VA Northeast Ohio Healthcare System (VANEOHS) – Research Service Guidance for Research Submissions

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VA Northeast Ohio Healthcare System (VANEOHS) – Research Service Guidance for Research Submissions

1. 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

2. 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/research-submissions and must be completed and signed electronically, and then emailed to Christina.Bennett2@va.gov

3. 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?

- All research personnel must be listed in the Project Cover Sheet (wizard/smart form) that is required as part of your study package in VAIRRS.
- You must also provide access to the project in VAIRRS for all your research personnel using the “Share this Project” function in the system. See next question below.

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.

4. Principal Investigator Requirements

- Principal Investigators must have VA paid appointments and cannot be interns, residents, fellows, or other trainees. If you are conducting VA research to fulfill the requirements of an academic program, you will be considered a student/trainee and will not be able to serve as Principal Investigator, even if you are a paid VA employee.
- 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/research-submissions) 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.

5. Research Financial Conflict of Interest Statements (FCOI)

Who needs to submit an FCOI form?

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. An FCOI is not required for other types of study personnel (e.g., research assistant, lab technician, etc.)

When is a FCOI form required?

FCOI forms are required (1) for new study submissions, (2) with a modification request if an investigator is being added to a project, and (3) if at any time your conflict of interest status changes. FCOI forms are also typically required at continuing review; consult the guidance from your board of oversight for details.

Where can I get a blank copy of the FCOI?

The research FCOI form can be downloaded from www.clevelandvaresearch.org/research-submissions and should be completed and signed electronically. When completing the form, please note that the Duty Station for Louis Stokes Cleveland VA Medical Center is 541. You can find the duty station ID for other locations here:
https://www.va.gov/directory/guide/rpt_fac_list.cfm

How do I submit the FCOI forms?

FCOI forms must be emailed to VHACLEresearchFCOI@va.gov when you create your submission in VAIRRS. **Per VA Office of Research & Development, FCOI forms MUST NOT be uploaded into VAIRRS.**

When emailing your FCOI form(s), please be specific in the subject line about the type of submission (e.g., IRB continuing review, IACUC modification, new study, SRS annual review) with which your FCOI form is associated. If you do not specify, processing of your FCOI will be delayed.

6. Training/Credentialing Requirements

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

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 by administrative personnel.

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

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 Training must be renewed every three years.

IACUC Training for Animal Research (if applicable)

Please see https://www.clevelandvaresearch.org/training-credentialing-1 for details about required training for animal research

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

7. 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/research-submissions. Please contact the Radiation Safety Officer at Ronald.Leuenberger@va.gov when you are preparing your study to begin the process. For new studies, submit your RSC application to the Radiation Safety Officer in advance of submitting your study in VAIRRS. You will need to obtain RSC approval and include the RSC approval letter with your new study submission in VAIRRS. If required, RSC approval must be obtained prior to IRB, SRS and RDC review and approval of the study.

8. 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.

When do I need a 10-9012 form?

VA Form 10-9012 is required for each investigational drug where a manufacturer's package insert is not available. The information asked for on the 10-9012 form is similar to what you would find in a package insert, and also provides a listing of all authorized prescribers for investigational drugs in the study and a designated contact person for questions.

How do I know if a drug is considered "investigational"?

Any chemical or biological compound being studied in a clinical investigation could be considered an investigational drug (or "study drug") – even an approved drug being studied for approved use. The interpretation depends on the parameters of the study. To avoid compliance issues, it's best to contact Research Pharmacist Dave Panning at David.Panning@va.gov to find out if the drugs in your study are investigational or not.

I have an investigational drug in my study. Now what do I do?

All studies involving investigational drugs must be approved by the Pharmacy and Therapeutics (P&T) Committee. Send your study protocol and Pharmacy Impact Form to the research pharmacist and the study will then be presented to the P&T Committee for review. The research pharmacist will provide you with pharmacy fee estimates that must be agreed to in advance of the P&T Committee review.

Do I have to pay for my investigational drugs?

All investigational drugs or supplies that are being used under an IND must be provided or paid for by the study sponsor. If your investigational drug is not under an IND, then you may or may not have to supply or pay for the drug – the research pharmacist will help you with this determination. Regardless of who pays for the drug itself, all investigational drug prescriptions must be dispensed through the research pharmacy and will be subject to pharmacy fees.

How does an investigational drug study work?

