



OCTRI Research Forum



Research Across the Bridge

Conducting a Project at VAPORHCS

DATE: June 21, 2022

PRESENTED BY: **Alissa Hooper**, Management and Program Analyst, VA; **Bridget Adams**, Manager, Regulatory Knowledge and Support, OHSU; **Sharon Jacky**, Administrative Director, VA

Objectives

- Important Resources
- Committee Structure
- Definition of Engagement
- Major Differences between VA and OHSU Research
- Forms and Submission Process
- VA Specific Requirements

Why so many rules?

The VA is:

- Highly Regulated – by Congress
- Highly Visible – news media
- Highly Reactive - it's the government



We must follow Veterans Affairs and Veterans Health Administration (VHA) Directives

- These Directives establish additional regulations specific to research within the VA

VA Research Website

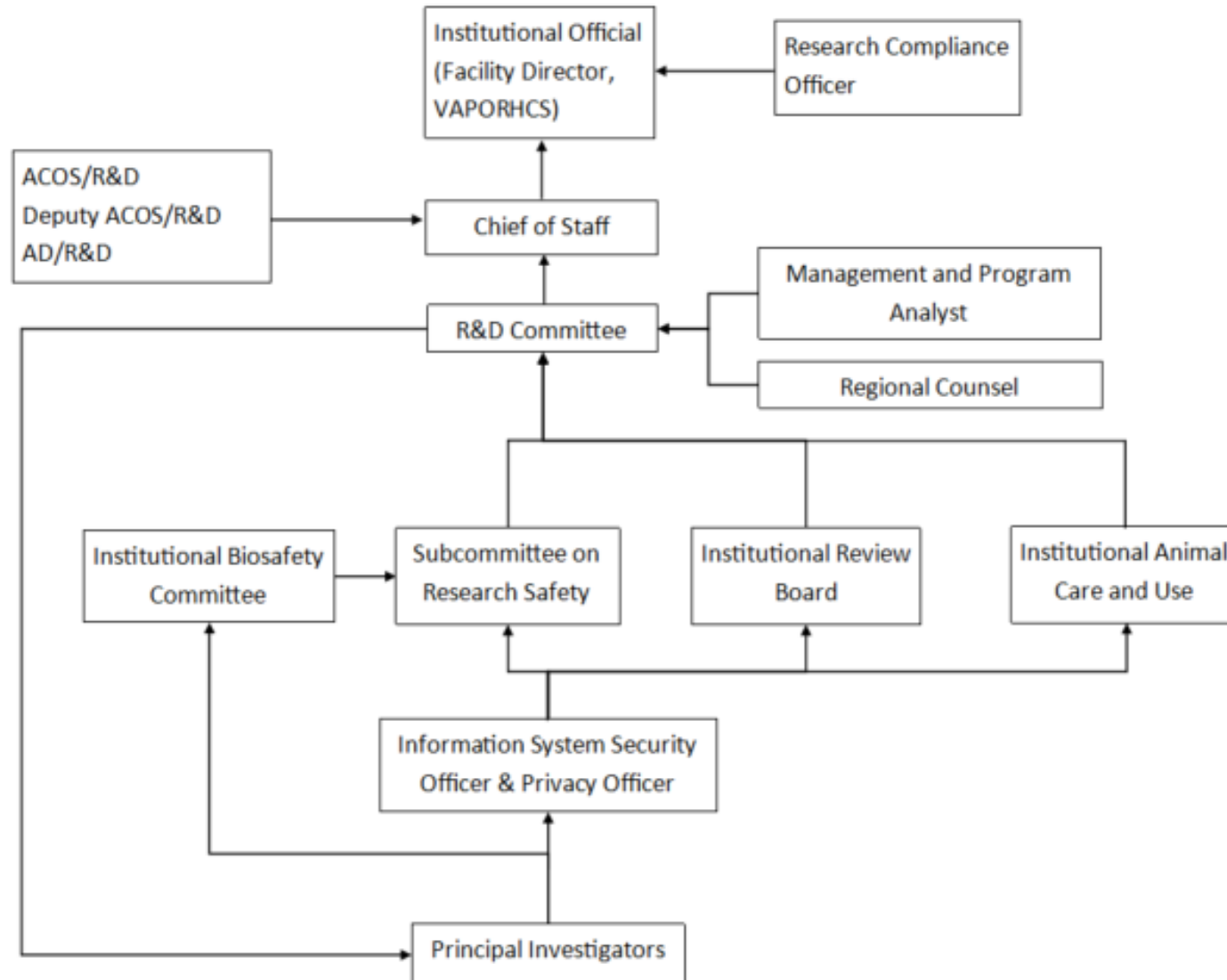
| ▼ Research & Development Service |
|--|
| R&D Homepage |
| Clinical Research Resources |
| Committee Information |
| Contact Us |
| Finance and Purchasing |
| Forms & Policies |
| Grant Submission |
| Human Research Protection Program (HRPP) |
| PI Resources |
| Research Program & Centers |
| Training |
| Veterinary Medical Unit |
| Portland VA Research Foundation |

