



NF/SGVHS Research Service

Standard Operating Procedure: HRPP Revision/Amendment Submission – Workflow for Researchers

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The VA Research Service webpage is referenced throughout this document and can be found at this link:
<https://www.nffre-research.org/va-research-resources>

General Submission Requirements

1. *Create a new package*

Open a new package in IRBNet/VAIRRS under your existing project. Training videos and documents explaining how to use IRBNet/VAIRRS are available on the Research Service website.

- Processes to complete in parallel:
 - On the Research Service webpage, review the document at the link called “Regulatory Structure for Human Research”. Ensure that your study revisions abide by VA research regulations.
 - Download and review the study revision/amendment coversheet from the Forms and Templates section of IRBNet/VAIRRS (the library called NF/SGHVS Research Administration Members – Gainesville, FL – Documents for Researchers). The coversheet provides guidance on the required forms/documents needed for various types of revisions.
 - Open a new revision/amendment on the appropriate external IRB website. Complete all applicable web forms and upload applicable study forms/documents. The only forms that you will not include are the ones that are provided to you after completion of VA pre-review (if applicable, these may include the Privacy Review Form VA 10-250, VA HIPAA authorization Form 10-0493, and/or ISSO signed ERDSP). Do not submit to the external IRB yet. HRPP pre-review should be completed first.
 - In IRBNet/VAIRRS, upload all required and “if applicable” documents to your package. For detailed information regarding specific revision/amendment package requirement, please review the sections below.
 - To prevent delays in processing your submission, ensure consistency across all forms/documents.

2. *Submit the package*

When ready, submit the revision package to HRPP in IRBNet/VAIRRS. The package will automatically be locked so no further edits are possible while under review by HRPP.

3. *Pre-Review by ISSO and/or PO (if applicable)*

The HRPP administrator will review your package, and route it for pre-review (if necessary) by the Information Systems Security Officer (ISSO), and the Privacy Officer (PO). If issues are found, the package will be unlocked so researchers can make revisions. The study team will be notified automatically by IRBNet/VAIRRS if the study package is unlocked.

4. *Research team addresses issues noted by HRPP*

After the researchers fix any issues noted by HRPP, they must click “Mark Revision Complete” in IRBNet/VAIRRS to lock the package. Failure to lock the package may result in delays, because HRPP administrators interpret unlocked packages as being under revision by the research team and will not know to process the submission.

5. *Completions of Pre-Review by HRPP*

After HRPP pre-review is complete, the HRPP administrator will upload any reviewer worksheets (VA Form 10-250, VA HIPAA authorization, or signed ERDSP) to the IRBNet/VAIRRS package. These are in the section called “Board Documents”. HRPP will then unlock the package. The research team will need to download these forms and then upload them to the appropriate section of the external IRB website.

6. *Submit revision to IRB*

Submit the IRB revision. After receiving IRB approval, upload the IRB approval letter to your IRBNet/VAIRRS package, along with updated versions of all required and “if applicable” forms (use the PDF versions from the IRB). When updating forms in IRBNet/VAIRRS you must use the “pencil icon” next to the form (this creates a version history and prevents multiple copies of the same document). When finished, researcher must click “Mark Revision Complete” in IRBNet/VAIRRS to re-lock the package. Failure to relock the package may result in delays, because HRPP administrators interpret unlocked packages as being under revision by the research team and will not know to process the submission.

7. *Submit package to HRPP*

Submit the IRBNet/VAIRRS package to HRPP again by unlocking the package and making a note of IRB approval via unlocked package message. A final review will be conducted, including by the Information Security Officer and the Privacy Officer, if applicable.

Additional Requirements by Revision Type:

All Revision/Amendment packages in IRBNet/VAIRRS will contain the following documents:

- Revision/Amendment Coversheet
([Forms and Templates](#) > Library: [NF/SGVHS Research Administration Members, Gainesville, FL – Documents for Researchers](#) > **Coversheet: Revision/Amendment**)
- ERDSP
([Forms and Templates](#) > Library: [NF/SGVHS Research Administration Members, Gainesville, FL – Documents for Researchers](#) > **Form: ERDSP Template**)
- Full PDF version of external IRB revision submission

Certain types of revisions will require additional documents. These documents are listed on the Revision/Amendment Coversheet and are explained in detail below:

Adding Staff (Non-Investigators)

If you are adding new study staff:

