VA Northeast Ohio Healthcare System (VANEOHS) – Research Service Guidance for Submitting a New Research Study

VA Innovation and Research Review System (VAIRRS) / IRBNet

The VA Innovation and Research Review System (VAIRRS) is the VA's enterprise version of IRBNet, a web-based software used by administrators, committee members, and researchers for electronic protocol submission/management and review and oversight of research. VAIRRS is currently in a phased implementation at all VA medical centers with research programs.

All submissions to the IRB, IACUC, SRS and RDC (e.g., new protocols, amendments, continuing reviews, closures) must be submitted electronically via VAIRRS. E-mail and hard copy submissions will not be accepted.

Accessing VAIRRS
You can access VAIRRS from virtually any computer by visiting https://gov.irbnet.org. VAIRRS does not require a connection to the VA network.

All users must be registered to access VAIRRS. New users can create an account by clicking on the "Register Now to get started!" link located on the login page. Be sure to select VA Northeast Ohio Healthcare System as your organization when registering.

- ALL Principal Investigators, Co-Investigators, study coordinators/primary contact personnel, and study staff MUST create and activate a VAIRRS account.
- For detailed guidance on how to create a new VAIRRS account, please refer to the New User Registration Training Energizer available at www.clevelandvaresearch.org

Instructions for Using VAIRRS
For detailed guidance on using VAIRRS, including downloadable resources with step-by-step instructions, visit www.clevelandvaresearch.org/vairrs-irbnet

Does my project qualify as research?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A **"systematic investigation"** is an activity that involves a prospective study plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a study question. Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

If you are unsure whether your project constitutes research, please complete a Research vs. Non-Research Operations Evaluation form for a determination. This form can be downloaded from www.clevelandvaresearch.org/new-studies and must be completed and signed electronically, and then emailed to Christina.Bennett2@va.gov

Study Personnel

Who should be listed on a study?

- Anyone participating in the conduct of the research on VA time or that will have access to VA space and/or VA data should be listed on the project.

What does it mean to be an investigator?

- Principal Investigator (PI) is an individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The PI oversees scientific, technical, and day-to-day management of the research
- Co-investigator (Co-I) is an individual who, under the direction of the PI, is involved in some or all aspects of the research project, including the: design of the study, conduct of the study, analysis and interpretation of identifiable data, and writing of manuscripts resulting from the project. The investigator must uphold professional and ethical standards and practices, adhere to all applicable Federal requirements, and comply with applicable local policies and procedures.

Where do I list my study personnel?

- Research personnel are listed in the Project Cover Sheet (wizard/smart form) that is required as part of your study package in VAIRRS.

How do I enable my study coordinator/research staff to access the project in VAIRRS?

- Provide access to all your study personnel by sharing the project with them in VAIRRS. Within your project, click "Share this Project" on the left side of the screen. Step-by-step instructions are available in the VAIRRS Researcher 1 Training Energizer available at www.clevelandvaresearch.org/vairrs-irbnet
- In order for you to share your project, your study staff will all need to have registered for an account in VAIRRS.
- Grant each team member the level of access that they require (Full, Write, or Read-only). A description of each is available in VAIRRS when sharing the project.
- **Prior to submitting your study for review, be sure all study personnel have a VAIRRS account and have been shared on the study.**

What if I want to add someone to the study after it has been approved?

- For human subjects research studies, see the "Checklist for adding individuals to VA approved human subjects research studies" available in the VAIRRS Forms & Templates library
- Typically, adding an investigator requires prospective approval via a modification request. Contact the Research Office to determine how to proceed.

Principal Investigator Requirements

- Principal Investigators must have VA paid appointments and cannot be interns, residents, or fellows.
- If you have not previously served as Principal Investigator on a study at VANEOHS, you will need to complete a **New Investigator Packet** (available at www.clevelandvaresearch.org/new-studies) and submit to the Research Office prior to submitting your study package. Email this packet to Christina.Bennett2@va.gov – DO NOT upload into VAIRRS.
- All PIs are required to complete the VA Technology Transfer Program TMS training (# 33534) annually. This will be assigned to you by the Research Office.

