PCS Wizard Completion Campaign

Thanks to your effort and commitment, we have reached a 70.9% completion rate for Project Cover Sheets (PCS). The PCS completion rate began at 32% back in October 2021 and in less than a year, more than 7,000 cover sheets have been completed! Please continue to work with investigators at your site to ensure wizards are completed for all new study submissions and all active projects that have transitioned to IRBNet.

To date, we have completed 13,264 Project Cover Sheets of the 18,708 active projects.

If you have questions regarding PCS, reference the VAIRRS FAQs or contact VAIRRS@va.gov.

DATA SHOUTOUTS

COVID-19 Research Dashboard
Nearly 900 COVID-19-related research projects were submitted to VAIRRS and can be easily tracked via our COVID-19 Research Dashboard.

In response to the COVID-19 pandemic, VA has managed the review of hundreds of research projects using VAIRRS. The dashboard allows users to find studies on specific topics and locations. An interactive map featured in the dashboard shows active VA studies on COVID-19, and users can quickly and easily search to find studies by specific topics and/or locations.

The COVID-19-related projects submitted to the VAIRRS platform support and advance VA's clinical and research missions, ultimately helping Veterans affected by the disease.

Visit the COVID-19 Research Dashboard

DID YOU KNOW?

VAIRRS Strategic Advisory Council
The VAIRRS Strategic Advisory Council (VSAC) conducted its inaugural meeting in June. The VSAC’s first goal was the review of the [VAIRRS FY2022-2024 Strategic Plan](#). The next goal of the VSAC is to aid in the restructuring of the VAIRRS Mentor Program. Expected improvements to the mentor program include entry/exit requirements, paid time for mentors and a collaborative platform to support mentor/mentee interaction.

### VAIRRS Change Control Board

Effective on September 6, 2022, the VAIRRS Change Control Board (CCB) intake process has been updated. Moving forward, all change requests must be submitted through the VAIRRS SharePoint CCB Requests link ([click here](#)). We are no longer accepting change requests via the VAIRRS inbox.

### COI Module

The Conflict of Interest (COI) module is currently under development with an expected deployment date of October 2022. Please complete the [COI Administrator Data Call Response form](#) or forward responses to your COI administrator.

### VAEDA

The VA Electronic Determination Aid (VAEDA) has completed the "soft launch" phase, and we are gearing up for the official launch on September 21, 2022. A national webinar will be held on the launch date to introduce VAEDA to all VA medical centers (VAMCs). See below for webinar information and registration.

VAEDA was created to reduce variability in research determination outcomes as well as save time and resources in your day-to-day processes. We are excited to launch this program to improve the efficiencies of VA Research enterprise operations.

### VA Box.Com

Available to your team now!
What is VA Box.Com? This tool easily enables teams to share and collaborate digital files, while allowing for the management of sophisticated business processes, like data governance and retention.

Need to Share Data? No Problem! All files uploaded to VA Box are encrypted using 256-bit AES encryption.

How do I get started?

- ORD will send an email with the approval to your request. The Box Intake Team will be copied on the email, and start processing your information.

- Box will follow up with you to walk through intake, acquisition, security and implementation/access, as applicable.

Questions?

More information can be found here (must have VA Network access) or email VABOXTEAM@va.gov.

VAIRRS AMBASSADOR - VA GREATER LOS ANGELES HEALTHCARE SYSTEM

VAIRRS Experience:

In February 2021, VA Greater Los Angeles (GLA) Healthcare System Research & Development announced the transition from iMedRIS to the IRBNet/VAIRRS platform. To assist with the transition, GLA offered seven Microsoft Teams training sessions for their 800+ researchers and staff. All sessions were led by Mr. Cody Knight, the GLA IRBNet administrator, who provided exceptional support and technical assistance. Additionally, VA GLA recorded a training session and made the video available to all researchers and staff via the GLA Internal Research Service SharePoint site for on-demand access with related IRBNet information, walkthrough tutorials and research forms.

GLA’s IRBNet data transition began on March 22, 2021 when ~500 active projects were migrated to the new system. Within the following two weeks, GLA committee coordinators manually uploaded all study documents into IRBNet for these projects, to complete the data migration process and successfully launch their IRBNet “go live” on April 5, 2021. During the first year of GLA’s integration, they prioritized communication efforts to inform their community about IRBNet updates and reminders of important deadlines.

GLA leadership’s (Drs. Linda Demer, Scott Krahl and Taigy Gooding) response to this transition and the skillset and proactiveness of the GLA team (Mr. Cody Knight, Dr.
Elizabeth Corey and Dr. Fredricka Martin) were instrumental in helping the facility reach their transition goals within a very short time period. VA GLA also had dedicated committee coordinators, Daniela Macias, Edward Hallisy, Alissa Simon, Margaret Roch, John Berard and Giselle Henry, who made the transition possible. In addition, the VA GLA communications manager, Ms. Cynthia Gammage, played a pivotal role, leading the email, training and SharePoint campaign efforts to keep the community informed.