All investigational drugs are required to be managed by the research pharmacy. They must be delivered to the research pharmacy for receipt, storage, dispensing, and any further disposition. The research pharmacist will work with you to get a special entry for your study into the VA drug file and will let you know what other documents may be required. When a subject is ready to be prescribed an investigational drug, only the authorized prescribers designated by the study may write for it. If it's the subject's first time receiving a drug in the study, the research pharmacist must see their signed informed consent before being able to dispense the drug. The pharmacist will let you know about any other necessary requirements.

9. Study Forms/Documents Required for New Studies

Where can I find blank copies of the forms to complete?

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.

IF SUBMITTING TO A COMMERCIAL IRB OR VA CENTRAL IRB, PLEASE SEE THOSE SECTIONS BELOW FOR SPECIFIC REQUIREMENTS.

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 when using the local VANEOHS IRB, VA Central IRB, or an external IRB (e.g., WIRB, Advarra, NCI CIRB).

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.

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
☐	**SRSS 10-0398 (use SRSS RPSS - Fillable Version)**	**Required for all projects**	Provides information about hazards to research personnel. Contact John.Schaffer@va.gov with questions.
☐	**SRS Local Appendix for VA Form 10-0398**	**Required for all projects**	Provides information about hazards to research personnel. Contact John.Schaffer@va.gov with questions.
☐	**Grant Application**	**Required for grant funded studies**	Submit a copy of your complete grant application
☐	**Budget**	**Required for all funded studies**	No required template, but budget should explain how research costs will be covered. For example, if applicable: research staff, supplies, participant stipends and/or facility lab fees or pharmacy fees. If your grant application or subaward includes your budget, you can submit that instead.
☐	IBC rDNA questionnaire	For studies involving recombinant or synthetic nucleic acid molecules	For review by the Case Western Reserve University (CWRU) Institutional Biosafety Committee (IBC). Contact Research Safety Coordinator John.Schaffer@va.gov for submission instructions.
☐	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 10-250	Required for all Human Subjects Research	Privacy Officer review form. Researcher completes only page 1.
☐	3.5A - RDC Non-Veteran Application	Human Subjects Research	For research studies involving non-Veterans, including family members, caregivers, and pregnant partners of research subjects.
☐	2.0A - Determinations Request	Exempt Human Subjects Research	If your study meets criteria for an exempt determination (see form)
☐	7.2A - Combined ICF and HIPAA Authorization	Non-Exempt Human Subjects Research	For requesting written informed consent and authorization from human subjects
☐	7.3A - ICF Template	Non-Exempt Human Subjects Research	For requesting written informed consent only when a separate HIPAA authorization document will be used
☐	HIPAA Authorization (VA Form 10-0493) standalone	Human Subjects Research	Separate HIPAA Authorization used in certain scenarios; contact IRB Office if uncertain.
☐	Oral Consent Script/ Letter/Information Sheet Guidance	Human Subjects Research	When informed consent will be obtained but a written signature is not
☐	7.1A - Request for Waiver or Alteration of IC	Non-Exempt Human Subjects Research	Request to waive requirement for obtaining informed consent
☐	7.0A - Request for Waiver of Documentation of Informed Consent	Non-Exempt Human Subjects Research	Request to waive requirement for documenting written/signed informed consent. Typically required when using a consent script.
☐	2.1 - Request for Waiver of HIPAA Authorization	Human Subjects Research	Request for access to PHI for research without subjects' written authorization
☐	3.2A Service Impact Form	Human Subjects Research	If your study requires institutional support from hospital services. Identify activities but leave costs blank.
☐	3.1A Pharmacy Impact Form	Drug Studies	Submit the copy that has been signed/approved by Pharmacy.
☐	VA Form 10-9012 - Investigational Drug Form	Drug Studies	Investigational Drug Form. Must be completed for each drug being evaluated in a research study where a manufacturer's package insert is not available.
☐	Radiation Safety Committee Approval	Studies Involving Radiation	Contact Radiation Safety Officer Ronald.Leuenberger@va.gov with questions.
☐	Peer Review Summary Statement	If peer-reviewed	Official scientific peer review statement from your funding agency

☐	Questionnaires, Informational Sheet, Recruitment Materials, Sponsor Documents	Human Subjects Research	All other materials that will be presented to research subjects, and any other relevant materials, as applicable
☐	IACUC ACORP and associated appendices	Required for all Animal Research	The 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.

