting and rewording of questions have been made. For additional guidance and details regarding these changes you may refer to the [VAIRRS Webinar](#) from June 13, 2023 titled “CIRB Continuing Review Process and Form Changes” which will be posted a week after the date of the webinar.

The new Continuing Review Process and Forms will:

- Create a Continuing Review submission process that fits within IRBNet.
- Provide better usability, improved instructions, and more efficient experience for research teams.
- Reduce duplication of reviews (VA Central IRB and local research reviews) on select content.
- Provide an easier mechanism for the Principal Investigator (PI) to review, compile and present Local Site Investigator (LSI) Continuing Review information in a complete PI Continuing Review package.

SIGNIFICANT FORM CHANGES:

Significant Form Changes	Description
Aligned PI and LSI Forms	<ul style="list-style-type: none">• All form sections are aligned between the PI and LSI• LSI Continuing Review forms will better support the PI Continuing Review compilation
Collection of Protocol Deviations and Adverse Events (AEs)	<ul style="list-style-type: none">• Deviations and AEs will no longer be listed within the Continuing Review form• New forms were created for the collection of Protocol Deviations and AEs – Forms 115d Protocol Deviation Log and 115e Adverse Event Log• LSIs will report Deviations and AEs for their site• PI will compile a list of Deviations and AEs from across all LSIs• The first page of each form provides detailed instructions on how to use these new logs. You may also refer to the CIRB Table of Reporting Requirements if guidance is needed in determining which deviations or AEs should be reported at time of Continuing Review.
Removed Amendment Listing	<ul style="list-style-type: none">• Removed requirement for PI and LSI to list all amendments submitted in the last reporting period as all amendments are accessible in IRBNet
Enrollment by Gender, Race, and Ethnic Group	<ul style="list-style-type: none">• Added to PI Continuing Review form a section to compile all LSI enrollment by Gender, Race, and Ethnic Group, if collected per the protocol

Study Personnel Additions	<ul style="list-style-type: none"> Removed option to add non-key personnel at time of Continuing Review Non-key personnel additions will continue to be managed by the local site The CIRB will only review key personnel additions via an Amendment package Definition of Key and Non-Key Personnel will be added to CIRB forms in the near future
Study Personnel Removals	<ul style="list-style-type: none"> Removed option to remove personnel at time of Continuing Review Non-key personnel removals will continue to be managed by the local site Key personnel removals must be submitted via an Amendment package to the CIRB only if it's the removal of a PI or LSI to ensure there is appropriate replacement and continued oversight of the project Definition of Key and Non-Key Personnel will be added to CIRB forms in the near future
Study Personnel Obtaining Informed Consent	<ul style="list-style-type: none"> Removed requirement to check a box for personnel obtaining informed consent
Study Personnel Training	<ul style="list-style-type: none"> Require attestation from PI or LSI that all personnel are up to date on their local training requirements <u>prior</u> to the submission of a Continuing Review Removed requirement to list HSR training dates for all personnel as this is being managed by the local site All study personnel must continue to follow local training requirements regardless of this change
Study Personnel fCOI	<ul style="list-style-type: none"> Require attestation from PI or LSI that all personnel serving in an Investigator role have undergone their annual fCOI review <u>prior</u> to the submission of a Continuing Review Removed requirement to upload local facility annual fCOI documentation for personnel The only fCOI documentation that must be provided for CIRB review is if there is a fCOI management plan for an individual on the project Discontinued Form 115c ACOS Assurance of COI to align with this new process All study personnel must continue to follow local fCOI requirements regardless of this change
Study Personnel Credentials	<ul style="list-style-type: none"> Require attestation from PI or LSI that all personnel are appropriately credentialed at their local facility <u>prior</u> to the submission of a Continuing Review Removed requirement to check a box that each individual listed is credentialed All study personnel must continue to follow local credentialing requirements regardless of this change

SIGNIFICANT PROCESS CHANGES:

Significant Process Changes	Description
VA Central IRB Review and Determination of LSI Continuing Review Packages	<ul style="list-style-type: none">LSI Continuing Review Determinations are changing from an “expedited” review with an “approval” to an “administrative” review that will be “acknowledged”This change will be apparent in the LSI Package Review Details and in the LSI Continuing Review Determination LetterAll LSI Continuing Reviews will continue to be approved under the PI Continuing ReviewThe PI Continuing Review will not change and will continue to be reviewed under expedited or convened review

CURRENT CONTINUING REVIEW FORMS:

Form Number	Form Name
115a	PI Continuing Review V.1
115b	LSI Investigator Continuing Review V.1
115d	Protocol Deviation Log V.1
115e	Adverse Event Log V.1

DISCONTINUED CONTINUING REVIEW FORM:

Form Number	Form Name
115c	Alternative Documentation of fCOI review for Continuing Review

WHAT'S NEXT?

June 14, 2023

- New Continuing Review 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 Continuing Review forms will temporarily remain in the IRBNet Forms and Templates library to accommodate continuing review submissions that are in progress. It is recommended that the PI work with local sites when planning to submit a continuing review during this transition period to ensure all sites are informed as to what form (new or old) should be used as all sites should submit on the same form. If there are any questions or if assistance is needed while compiling a submission during this time, please contact Mary Eckart mary.eckart@va.gov or Mikaela Myers mikaela.myers@va.gov for support.
- Form 115c will no longer be required to be submitted with a Continuing Review.
- Email communication will go out to local site Liaisons and all VA Central IRB researchers.

August 14, 2023

- On this date the VA Central IRB will only accept the new Continuing Review Forms. Any package submitted with an old form will be returned for the new form to be submitted.
- A reminder email communication will go out to local site Liaisons and all VA Central IRB researchers.