REQUIREMENTS FOR A STUDY SUBMISSION PACKAGE

A. Conflict of Interest Statements

- All investigators (PI, co-investigators, etc.) must submit a Research Financial Conflict of Interest Statement (OGE Form 450 Alt VA) for each study in which they are listed as an investigator.
- This form can be downloaded from www.clevelandvaresearch.org/new-studies and should be completed and signed electronically.
- **COI forms must be emailed to Christina.Bennett2@va.gov when you create your submission in VAIRRS. Per VA Office of Research & Development, COI forms MUST NOT be uploaded into VAIRRS.**

B. Training/Credentialing Requirements

1. **VA Appointment**
   Everyone listed on the study must have a valid VA appointment (paid or Without Compensation, i.e., WOC). Anyone without a VA appointment will need to obtain a Without Compensation appointment. WOC application forms can be found here: https://www.clevelandvaresearch.org/employee-forms-1

2. **Research Scope of Practice**
   - Each member of the research team must have a Research Scope of Practice on file with the VANEOHS Research Office.
   - The Scope of Practice should cover ALL research activities the individual will conduct across all studies in which they are involved. This document should be updated as needed when roles/responsibilities change.
   - The Scope of Practice form can be downloaded from https://www.clevelandvaresearch.org/employee-forms-1 and should be submitted to Christina.Raymond2@va.gov .
   - Once processed by the Research Office, your completed, approved Scope of Practice will be uploaded to your profile in VAIRRS.

3. **CV/resume**
   All research staff must have a CV/resume on file with the Research Office. This should be uploaded to your User Profile in VAIRRS. For detailed guidance on how to submit a training & credentials record in VAIRRS, see the "New User Registration" training energizer posted in the VAIRRS Resources at www.clevelandvaresearch.org/vairrs-irbnet

4. **Human Subjects Research Training (if applicable)**
   VA CITI Human Subjects Protection (HSP) Training is required for study personnel conducting human subjects research. See https://www.clevelandvaresearch.org/training-credentialing-1

5. **IACUC Training for Animal Research (if applicable)**
   Please see https://www.clevelandvaresearch.org/training-credentialing-1 for details about required training for animal research

6. **Link Training Records to a Submission in VAIRRS**
   Your completed training records are visible in your User Profile in VAIRRS. To highlight training records relevant to a specific study submission, you can link those training records to your submission. This will allow administrators and board members/reviewers to easily confirm that all research staff have completed the training required for a given study submission. Training records can be linked in the Designer page when creating a new study. See the VAIRRS Researcher 1 Training Energizer that can be downloaded at www.clevelandvaresearch.org/vairrs-irbnet

C. Radiation Safety Committee Approval

Research studies involving radiation typically require approval from the Radiation Safety Committee (RSC). Required RSC forms can be downloaded from www.clevelandvaresearch.org/new-studies. Please contact the Radiation Safety Officer at Ronald.Leuenberger@va.gov when you are preparing your study to begin the process. If required, RSC approval must be obtained prior to IRB approval of the study.

D. Pharmacy & Therapeutics (P&T) Committee Approval

Research studies involving investigational drugs typically require approval from the P&T Committee. Please contact Research Pharmacist Dave Panning at David.Panning@va.gov when you are preparing your study to begin the process. If required, P&T approval must be obtained prior to IRB approval of the study.

E. Study Forms/Documents

Blank copies of forms must be downloaded from the VAIRRS "Forms and Templates" page. You can also download blank forms from the project "Designer" page when you are in the process of creating a new study.

When preparing a new study, always download blank forms and templates directly from VAIRRS to ensure you are using the most current version of the forms. Do not use old copies of forms you have saved on your computer.

