NF/SG VETERANS HEALTH SYSTEM (NF/SG VHS) – Research Service Guidance for Research Submissions

Contents

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1. Administrative Oversight Responsibility of Investigators and Staff

A message from ACOS/Research and DCOS/Research:
Many people who pursue careers in medical research do so to fulfill a love of science, learning, discovery, and ultimately to help patients overcome disease and functional limitations. However, along with those worthwhile goals is the need to follow a variety of regulations that ensure responsible conduct of research. There are multiple oversight boards and personnel including the Institutional Review Board (IRB), Human Research Protections Program (HRPP), Subcommittee on Research Safety (SRS), Research Compliance Officers (RCO), Privacy Officers (PO), and Information Security Officers (ISSO). The RCO, PO, and ISSO are independent from VA Research Service, to ensure objective oversight. Researchers should understand that oversight boards/personnel provide a service your research program, including by protecting you from liability, helping research administration run smoothly, protecting patient safety and privacy, and safeguarding your data. Please be mindful to respond promptly and politely to mails or phone calls received from research oversight personnel. In addition, please make an effort to learn and follow applicable regulations. Cooperation in these aspects of research will make for a more collegial, productive, and pleasant experience for everyone involved.

2. 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.
All submissions to the IRB, IACUC, SRS and RDC (e.g., new protocols, amendments, continuing reviews, closures) must be submitted electronically via IRBNet/VAIRRS. E-mail andhard 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 North Florida/South Georgia Veterans Health System, Gainesville, FL 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.

Instructions for Using VAIRRS
For detailed guidance on using VAIRRS, view the section called “IRBNet (VAIRRS) Tutorials for Researchers” on the NF/SG Research Service website:
https://www.nffre-research.org/va-research-resources

3. 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 refer to VHA Program Guide 1200.01 by clicking here.

4. Study Personnel

Who should be listed on a study?

- In general, anyone comes into contact with research participants, study data, biospecimens, medical records, etc. should be listed as a member of the study.
- Individuals with only incidental access to study information (such as department administrators who process payments or conduct regulatory audits) may not need to be included.

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, administrative, 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?

- You must 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.
- 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.

For detailed guidance on using VAIRRS, view the section called "IRBNet (VAIRRS) Tutorials for Researchers" on the NF/SG Research Service website:

https://www.nffre-research.org/va-research-resources

5. Principal Investigator Requirements

- Principal Investigators must have VA paid or "WOC" appointments and cannot be interns, residents, fellows, or other trainees. Only investigators with 5/8ths paid VA appointment can serve as a PI on a study funded by VA Office of Research and Development. If you are conducting VA research to fulfill the requirements of an academic program, you will be considered a student/trainee and willnot 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 NF/SG VHS, you will need to complete a **New Investigator Form** (available in the Forms and Templates Library) and submit to HRPP as part of your submission package.

6. 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, (3) if at any time your conflict of interest status changes, and (4) annually when submitting the VA Annual Status Report.

Where can I get a blank copy of the FCOI?

The research FCOI form can be downloaded from the Forms and Templates library in IRBNet/VAIRRS and should be completed and signed electronically. When completing the form, please note that the Duty Station for Malcom Randall VA Medical Center is 573.

How do I submit the FCOI forms?

FCOI forms must be emailed to VHANFLResearchStudy@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.
You can submit your IRBNet/VAIRRS study package even if still waiting to receive FCOI forms, or awaiting review of FCOI forms.

7. 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. For more information about the WOC appointment procedures, email Helen.Vaillancourt@va.gov.

Research Scope of Practice for WOC Study Team Members

- Each member of the research team that has a WOC appointment must have a Research Scope of Practice on file with the NF/SG VHS 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.

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, view the section called "IRBNet (VAIRRS) Tutorials for Researchers" on the NF/SG Research Service website: https://www.nffre-research.org/va-research-resources

Human Subjects Research Training (if applicable)

VA CITI Human Subjects Protection (HSP) Training is required for study personnel conducting human subjects research. Training must be renewed every three years.

