Summary of Changes:

New Project Submission Forms

DATE: October 25, 2023

OVERVIEW: This is a summary of significant changes that were made to VA Central IRB new project submission forms. The changes stated in this document will take effect October 25, 2023. In addition to the forms and related 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 and past changes you may refer to VA Central IRB Webinars from June 27, 2023 and October 24, 2023.

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.
- Eliminate duplicate questions across submission forms.

FORM CHANGES
Release Date: 10/25/2023
Must Use By: 01/02/2024

Form Name	Summary of Significant Changes
100 Protocol Template	This Protocol Template is assigned as Form 100. This template will be used only for projects that involve subject interactions/interventions. New sections were added to the Protocol Template to collect more comprehensive information and focus on the multi-site aspects of the project. The Protocol Template has incorporated elements of Form 108 and includes more detailed instructions on how to write the protocol.
101 Protocol Template – Data/Specimen Only	**New Form:** This Protocol Template is assigned as Form 101 and will be used for data/specimen projects only. New sections were added to the Protocol Template to collect more comprehensive information and focus on the multi-site aspects of the project. The Protocol Template has incorporated elements of Form 108 and includes more detailed instructions on how to write the protocol.

	Form 104 LSI New Project Supplement form was renamed and is now a single Form 104 required for all LSI new project submissions. Form 104 was revised to capture project activities that are specific to a participating local site in a Principal Investigator (PI) multi-site research project. Content within this form was significantly reduced to remove the requirement to document project level information as that information has already been described and approved within the PI project.
104 LSI New Project Supplement	
	See additional information regarding these changes in the Process Updates table on pages 3-5.
105 Request for Exemption	No significant changes.
107 Co-PI Supplement Different VA Facility	**New Form:** Replacing Forms 105a and 108a. This new form can be used for exempt and non-exempt projects. However, this form is only required when there is a Co-PI at a different VA facility. Co-PIs from the same VA facility do not complete this form. Co-PIs, whether from the same or different facility, will be documented in the PI Project Cover Sheet Wizard and in the Protocol.
109 Coordinating Center Supplement	***Form Under Development:*** *This form will be released in early 2024 and will be replacing Form 108b.*

WIZARD CHANGES
Release Date: 10/25/2023
Must Use By: 10/25/2023

Wizard Name	Summary of Significant Changes
	The IRB Information Sheet Wizard has been revised as it pertains to VA Central IRB multi-site projects.
	For a <u>lead PI</u> completing the wizard, new questions were added and existing questions were revised to ensure comprehensive project level information is captured.
IRB Information Sheet Wizard	For a <u>LSI</u> completing the wizard, there were significant revisions. The LSI will no longer be required to answer questions that are specific to the overall project as the project level information will be documented in the lead PI IRB Information Sheet Wizard. The LSI will only be required to enter information as it pertains to their local site activity.
	See additional information regarding these changes in the Process Updates table on pages 3-5.

DISCONTINUED FORMS

Discontinuation Date: 01/02/2024

Form Name	Where Information Will Be Captured
104 NSI LSI No Intervention	Form 104 LSI New Project Supplement
104a Co-LSIs added to New Project	Project Cover Sheet Wizard
105a Co-PISC Exempt New Project Supplement	Project Cover Sheet Wizard and if applicable, New Form 107 Co-PI at Different Facility
108 PISC New Project Application	Protocol Template, IRB Information Sheet Wizard, Project Cover Sheet Wizard, and ERDSP
108a Co-PISC New Project Supplement	Project Cover Sheet Wizard and if applicable, New Form 107 Co-PI at Different Facility
110a Vulnerable Population Pregnant Women	IRB Information Sheet Wizard and Protocol Template
110b Vulnerable Population Prisoners	IRB Information Sheet Wizard and Protocol Template

PROCESS UPDATES:

The following information provides important reminders and requirements related to the new project submission form changes.
1. The CIRB will not require projects submitted prior to January 2, 2024 to convert existing forms to the new forms. For example, if a project was initially approved in 2021 with the old protocol template and Form 108, the study team is not required to update their study documents to the new protocol template.   **NOTE**: **The only exception is the IRB Information Sheet wizard**. The IRB Information Sheet wizard will be updated in IRBNet on October 25, 2023. When this update occurs, all projects with an existing IRB Information Sheet wizard will be prompted and required to answer the new questions in the form the next time the form is revised.   More information will be shared with the field regarding wizard changes at an upcoming VAIRRS webinar later this year.
2. When Form 108 is discontinued, all information that was captured in Form 108 will now be captured across the IRB Information Sheet Wizard, Project Cover Sheet Wizard, Protocol Template, and the ERDSP.

3. LSI new project submission documents, Form 104 LSI New Project Supplement and IRB Information Sheet wizard were revised to remove all questions pertaining to PI project level information. These forms are now designed for the LSI to provide local context information pertaining to their site's involvement in the PI project. LSIs will no longer document project level information in the LSI submission. All project level information (e.g., study procedures, risk level, expedited review category, waivers, etc.) will be described and approved within the PI project. The PI is responsible for ensuring that all local participating site activities and procedures are described in the protocol and other applicable project materials.

