## PCS Wizard Completion Campaign: HALFWAY THERE!

We are sending a BIG thank you to the research office staff and investigator community for your efforts in completing the Project Cover Sheet Wizard for all of your active projects.

Because of your commitment, there are **9,568 completed Project Cover Sheets**, accounting for 52.5% of the 18,219 Active Projects (as of January 10, 2022).

**BUT we have more work to do…** Your participation and support of the VAIRRS transition play a pivotal role in the program's overall success. When you complete the Project Cover Sheet, we are one step closer to a fully comprehensive, all-inclusive system built to serve you!



**In early 2022:** To ensure data integrity, the VAIRRS Program will be reaching out to each research office to confirm their active projects logged in IRBNet. Based on

responses to our earlier emails, a number of closed projects are still reported as active at one or more subcommittees.

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## COVID-RELATED RESEARCH

ORD has transitioned its COVID-19 research data into VAIRRS by including a question related to COVID-19 in the Project Cover Sheet. As of January 10, 2022, there are 811 active projects related to COVID-19 research taking place at 100 VA Medical Centers.

**Please ensure all COVID-related research studies at your site have a completed Project Cover Sheet Wizard and are appropriately identified as a COVID-related research study.**

## DID YOU KNOW?

### Field Level Dashboards

The second iteration of field-level dashboards will be demonstrated to the field focus group in early February 2022*.*

### TMS Integration

We are in the final stages of TMS integration! The VAIRRS Administrators will be notified as soon as integration is complete.

### VAIRRS Site Discussions

The goal of a site discussion is to improve the workflow for IRBNet at your VAMC. Thank you to the Tier 1 sites for taking the time to share your VAIRRS experience. Your feedback is critical in determining the program offerings and training webinars for 2022.

To date, 29 Tier 2 sites have completed discussions and Tier 3 site discussions will be scheduled for February 2022.

We aim to ensure that the IRBNet integration runs as smoothly as possible and look to address any concerns you may have during the call.

## Privacy Officer Guidance

The privacy review is not limited to the Waiver of Written HIPAA Authorization Request. The privacy review includes the protocol, IRB Information Sheet, Enterprise Research Data Security Plan (EDRSP) and the New Project Application. Consistent information across these documents is necessary to avoid discrepancies in how the data is accessed, collected, used, and disclosed. A frequent error is labeling data as "de-identified," but still using dates or another unique code on a repeating basis over time. Other examples include the different data sources noted on the Waiver of Written HIPAA Authorization Request or in Section 3 of the ERDSP. **Review the documents prior to submission to ensure that responses are the same.**

## VAIRRS AMBASSADOR - BOSTON

**About Boston:** The VA Boston Healthcare System (VABHS) has a large research program that spans three campuses and consists of 1,315 researchers and 1,100 projects. All projects are fully reviewed in VAIRRS.

**VAIRRS Experience:** We launched VAIRRS as part of Tier 1, while working remotely due to COVID. To ease the transition, we conducted 10 three-hour live remote training sessions. A training session recording, tips sheets, FAQs, and energizers were posted on the internal VABHS Research SharePoint site to enhance VAIRRS resources available to our team.

**Proactive Practices:** Since the transition, we have been offering weekly two-hour virtual office hours, providing time for any researcher to sign on and work one-on-one with a committee coordinator to review an upcoming submission and get hands on instructions for submitting the package in VAIRRS. This has been extremely helpful to both new and experienced users.

# VA CENTRAL IRB

## Update from VHA's Research Support Division (RSD)

Effective January 14, 2022, RSD is requiring that all LSI applications (including exempt research) submitted to the VA CIRB will need to have their own site-specific ERDSP. It is recommended that the PI/SC complete a study-wide ERDSP and send an unsigned copy of it to the local Investigators once PI/SC approval has been obtained. VA CIRB staff are working with the RSD to clarify the specific questions can be retained from the PISC ERDSP and which ones need to be completed for the specific site application. If you have a PISC application currently under review, the approval letter will instruct you to initiate LSI applications and include site-specific ERDSP forms.

## Update from VA CIRB

**Exemption applications:  New Guidance**

| | | |
|---|---|---|
| If you are submitting an application to the CIRB for a multi-site exempt study, we are now requiring that you initiate a PI/SC application first, and when you get a determination letter or letter of approval for limited IRB review, follow that with an LSI application as is done for non-exempt research. | The **PI/SC application** should include the IRBNet wizards (Information Sheet and Project Cover Sheet), Form 102 (and, if needed, additional FCOI documentation), Form 105, Protocol, Enterprise Research Data Security Plan (ERDSP), CV/ Biosketches for Investigators, Form 103: Waiver of HIPAA Authorization – *if applicable,* Form 10-0493: MODEL HIPAA Authorization Form – *if applicable,* MODEL Information Sheet or Consent Scripts – *if applicable* | The **LSI application** should include the IRBNet wizards (Information Sheet and Project Cover Sheet), Form 102 (and, if needed, additional FCOI documentation),  LOCAL Enterprise Research Data Security Plan (ERDSP), CV/ Biosketches for Investigators, LOCAL HIPAA Authorization Form – *if applicable,* LOCAL Information Sheet or Consent Scripts – *if applicable* |

If you are submitting an application to the CIRB for a multi-site exempt study, we are now requiring that you initiate a PI/SC application first, and when you get a determination letter or letter of approval for limited IRB review, follow that with an LSI application as is done for non-exempt research. For a list of requirements, click here.

