

**From:** Veterans Health <veteranshealth@messages.va.gov>  
**Sent:** Thursday, March 17, 2022 1:51 PM  
**Subject:** VAIRRS March Newsletter



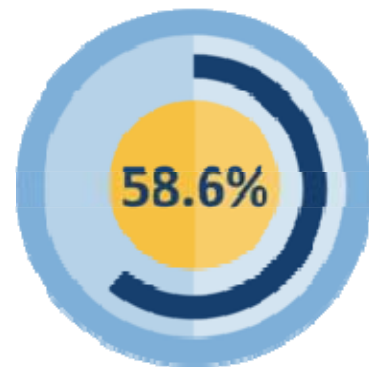
## PCS Wizard Completion Campaign

Thank you to the research office staff and investigator community for your dedicated efforts in completing the Project Cover Sheet wizard for all active projects. Your commitment has led us to a new milestone as we approach 60% completion!

If you have not validated your site's list of active projects yet, please do so at your earliest convenience.

As we move forward on our mission of verifying all data within VAIRRS, we are working to match Central IRB projects with local projects in IRBNet. We will follow up with sites individually if more information is needed.

There are currently **10,039 completed Project Cover Sheets**, accounting for 58.6% of the 18,232 Active Projects (as of March 12, 2022).



**Updated FAQs Available on the VAIRRS Webpage**

The VAIRRS FAQ webpage is updated to better serve you! We encourage you to use the FAQs as a reference tool for quick, accessible guidance on anything VAIRRS-related. [Click here to see the new VAIRRS FAQs.](#)

## DID YOU KNOW?

### Major Updates to the Project Cover Sheet Wizard!

Find the updated Project Cover Sheet outline in the VAIRRS Toolkit for review. The new PCS will be deployed to the sandbox in the coming weeks. We suggest you take a moment to review the revised outline to ensure research office staff are aware of the upcoming changes. More detail regarding the updates can be found in the VAIRRS Library Updates section below.

### IRBNet Notification Configuration

The auto-generated notifications can be customized for your site. Please contact IRBNet Support at [govsupport@irbnet.org](mailto:govsupport@irbnet.org) for more information.

### Committee Member Recusal Function

Recusals can be noted on the Reviews and Minutes page. Under the Voting section, you can add or remove recused committee members, and the recused members will be recorded in the minutes.

Votes For:       Votes Opposed:       Abstained:

**Recused:**  

### VAIRRS Strategic Advisory Council

We are in the process of forming a VAIRRS Strategic Advisory Council (VSAC) that will be responsible for advising the VAIRRS Program on strategic initiatives for 2022 and



beyond. The goal of the VSAC is to ensure 1) we are meeting the needs of our end-users and 2) the impact of strategic initiatives on the field are understood and considered prior to implementation. Submit nominations for individuals you recommend to serve on the VSAC through the VAIRRS SharePoint portal: [VAIRRS Strategic Advisory Council Nomination](#)

## Privacy Officer Guidance

**Central Research Privacy Board (CRPB) Closure:** On December 2, 2021, the Office of Research and Development (ORD) provided a status report to the nine VA sites relying on the CRPB. The referenced email conveyed that a status report would be sent concerning ORD plans for the VA CRPB continuation or closure. The ORD cited CRPB continuation would be contingent on increased utilization of the CRPB. There have been no new submissions to the CRPB since December 2nd. As such, **ORD will close the VA CRPB on May 31, 2022**, in compliance with the Memorandum of Understanding (MOU), Section E, Termination Provisions. **No new applications will be accepted by the CRPB, effective February 23, 2022.** ORD will send formal closure letters to each of the nine sites in May 2022.

## VAIRRS AMBASSADOR - MILWAUKEE

**About Milwaukee:** The Clement J. Zablocki VA Medical Center is a moderate-sized research program with 163 researchers and 178 active projects.

**VAIRRS Experience:** The Milwaukee VAMC launched VAIRRS as a part of Tier 2. Milwaukee conducted two 1-hour live remote training sessions for researchers and shorter sessions for committee members, all of which were recorded. The center created over 20 short PDF tutorials, addressing specific actions for researchers or committee members. These resources are available on their internal SharePoint site. In addition, the Clement J. Zablocki VAMC designated one staff member as their VAIRRS “guru” and directed users to contact them for individual assistance, creating a more personal, direct support system.