   NOTE: Local site study teams and local site research administration have access project level information through the PI project in IRBNet. All project documentation (Protocol, PI Information Sheet Wizard, MODEL Documents, Determination Letters, etc.) can be accessed by navigating to the **Project Overview** page in IRBNet and clicking on the lead site "**Details**" hyperlink as illustrated in the screenshot below. For detailed instructions on how to access the PI project, please refer to IRBNet Forms and Templates library (VA Central IRB Administration, Washington, DC – Documents for Researchers) and review the document titled "**003-Instructions: Multi-Site Projects in IRBNet.**"

This is a multi-site project. IRBNet automatically grants permission for the research team and reviewing committees at each participating site to view the status, documentation and details of the project at other participating sites. To view the details of this project at another participating site, click the "Details" link for that site or select that site from the Jump list. This multi-site project is being conducted at the following sites:

Jump To: Edward Hines VA Hospital, Hines, IL [Jump]

Lead Site	Site	Principal Investigator	Project Coordinator	Board Action	Reviewing Committee	
Yes	Edward Hines VA Hospital, Hines, IL			Work in progress (Not submitted)	-	Details
No	Bay Pines VA Health Care System, Bay Pines, FL			Acknowledged	Bay Pines VAHCS RDC	Details
No	Clement J. Zablocki VA Medical Center, Milwaukee, WI			Work in progress (Not submitted)	-	Details
No	Corporal Michael J. Crescenz VA Medical Center, Philadelphia, PA			Pending Review	VA Central IRB Panel 1	Details
No	Durham VA Medical Center, Durham, NC			Work in progress (Not submitted)	-	Details
No	Edward Hines VA Hospital, Hines, IL			Approved	VA Central IRB Panel 1	Details
No	Kansas City VA Medical Center, Kansas City, MO			Pending Review	VA Central IRB Administration	Details
No	Maryland VA Health Care System, Baltimore, MD			Exempt	Maryland SRS Committee	Details
	20 Sites found, displaying 1 to 8.				[First/Prev] 1 2 3 [Next/Last]	

4. The Project Cover Sheet Wizard will be the new source documentation when key study personnel are listed, added or removed from a project. The Project Cover Sheet will capture Investigator and study team information that was previously collected in Forms 108 and 104.

   NOTE: There is a new Study Team Tracking wizard currently under development with VAIRRS that will be released in the near future. More information will be shared with the field regarding the new Study Team Tracking wizard at an upcoming VAIRRS webinar later this year.

5. The PI team has a responsibility to review LSI New Project packages prior to the LSI submitting to the VA Central IRB to ensure the site is following the currently approved protocol and using the correct MODEL documents. This will allow for a more efficient review process with the VA Central IRB and can reduce the need to unlock the LSI package for corrections.

   NOTE: When the PI is also serving as an LSI, it is recommended to have the PI submit their LSI New Project first in order to serve as a model LSI application. This may streamline the submission process for other LSI New Project packages.

6. LSI site-specific differences or changes that are submitted at the time of an LSI New Project submission or an LSI Amendment submission will require concurrence from the lead PI. LSI site-specific differences require the following:

   - The lead PI must provide a memo (or email) with concurrence of the site-specific differences and indicate that this will not be implemented across all participating local sites. The memo or email must be uploaded to the IRBNet package for VA Central IRB review.

   EXAMPLE: The LSI plans to submit an amendment to the VA Central IRB requesting approval to use a revised recruitment flyer at their local facility. The LSI redesigned a recruitment flyer that was approved as a MODEL document under the PI project by adding new images and new content (in addition to their local contact information). In this scenario, the PI must provide a memo or email concurring with the LSI change to the MODEL recruitment flyer and indicate that this change is site-specific and will not be implemented across other participating sites. NOTE: If the PI plans to incorporate the LSI revisions into the PI MODEL recruitment flyer for other participating local sites to use, then the PI should not provide concurrence for the requested LSI change, but rather submit the change as a PI Amendment.

   NOTE: Some local site-specific differences must be approved at the PI project level and cannot be approved in an LSI submission. If the LSI is requesting or planning site-specific differences to study design, procedures, or activities that are not currently approved under the PI project, the PI must first update their project via an Amendment package prior to the local site beginning procedures or activities that are not yet approved (e.g., use of a local site data source; local site establishing a non-VA collaboration with a University; changes that require revisions to project waivers, etc.). The PI is responsible for ensuring that all local participating site activities and procedures are described in the protocol and other project materials.

7. Whether a PI or LSI project, all project documents must stay up to date and always reflect what the project is currently approved for. When an approved project submits an Amendment, all applicable documents must be updated if impacted by that change.

8. Continue to always download VA Central IRB forms directly from IRBNet Forms and Templates library when they are needed to ensure the current version is being used and submitted with a package.

WHAT'S NEXT?

October 25, 2023
- New Project 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 <u>temporarily</u> 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.

January 2, 2024
- Packages submitted on or after this date must include the new forms.
- Any package submitted on or after this date with an old or discontinued form will be returned for correction.