<https://www.va.gov/PortlandResearch/index.asp>

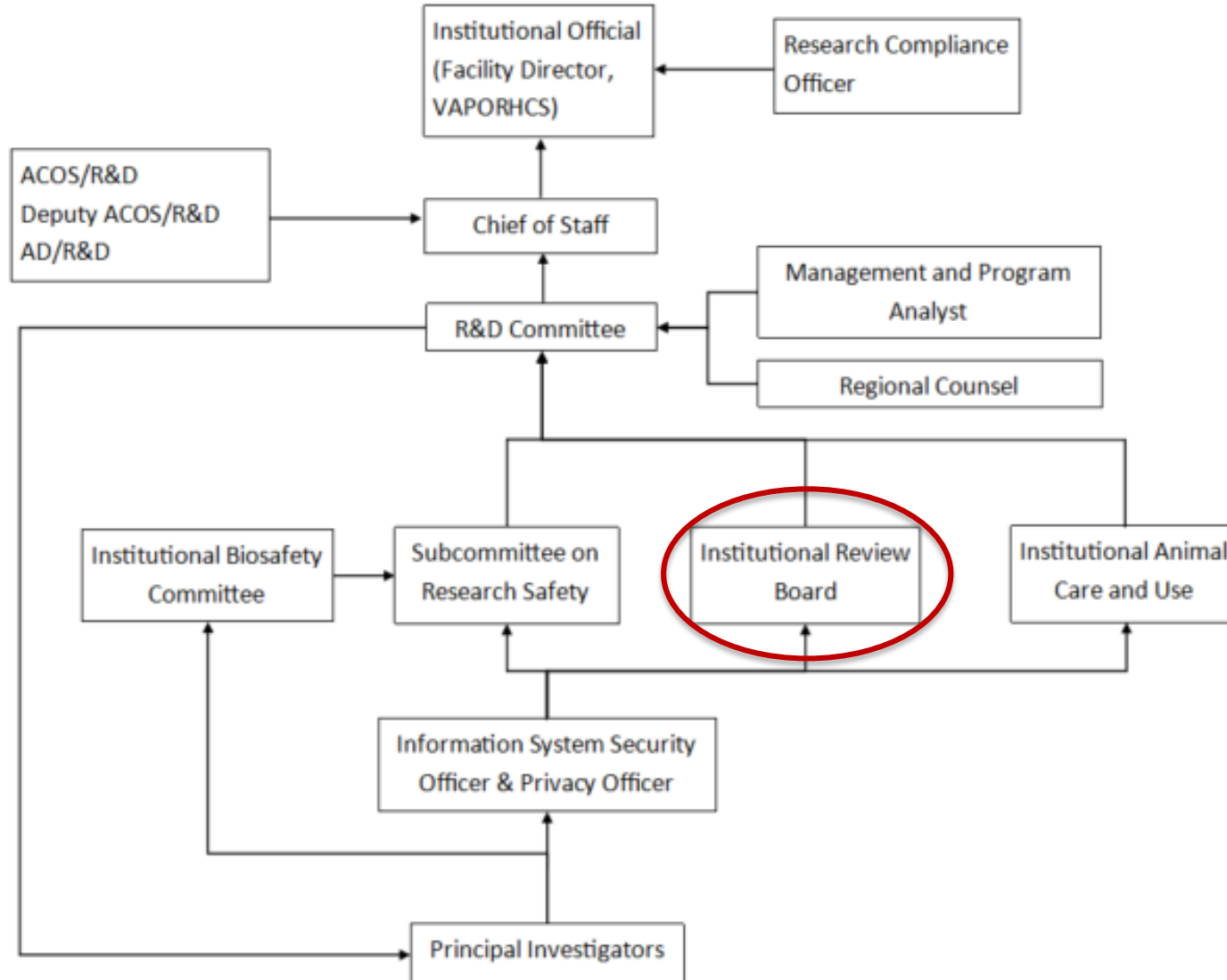
This website includes information on:

- Points of Contact
- Policies/Procedures
- Forms
- Requesting an Appointment
- Training
- Submitting Proposals

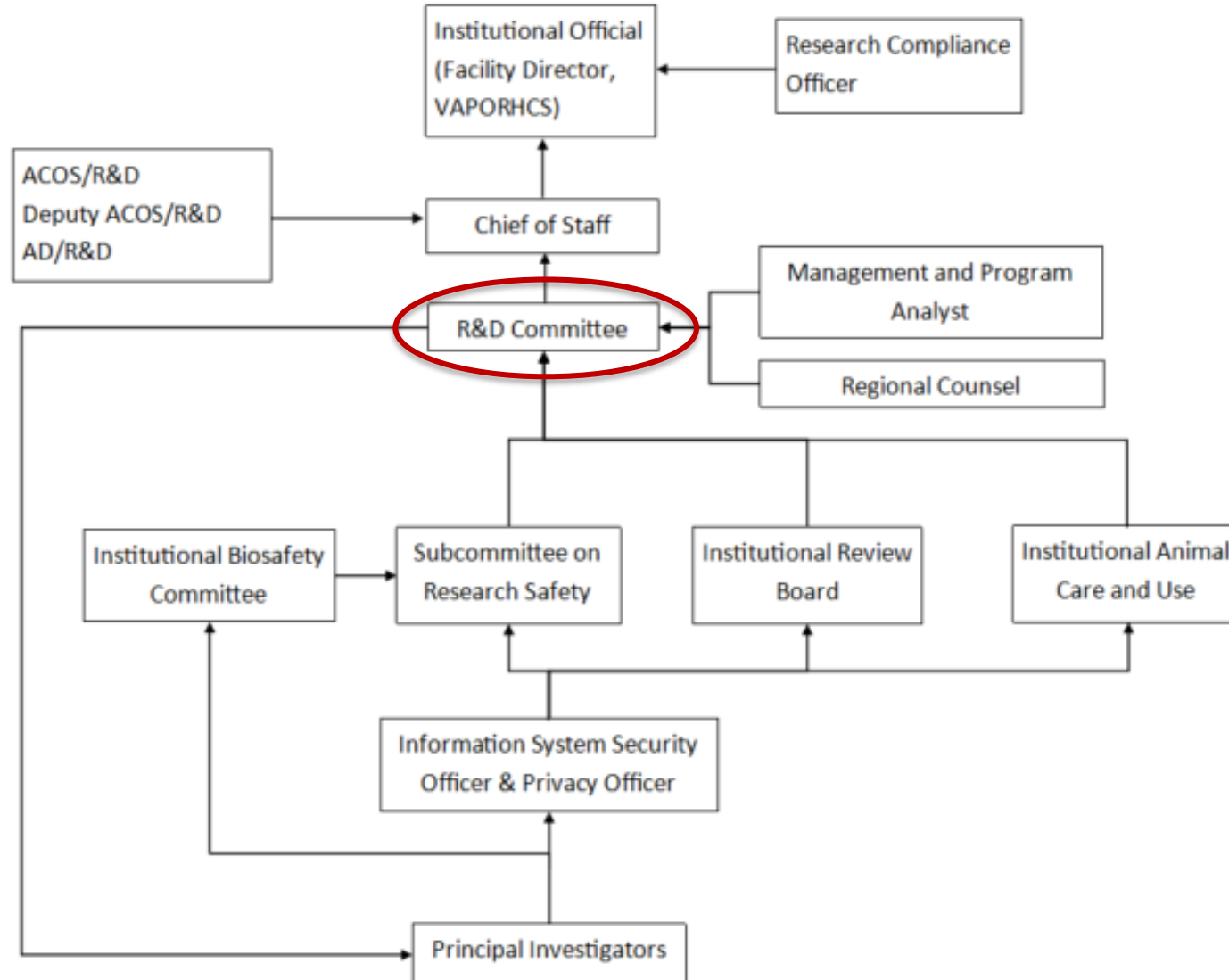
Committee Governance Structure



Committee Governance Structure



Committee Governance Structure



VA In-house IRB

- Meets 1st Wednesday of each month
 - Initial review deadline 2nd Monday
 - Modification review deadline 3rd Monday
- PI invited to discuss initial review
 - for studies reviewed by convened board
- IRB Analysts will contact you with any revisions



Single IRB Requirement

- Required for all federally funded projects
- Reliance Agreements and SOPs
- Timelines
 - ORD recognizes IRB, approx. 60 days
 - ORD doesn't recognize IRB, approx. 6 months
- Single IRB Exception
 - When Appropriate
 - Not a currently recognized IRB by ORD
 - Time sensitive project
 - First steps
 - Email PVAMC-IRB@va.gov with details

VA External IRBs of Record

External IRBs

- NCI CIRB, Advarra, Sterling, WCG IRB (formerly WIRB), 'All of Us' (only for the All of Us study)
 - Submission process specific to each IRB
 - All require a Project Application submitted through VAIRRS for R&DC review
 - Includes Information Security and Privacy Review
 - Contact PVAMC-IRB@va.gov

VA External IRBs of Record cont.