**Proactive Practices:** The VAIRRS “guru” continues to provide one-on-one instruction as needed. Their Translational Research Unit (TRU) team of study coordinators assists researchers who do not have a coordinator to prepare and submit packages. Research office staff frequently email PDF tutorials to researchers to aid with an upcoming

submission or package revision. They also have created instructional documents by submission type in each committee library in IRBNet.



**The Milwaukee Team!**

(Left to right): Susan Ahlf (IRB Administrator), Christine Wurm (IRB/R&DC Coordinator), Carlos Marquez (IRBNet Support/VA Grants Manager), Shelley Baumgardt (IACUC/Safety Coordinator)

## VA CENTRAL IRB

<b>CENTRAL IRB (CIRB) PROJECT ACCESS</b>		
Role	Type of access required	Where to request access
PISC and PISC study team	The PI "owns" the PISC IRBNet project and should have ownership of each project where they are named as the PI. The PI is responsible for sharing the project with study team members.	Contact the CIRB if the PI does not have access to the project. Study team members must contact the PI to be granted access.
LSI and LSI study team	The LSI "owns" the local site's IRBNet project and should have ownership of the LSI project. The LSI is responsible for sharing the project with LSI study team members.	Contact the CIRB if the LSI does not have access to the LSI's project. LSI study team members must contact the LSI to be granted access.
Local Site Liaison	The Local Site Liaison should have access to PISC and LSI projects at their facility.	Contact your facility's local research office and request access to IRBNet for PISC and LSI projects. The local research office can submit the request to IRBNet Support.

Research Compliance Officer	The Research Compliance Officer should have access to PISC and LSI projects at their facility.	Contact your facility's local research office and request access to IRBNet for PISC and LSI projects. The local research office can submit the request to IRBNet Support.
Local Research Office	The local research office should have access to all CIRB projects at their site. In some cases, where the active project was uploaded when the CIRB transitioned to IRBNet, the research office may not have access to the project if the CIRB shell has not been submitted through the local research office.	Contact the CIRB if the research office identifies a CIRB project to which they do not have access. The CIRB will submit the project to the local research administration workspace to grant access. The VAIRRS Team is identifying all duplicate projects with a local version and CIRB shell. Each site will be notified of the duplicate projects, along with the IRBNet IDs and whether the projects are candidates for reconciliation.

## VA CENTRAL IRB QUARTERLY WEBINAR

**Topic:** Duplicate Project Reconciliation

**Purpose:** Discuss project reconciliation process for local Central IRB projects with a duplicate Central IRB project shell in IRBNet.

**Date:** Thursday, March 31, 2022

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

**Target Audience:** Research Office Staff, Investigators, Study Team Members

[CLICK HERE TO REGISTER!](#)

## LEARNING CORNER

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

**Topic:** VAIRRS Monthly Webinar: Tracking Projects Across Multiple Committees  
(Presented by VAIRRS January Ambassador - VA Boston Health Care System)

**Date:** Tuesday, March 22, 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 Presenters:** Carole Palumbo and Angie Foster

**Target Audience:** IRB members, research office staff, compliance officers, investigator and study team members, and research committee members (IRB; safety; animal; and R&D Committee)

[CLICK HERE TO REGISTER!](#)

*\*We suggest you log on using Google Chrome or Microsoft Edge.*



## VAIRRS Library Update

There have been a few modifications made to the following items:

### Project Cover Sheet

- New questions for Cerner access
- COI response options updated
- Research Topic Areas
- Additional instructions and navigation tools

### 2.0A Determinations Request

- Removed options for pregnant women and non-Veterans
- Removed target dates

### R&DC Forms

- The R&DC forms have been upgraded to Adobe fillable forms. The forms are available in the VAIRRS Toolkit and will be posted to IRBNet on **March 18<sup>th</sup>**.

