

## 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**.

### 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:

- Note that this process will require 3 separate 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 COIs: 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 (COI) 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”.
- All study personnel must complete training required by VA Research Service and/or IACUC
  - CITI account must be linked to the user’s IRBNet profile with appropriate trainings completed
    - 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](mailto:VHANFLResearchStudy@va.gov)).

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

In IRBNet/VAIRRS, complete the following:

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

### 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:

- ACORP Main Body and all applicable appendices
- ERDSP Form
- VA Project Cover Sheet Wizard
- TMS training certificates uploaded to IRBNet profiles

## North Florida/South Georgia Veterans Health System

- CITI training linked to IRBNet profiles

### 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/VAIRRS 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/VAIRRS to lock the package. Locking the package will trigger an IRBNet notification sent to the IACUC coordinators 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/VAIRRS Project Mail that the Veterinary Consult is available for their review.
- In response to Veterinary comments, the PI submits any updates/revisions using Track Changes to their submission in the unlocked package in VAIRRS.
- 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 form, 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 IACUC agenda meeting for committee review.

### 9. *IACUC Review*

Once the package has been deemed ready by the IACUC coordinator, the study placed under the next IACUC agenda meeting for review and approval. 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 discussion (including all required modifications and conditions for approval) and action taken is sent to the PI and research team via IRBNet/VAIRRS Project Mail. The PI must respond and provide the required modifications using tracked changes to the unlocked package to the IACUC Office via IRBNet/VAIRRS. Once the IACUC Coordinator receives the modifications from the PI via VAIRRS, the designated reviewers are alerted via VAIRRS Committee Mail, who may then approve them. 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 following documents will be available under Board Documents in IRBNet/VAIRRS:

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- 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 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.*