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. For instructions please view the "IRBNet (VAIRRS) Tutorials for Researchers" on the NF/SG Research Service website: https://www.nffre-research.org/va-research-resources

8. Radiation Safety Committee Approval

Research studies involving radiation typically require approval from the Radiation Safety Committee (RSC). Please contact the Radiation Safety Officer at Kathleen.Thomas@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. The RSC application will consist of the following:

	Form Name
☐	Human Use of Ionizing Radiation for Research Form
☐	Protocol
☐	Informed Consent Forms

You will need to obtain RSC approval and include the RSC approval letter with your new study submission to the Subcommittee on Research Safety (SRS) in VAIRRS. If required, RSC approval must be obtained prior to IRB, SRS and RDC review and approval of the study.

9. Subcommittee on Research Safety (SRS) Review

All research study submissions require review by the SRS Committee. A separate study package must be created and include the following completed documents, which can be found under Forms and Templates in the NF/SGVHS SRS, Gainesville, FL – Documents for Researchers library:

	Form Name
☐	01 SRS Coversheet
☐	02 Safety Evaluation
☐	05 SRS Abstract

Depending on the safety concerns of the protocol, additional approvals or documents may be required. These additional items are described below:

	Form Name	Description
☐	UF Institutional Biosafety Committee (IBC) Approval Letter	Required for protocols that involve the use of recombinant DNA. For information on submitting to the UF IBC, visit http://ibc.research.ufl.edu/
☐	CEOSH Chemical Inventory	Required for protocols that involve the use of chemicals. See Section 6 of the SRS Evaluation form for more information.
☐	VA Radiation Safety Committee (RSC) Approval Letter	Required for studies involving radioactive material and/or ionizing radiation. A description of the submission documents and procedures can be found in Section 7.

☐	Liquid Nitrogen Training Certificates	Required for protocols involving use of liquid nitrogen. This training is available through the CITI Program website.

10. Investigational Drug Service (IDS) Review

Research studies involving investigational drugs typically require review by the IDS. Please contact Research Pharmacist Alan Mumford at Alan.Mumford@va.gov when you are preparing your study to begin the process.

When do I need a 10-9012 form?

VA Form 10-9012 is required for each investigational drug. 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 Alan Mumford at Alan.Mumford@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 reviewed by the Investigational Drug Service (IDS). Send your study protocol and Pharmacy Impact Form to the research pharmacist for review. A VA Form 10-9012 must also be completed and signed by the research pharmacist and attached to the package submission in VAIRRS.

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.

11. 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/IRBNet "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, <u>always</u> 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/IRBNet (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.)

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.
☐	Single IRB PI Questionnaire	Required for all Human Subjects Research project	Helps investigators determine whether their study is subject to single IRB requirements. More information can be found here.
☐	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.
☐	Abstract	Required for all Human Subjects Research	The abstract is a concise summary used for R&D Committee review of your submission.
☐	Information Security Privacy Research Certification	Required for all Human Subjects Research	This form is a signed certification from the VA PI on a research study regarding responsibility for data safeguarding.
☐	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 enrolling non-Veterans, including family members, caregivers, and pregnant partners of research subjects.

☐	Informed Consent Form	Non-Exempt Human Subjects Research	For requesting written informed consent from a research participant to enroll in a study. This is required unless a waiver of Informed Consent is approved by the IRB.
☐	HIPAA Authorization (VA Form 10-0493) standalone	Human Subjects Research	Separate HIPAA Authorization. The HIPAA authorization determines who research data can be shared with, and is crucial for data sharing with non-VA institutions who are collaborating in the research.
☐	VA Form 10-9012 - Investigational Drug Form	Drug Studies	Investigational Drug Form. Must be completed for each drug being evaluated in a research study
☐	Questionnaires, Informational Sheet, Recruitment Materials, Sponsor Documents		All other materials that will be presented to research subjects, as applicable. Internal forms that are not presented to research subjects do not need approval (e.g., instructions to staff, checklists, etc.).
☐	Real SSN Access Form (DART/VINCI) (if applicable)	Human Subjects Research	This form is required for all VHA research requests for real SSN data requested through VINCI DART for obtaining VA patient data. The form must be signed by the ACOS of Research and approved by the IRB of record before being submitted to DART.
☐	New Investigator Form (if applicable)		The New Investigator Form is required for principal investigators who have not previously conducted research at the VA.
☐	IRB Submission (PDF format)	All non-exempt project submissions	A PDF document of your full IRB submission must be included in your submission to HRPP so that it may be reviewed by the PO and ISSO for compliance with VA regulations.

