U.S. Department of Veterans Affairs
North Florida / South Georgia Veterans Health System

NF/SGVHS Research Service

Standard Operating Procedure:

VA Central IRB Local Site Investigator (LSI) Submission and Approval – Workflow for Researchers

Updated: 2/6/2024

The following instructions apply to Local Site Investigator (LSI) applications. If you are submitting as the Principal Investigator (e.g., lead site), visit the VA Research Resources webpage for PISC specific guidance.

****If your project submission involves the use of Artificial Intelligence (AI), contact Dr. David Clark, Associate Chief of Staff for Research – David.Clark1@va.gov****

1. *PISC site shares the multi-site project with the LSI, creating a project workspace for the local site.*
   Note: If the PI has not shared the project with the LSI in IRBNet, contact them directly and request that they share the project utilizing the Multi-Site function. Do **not** create a new project. It is important that the LSI project in IRBNet is directly linked to the PI project.

2. *Share the project with study staff and the Research Service Administrators*
   Provide study staff members with the appropriate level of access (full, write, or read). In addition to study staff, share full access to the project with North Florida/South Georgia Research Service Administrators:
   - Paige Webb – Research Committee Manager
   - Sofia Ortiz – HRPP Administrator
   - Tiffany Ramsey – Research Committee Manager

3. *Create a package within the shared project*
   With your project open, click “Create a New Package” from the Project Administration menu. This will be package -1 in IRBNet.

IRBNet Wizards	
Title	Source
Project Coversheet Wizard	IRBNet Designer
Study Team Tracking Wizard	
IRB Information Sheet Wizard	
Required Forms	
Form 102 – Local Associate Chief of Staff – Research Review Form (unsigned)	IRBNet Forms and Templates Library – VA Central IRB Administration, Washington, DC – Documents for Researchers
Form 104 – Local Site Investigator New Project Supplement	
Enterprise Research Data Security Plan (ERDSP)	
CVs or Biosketches for study staff in investigator roles	Study staff member
If Applicable	
Local informed consent form or combined consent/HIPAA form – Clean and Track Change Versions	VA CIRB approved templates are provided by the Principal Investigator (PISC) site.
Local HIPAA authorization (VA Form 10-0493) – Clean and Track Change Versions	
Local recruitment materials/scripts – Clean and Track Change Versions	
Local waiver requests (Form 112a, 112b, and/or 103) only when PI waiver does not apply (e.g., accessing data in a local site database)	IRBNet Forms and Templates Library – VA Central IRB Administration, Washington, DC – Documents for Researchers

4. *Submit Package -1*
   When ready, submit the package. Under the Project Administration menu, click “Submit this Package” and follow the prompts to submit the package to the “NF/SGVHS Research Administration Members, Gainesville, FL” board. The package will automatically be locked so no further edits are possible while under review.

5. *Create your Conflict of Interest disclosure package, link COI disclosures, and submit for review*
   Once the first package has been submitted, you will be able to create a second package to submit the Conflict of Interest (COI) disclosures completed for this project in the My COI workspace. For instructions on how to complete a COI disclosure in IRBNet and submit them to the NF/SGVHS Conflict of Interest board, visit the VA Research Resources webpage and download the document titled “Conflict of Interest – Submission Instructions”.

6. *SRS Submission (if applicable)*
   Studies requiring review by the Subcommittee on Research Safety (SRS) should also create a separate package for this purpose.

7. *Administrative Review*
   A Research Service administrator will review your package. Any issues (e.g., incomplete/missing documents or recommended edits to documents) will be noted and the package will be unlocked for the study team to address these issues. The study team will be notified automatically by IRBNet/VAIRRS if the study package is unlocked.

8. *Address Administrative Review Corrections*
   After the researchers have fixed any issues noted by the Research Service administrator, they must click “Mark Revisions Complete” in IRBNet/VAIRRS to lock the package. Failure to lock the package may result in delays as an unlocked package is interpreted as being under revision by the research team.

9. *Submission to the VA CIRB*
   Once all administrative review issues have been addressed, the Research Service administrator will submit the package to the VA CIRB on behalf of the Local Site Investigator.

10. *VA CIRB Review and Approval*
    The VA CIRB will conduct their review of the LSI package. If there are any corrections required, the package will be unlocked for the investigator to make changes. All document changes must be done in track changes and both a track change and clean version of the modified document must be uploaded to the package along with a Form 140 CIRB Memo (available on IRBNet/VAIRRS in the Forms and Templates Library - VA Central IRB Administration, Washington, DC – Documents for Researchers). Once all corrections have been addressed, the VA CIRB will complete their review and approve the LSI submission.

11. *R&DC Review and Approval*
    The study will be routed for review and approval by the VA Research and Development Committee.

12. *Informed Consent Compliance Training (if applicable)*
    Following the R&DC meeting, the study team will receive instruction on how to schedule informed consent training with the Research Compliance Officer(s).

13. *Release of R&DC Approval Letter*
    The Research Committee Manager will upload the ACOS approval letter signed by the VA Associate Chief of Staff for Research (ACOS/Research). You may only begin conducting research activity **after** you have received your signed letter. *Note: The ACOS approval letter is different from the ACOS Assurance Letter, which is part of the Just-In-Time submission for VA-funded awards and is handled by the Grants Administrator.*