Summary of Changes:

CIRB Forms and Processes

DATE: September 11, 2024

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

1. Coordinating Center Submission Process
2. New Form 110 Research Supplement
3. New PI and LSI Submission Checklists
4. Revised Form 103 Request for Privacy Review and Waiver of HIPAA Authorization

For detailed information regarding these changes you may also refer the slides and a recording of the VA CIRB Webinar which will be made available at ePROS Webinar Archive (va.gov) on or around September 20, 2024.

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

Form Name	Summary of Revisions or New Form	Must Use By
103 Request for Privacy Review and Waiver of HIPAA Authorization - *Revised*	On October 01, 2024, the VA Central IRB will only accept the revised version of Form 103 Waiver of HIPAA Authorization. Any package submitted with an old form will be returned for the new form to be submitted. For existing projects, study teams will only be required to submit the new version if they are making revisions to a previously approved Form 103 Waiver of HIPAA Authorization. Significant changes in form purpose and elements include: • Updated name of the form from "Request for Waiver of HIPAA Authorization" to "Request for Privacy Review and Waiver of HIPAA Authorization" • Instructions were revised to provide clarity on CIRB panel submission processes; Added guidance on when a revision is required; provided clarification on when additional Privacy Act requirements must be met.	October 01, 2024

	• Section 1 was revised to move the Investigator Certification to this section instead of Section 5 on the previous version of the Form 103 (NOTE: The revisions to the new Section 5 are noted below). • Section 2 was revised to provide examples of the request types for the applicable waiver type as well as guidance to remind when a separate informed consent form and VA form 10-0493 must be used as well as regulatory reminder to provide signed copies to the participants of the VA Form 10-0493 and /or the combined ICF with HIPAA Authorization elements. • Section 3 the instruction language was revised to remind research team members that the final waiver determination is made by the CIRB or their designated reviewer. • Section 4 was revised as follows: ○ Instructions: Updated to add separations of the aims/phases as well as participant group. ○ Item 1: Example response language was provided as well as clarity on the waiver authority versus the signed HIPAA authorization. ○ Item 2: Example response language was provided. ○ Item 3: New standardized language was provided as well as the applicable aim and participant group along with comments by the research team. ○ NOTE: Section 4, questions 4 through 8 on the previous version of the Form 103 were moved to Section 5. • Section 5 was revised as follows: ○ Moved Investigator's Certification to Section 1 of this version. ○ Item 1 (This was question 4 on the previous version of the Form 103): ○ Clarification was provided to remind research team members that this request for information is not limited to the recruitment phase of the project. ○ The HIPAA identifiers table was revised to provide education/guidance and clarification on the identifiers as well as provided some standardization responses, where applicable. (This was the HIPAA identifiers table (three columns) under question 4 on the previous version of the Form 103.) The cell "Social Security Number" was expanded to include Question 4(a) from the prior version of the Form 103). ○ Item 1a: Clarification was provided on the type of PHI (This was Question 4(b) from the prior version of the Form 103). ○ Item 1b: Added a new question on the use of 38 USC 7332 protected information.	

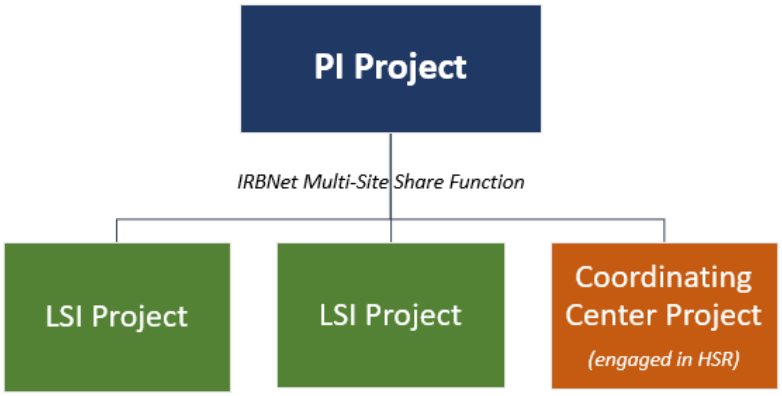
	○ Item 1c: Added a new question on the planned future use of banked data and/or specimens ○ Item 2: Added a data source table (This was question 5 on the prior version of the Form 103.) ○ Item 3: Revised the previous version question, Section 4, item 6, to add standardized responses (This was part of question 6 on the prior version of the Form 103.) ○ Item 4: Added guidance to provide VINCI data users on their responsibilities at study closure. (This was part of question 7 on the prior version of the Form 103.) ○ Item 5: Added guidance and standardized responses on data sharing and disclosures. (This was part of question 8 on the prior version of the Form 103.) ○ Item 6: Added a new question on the two de-identification methods allowed by HIPAA. • Section 6: Added a reminder to the CIRB reviewer of their responsibilities when reviewing the waiver request.	
109 Coordinating Center Supplement - *Revised*	• This form replaces VA CIRB Form 108b. • Minor administrative changes were made. • This form will continue to be required to be submitted when a project has a Coordinating Center that is engaged in human subjects research and is required to submit a project according to the Coordinating Center Submission Process.	October 15, 2024
110 Research Supplement - *New*	• This form is intended be submitted at the time of a PI New Project when the submission includes an Industry or FDA approved protocol and the protocol does not contain all of the required sections of the VA CIRB Protocol Template 100 or 101, as applicable. • This form will capture VA-specific content to ensure it is included for VA CIRB review when the required sections are not included in the Industry or FDA approved protocol.	October 15, 2024
115cc Coordinating Center Continuing Review Supplement - *New*	• This is a new form that will be completed and submitted to the VA CIRB when a Coordinating Center is required to submit a Continuing Review. • Refer to the detailed Instructions and Flowcharts for additional guidance in IRBNet Forms and Templates library (VA Central IRB Administration, Washington, DC – Documents for Researchers)	October 15, 2024