OHSU IRB3

- For studies conducted at both VAPORHCS and OHSU
- Submitted through eIRB
- VA requirements are still applicable for the VA components
- Submission in VAIRRS: Project Application for R&DC review

VA Central IRB

- IRB review for multi-site projects
 - Not all sites must be VA to use this board
- Submitted through VAIRRS
- Contact Danielle Beaudry, Danielle.Beaudry@va.gov

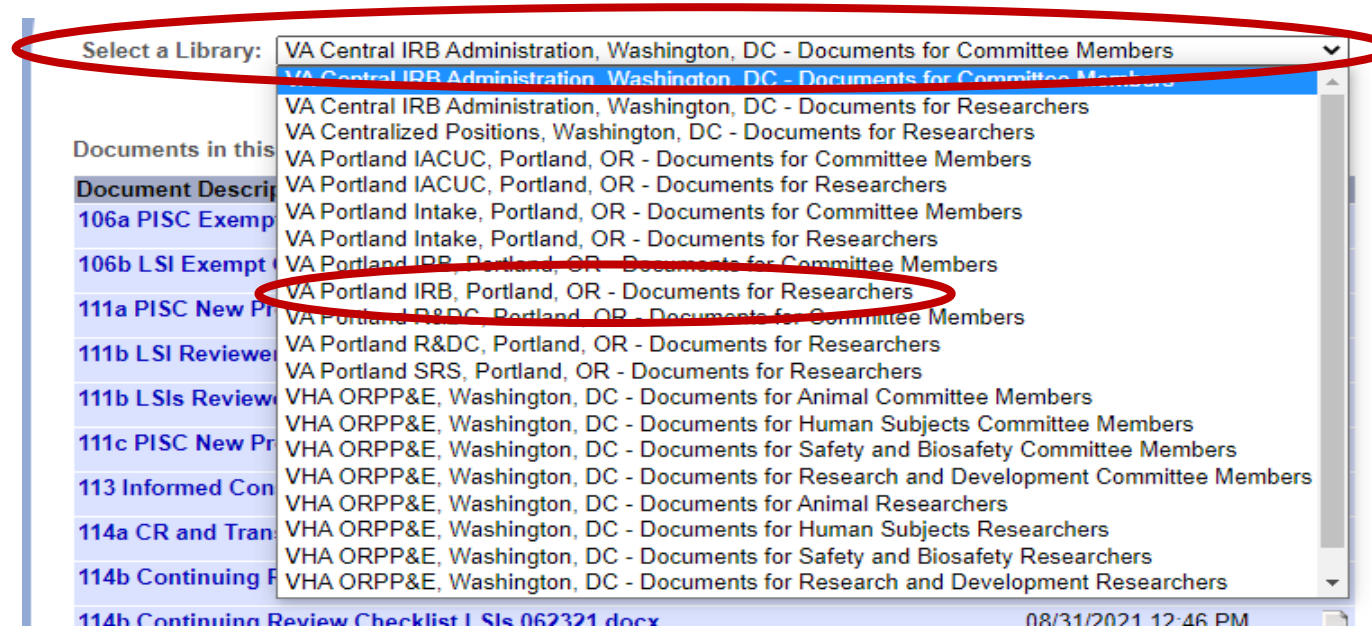
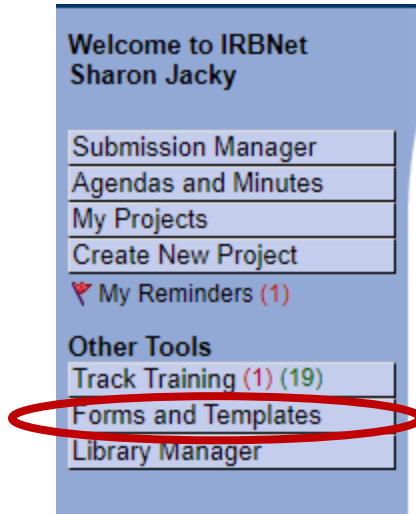
VAIRRS

- VA Innovation and Research Review System
- <https://gov.irbnet.org/>
- There is a difference between **Project** and **Package**!
 - Submit a **Project**
 - Initial submission of a study
 - Submit a **Package**
 - Continuing review, amendment, study closure
- All projects/packages must be signed and submitted initially by the PI
 - All subsequent modifications of that package may be returned (Mark/Lock - revisions complete) by anyone with access to the package

VAIRRS cont.

VA forms and documents can be found by:

- Clicking “Forms and Templates” using the left-hand navigation menu
- Under Select a Library locate “VA Portland IRB, Portland, OR – Documents for Researchers”












VAIRRS cont.

- VAIRRS help guides can be found in the “VA IRB Portland OR – Documents for Researchers

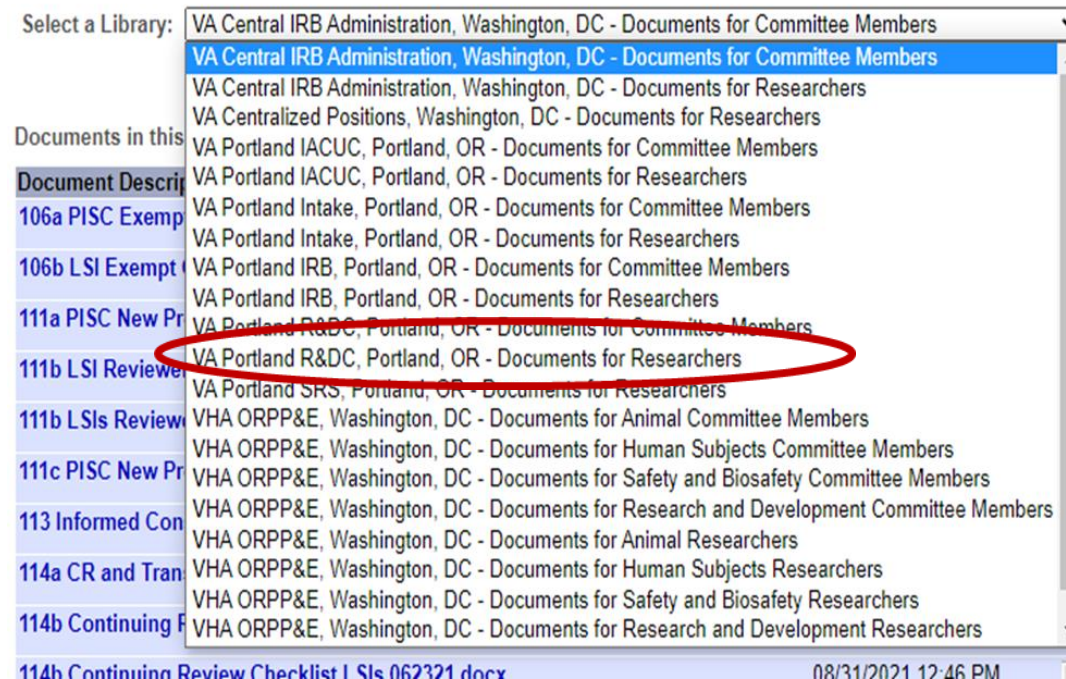
Select a Library: ▼

Documents in this Library:

| Document Description | Last Updated | |
|---|---------------------|---|
| 0-HELP GUIDE_Signing A Package | 01/25/2022 05:53 PM |  |
| 0-HELP GUIDE_STUDY-TEAMS_Minor Revisions-Finding Approval-Ltr-Docs.docx | 12/09/2021 11:13 AM |  |
| 0-HELP-GUIDE_Amendment Request | 07/29/2021 05:23 PM |  |
| 0-HELP-GUIDE_Annual Check-In | 07/29/2021 05:24 PM |  |
| 0-HELP-GUIDE_Continuing Review | 01/19/2022 05:42 PM |  |
| 0-HELP-GUIDE_Finalization Report | 07/29/2021 05:25 PM |  |
| 0-Help-Guide_New Project (Exempt Request) | 07/29/2021 05:26 PM |  |
| 0-HELP-GUIDE_New Project (non-exempt) | 07/29/2021 05:25 PM |  |
| 0-HELP-GUIDE_Personnel Change | 01/24/2022 01:17 PM |  |

VAIRRS cont.

- For Joint Submissions
- VA forms and documents can be found by:
 - Clicking “Forms and Templates” using the left-hand navigation menu
 - Under Select a Library locate “VA Portland RDC, Portland, OR – Documents for Researchers”



Other VA Committees

- Subcommittee on Research Safety (SRS)
 - Human specimen (blood, urine, tissue, etc.) processing within research space
- Research and Development (R&D) Committee
 - Governing body of the R&D Service at VAPORHCS
 - **All** new studies are reviewed and voted on by the R&DC before final approvals are issued
 - R&DC only needs to review the study and initial submission

When is the VA engaged?

- VA is engaged in research any time an individual will be using VA time and/or VA space and/or VA resources.
 - **VA time**: using time for project activities that VA is paying for or under a without compensation appointment
 - **VA space**: lab, office, conference rooms, etc.
 - **VA resources**: printers, imaging, pharmacy, path and lab, electronic health record, etc.
- *Note: The VA requirements are more expansive than OHRP regulations governing OHSU.

When is VA not Engaged

- VA is not engaged when:
 - Physicians hand out flyers** to their patients, but they are prohibited from:
 - Answering questions about the study
 - Consenting/enrolling
 - Providing Veteran contact information to the study team

**physicians can hand out flyers from non-VA approved research studies, but such flyers are prohibited from being posted in VA space or left in VA waiting rooms

Research Study Scenario

- **Title:** A behavioral treatment intervention for Veterans with PTSD
- **Funding:** NIH funding to OHSU
- **Protocol Description:**

Patients >18 years old with PTSD. The study involves 5 behavioral treatment sessions and then 12 monthly OHSU REDCap Surveys.

The veterans can participate in the treatment sessions online or in person.

Data collected will go into a repository for future research and recruitment purposes.

- **Study Staff:**

PI has paid appointments at the VA and OHSU.

The study coordinator is an OHSU employee and needs access to both VA and OHSU medical records and secure drives to conduct the study

The behavioral therapist is an OHSU employee whose study involvement is limited to the behavioral treatment sessions that will only be conducted at OHSU.

Research Study Scenario, cont.

Recruitment:

- Veterans will be recruited from the VA, OHSU, and Community.
 - Veterans may be recruited in the VA clinics,
 - VA and OHSU medical records will be reviewed to identify potential subjects,
 - Social media ads will be used to recruit veterans in the community.

Data Collection/Use:

- The PI wants to collect:
 - Names, contact information, MRNs of the veterans they screen to track who has been screened, reasons veterans did/did not qualify for the study, and whether they did/did not agree to participate in the study.
 - The PI is planning to write a new grant and this screening/recruitment information would be helpful for preparing that grant and recruiting for a similar study.
 - The data collected in this study will be submitted to an NIH repository for data sharing and to an OHSU departmental recruitment repository.

Knowledge Check

- Which IRB needs to review this study?
- OHSU only? VA only? or Affiliate Board?

A: Affiliate Board – for the following reasons

Federal funding is flowing through OHSU and \$ engages OHSU in the research

VA and OHSU personnel will be involved in the study

VA and OHSU resources will be used in the study

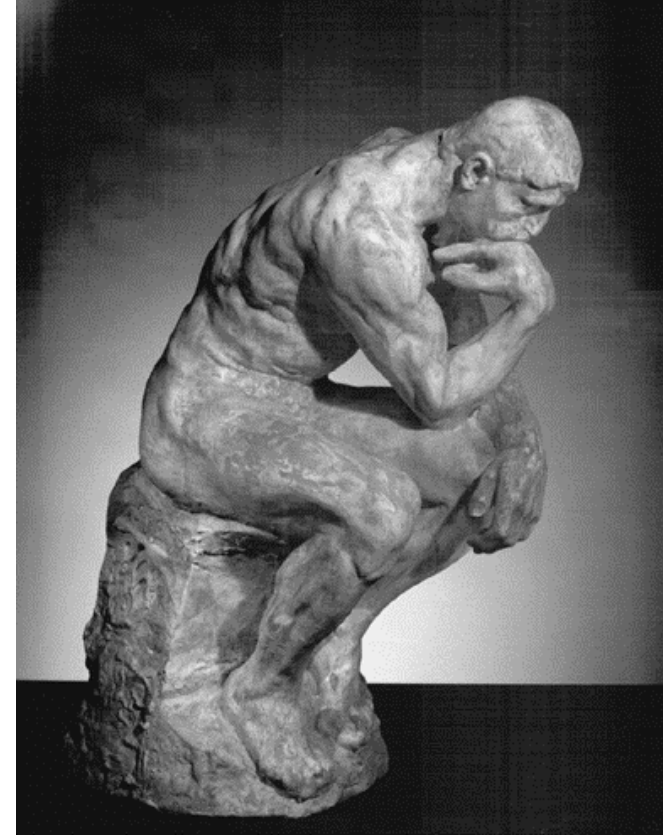
Plan to use OHSU's instance of REDCap

Additional Requirements for Research Conducted at the VA

- Distinguishing VA Research from Non-VA Research (IRQ; additional form)
 - Protocol, consent, etc. need to be consistent with what's VA research vs. non-VA research
- Disclosing PHI outside VAPORHCS (without signed authorization)
- VA consent should only include VA components of the research (VA ICF template)
- Statement regarding how the research meets the VA Mission (protocol template)
- VAPORHCS local policy for obtaining specimens for research purposes only (IRQ)
- Requirements and Restrictions for Special Subject Populations (IRQ; protocol template)
- Access to PHI prior to obtaining consent (Waiver of Authorization for Screening/recruitment)
- International Research (IRQ)
- VAPORHCS local policy for recruitment/initial contact with Subjects (IRB P&P)
- Off-Site Storage and For-Profit Banking Waivers (IRQ)
- Justification for Including/Enrolling Non-Veterans (protocol template)
- VA has liability for injuries incurred during participation in VA research, so VA would cover cost of treatment (even for industry sponsored studies)
- VHA Records Control Schedule 10-1
- R&D Committee Final Review of Initial Submissions

