Workflow for New Study Approval – Researcher's Perspective

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

• If your project involves funding that is administered outside of the VA, please consult with the ACOS and DCOS. Insufficient planning for financial and regulatory aspects of the research may delay or prevent approval of your study.

• Read the guidance documents on the VA Research Service website. Refer to links called "*Preparing for a New Study*" and "*Research Submission Guidance*".
If you would like to schedule an initial consultation about the regulatory structure of your study and how to manage your submission, please contact Dr. Clark.

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

• Processes to complete in parallel:
  - 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 link their CITI training account. Also upload the Government Ethics certificate obtained from the VA Talent Management System (TMS) website. Instructions for these steps are on the Research Service website under "*IRBNet (VAIRRS) Tutorials for Researchers*".
  - Open a new project on the appropriate IRB website. Complete all web forms and upload all study forms and documents. The only forms that you will not include are the ones that are provided to you after completion of VA pre-review (HRPP Memo or VA Endorsement Letter, the Privacy Review (Form VA 10-250), and VA HIPAA authorization (VA Form 10-0493, if applicable).
  - To prevent delays in processing your submission, ensure consistency across all forms/documents, including sample size, recruitment methods, HIPAA authorization, data storage locations, etc.
  - All investigator must complete Financial Conflict of Interest documents. Once completed, send them together in one email to VHANFLResearchStudy@va.gov. Include the IRBNet/VAIRRS project number in the email.
  - For any potential regulatory issues, read applicable handbook/directives and consult with appropriate parties for resolution. Initial guidance is provided on the VA Research Service website; click the link called "*Preparing for a New Study*".

• In IRBNet/VAIRRS, upload all required and "if applicable" documents to your package. For an explanation of documents to include, please see the link called "*Research Submission Guidance*" on the VA Research Service website.

• Studies requiring review by the Subcommittee on Research Safety (SRS) should also create a separate package for this purpose.

• When ready, submit the package(s). The package(s) will automatically be locked so no further edits are possible while under review.

• The HRPP administrator will review your package, and also route it for pre-review (if necessary) by the Information Security Officer (ISO), the Privacy Officer (PO), and Subcommittee on Research Safety (SRS). 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 is 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 the signed HRPP Memo, completed Privacy Review (Form VA 10-250), and approved version of the HIPAA Authorization (if applicable) to the IRBNet/VAIRRS package. These should be located 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 IRB project.

• Submit the IRB project. 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, if applicable). 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. When final HRPP approval is granted the study will be routed for final review and approval by the VA Research and Development Committee.

• The Research Compliance Officer(s) will request a meeting with the Principal Investigator and research coordinator(s) to discuss procedures for record-keeping of Informed Consent Forms and HIPAA authorization forms.

• You cannot begin your study until the VA Research and Development Committee (R&DC) approves the study and you receive the approval letter signed by the VA Associate Chief of Staff for Research (ACOS/Research).