## IRBNet Wizards - "Back to Basics"

### Unlocking/Locking Packages

The following matrix outlines the scenarios when a package should be unlocked. It is important to remember that unlocking a package allows for changes to the submitted study documents. It is advised that packages only be unlocked before review. If the package has been assigned to a reviewer, further revisions should be submitted in a subsequent package.

UNLOCKING/LOCKING MATRIX		
Scenario	Suggested Action	Why This Action?
While conducting an <b>administrative review in the Research Administration workspace</b> , the administrator identifies an issue with the submission package that requires revisions by the study team.	Unlock the package and request updates within the same package.	Unlocking the package is the appropriate action because the package has not been assigned to a reviewer. A board member has not reviewed the study documents, and therefore, revisions to submitted documents within the same package are acceptable.
While conducting a <b>regulatory pre-review in the board workspace</b> , the administrator identifies an issue with the package that requires revisions by the study team. The reviewer has not been assigned and the package has not been submitted to multiple boards.	Unlock the package and request updates within the same package.	Unlocking the package is the appropriate action because the package has not been assigned to a reviewer. A board member has not reviewed the study documents, and therefore, revisions to submitted documents within the same package are acceptable. There is no potential conflict with other boards as the package has not been submitted to multiple boards.
While conducting a <b>regulatory pre-review in the board workspace</b> , the administrator identifies an issue with the package that requires revisions by the study team. The reviewer has not been	The administrator must reference the All Reviews page to determine whether the package is currently under review at multiple boards. Packages sent to multiple boards should not be unlocked.	Unlocking a package will impact all boards where the package is under review. For instance, if a package is under review at the SRSS and IBC, unlocking the package in the IBC workspace will also unlock the

<p>assigned; however, the <b>package has been submitted to multiple boards.</b></p>	<p>Instead, request a new package be submitted with the required revisions.</p>	<p>package in the SRSS workspace. To maintain integrity of the submitted package and an accurate document history, revisions should be submitted in a new package.</p>
<p>During the <b>committee member's review or board meeting</b>, an issue was identified with the package that requires revisions by the study team.</p>	<ol style="list-style-type: none"> <li>1) Record reviewer comments and/or board comments</li> <li>2) Record action as "Modifications Required" or "Information Required"</li> <li>3) Request new package with revisions</li> <li>4) Instruct study team to select the Follow-Up/Response submission type for the revised package</li> </ol>	<p>The versioning feature within IRBNet is designed to work alongside the Unlock/Lock feature. If a package is unlocked after board member review, the version history is not captured. Further, it becomes difficult to ascertain which documents have been revised or replaced. The system is designed so that if the board requires modifications, then those changes should be submitted in a new package. The new package can then be shared with the reviewers and they can track it in their queue. Board members may view all documents submitted for a project in the Designer page or on the Submission Detail page by selecting "All Project Documents."</p>

## IRBNet TOPICS

*Action: You Spoke, We Listened*

### CONCERN: Lack of Project Cover Sheet Instruction

The Project Cover Sheet was initially developed with the intent for all questions and response options to be self-explanatory. We have received feedback that a companion guide is required to assist investigators in completing the wizard.

### SOLUTION: Wizard Guide and Updated PCS

In addition to the recently published [Wizard Guide](#), the PCS is under development to include various instructional and navigational tools. We expect the revised wizard to be



published in early April. In the meantime, you may review the additional instructions and tools in the revised PCS outline posted to the VAIRRS toolkit.

## HELP DESK AND TEAM RESOURCES

IRBNet support is available at [govsupport@irbnet.org](mailto:govsupport@irbnet.org) for technical issues and questions related to IRBNet. For regulatory questions or questions about processes subject to regulatory guidance, visit the [ORD FAQs](#) page and use the search tools to find the answer. For VAIRRS-specific questions, please refer to the new [VAIRRS FAQs](#) page. For further assistance, email [VAIRRS@va.gov](mailto: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](mailto: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

- BLR&D Eligibility Program Transitions to VAIRRS
- VAIRRS Field Strategic Advisory Group Kickoff
- RCO and COI Workspace Update
- TMS Integration Update

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Thank you,  
*VAIRRS Program Team*

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

**VAIRRS SharePoint:** <https://dva.gov.sharepoint.com/sites/VHAORPPE/VAIRRS>

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

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