Forms and Submission Process: IRB Submission Considerations

- VA Appointments
- Required Training
- Submission Forms
- Submission Procedures
 - eIRB
 - VAIRRS
- Privacy/Data Security
 - ERDSP and 10-250
- Research Compliance Officer
- Records Retention
- Repositories and Future Research
- Clear distinction between ‘VA Research’ and ‘non-VA Research’



VA Appointments (paid or WOC)

Required if:

- You will work on site at VAPORHCS
- You need access to the electronic health record system
- You will directly interact with VAPORHCS participants
- You will see identifiable data for VAPORHCS participants

Note: if you will use your healthcare license (*MD, RN, MS Counseling, EMT, MSW, etc.*) for this Research project, you also need to be credentialed in VetPro. This can also be a lengthy process.

VA Appointment Options

- **Paid VA Employee**
- **Without Compensation (WOC)** – when any of the following apply:
 - You are not paid by VAPORHCS, e.g., paid by OHSU or the Portland VA Research Foundation (PVARF)
 - **Warning!** Obtaining a WOC appointments can be lengthy –approx. 7 weeks
 - Follow the [VA R&D Appointment Requirements Checklist](#)

PLEASE NOTE: VA Contractors and Fee Basis employees are prohibited from conducting research at the VA.

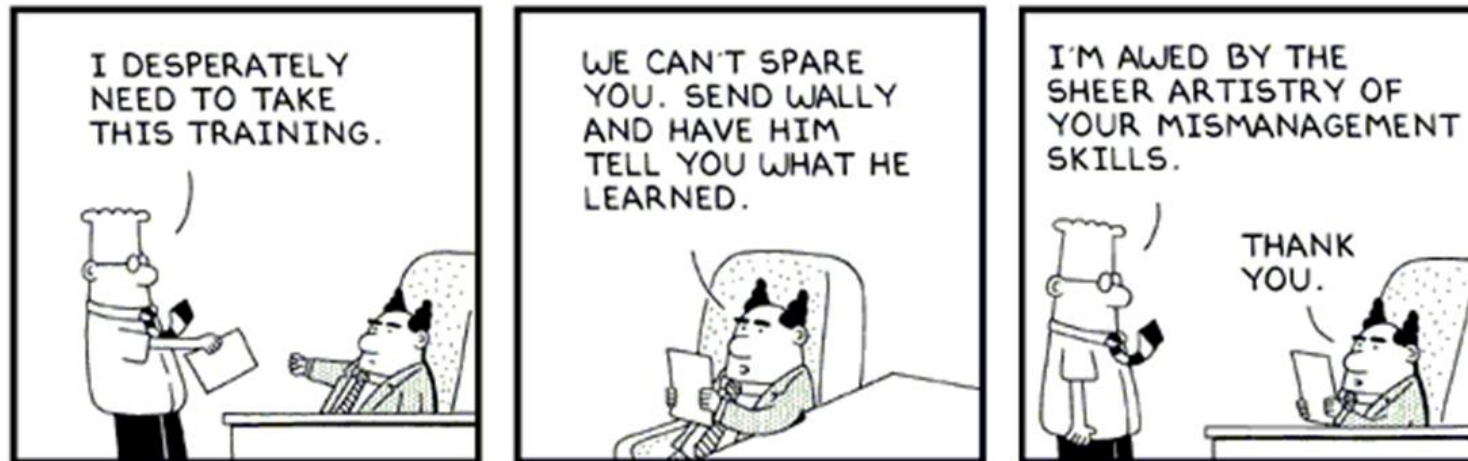


*"Kindly fill out this application
for the reduction of bureaucracy."*

Required Training

VA specific trainings are required for all personnel working on VA-approved studies, to include:

- Collaborative Institutional Training Initiative (CITI)
 - Reciprocity with OHSU, plus VA-specific modules
- Talent Management System (TMS)
- Additional requirements based on research activities
 - <https://www.va.gov/PortlandResearch/training/index.asp>



Knowledge Check

Scenario - Study Staff:

PI has paid appointments at the VA and OHSU.

The study coordinator is an OHSU employee and needs access to both VA and OHSU medical records and secure drives to conduct the study

The behavioral therapist is an OHSU employee whose study involvement is limited to the behavioral treatment sessions that will only be conducted at OHSU.

Which staff need a WOC appointment?

PI? Study Coordinator? Therapist?

- Study Coordinator because...
 - Coordinator need access to VA systems and will use VA space to conduct the study
- Why doesn't the therapist need a WOC appointment?
 - Because they are participating in the study on their OHSU paid time and
 - They are only interacting with the subjects at OHSU after they have consented to the study.

Submission Forms

- For the required VA templates and forms see the OHSU IRB-3 tab of the HRPP page
(<https://www.va.gov/PortlandResearch/hrpp/index.asp?tab=1>)
- Form versions may change without notice
 - Always download forms from the website
 - Check for updates before you submit

Submission Procedures

New VA-only Submissions:

- Submit the PPQ & abstract to Research.Grants@va.gov
- Submit protocol documents through VAIRRS

New Joint OHSU/VA Study Submissions:

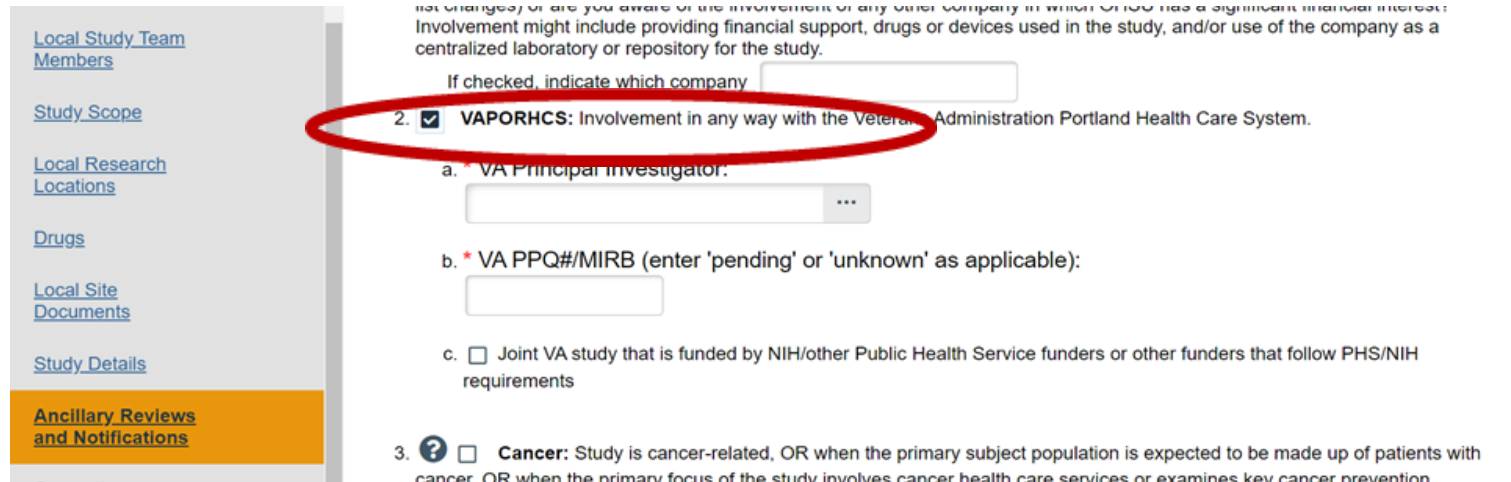
- Submit through **both** eIRB and VAIRRS
 - Once study is approved in eIRB, submit the Project Application with IRB approved documents in through VAIRRS

Modifications/amendments and Annual Review/Check-in for Ongoing Studies:

- VA-only: VAIRRS
- VAPORHCS and OHSU Joint studies: eIRB and VAIRRS

VAPORHCS/OHSU Joint Studies

- Submit joint studies to OHSU through eIRB
- Title the study beginning with: VAPORHCS/OHSU J:
- Indicate on the eIRB smart form that the VA is involved



The screenshot displays the eIRB smart form interface. On the left, a sidebar contains navigation links: [Local Study Team Members](#), [Study Scope](#), [Local Research Locations](#), [Drugs](#), [Local Site Documents](#), [Study Details](#), and [Ancillary Reviews and Notifications](#). The main content area shows a question about VA involvement. A red oval highlights the checkbox for "VAPORHCS: Involvement in any way with the Veterans Administration Portland Health Care System." Below this, there are input fields for "VA Principal Investigator:", "VA PPQ#/MIRB (enter 'pending' or 'unknown' as applicable):", and a checkbox for "Joint VA study that is funded by NIH/other Public Health Service funders or other funders that follow PHS/NIH requirements". At the bottom, there is a question about cancer-related studies.

Local Study Team Members

Study Scope

Local Research Locations

Drugs

Local Site Documents

Study Details

Ancillary Reviews and Notifications

2. ☒ **VAPORHCS: Involvement in any way with the Veterans Administration Portland Health Care System.**

a. * VA Principal Investigator:

b. * VA PPQ#/MIRB (enter 'pending' or 'unknown' as applicable):

c. ☐ Joint VA study that is funded by NIH/other Public Health Service funders or other funders that follow PHS/NIH requirements

3. ☐ **Cancer:** Study is cancer-related, OR when the primary subject population is expected to be made up of patients with cancer. OR when the primary focus of the study involves cancer health care services or examines key cancer prevention

- Follow prompts in eIRB for additional VA questions and required documents
- For details on submitting a joint study see the [OHSU IRB-3 tab](#) of the HRPP page for further instructions

Study Submission Tips for VA's In-House IRB

- PPQ, and associated documents, submitted to Research.Grants@va.gov
- Protocol documents submitted through VAIRRS
- Consent forms and advertisements must be in MS Word format

VAPORHCS local policy for recruitment/initial contact with Subjects (IRB P&P)

Can the PI recruit patients for this joint VA/OHSU study in their VA clinic?

- Yes, any physician can refer patients to a clinical trial as part of their clinical care in the best interest of the patient. However, this presents a conflict of their role as provider and researcher that can be managed under the following conditions:
 - If the provider is a member of the study team, they can't discuss the study, only hand out the flyer with contact information for someone else on the study. If the provider is the PI on the study, a clinic nurse, or someone else unaffiliated with the study, would need to hand out the flyer. No discussion of the study can take place
 - The flyer cannot include the PIs or any of the VA care providers names as study contacts

Informed Consent

- You may need an OHSU and a VA consent form for joint studies
- The VAPORHCS consent should only cover the research activities conducted on VA time, with VA resources, and/or on VA property
 - VA ICF and HIPAA authorization may not be combined
 - VA has liability for injuries incurred during participation in VA research, so VA would cover cost of treatment
 - VA participants cannot be billed for participation for research related procedures
- If all work is done at the VA and OHSU only administers the funds, only a VA ICF may be required
- Transfer of ownership of a copy of the data
 - What is this?
 - Why do you need the language?

Knowledge Check

Veterans will be recruited :

- in the VA clinics
- VA and OHSU medical record review to identify potential subjects
- Social media ads will be used to recruit veterans in the community

What recruitment materials/documents are needed for the IRB submission?

- 1) VA Flyer with contact information for research team
- 2) VA waiver for screening/recruitment
- 3) OHSU Waiver of Authorization
- 3) Social Media ad for VA Facebook

A:

4) All of the above

Knowledge Check

Veterans will be recruited :

- in the VA clinics
- VA and OHSU medical record review to identify potential subjects
- Social media ads will be used to recruit veterans in the community

Does the study need a VA Consent and Authorization?

- 1) Yes
- 2) No
- 3) I'm not sure

YES – the participants recruited in the VA clinics and through the VA medical record search need to sign a VA consent form BEFORE any of their data can be transferred to OHSU

Knowledge Check

Veterans will be recruited :

- in the VA clinics
- VA and OHSU medical record review to identify potential subjects
- Social media ads will be used to recruit veterans in the community

Does the study need an OHSU Consent/Authorization?

- 1) Yes
- 2) No
- 3) I'm not sure

YES– All subjects need to sign an OHSU consent/ authorization form before any study activities occur at OHSU.

Individuals (including veterans) recruited at OHSU or from the community only need to sign the OHSU consent form.

Veterans recruited from the community are not considered VA participants and will not sign a VA consent.

Knowledge Check

Veterans will be recruited :

- in the VA clinics
- VA and OHSU medical record review to identify potential subjects
- Social media ads will be used to recruit veterans in the community

Where does consent need to take place for veterans recruited at the VA?