1. *Create a New Package*
2. *VA or WOC Employment Status*
 - all study personnel must have a VA appointment (paid or without compensation).
3. *Complete All Training Requirements*
 - All study personnel must complete training required by VA Research Service and/or by the IRB.
 - VA Talent Management System (TMS) -everyone must upload the following TMS training certificates to their IRBNet profile:
 - Government Ethics
 - HIPAA Focused Web-Based Training
 - CITI Program -everyone must have their CITI account linked to their IRBNet profile (instructions are located on the Research Service Website under “IRBNet (VAIRRS) Tutorials for Researchers”) with the following trainings completed:
 - CITI Human Subjects Protection (HSP)
 - Special Trainings -indicate on the **Coversheet: Revision/Amendment** whether a staff member will need the below certifications:
 - CITI Bloodborne Pathogens – required for study staff that will be handling/processing human biospecimens for research
 - CITI Biohazard Shipping – required for study staff that will be packaging and shipping human biospecimens for research
4. *Share the Project*
 - In IRBNet, share the project with all study personnel
5. *Submit IRBNet package to NF/SGVHS Research Administration Members*
 - An HRPP administrator will perform an administrative review. If corrections are needed, the administrator will unlock the package for the study team to update.
6. *Submit to IRB*
 - Once all requirements have been satisfied, HRPP administrator will unlock the package and notify the research team that the revision can be submitted to the external IRB.
7. *Upload IRB Approval*
 - Once IRB approval has been received, upload the IRB approval letter and final external IRB submission PDF to the IRBNet/VAIRRS package. Then click [Mark Revisions Complete](#) to lock the package.

Adding Co-Investigators (Co-I)

If you are adding a Co-I:

1. *Employment status, training, share project*
 - Follow steps 1 – 4 from the **Adding Staff (Non-investigators)** section above
2. *Financial Conflict of Interest (COI)*
 - The new investigator(s) must complete a Financial Conflict of Interest submission using the “My COI” module in IRBNet. Instructions can be found on the Research Service website under the heading “IRBNet (VAIRRS) Tutorials for Researchers”.
3. *Submit IRBNet package to NF/SGVHS Research Administration Members*
 - An HRPP administrator will perform an administrative review. If corrections are needed, the administrator will unlock the package for the study team to update.
4. *Submit to IRB*
 - Once all requirements have been satisfied, HRPP administrator will unlock the package and notify the research team that the revision can be submitted to the external IRB.
5. *Upload IRB Approval*
 - Once IRB approval has been received, upload the IRB approval letter and final external IRB submission

PDF to the IRBNet/VAIRRS package. Then click [Mark Revisions Complete](#) to lock the package.

Change of Principal Investigator (PI)

If you are changing the PI:

1. *Employment status, training, share project*
 - Follow steps 1 – 4 from the **Adding Staff (Non-investigators)** section above
2. *Financial Conflict of Interest (COI)*
 - The new investigator must complete a Financial Conflict of Interest submission using the “My COI” module in IRBNet. Instructions can be found on the Research Service website under the heading “IRBNet (VAIRRS) Tutorials for Researchers”.
3. *Must fit the definition of a VA Investigator*
 - The new PI must fit the VHA 1200.05 definition of a VA Investigator
4. *Submit IRBNet package to NF/SGVHS Research Administration Members*
 - An HRPP administrator will perform an administrative review. If corrections are needed, the administrator will unlock the package for the study team to update.
5. *Submit to IRB*
 - Once the PI change request has been pre-reviewed, the HRPP administrator will notify the research team that the revision can be submitted to the external IRB.
6. *Upload IRB Approval*
 - Once IRB approval has been received, upload the IRB approval letter and final external IRB submission PDF to the IRBNet/VAIRRS package. Then click [Mark Revisions Complete](#) to lock the package.
7. *R&DC Review and Approval*
 - Following the receipt of IRB approval documents, your revision/amendment package will be sent to the R&D Committee for review at the next meeting.

Updating Enrollment to Include Non-Veterans

If you are seeking approval to enroll non-veteran research participants:

1. *Justification*
 - Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment, but only when there are insufficient Veteran patients suitable for the study. The investigator must justify include non-Veterans, and the R&D Committee must review the justification and provide specific approval for recruitment of non-Veterans (VHA Directive 1200.01)
2. *Enrollment of Non-Vets application*
 - Complete the **Enrollment of Non-Vets** form
([Forms and Templates](#) > Library: [NF/SGVHS Research Administration Members, Gainesville, FL – Documents for Researchers](#) > **Form: Enrollment of Non-Vets**)
3. *Submit IRBNet package to NF/SGVHS Research Administration Members*
 - An HRPP administrator will perform an administrative review. If corrections are needed, the administrator will unlock the package for the study team to update.
4. *Submit to IRB*
 - Once the non-veteran enrollment request has been pre-reviewed, the HRPP staff will notify the research team that the revision can be submitted to the external IRB.
5. *Upload IRB Approval*
 - Once IRB approval has been received, upload the IRB approval letter and final external IRB submission PDF to the IRBNet/VAIRRS package. Then click [Mark Revisions Complete](#) to lock the package.
6. *R&DC Review and Approval*
 - Following the receipt of IRB approval documents, your IRBNet/VAIRRS revision/amendment package will

be sent to the R&D Committee for review at the next meeting. You may not enroll non-Veteran subjects until you have received R&D Committee approval notification.

