North Florida/South Georgia Veterans Health System

IACUC 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**.

The VA Innovation and Research Review System (VAIRRS) is the VA's enterprise instance of IRBNet. VAIRRS will be used by all VA medical centers with research programs and will provide an enterprise platform to support the management of research oversight committees. This program is referred to as IRBNet throughout this document.

1. *Create a new project in IRBNet*

Open a new project in IRBNet by clicking on Create New Project. There are training videos and documents explaining how to use IRBNet on the Research Service website.

Processes to complete in parallel:

- Note that this process will require 3 submission packages in IRBNet:
    1. Submission for IACUC: explained in this document
    2. Submission for SRS: Create a separate package for submission to the Subcommittee on Research Safety (SRS). Instructions are located in Forms and Templates > Library: NF/SGVHS SRS, Gainesville, FL – Documents for Researchers under "00 SRS SUBMISSION GUIDE".
    3. Submission for FCOIs: The Principal and all Co-Investigators who are listed on the grant and/or listed as PI or Co-I on the ACORP must complete a Financial Conflict of Interest (FCOI) 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". FCOIs must be submitted in a package that is separate from the package used to submit study documents (e.g., protocol, consent forms, etc.).
- All Office of Research & Development (ORD) and locally required training must be current and available in the User's IRBNet account
    - CITI account must be linked to the User's IRBNet profile
        - Working with VA IACUC
        - VA ORD Biosecurity
        - Any species-specific training (if applicable)
- *A complete list of required training can be located on the Research Service website > "Tracking Regulatory Training", Appendix A*For any potential regulatory issues, refer to applicable handbook/directives and consult with appropriate parties for resolution (you can email the general research group VHANFLResearchStudy@va.gov).

2. *Complete VA Project Coversheet Wizard and Upload Required Documents*

In IRBNet, complete the following:

Required	Location
1. Research Protocol Submission Coversheet 2. ACORP Main Body 3. Applicable ACORP Appendices 4. IACUC Abstract 5. ERDSP Wizard	IRBNet > Forms and Templates > Library: NFSGVHS IACUC, Gainesville, FL – Documents for Researchers IRBNet submission > Designer > Start a Wizard > ERDSP Wizard
6. VA Project Coversheet Wizard	In IRBNet submission > Designer > Start a Wizard > Project Coversheet Wizard
7. UF IACUC Documents (if applicable)	

3. *Submit Package*
   Submit the completed IACUC package: Project Administration > Submit this Package > Select a Board: NF/SGVHS Research Administration Members. The package(s) will automatically be locked so no further edits are possible while under review. A complete package should include all of the items listed in the chart in item 2. Above.

4. *IACUC Administrative Review*
   The IACUC Coordinator will review the package. Any issues (e.g., incomplete/missing documents or recommended edits to documents, missing/expired training) 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 if the study package is unlocked. The IACUC Coordinator will also send a message to the study team via IRBNet Project Mail, usually with a subject line beginning with "Action Required…".

5. *Address issues noted by the IACUC Coordinator*
   After the researchers fix any issues noted by the IACUC Coordinator, they must click **Mark Revision Complete** in IRBNet to lock the package. Locking the package will trigger an IRBNet notification sent to the IACUC Coordinator that revisions are complete.

6. *Veterinary Consult*
   The IACUC Coordinator will alert the Veterinary Medical Officer (VMO) and requests that they conduct the veterinary consultation and provide their comments (usually embedded in an electronic copy of change-tracked Microsoft Word documents) if any. If the Veterinarian has comments or concerns, then the protocol undergoes a round of edits as outlined below:
   - The IACUC Coordinator will unlock the package and alert the Research Team via IRBNet Project Mail that the Veterinary Consult is available for their review.
   - In response to Veterinary comments, the PI submits any updates/revisions using Tracked Changes to their submission in the unlocked package in IRBNet.
   - The Veterinarian will review the tracked changes. There may be another set of comments/concerns from the Vet that will need to be addressed by the PI. Veterinary consult must be complete before moving forward to IACUC review.

7. *ISSO Review (if applicable)*
   Depending on the responses to the ERDSP Wizard, the package may require review by the Information Systems Security Officer (ISSO). If the package does require ISSO review, the IACUC Coordinator will route the package to the ISSO. If issues are found, the package will be unlocked so the study team can make the appropriate revisions.

8. *Administrative Review Complete*
   At this point, IACUC administrative review is complete. Package will be placed on the next open IACUC agenda for committee review.

9. *IACUC Review*
   Agenda items will be reviewed and discussed during a convened meeting.. There are three possible outcomes for the study:
   - Approval (skip step 14)
   - Require modifications to secure approval
   - Disapproval

10. *Require Modifications to Secure Approval (if applicable)*
    If the protocol requires modifications to secure approval, the Committee will send the package to Designated Member Review (DMR). A written record of the IACUC's required modifications and conditions for approval, and action taken is sent to the PI and research team via IRBNet Project Mail. The PI must respond and provide the required modifications using tracked changes to the unlocked IRBNet package . Once the IACUC Coordinator receives the modifications from the PI via IRBNet, the designated reviewers are alerted via Committee Mail, who may then review. Any of the designated reviewers may request that the modified documents go back to the full committee for review.

11. *IACUC Approval*

Once IACUC has given full approval for the study, The PI and Research Team will receive an approval notification indicating the date of approval, approval duration, and date of next report due. The following documents will be available under Board Documents in IRBNet:

- ACORP Main Body
- Approved Applicable Appendices
- Clean Word documents (to be used for future amendments/modifications/submissions)

12. *R&DC Review and Approval*

Once IACUC **and SRS** approval is in place the study will be routed by the IACUC Coordinator for review by the VA Research and Development Committee (R&DC). Once R&DC approval is in place, the following documents will be available under Board Documents:

- Signed ACOS R&D approval letter

13. *Begin study **after** R&DC approval letter is received.*

Work on any VA research is permitted to begin only after R&DC approves the study and you receive the ACOS R&D 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.