- 1) At the VA
- 2) At OHSU
- 3) In the community
- 4) All of the above

Consent must take place at the VA prior to any information being shared by the study team with OHSU.

For participants recruited at OHSU and from the community, consent should take place as outlined in the protocol.

Note: Prior to consent, if a prospective VA participant needs an OHSU MRN, the study team must transfer the participant to the OHSU enrollment office to have an MRN created. The study team is not authorized to provide OHSU any information directly, prior to consent, but the prospective participant can provide the information.



Knowledge Check

The PI wants to collect names, contact information, MRNs of the veterans they screen so that they track who has been screened, reason they did/did not qualify for the study, and whether they did/did not agree to participate in the study.

Does the study need a VA Waiver for Recruitment/Screening?

- 1) Yes
- 2) No
- 3) I'm not Sure

Yes - VA Waiver for Recruitment/Screening is needed to review medical records and to request information from participants prior to signing the consent and HIPAA authorization. Any data collected under the Recruitment/Screening waiver **MUST** never leave the VA!

Knowledge Check

The PI wants to collect names, contact information, MRNs of the veterans they screen so that they track who has been screened, reason they did/did not qualify for the study, and whether they did/did not agree to participate in the study.

Which HIPAA document does the study need for OHSU?

- 1) Waiver Of Authorization
- 2) Prep to Research
- 3) Both

Waiver of Authorization - If OHSU screening data will go to the VA, or if the PI plans to analyze any screening data in a research fashion it needs a waiver of authorization.

Privacy and Data Security

- The VA Privacy Officer (PO) and Information System Security Officer (ISSO) review all human subjects studies
- Both reviews are done automatically after submission in VAIRRS or eIRB
 - **Privacy Officer: Brooke Smith**
(tells you what needs to be protected)
 - Brooke.Smith@va.gov (503)220-8262 x59602
 - **Information System Security Officer: Scott Griffin**
(tells you how to protect it)
 - Scott.Griffin1@va.gov (503)220-8262 x51369



Reach out to them if you have questions!

Required Privacy and Data Security Practices

- VA does not allow VA PHI/PII to leave the VA without a signed authorization from the subject
 - even if the data are only going to OHSU;
 - even if there's a waiver of authorization for the OHSU component of the study
- Never use OHSU email to send VA PHI/PII
 - Even if you're encrypting the OHSU email using “Secure:”
 - Instead use VA hosted products such as MS Teams, Outlook RMS encryption, PKI encryption, VistA, or others listed on the [VA Research website](#)
- Acceptable storage locations (with IRB, PO and ISSO approval)
 - OneDrive, Microsoft Products, OHSU and VA network drives

VA Data

VA information is protected by the Privacy Act of 1974 (5 USC 522a), 38 USC 5701, 38 USC 5705, and 38 USC 7332, NOT JUST HIPAA.

Sharing de-identified data outside the VA without signed authorization, consider the following issues:

1. Is it truly de-identified? See appendix A of [VHA Directive 1605.01](#); [IRQ Appendix J](#).
2. Is the data coded? *If a code is being used to track an individual's information across time, regardless of the length of time, it is a unique identifier (18th HIPAA identifier). Study numbers that are used across time to track and link information on a subject are considered to be identifiers. If it is a one-time use only, it is not considered to be an identifier.*
3. Are dates included? *Remember all elements of date (except year) directly related to an individual is a HIPAA identifier.*

Repositories and Future Research

If data and/or specimens will be stored for future research, VAPORHCS policy requires that they be transferred to a freestanding research repository

- Creation of a repository requires a separate submission to the IRB
- If the protocol, HIPAA authorization, or the waiver of authorization state that identifiers will be removed as soon as they are no longer needed for the research, then they must be archived
- See [IRB Review of Repositories Located at the VAPORHCS](#) and VHA Handbook 1200.12 for official policy

Secure Storage Options

- OHSU REDCap, OHSU network drives, OneDrive, MS Teams
 - All data types
- OHSU Dropbox
 - Determination Pending
- OHSU SharePoint
 - Determination Pending
- VA REDCap
 - Deidentified data only
- VA Network, OneDrive, MS Teams
 - All data types

Knowledge Check

The PI wants to collect names, contact information, MRNs of the veterans they screen so that they track who has been screened, reason they did/did not qualify for the study, and whether they did/did not agree to participate in the study. The PI is planning to write a new grant and this information would be helpful for preparing that grant and recruiting for a similar study. The data collected in this study will be submitted to a NIH repository for data sharing and to an OHSU departmental repository.

Which of the study data can be stored in the OHSU departmental repository?

- 1) OHSU Screening Data
- 2) OHSU consented and authorized data
- 3) VA screening data
- 4) VA consented and authorized data
- 5) None of the above

A: 1,2 & 4 - OHSU screening, OHSU consented/authorized, and VA consented and authorized

- OHSU screening data could be stored in the OHSU departmental repository with IRB approval and a WOA
- The VA screening data **cannot** leave the VA
- The data collected can be stored in an OHSU repository with participant consent and authorization (VA or OHSU) and IRB approval.

Knowledge Check

Screening data is collected at the VA and OHSU. After consent, study procedures will be conducted and data collected at OHSU. Data will be stored long-term in an OHSU repository.

Where can the VA screening data be stored?

- 1) OHSU
- 2) VA
- 3) All of the above

A: VA

Screening information can be stored at the VA with the appropriate waiver for screening/recruitment. Since data cannot leave the VA without a signed authorization form, screening data cannot be shared outside of the VA.

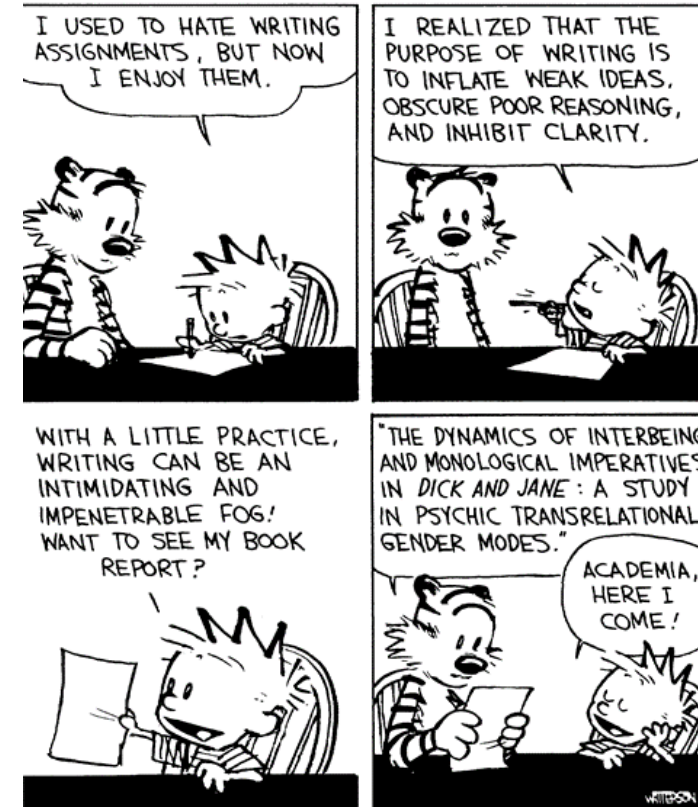
Data collected after consent can be stored in OHSU REDCap and other secure OHSU systems/drives with IRB approval.