10. Requirements for VA Central IRB Studies

Human subjects research studies that are approved by the VA Central IRB must also be approved by each local VA facility at which they are to be conducted. Effective March 15, 2021, all submissions for VA Central IRB must be submitted through VAIRRS/IRBNet.

VA CIRB IS WORKING TO ESTABLISH A PROCESS FOR SUBMISSIONS IN VAIRRS. PRIOR TO PREPARING A CIRB NEW STUDY IN VAIRRS, CONTACT VANEOHS RDC COORDINATOR Christina.Bennett2@va.gov FOR GUIDANCE.

How do I submit a new study application to CIRB in VAIRRS?

Please note that all **new study applications** for VA CIRB must be submitted in IRBNet to **your local research office ONLY** in order to initiate both the local and CIRB study review process. The **local research office** will submit to CIRB. Please include the note "CIRB IRB Review" as a reminder to them. After initial study approval, all CIRB submissions (e.g., adverse events, continuing review, amendments, etc.) should be submitted in IRBNet **directly to the Central IRB**.

What documents are required by VA Central IRB?

CIRB guidance documents and form templates are available from the Forms and Templates page in VAIRRS, by selecting the library for "VA Central IRB Administration - Documents for Researchers." Please use the CIRB guidance regarding what forms are required by CIRB.

What documents are required by the VA Northeast Ohio Healthcare System local Research Office?

You must submit locally required documents for SRS and RDC review. The checklist below outlines which local forms should be included. Please see Section 9 above for detailed descriptions of each form.

	Required (for local Research Office)
☐	Data Management and Access Plan (DMAP)
☐	SRSS 10-0398 (Research Protocol Safety Survey)
☐	SRS Local Appendix for VA Form 10-0398

(table continued on next page)

	If Applicable (for local Research Office)
☐	Grant Application
☐	Budget
☐	Peer Review Summary Statement
☐	IBC rDNA questionnaire
☐	3.5A - RDC Non-Veteran Application
☐	3.2A Service Impact Form
☐	3.1A Pharmacy Impact Form (approved)
☐	VA Form 10-9012 - Investigational Drug Form
☐	Radiation Safety Committee Approval

11. Local Requirements for Commercial IRB Studies

VHA Directive 1200.05 (Paragraph 5.f(8)(a) was amended on March 3, 2020 permitting VA Facilities to use commercial IRBs for cooperative (multi-site) research activities as approved by ORD. Only commercial IRBs vetted and approved by ORD can be used by VA Facilities in which ORD has executed an agreement with the commercial IRB(s).

VA Northeast Ohio Healthcare System currently has reliance agreements to use the following VA ORD-approved commercial IRBs for cooperative (multi-site) non-exempt human subjects research:

1. Advarra
2. WCG IRB (formerly WIRB)

Local SOPs for the use of these commercial IRBs can be found at https://www.clevelandvaresearch.org/research-sops. Please review the SOPs carefully; they include a list of investigator responsibilities.

The cost of using a commercial IRB is typically covered by the study sponsor. Neither the VA nor the VA NPC (e.g., Cleveland VA Medical Research & Education Foundation) may contract directly for IRB review services.
Human subjects research studies that are overseen by a VA ORD-approved commercial IRB must also be approved by each local VA facility at which they are to be conducted. Investigators must submit a new study package for review and approval by the VANEOHS SRS (if applicable) and R&D Committee.

There are a few differences in the local requirements for new studies that are using the VA Central IRB. The checklist below outlines which forms should be included in your local submission (to VANEOHS) for a new VA Central IRB study. Please see Section E above for detailed descriptions of each form. **Your study must first be submitted to VANEOHS and receive preliminary PO/ISSO reviews prior to being submitted to the commercial IRB.**

	Required
☐	Project Cover Sheet
☐	IRB Information Sheet
☐	Data Management and Access Plan (DMAP)
☐	ERDSP (Enterprise Research Data Security Plan)
☐	SRSS 10-0398 (Research Protocol Safety Survey)
☐	SRS Local Appendix for VA Form 10-0398
☐	Protocol Reviewed by Commercial IRB
☐	VA 10-250

	If Applicable
☐	Grant Application
☐	Budget
☐	Peer Review Summary Statement
☐	IBC rDNA questionnaire
☐	3.5A - RDC Non-Veteran Application
☐	3.2A Service Impact Form
☐	3.1A Pharmacy Impact Form (approved)
☐	VA Form 10-9012 - Investigational Drug Form
☐	Radiation Safety Committee Approval