12. 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 IRBNet/VAIRRS.

PRIOR TO PREPARING A CIRB NEW STUDY, CONTACT NF/SGVHS HRPP ADMINISTRATOR LISA.CAMPBELL3@VA.GOV FOR GUIDANCE.

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

Please note that all **new study applications** for VA CIRB must be submitted in IRBNet/VAIRRS to **yourlocal 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 NF/SG Veterans Health System local Research Office?

You must submit locally required documents for SRS review in a separate package. The checklist below outlines which local forms should be included. These forms can be found in the Forms and Templates library titled NF/SGVHS SRS, Gainesville, FL – Documents for Researchers. Please see Section 8 above for detailed descriptions of each form.

	Required (for local Research Office)
☐	01 SRS cover sheet
☐	02 Safety Evaluation
☐	05 SRS Abstract
	If Applicable (for SRS)
☐	UF Institutional Biosafety Committee (IBC) Approval Letter
☐	CEOSH Chemical Inventory
☐	VA Radiation Safety Committee (RSC) Approval Letter
☐	Liquid Nitrogen Training Certificates

13. 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).

The NF/SG Veterans Health 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. Western IRB – Copernicus Group (WCG IRB; formerly known as WIRB)

The cost of using a commercial IRB is typically covered by the study sponsor. Neither the VA nor the VA non-profit corporation (i.e., North Florida Foundation for Research and Education) 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 to HRPP and SRS for review.

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 NF/SG VHS) for a new commercial IRB study. Please see Section E above fordetailed descriptions of each form. **Your study must first be submitted to HRPP 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)
☐	Protocol Reviewed by Commercial IRB
☐	VA 10-250

	If Applicable
☐	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.

14. Signature Requirements

Signing the Study Package in VAIRRS

- Packages must be electronically signed by the Principal Investigator and Co-Investigators before they are submitted. The "Designee" signature mode is not accepted (i.e., someone else cannotsign 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.

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: On a VA networked computer, your PIV card must be inserted into the card reader to add your digital signature to the document.

15. 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 view the section called “IRBNet (VAIRRS) Tutorials for Researchers” on the NF/SG Research Service website:

https://www.nffre-research.org/va-research-resources

All projects that were approved at NF/SG VHS 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 HRPP Office at VHANFLResearchStudy@va.gov so we can transfer ownership of your project(s) to you.

16. 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 sent to VHANFLResearchStudy@va.gov
   (please send the COI forms for all investigators as attachments within a single email).
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 may substantially delay your approval.

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

Contact the HRPP Office immediately by emailing VHANFLResearchStudy@va.gov

18. What happens after I submit my package?

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

For NEW projects:

1. HRPP staff conduct administrative review to ensure package is complete and basic requirements met.

1. Study is forwarded to the Privacy Officer and Information Systems Security Officer(s) to conduct their pre-reviews. Once their reviews are complete and there are no outstanding items that need to be addressed, the HRPP Office will issue the HRPP

Memo (UF IRB-01) or Commercial IRB Endorsement Letter (Advarra and WIRB), the PO-reviewed HIPAA authorization and Privacy Review Checklist (VA 10-250), and the ISSO signed ERDSP for submission to the IRB of record.

2. Review & determination from sub-committees (SRS, IACUC, RSC) and/or external committees (e.g., VA Central IRB, NCI CIRB, WCG IRB, Advarra, UF IRB-01) as applicable
3. If human subjects research, will require final PO and ISSO review prior to study initiation.
4. Review and approval by R&D Committee.
5. Study staff that will be consenting participants in Human Subjects Research receive Informed Consent Training by the Research Compliance Officers (Katie Yeckring and Marlene Thomas).
6. Once all required approvals have been obtained, the ACOS study approval letter is sent to PI to indicate the 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. HRPP will issue any additional documents for IRB submission 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.

19. Contact Information

For questions that are specific to a study that already exists in IRBNet/VAIRRS, please use the "Project Mail" feature in IRBNet/VAIRRS to contact HRPP staff.
For all other inquiries please email VHANFLResearchStudy@va.gov.