Revision/Amendment Workflow – Guide for Researchers

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

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

- Processes to complete in parallel:
  - 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.

- 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.

- The HRPP administrator will review your package, and route it for pre-review (if necessary) by the Information Systems Security Officer (ISSO), 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.

- 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.

- 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.

- 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.

- Submit the IRBNet/VAIRRS package to HRPP again. 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 from the Forms and Templates library
- ERDSP
- PDF 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:

- **If you are adding new study staff:**
  - All study personnel must complete training required by VA Research Service and and/or by the IRB.
  - In VAIRRS, share the project with all of your staff and co-investigators. New users of VAIRRS must register, and then link their CITI training account. Everyone must also upload their certificates from the VA Talent Management System (TMS) website for Government Ethics training and Privacy and HIPAA Focused Web-Based Training. Instructions for registering and linking/uploading training are on the Research Service website under "IRBNet (VAIRRS) Tutorials for Researchers".
    - Special Trainings – indicate on the coversheet 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.
  - **If you are adding a co-investigator or changing the Principal Investigator**: 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".
  - Once all training requirements have been satisfied, HRPP staff will notify the research team that the revision can be submitted to the external IRB.
  - When you receive IRB approval, upload the IRB approval letter and final submission PDF to the IRBNet/VAIRRS package and click "Mark Revisions Complete" to lock the package.

- **If you are seeking approval to enroll non-veteran research participants:**
  - 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)
    - Complete the "NF-SG_Use of Non-Vets application" from the Forms and Templates Library (the library called NF/SGHVS Research Administration Members – Gainesville, FL – Documents for Researchers)
    - 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.
    - When you receive IRB approval, upload the IRB approval letter and final submission PDF to the package and click "Mark Revisions Complete" to lock the package.
    - 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.

- **If you are changing the Principal Investigator (PI):**
    - The new PI must fit the VHA 1200.05 definition of a VA Investigator and have completed the necessary trainings detailed in the "If you are adding new study staff" section of this document.
    - Once the PI change request has been pre-reviewed, the HRPP staff will notify the research team that the revision can be submitted to the external IRB.
    - When you receive IRB approval, upload the IRB approval letter and final submission PDF to the package and click "Mark Revisions Complete" to lock the package.
    - 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.

- **If you are making changes to your project that affect sections of the ERDSP:**
    - 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).
    - Once all ISSO concerns have been addressed, a signed ERDSP will be uploaded to the ***Board Documents*** section for submission to the external IRB.
    - When you receive IRB approval, upload the IRB approval letter and final submission PDF to the package and click "Mark Revisions Complete" to lock the package.

- **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):**
    - You must include the following forms in your submission package:
        - 1.4 NF-SG_Privacy checklist (10-250)
        - Current approved HIPAA authorization
        - Draft of new HIPAA authorization

        - Revised informed consent form (if applicable)
    - The revision will be shared with the facility Privacy Officer (PO) for 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.
    - 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.
    - When you receive IRB approval, upload the IRB approval letter and final submission PDF to the package and click "Mark Revisions Complete" to lock the package.
    - Once IRB approval documents have been submitted, HRPP staff will notify the PO that the package is ready for their post-IRB final review.

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

- **If you are seeking approval to utilize VINCI**:
    - You must include the following form in your package submission:
        - 2.7 NF-SG_Real SSN Access form (use of VINCI)vJuly2021
    - 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.
    - Submit the signed Real SSN Access form to the IRB. Once approved, upload the IRB approval letter to your package and click "Mark Revisions Complete" to submit to the HRPP office.
    - 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.