Enterprise Research Data Security Plan (ERDSP)

If you are making changes to your project that affect sections of the ERDSP:

1. *Submit IRBNet package to NF/SGVHS Research Administration Members*
 - An HRPP administrator will perform an administrative review. If corrections are needed, the administrator will unlock the package for the study team to update.
2. *ISSO Pre-Review*
 - The revision will be shared with the facility Information Systems Security Officer (ISSO) for review.
 - If the ISSO has concerns or requests clarifications, the comments from their review will be added to an **ISSO Pre-Review** document that will be published to the **Board Documents** section for the PI to review and use in their response, if needed.
 - Any changes to existing documents in the package as a result of ISSO review must be made using the “pencil” edit icon (this creates a version history and prevents multiple copies of the same document).
3. *ERDSP signed by ISSO*
 - Once all ISSO concerns have been addressed, a signed ERDSP will be uploaded to the Board Documents section for submission to the external IRB.
4. *Submit to IRB*
 - Once all requirements have been satisfied and pre-review is complete, the HRPP admin will unlock the package and notify the study team that the revision can be submitted to the external IRB.
5. *Upload IRB Approval*
 - Once IRB approval has been received, upload the IRB approval letter and final external IRB submission PDF to the IRBNet/VAIRRS package. Then click [Mark Revisions Complete](#) to lock the package.
6. *ISSO Final Review*
 - ISSO will conduct a final review.

HIPAA Authorization Modifications

If you are making changes to your project that affect the privacy of study subjects (such as data storage, data sharing, any changes to the HIPAA authorization):

1. *Create a new package*
2. *Upload all required forms -In addition to uploading the Revision/Amendment Coversheet, ERDSP, and external IRB submission, you must also include:*
 - 1.4 NF-SG_Privacy checklist (10-250)
 - Current approved HIPAA authorization
 - Draft of new HIPAA authorization
 - Revised informed consent form (if applicable)
3. *Submit IRBNet package to NF/SGVHS Research Administration Members*
 - An HRPP administrator will perform an administrative review. If corrections are needed, the administrator will unlock the package for the study team to update.
4. *Privacy Officer (PO) pre-review*
 - The revision will be shared with the facility PO for pre-review.
 - If the PO has concerns or requests clarifications, the comments from their review will be added to a **PO pre-review** document that will be published to the Board Documents section for the PI to review and use in their response, if needed.
5. *Board Documents: HIPAA Authorization*

- The PO will provide an updated final version of the HIPAA authorization once their pre-review is complete. HRPP staff will upload this HIPAA authorization to the [Board Documents](#) section for the PI to download and submit as part of their revision to the external IRB.
6. *Submit to IRB*
 - Once all requirements have been satisfied and pre-review is complete, the HRPP admin will unlock the package and notify the study team that the revision can be submitted to the external IRB.
 7. *Upload IRB Approval*
 - Once IRB approval has been received, upload the IRB approval letter and final external IRB submission PDF to the IRBNet/VAIRRS package. Then click [Mark Revisions Complete](#) to lock the package.
 8. *PO Final Review*
 - Once IRB approval documents have been submitted, HRPP staff will notify the PO that the package is ready for their post-IRB final review.

Modification to Approved Study Documents

If you are making changes to existing, approved study documents (e.g., study protocol, investigator's brochure, informed consent forms, etc.):

1. *Create a package*
2. *Upload Coversheet: Revision/Amendment, ERDSP, and PDF of external IRB application*
3. *Upload modified documents and submit to NF/SGVHS Research Administration Members*
 - Submit the modified documents as part of your IRBNet/VAIRRS package. HRPP staff will review for VA-specific regulatory issues, and to determine whether the revision requires additional review by the PO or ISSO.
4. *Submit to IRB*
 - If your package does not require additional pre-review, you will receive confirmation that you are permitted to submit to the external IRB for approval.
5. *Upload IRB approval*
 - When you receive IRB approval, upload the IRB approval letter, any stamped documents, and final submission PDF to the package and click [Mark Revisions Complete](#) to lock the package.

Adding the Use of VINCI (VA Informatics and Computing Infrastructure)

If you are seeking approval to utilize VINCI:

1. *Create package*
2. *Upload all required forms -In addition to uploading the Revision/Amendment Coversheet, ERDSP, and external IRB submission, you must also include:*
 - Real SSN Access form
(Forms and Templates > Library: NF/SGVHS Research Administration Members, Gainesville, FL – Documents for Researchers > **Form: VINCI Real SSN Access**)
3. *Submit IRBNet package to NF/SGVHS Research Administration Members*
 - An HRPP administrator will perform an administrative review. If corrections are needed, the administrator will unlock the package for the study team to update.
4. *Board Documents: Real SSN Access form*
 - HRPP staff will obtain the signature of the ACOS/R on this form and upload the signed document to the [Board Documents](#) section of your submission.
5. *Submit to IRB*
 - Once all requirements have been satisfied and pre-review is complete, the HRPP admin will unlock the package and notify the study team that the revision can be submitted to the external IRB.
 - Download the ACOS/R signed Real SSN Access form from [Board Documents](#), then upload to the IRBNet

package.

- Submit the package to IRB.

6. *Upload IRB approval*

- When you receive IRB approval, upload the IRB approval letter, any stamped documents, and final submission PDF to the package and click [Mark Revisions Complete](#) to lock the package.

7. *Data Access Request Tracker (DART)*

- For instructions on how to complete your DART request once you have received IRB approval, please consult the DART User Guide [here](#) from a VA-networked computer.