

## **Study Closure Workflow – Guide for Researchers**

The VA Research Service website is referenced in 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.

- Download and review the Study Closure Coversheet from the Forms and Templates section of IRBNet/VAIRRS (the library called NF/SGHVS Research Administration Members – Gainesville, FL – Documents for Researchers).
- Open a study closure submission on the appropriate external IRB website. Complete all applicable web forms and upload applicable study forms/documents. Do not submit the study closure to the external IRB yet. First submit to HRPP for pre-review.
- In IRBNet/VAIRRS, upload all required documents:
  - Study Closure Coversheet
  - PDF download of the study closure submission from the external IRB website
  - Study Closure Acknowledgment Checklist (located on Research Service website)
- When ready, submit the IRB closure 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. 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 research team will be instructed to submit the study closure submission with the external IRB.
- Submit the IRB study closure. After receiving IRB approval, upload the IRB approval/closure letter to your IRBNet/VAIRRS package. 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.

If the lab is closing and/or if the Principal Investigator is department from NF/SGVHS, please also review the following guidance documents on the Research Service website:

- Laboratory Close-out Checklist
- Investigator Departure Checklist