1. **Smart Forms/Wizards**
   VA Office of Research & Development has created two required smart forms to be used in VAIRRS (listed below). The smart forms are completed within VAIRRS by selecting "Add a Wizard" in the project Designer. ****These forms will indicate if additional requirements/forms should be submitted with your project. Be sure to complete the forms below first.****

	Form Name	When Applicable	Description
☐	**Project Cover Sheet**	**Required for all projects**	Collects project-level information (personnel, funding, etc.)
☐	**IRB Information Sheet**	**Required for all exempt and non-exempt human subjects research**	Provides details about human subjects research procedures. Required even when using an external IRB.

NOTE: The above smart forms must be kept up to date throughout the life of your project. If there are changes to your project (e.g., modification, etc.), you will need to update your Project Cover Sheet and IRB Information Sheet as applicable. You can do this in subsequent packages by adding a wizard in VAIRRS (in the Designer) and selecting "Clone an existing wizard." This will allow you to copy your current smart form and make changes as needed.

2. Other Forms/Documents

Please see the table below for information about various study forms and when they would be required. These forms should be downloaded as blank copies, completed, and then uploaded/attached to your study package in VAIRRS.

	Form Name	When Applicable	Description
☐	**Data Management and Access Plan (DMAP)**	**Required for all projects**	Provides plan for public disclosure of datasets after publication of results
☐	**ERDSP (Enterprise Research Data Security Plan)**	**Required for all projects**	Provides information on data security. Local ISSO for VANEOHS Research is Robert Hall at Robert.Hall7@va.gov
☐	**VA Form 10-0398 (safety survey)**	**Required for all projects**	Provides information about hazards to research personnel. Contact John.Schaffer@va.gov with questions.
☐	**VANEOHS Local SRS Appendix to VA 10-0398**	**Required for all projects**	Provides information about hazards to research personnel. Contact John.Schaffer@va.gov with questions.
☐	IBC rDNA questionnaire	For studies involving recombinant DNA	For Institutional Biosafety Committee review.
☐	Protocol	Required for all Human Subjects Research	Describes research procedures for human studies. Use provided template. If there is a sponsor protocol, submit that in addition to completing the required protocol template.
☐	VA Form 10-250	Required for all human subjects research	Privacy Officer review form
☐	RDC Non-Veteran Application	Human Subjects Research	For research studies involving non-Veterans
☐	Determinations Request	Exempt Human Subjects Research	If your study meets criteria for an exempt determination (see form)
☐	Informed Consent and HIPAA Authorization (combined)	Non-Exempt Human Subjects Research	For requesting written consent and authorization of human subjects
☐	HIPAA Authorization (standalone)	Human Subjects Research	Used in certain scenarios; contact IRB Office if uncertain.
☐	Consent Script	Human Subjects Research	When informed consent will be obtained but a written signature is not
☐	Waiver of Informed Consent	Non-Exempt Human Subjects Research	Request to waive requirement for obtaining informed consent
☐	HIPAA Waiver	Human Subjects Research	Request for access to PHI for research without subjects' written authorization
☐	Service Impact Form	Human Subjects Research	If your study requires institutional support from hospital services. Identify activities but leave costs blank.
☐	Pharmacy Impact Form	Drug Studies	
☐	10-9012 Drug Form	Drug Studies	Investigational Drug Form
☐	Peer Review/Summary Stmt.	If peer-reviewed	Official peer review from funding agency

☐	Questionnaires, Informational Sheet, Recruitment Materials, Sponsor Documents	Human Subjects Research	All other materials that will be presented to research subjects
☐	ACORP and associated appendices	Required for all Animal Research	Animal Component of Research Protocol (ACORP) is a national VA form required for all animal studies. Contact IACUC Coordinator Karen.Day2@va.gov with questions.