ORD Requirement: VA Facility Commercial IRB Endorsement Letter

As of May 11, 2020, any research study submitted by a VA Investigator to a commercial IRB approved by ORD must include the following letter: "VA Facility Commercial IRB Endorsement Letter." The purpose of the letter is to ensure that the VA Facility is aware that the VA Investigator is submitting a cooperative study to the ORD-approved commercial IRB and confirmed that neither the VA nor the VA NPC is contracting directly for the IRB review services provided by the commercial IRB. The commercial IRBs have requested this institutional documentation as part of standard processing of investigator applications.
The "VA Facility Endorsement Letter" must be signed by one of the following:

- the Associate Chief of Staff for Research and Development (ACOS/R&D),
- Administrative Officer for Research & Development (AO/R&/D), or
- the VA Facility's Liaison for the commercial IRB

The VA Principal Investigator is not authorized to sign the VA Facility Commercial IRB Endorsement Letter. This letter must be included with the VA Investigator's study application materials to the commercial IRB. **Any VA study application submitted without the signed VA Facility Commercial IRB Endorsement letter will not be processed by the applicable commercial IRB.**

The ORD VA Facility Commercial IRB Endorsement Letter template is available for download on the ORD website at (https://www.research.va.gov/programs/orppe/single_irb.cfm). VA Facilities are encouraged to check the ORD website for frequent updates to information, instructions and templates.

Preliminary reviews from the Privacy Officer (PO) and Information System Security Officer (ISSO) reviews must be completed prior to submission of the research project to the commercial IRB for review. This is a requirement before the above-mentioned endorsement letter can be signed.

12. 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 (i.e., someone else cannot sign on behalf of the PI.)
- 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

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:

1. When you are ready to sign the document, if it is not already a PDF, save as a PDF.
2. Open the PDF. If using Adobe Reader: In the right panel, click the wrench for "More Tools." Click the icon that says "Certificates."
3. If using Adobe Acrobat DC (full program): In the righthand menu, click the search bar (Search tools) and search for "Digitally Sign"
4. 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.

13. Submitting a Continuing Review, Modification, or Other Submission for an Existing Project

If you need to submit a continuing review, modification, or other submission (e.g., adverse event, DSMB report, closure, etc.) for an existing project, you need to create a new package within the existing project. **DO NOT create a new project**.

For detailed guidance on how to create a new package in VAIRRS, please refer to the Researcher Energizer 2 which provides step-by-step instructions on this process. Training Energizers can be found in the "Resources" section at https://www.clevelandvaresearch.org/vairrs-irbnet.

All projects that were approved at VANEOHS prior to the implementation of VAIRRS have been entered into the system so that you may submit any required actions in VAIRRS moving forward. If you do not yet have access to your existing studies in VAIRRS, please contact the Research Office at VHACLEVAIRRS@va.gov so we can transfer ownership of your project(s) to you.

14. When is a package 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 VHACLEresearchFCOI@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 required 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 returned to you and will substantially delay your approval.

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

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

16. What happens after I submit my package?

When you submit your study, your submission is locked and sent to the Research Office for review. Once submitted, you can no longer delete or revise your package. The Research Office will be automatically notified of the new submission by VAIRRS.

For NEW projects:

1. R&D staff conduct administrative review to ensure package is complete and basic requirements met
2. 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 may conduct a review to ensure scientific merit

3. Study is forwarded to applicable sub-committees, whose staff conduct a detailed pre-review before sending to their board for official review
4. If human subjects research, will require initial Privacy Officer (PO) review prior to IRB review. All studies will be reviewed by the Information System Security Officer (ISSO).
5. 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
6. If human subjects research, will require final PO review prior to study initiation. If ISSO second review was required, will need final ISSO review prior to study initiation.
7. Review by R&D Committee
8. Once all required approvals have been obtained, the ACOS study approval letter is sent to PI to indicate project may begin

For modifications, continuing reviews, etc. for EXISTING projects:

1. Study is forwarded to applicable sub-committee(s), whose staff conduct a detailed pre-review before sending to their board for official review
2. Depending on the type of submission and what is proposed, the package may be reviewed by the Privacy Officer (PO) and/or Information System Security Officer (ISSO) if required.
3. The applicable committee/sub-committee(s) will issue a decision letter after board review and publish board documents as applicable

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.

17. 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.
- FAQs and downloadable, step-by-step guidance for using VAIRRS

18. Contact Information

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