HRPP New Study Submission and Approval
Workflow 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

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 the 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. David Clark.

1. *Create a new project in IRBNet*
   Open a new project in IRBNet/VAIRRS by clicking on Create New Project. 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/or by the IRB.
   - In VAIRRS, share the project with all your staff and co-investigators. New users of VAIRRS must link their CITI training account. Everyone must also upload their certificates from the VA Talent Management System (TMS) website for Government Ethics training and for Privacy and HIPAA Focused Web-Based Training. Instructions for linking/uploading training 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 investigators who are listed on the study (Principal and Co-Investigators) 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".
   - For any potential regulatory issues, refer to 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".

2. *Upload New Study Coversheet and Required Documents*
   In IRBNet/VAIRRS, upload all "required" and "if applicable" documents to your package. For an explanation of documents to include, please see the New Study Coversheet in the IRBNet Library called "NF/SGHVS Research Administration Members – Gainesville, FL – Documents for Researchers".

3. *SRS Submission (if applicable)*
   Studies requiring review by the Subcommittee on Research Safety (SRS) should also create a separate package for this purpose. To determine if this is required for your study, please see the New Study Coversheet in the IRBNet Library called "NF/SGHVS Research Administration Members – Gainesville, FL – Documents for Researchers".

4. *Submit Package*
   When ready, submit the package(s). In the specific package under Project Submission, click Submit this Package and follow the prompts. The package(s) will automatically be locked so no further edits are possible while under review.

5. *HRPP Administrative Review*
   The HRPP 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 so the study team can address these issues. The study team will be notified automatically by IRBNet/VAIRRS if the study package is unlocked.

6. *Address 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.

7. *ISSO and PO Pre-Review*
   Once all issues noted by HRPP have been addressed, the HRPP administrator will route the package for pre-review (if necessary) by the Information Systems Security Officer (ISSO), the Privacy Officer (PO), and Subcommittee on Research Safety (SRS). If issues are found, the package will be unlocked so researchers can make revisions.

8. *Pre-Review Complete*
   After the 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, located in the Board Documents section. HRPP will then unlock the package. The research team will need to download these forms and then upload them to the appropriate section on the IRB's website.

9. *Submit the study to the IRB*
   Submit the study to the IRB using the IRB's website. After IRB approval is granted, the finalized documents (e.g., IRB approval letter, Informed Consent Form, Protocol, etc.) will need to be submitted to HRPP in IRBNet.

10. *Submit the package back to HRPP*
    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, the 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.

11. *ISSO and PO Final Review*
    The HRPP administrator will route the study for a final review by the Information Security Officer and the Privacy Officer.

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

13. *Research Compliance Training*
    Following the R&DC meeting, HRPP staff will notify the study team that they must complete their informed consent training with the Research Compliance Officer(s). Instructions will be sent via Project Mail on how to arrange this training.

14. *Begin study **after** approval letter has been received.*
    You cannot begin your study until the VA Research and Development Committee (R&DC) approves the study and you receive the ACOS approval letter signed by the VA Associate Chief of Staff for Research (ACOS/Research).
    Note: The ACOS approval letter is different from the ACOS Assurance Letter. The latter is part of the Just-In-Time submission for VA-funded awards, and is handled by the Grants Administrator.