F. Signature Requirements

Signing the Study Package in VAIRRS

- Packages must be electronically signed by the Principal Investigator before they are submitted. The "Designee" signature mode is not accepted.
- To sign a package, open the project in VAIRRS and click "Sign this Package" on the left side of the screen. Step-by-step instructions are available at www.clevelandvaresearch.org/vairrs-irbnet
- Digital signature instructions for individual documents

Signing Individual Study Forms Before Uploading Into VAIRRS

Some forms that you will submit as part of your package have a signature field on the form itself, typically requiring PI signature. If an electronic signature box, simply click the box and you will be prompted to enter your VA PIV credentials. Otherwise, follow the instructions below to stamp any document with an official VA signature.

Instructions for adding digital signature to a document using Adobe:

3. When you are ready to sign the document, if it is not already a PDF, save as a PDF.
4. Open the PDF.
5. If using Adobe Reader: In the right panel, click the wrench for "More Tools." Click the icon that says "Certificates."
6. If using Adobe Acrobat DC (full program): In the righthand menu, click the search bar (Search tools) and search for "Digitally Sign"
7. At the top of the page, click "Digitally Sign" and follow the prompts to add your signature and save the document. NOTE: Your PIV card must be in the computer to add your digital signature to the document.

When is a study ready to submit?

1. PI meets requirements for who can be Principal Investigator
2. Conflict of Interest statements for all investigators have been emailed to Christina.Bennett2@va.gov
3. Training/Credentialing requirements completed/up to date for all study personnel
4. Have contacted Radiation Safety Committee and/or Pharmacy (P&T) Committee to obtain approvals, if applicable
5. All study documents completed and included in your study package in VAIRRS
6. All study personnel have been shared/given access to the study in VAIRRS
7. PI has signed the package

NOTE: If you submit an incomplete package, it will be withdrawn; this will result in delays in your approval.

What if I submit a package accidentally, or need to change something?

Contact the Research Office immediately by emailing VHACLEVAIRRS@va.gov

What happens after I submit my project?

When you submit your study, your submission is locked and sent to the Research Office for review. Once submitted, it is like dropping your packet in a mailbox; you can no longer delete or revise your package.

1. The Research Office will be automatically notified of the new submission by VAIRRS
2. R&D staff conduct administrative review to ensure package is complete and basic requirements met
3. If the proposal did not undergo peer-review by the funding agency (e.g., in the case of unfunded or industry-funded research), or the peer review summary statement (e.g., from NIH, DoD, etc.) was not submitted with the study package, an RDC member will conduct a review to ensure scientific merit
4. Study is forwarded to applicable sub-committees, whose staff conduct a detailed pre-review before sending to their board for official review
5. If human subjects research, will require initial Privacy Officer (PO) review prior to IRB review. Studies will be reviewed by the Information System Security Officer (ISSO) if required.
6. Review & determination from sub-committees (e.g., IRB, SRS, IACUC) and/or external committees (e.g., VA Central IRB, NCI CIRB, WIRB, Advarra) as applicable
7. If human subjects research, will require final PO review prior to study initiation. If ISSO review was required, will need final ISSO review prior to study initiation.
8. Review by R&D Committee
9. Once all required approvals have been obtained, the ACOS study approval letter is sent to PI to indicate project may begin

NOTE: You can view the current status of your package from the Project Overview page after opening your submitted study in VAIRRS. You will receive an automatic notification of board actions when they occur. You can review board documents and review decisions from the Reviews page when viewing your project in VAIRRS.

Post-Submission Topics

Please visit www.clevelandvaresearch.org/vairrs-irbnet for guidance on the following:

- Responding to a request for revisions
- Managing studies and alerts, reviewing board decisions and documents, etc.
- Submitting modifications, continuing reviews, etc.
- FAQs and downloadable, step-by-step guidance for using VAIRRS

Contact Information

Contact Information for VANEOHS Research Office staff is available on the research website at https://www.clevelandvaresearch.org/contact-us-1