VA CENTRAL IRB

Removal of Investigator Signature Line & Admin Updates

The VA Central IRB has removed investigator signature lines from ALL submission forms and made additional minor administrative updates. All updated forms can be found in the VA Central IRB Forms and Templates Library. Please ensure you begin using these new forms for your next Central IRB submission. Beginning Monday, October 3rd, any package that is received with an outdated form will be returned for the updated form to be completed and uploaded.

Enterprise Research Data Security Plan

The VA Central IRB continues to support the Central ISSO review for multi-site project submissions. Below are useful tips and guidance that can be followed when submitting an Enterprise Research Data Security Plan (ERDSP) for a Central IRB project.

Research Projects Approved Prior to May 2021: An ERDSP is NOT required for research projects approved by the Central IRB prior to May 2021. However, amendments to
research projects approved prior to May 2021 may require an ERDSP. To determine if an ERDSP is required for a protocol amendment, VA investigators must use Appendix B (Research Study Amendment ERDSP Determination Aid) of the ERDSP User Guide. This guide can be found in the IRBNet Forms and Templates Library.

**IMPORTANT NOTE**: If an ERDSP was never submitted for a project and you are now submitting one for the first time because of a protocol amendment, the entire ERDSP should NOT be completed. In this case, only Appendix B should be completed.

**New Research Projects**: An ERDSP is required for all new principal investigator/study chair (PISC) and local site investigator (LSI) projects.

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**LEARNING CORNER**

The Office of Research Protections, Policy, and Education (ORPP&E) is hosting two webinars next week!

**VAIRRS Webinar**

**Topic**: VAIRRS Monthly Webinar - IRBNet Basics for Investigators

**Date**: Tuesday, September 20, 2022

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

**Purpose**: With the beginning of fall and the start of a new semester, the VAIRRS Support Team is offering a refresher course, *IRBNet Basics for Investigators*, for new investigators at VA. This webinar will cover basics, like how investigators access and enroll in IRBNet to creating and revising a package in IRBNet.

**Lead Presenters**: Angela Foster and the VAIRRS Support Team

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

[CLICK HERE TO REGISTER!]

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

**Topic:** VA Electronic Determination Aid (VAEDA) Full Launch

**Date:** Wednesday, September 21, 2022

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

**Purpose:** Provide an overview and demonstration of VAEDA, discuss its purpose and respond to any questions

**Lead Presenters:** Dr. Molly Klote, Dr. Jeffrey Ferraro, Dr. Don Workman and Angela Foster

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

TEAM SPOTLIGHT: The VAIRRS Support Team

The VAIRRS Support Team is the driving force, or the "behind the curtain," if you will, of the VAIRRS program. VAIRRS Support is responsible for intake of the VAIRRS@va.gov inbox (200+ emails per month), communications (monthly newsletters, website updates, user guides, webinars), one-on-one site support (6+ facilities), dashboards, CCB support and so much more! When you're struggling with a new platform or looking for a more efficient way to accomplish tasks, the team is here to help!

"BACK TO BASICS"

**Document Version History**

It is recommended that investigators are instructed to use the pencil icon whenever documents within a package must be updated. The use of the pencil icon enables document versioning within IRBNet. In the event the pencil icon is not used, administrators may enforce document versioning on the designer page using the "drag and drop" function. Instructions are as follows:

1. Click on the document type in the ‘Documents in this Package’ section.

2. While holding down the mouse button, drag the item to the appropriate document in the ‘Documents from Previous Packages’ section.
3. Hover over the paper icon.
4. A pop-up will appear, which reads, "Add to this Document Revision History."
5. Release the mouse button.
6. A second pop-up *may* appear if the document types are not the same.
7. Select 'Continue.'
8. The document versions will be viewable by clicking the multiple paper icon in the ‘Documents in this Package’ section.

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**IRBNet TOPICS**

*Action: You Spoke, We Listened*

**CONCERN**

Many of our users have found it difficult to locate training resources.

**SOLUTION**
We are introducing role-based training pathways in fall 2022. Training resources will be categorized by role (administrator, member, investigator) to improve access.

HELP DESK AND TEAM RESOURCES

IRBNet support is available at 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. If you still need help, 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 through the VAIRRS SharePoint CCB Requests link (click here). 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 next study event as soon as possible.

LOOKING AHEAD

- COI Module Deployment
- New Training Pathways
- Mentor Recruitment Announcement
- VAIRRS October Webinar

Thank you,
VAIRRS Support 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

Keep updated & let us know how we're doing.

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