## Form Updates & New Instructions in VA CIRB IRBNet Library for Researchers

**Updated:** Instructions ERDSP Guide v2.2; ERDSP Template v2.7; Updated IRB Signature lines for Forms 103, 112a, 112b; Updated instructions Forms 115a, and 115b

**New:** Flowchart – PISC and LSI Exempt Project Submission Process; INSTRUCTIONS – PISC and LSI Exempt Project Submission Process

## LEARNING CORNER

The Office of Research Protections, Policy, and Education (ORPP&E) is hosting a webinar:

**Topic:** VAIRRS Monthly Webinar - Feasibility & Alignment Review, Scientific Review

**Date:** Monday, January 31, 2022

**Time:** 2:00 - 3:00 PM (EDT)

**Purpose:** Provide expert advice, training, demonstration, and/or direction to the VA research community regarding the various topics around the VAIRRS transition.

**Lead Presenter:** Dr. Mary (Molly) Klote

**Target Audience:** R&D Committee members, IRB members, research office staff, compliance officers &Investigator and study team members

**CLICK HERE TO REGISTER!**
*We suggest you log on using Google Chrome or Microsoft Edge.*

# VAIRRS Library Update

The R&DC forms have been converted to PDF fillable forms posted on the VAIRRS SharePoint site under the VAIRRS Toolkit for review and comment until February 11th. Final forms will be uploaded to the Documents Library in IRBNet.

## IRBNet Wizards - "Back to Basics"

**IRBNet Package Requirements**
The list of expectations for all sites is as follows:

**For Active studies converted at the time of IRBNet enrollment:**

- The converted project is shared or transferred to the PI.

- All study actions completed at an internal or external committee are recorded in IRBNet.

- Project status and relevant dates are maintained at the R&DC and each subcommittee.

- The Project Cover Sheet is completed ASAP

- The IRB Information Sheet (if applicable) is completed at the next CR/annual update

**For new study submissions received since enrollment:**

- The Project Cover Sheet and IRB Information Sheet (if applicable) are completed at study submission

- All study actions completed at an internal or external committee are recorded in IRBNet

- Project status and relevant dates are maintained at the R&DC and each subcommittee

# IRBNet TOPICS
*Action: You Spoke, We Listened*

## CONCERN

ORPP&E designed the Project Cover Sheet Wizard to be as straightforward as possible. While the Project Cover Sheet Wizard was developed with the intent that study teams would not need a companion guide in order to complete, we have heard that some of the questions on the wizard and supporting logic require further explanation.

## SOLUTION

The VAIRRS Program has developed a Project Cover Sheet Wizard Guide to assist in the completion of the Wizard. We are also updating the online Wizard with additional guidance language, navigational help, and tool-tips. The guide is currently under final review and will be posted on the VAIRRS SharePoint under the VAIRRS Toolkit folder by February 4th. We ask that you review the guide and send us your feedback by Friday, February 11th.

# HELP DESK AND TEAM RESOURCES

IRBNet support is available at govsupport@irbnet.org for **technical issues and questions related to IRBNet**.

For **regulatory queries or questions about processes subject to regulatory guidance**, visit the ORD FAQs or email the ORD Regulatory Team at vhacoordregulatory@va.gov.

**For further programmatic support and assistance**, email VAIRRS@va.gov.

The VAIRRS User Group Listserv is also available if you would like to reach out to other users. Email the VAIRRS team to be added to the listserv.

Training resources and the VAIRRS Toolkit are available on the VAIRRS SharePoint portal.

The **VAIRRS Change Control Board** meets monthly to review requested changes and potential new forms and letter templates. Please submit your suggestions to VAIRRS@va.gov.

*Reminder: It is expected that all VAIRRS sites will use the standard library and supplement with local forms as necessary. The Project Cover Sheet and IRB Information Sheet wizards must be completed at the following study event as soon as possible.*

## LOOKING AHEAD

- **TMS Integration Completion**

- **VAIRRS Monthly Webinar will be held on the 4th Tuesday of every month. Send us your topic ideas!**

- **Records Control Guidance**

- **IRB Annual Progress and Continuing Review Wizard**

Thank you,

*VAIRRS Program Team*

*VAIRRS WEBSITE:* *https://www.research.va.gov/programs/orppe/vairrs/default.cfm*

*VAIRRS SharePoint:* *https://dvagov.sharepoint.com/sites/VHAORPPE/VAIRRS*

*ORD Policy and Guidance FAQs:* *https://www.research.va.gov/resources/policies/faq-search.cfm*

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