VA Requirements for Study Conduct

- Research Flags
- Audits and Monitoring Visits
- Reportable Events
- Master List
- Notice of Privacy Practices for participants not enrolled in care at VAPORHCS
- Research records maintained in accordance with Good Clinical Practice and the Records Control Schedule 10-1
- Accounting of Disclosures

Research Flags

- If IRB requires a Research Flags,
 - Flags may be required at both OHSU and the VA
 - For VA:
 - Attach flag to each participant in electronic health record system
 - Conduct annual review of participant flags
 - For OHSU:
 - Register patients in eCRIS within **24 hours** of consent to automatically set the research indicator in EPIC



VA Audits

All research studies will be audited at least:

- once every 3 years **or**
- once during the study if active less than 3 years

➤ If new to VA research, we strongly encourage you to request an audit after the first three subjects have been enrolled

All Consent forms will be audited

Acting Research Compliance Officer

Brooke.Smith@va.gov;

(503) 220-8262 ext. 52970



Monitoring Visits

- Inform PVAMC-IRB@va.gov as soon as you schedule a monitoring visit
 - Procedures for sign-in and sign-out will be sent to you
- Prepare the Monitoring Visit Report for the monitor to complete and sign before leaving
- Contact the Research Administration Office if any serious non-compliance or unreported problems are found
- Complete OHSU [Epic for Research Monitors/Auditors request form](#) for OHSU subjects.

Who may access the VA electronic health record system?

- Only those with active VA appointments approved by the IRB with an approved Scope of Work form listing electronic health record system access may access identifiable information
- Outside monitors may NOT directly access the VA electronic health records
 - Approved study staff member must be present and drive the computer

Reporting Research Events

- The VA [Reportable Events Form](#) has definitions of the events and timelines for report categories
 - Unanticipated Problems Involving Risk to Subjects or Others
 - Apparent Serious or Continuing Non-Compliance
 - Research Information Security and Privacy Incidents
 - Local Deaths that are unexpected, related or possibly related
- Submit the event as an RNI in the eIRB system
- If sponsor “AE Reports” lack meaningful analysis of whether an event is an unanticipated problem, the PI must determine if the event was an unanticipated problem that needs reporting. If not, retain report and submit at time of annual review/check-in

Knowledge Check

Oh no! During the study, the research coordinator accidentally emailed the VA patient screen failure list, that contains protected health information, to the PI's OHSU email account. The coordinator used the OHSU encrypted email process.

What does the study team need to do (select all that apply)?

- 1) Notify the VA Privacy Officer (PO)
- 2) Notify the Information System Security Officer (ISSO)
- 3) Delete all instances of the email as directed by the PO
- 4) Submit RNI in the eIRB

A:

- Select all of the above
- If instructed by the PO to delete all instances of the email, delete the email from inbox, sent items, and deleted items

Master List

- Study teams are required to keep a master list of all subjects for whom **a signed informed consent has been obtained** in the study
 - This is the document the RCO uses to ensure 100% of all ICFs have been audited for a given project

VA privacy requirements

If the VA component of your study enrolls non-Veterans or Veterans that are not enrolled in VHA healthcare:

- For studies with in-person contact, you will need to collect [VA Form 10-0483](#) which is an acknowledgment of the [VHA Notice of Privacy Practices](#) at the first visit.
- Maintain this signed form with the signed [VA informed consent](#) document and signed [authorization form](#)

If you are collecting audio or video recordings:

- If you are approved to conduct your study under a [VA approved waiver](#) and you will not be collecting a signed VA informed consent and authorization describing the recording, you must either collect signed consent on [VA Form 10-3203](#) **or** record the subject's verbal consent on the recording itself. You must obtain written consent to record a participant if you're meeting in-person.
 - The recording of verbal “consent to be recorded” must be maintained according to the VA records control schedule, just like a signed consent.

Research Records

- Good Clinical Practice
 - Study teams will maintain their active study records in compliance with GCP requirements
- Records Control Schedule 10-1
- All VA study files (hard copy and electronic) must be archived upon closure through the VA Research Administration Office
 - If VA records were maintained solely at OHSU, a complete copy must be sent back to the VA Research Administration Office upon study closure

Do not destroy any data/information at any time without consulting with the Research Administration Office first

Knowledge Check

Screening data is collected at the VA and OHSU. After consent, study procedures will be conducted and data collected at OHSU. Data will be stored long-term in an OHSU repository.

Can documents for screen failures at the VA be destroyed?

- 1) Yes
- 2) No
- 3) I'm not sure

A: No

All documents associated with a study at the VA must be retained in accordance with the VA records control schedule, RCS 10-1.

If you discover VA documents are missing or destroyed contact the Privacy Officer, Information System Security Officer, and the Records manager for the VA immediately and submit an RNI report to the IRB.

Accounting of Disclosures

- Disclosures of PHI **outside** of the VA must be tracked
 - VA requires an accounting of all disclosures (see required fields and sample spreadsheet on the VA Research website:
<https://www.va.gov/portlandresearch/documents/irb/acctg-of-disclosures.xls>)
 - For example, if you have a joint study being conducted at both VA and OHSU and VA PHI will be disclosed to OHSU, this will need to be recorded as a disclosure.
 - Exception: disclosures of limited data sets for research purposes do not need to be recorded as a disclosure
 - OHSU requires accounting of PHI disclosures that are under a waiver of authorization. OHSU accounting of disclosures information can be found <https://www.ohsu.edu/information-technology/resources>

Industry Sponsored Research

- Usually requires separate OHSU and VA sites (consult VA IRB admin staff first!)

Questions? Resources!

- VA Clinical Research Alliance (VACRA)
 - Meetings are currently on hold due to staffing shortages
- Webpage for PIs and coordinators
 - <https://www.va.gov/PortlandResearch/crcresources/index.asp>
- If your project involves a study drug, reach out to VA Research Pharmacy early in the planning process
- If you want to use OHSU's REDCap you must submit through the affiliate IRB

Research & Development Office

Phone & Fax

Main Office: (503) 273-5125

- When calling from VA just dial 55125

Secure FAX: (503) 273-5152

Location

Building 101, Room 502

Website

<https://www.va.gov/PortlandResearch/>

Email

IRB Analysts – pvamc-irb@va.gov