NEW SUBMISSION CHECKLISTS

Checklist Name	Summary of New Checklists
PI Study Team Submission Checklist	**New Checklist:** This checklist may be completed by the study team when preparing a Principal Investigator (PI) New Project Submission. • Only complete sections which are applicable to the PI New Project—Non-exempt subject interaction, Non-exempt data/specimen analysis only (no subject interaction) **OR** Exempt. • If used, upload completed checklist in CIRB submission package.
LSI Study Team Submission Checklist	**New Checklist:** This checklist may be completed by the study team when preparing a Local Site Investigator (LSI) New Project Submission. • Only complete sections which are applicable to the LSI New Project—Non-exempt **OR** Exempt. • If used, upload completed checklist in CIRB submission package.

SUBMISSION PROCESS CHANGES

Process	Summary of Process Changes and Requirements
Coordinating Center Submission Process	This submission process has been developed to document and support regulatory compliance and oversight of Coordinating Centers in IRBNet. This process is required to be follow only when the Coordinating Center is engaged in human subjects research to capture center activities when regulated under the Common Rule. Examples of Coordinating Center activities that may engage the center in human subjects research can include but are not limited to: • Analyzing identifiable participant data • Mailing recruitment materials to potential participants • Obtaining informed consent • Administering surveys or questionnaires to participants If the Coordinating Center is **not** engaged in human subjects research, the Coordinating Center Submission process should **not** be followed. Instead the Coordinating Center can be submitted as a component of the PI project and their role can be described in the PI Protocol. Refer to Health and Human Services (HHS) Guidance Engagement of Institutions in Human Subjects Research (2008) | HHS.gov for additional information regarding engagement. **IMPORTANT NOTE**: When the lead PI is overseeing (coordinating/managing) the multi-site project, that does equate the PI as the Coordinating Center and therefore should not follow the Coordinating Center Submission Process. Only when there is a

	true Coordinating Center that is separate from the PI (e.g., CSP Boston Coordinating Center), then this process should be followed. Following this new process, Coordinating Centers are now required to submit a project that is linked to the lead PI project through the multi-site sharing function. The Coordinating Center project will follow a similar submission and review process to the Co-PIs at Different Facilities and LSI Project submission process. Detailed Instructions and Flowcharts for the Coordinating Center Submission Process can be found on IRBNet Forms and Templates library (VA Central IRB Administration, Washington, DC – Documents for Researchers). **Multi-Site Project with a Coordinating Center** 

WHAT'S NEXT?

- All New Forms have been uploaded to IRBNet Forms and Templates library (VA Central IRB Administration, Washington, DC – Documents for Researchers) and are available for use as of September 11, 2024.

- The VA Central IRB will only accept New or Revised Forms according to the "Must Use By" noted in the above **Form Changes** table. Any package submitted with an old form after the "Must Use By" date will be returned for the new form to be submitted.

- The VA Central IRB may make improvements to the processes, forms and/or guidance documents following implementation. If changes are made, they will be communicated to the field via email, VAIRRS Newsletter, and/or VA Central IRB website.

- User feedback on any of our new processes, forms and/or guidance documents can be shared with the VA Central IRB at vacentralirb@va.gov.