

From: Veterans Health <veteranshealth@messages.va.gov>
Sent: Tuesday, September 28, 2021 10:50 AM
Subject: VAIRRS News: September Recap



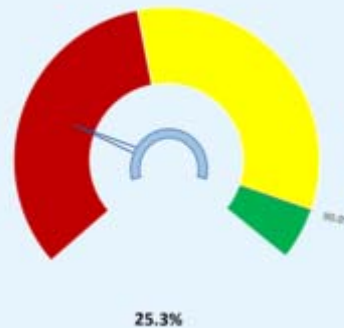
SERVING VHA RESEARCH



VAIRRS 2.0 - WIZARD COMPLETION CAMPAIGN

The next phase of the VAIRRS Program includes leveraging the enterprise dataset and continued training. We aim to have **the Project Cover Sheet completed** for all active and new studies by **December 15, 2021**.

As of September 12, 2021, 4,764 Project Cover Sheets have been completed for 18,853 Active Projects (25.3%). This figure includes all active projects, including those predating VAIRRS integration.



COVID-RELATED RESEARCH

ORD is transitioning its COVID-19 research data into VAIRRS. The Project Cover Sheet was updated to include a question for researchers to indicate whether their project is related to COVID-19 research. Once the transition is complete, the VA's COVID-19 Response dashboards will become a part of the suite of dashboards ORPP&E has created for its stakeholders.

DID YOU KNOW ?

Field Level Dashboards

Thank you to everyone who participated in the Field-level Dashboard Focus Groups. The dashboard development is currently underway. We expect to publish the first round of dashboards in early October. Invites will be sent to all focus group participants.

CITI and TMS Integration

CITI Integration Update: As of September 7, 2021, VAIRRS has implemented CITI integration across 101 VAMCs. Researchers at those sites can now link their IRBNet profiles to CITI so that their training completed at the VA will get pulled in and automatically accepted on a nightly basis. Please refer to the ["Link to CITI Account" guide](#) located on the VAIRRS SharePoint site for further details. Research offices at those sites are being notified via email, including the guide's delivery.

Privacy Officer Guidance

VHA Directive 1605.01, Privacy and Release of Information, Section 13 notes that the facility Privacy Officer is responsible for reviewing the HIPAA authorization to ensure legal authority exists prior to the use, access, collection, creation, and disclosure of PHI (obtained orally or in writing) by research investigators. The IRBNet/VAIRRS process fully supports this review. The legal authority is granted by either **a)** Written HIPAA Authorization combined with an informed consent form (ICF) or a separate VA Form 10-0493 "Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research" assigned by the subject or their personal representative or **b)** a Waiver of HIPAA Authorization granted by an Institutional Review Board (IRB) or a Privacy Board. The facility Research Office and Privacy Officer should work together to establish open communication channels to ensure transparency and visibility in the VAIRRS system. The Privacy Officer's review results may be recorded using the Reviewer Comments section and Reviewer Recommendation field.

IRBNet Wizards - "Back to Basics"

What should be entered into IRBNet?	Who should enter data?	When should data be entered?	Why does this data need to be entered?
Project Cover Sheet	PI	<ul style="list-style-type: none"> Initial Application Changes or updates to study that result in a change to previous response Converted studies must complete the PCS by 12/15/2021 	ORD is developing dashboards for leadership and the VAMCs that will provide a detailed overview of the research enterprise. In order to accurately reflect activity at your site, all actions, including amendments, CRs, reports, etc. should be entered into IRBNet.
IRB Information Sheet	PI	<ul style="list-style-type: none"> Initial Application for all studies under the oversight of a VA or non-VA IRB Changes or updates to study that result in a change to previous response 	
Initial and subsequent study actions (CR, Amendments, Report, etc.)	Committee Administrator	<ul style="list-style-type: none"> All committee and subcommittee actions should be recorded in IRBNet as a board action Board actions for studies under the oversight of a non-VA IRB must also be recorded in IRBNet 	

VA Central IRB

VA Central IRB Refresher Training

The CIRB will host quarterly IRBNet training during FY22 for all-new Study Coordinators and study teams on October 7, 2021, at 2 PM EST. Webinar invites will be distributed the week of September 27, 2021.

1. Please remember that Initial applications (PI/SC and LSI) need to go to local Research Office initially for whatever pre-review is done by the local facility. After their pre-review, the Research Office will either submit the packet (if it only contains CIRB documents), or will alert the study team to submit a new packet to the VA CIRB with only CIRB-related documents included. When the Central IRB staff get a submission that has not gone to the local research office,

we will send it to them, include a note to explain why, and send instructions to the study team to submit it correctly the next time.

2. Financial Conflict of Interest documentation: The VA CIRB will accept PDF email files from approving official.
3. To view documents approved and issued prior to the VA CIRB transition to IRBNet (March 2021) refer to the VA Central IRB SharePoint. The site is still available to view these study documents.

YOU SPOKE, WE LISTENED, WHAT WE ARE DOING

Concerns: Instructions for completing the wizards

Many of you have expressed the need for an instructional guide to complete the Project Cover Sheet and IRB Information Sheet wizards.

Solutions: Wizards Guides Coming Soon!

- The VAIRRS Program Support Team is developing a wizard guide to complement the wizards. The Project Cover Sheet Wizard Guide will be published in October. The IRB Information Sheet Wizard Guide is still in development and will be published this Fall. The draft guides will be posted to the VAIRRS SharePoint site for your review and comment.

The VAIRRS Program would like to welcome...

Raya Fares, Bria White, Alli Schulman, Harrison Segall, Norma Asimba and Siree Therdsateerasak. The new members of the team are excited to join an innovative program, igniting major improvements for the enterprise.



HELP DESK AND TEAM RESOURCES

IRBNet support is available at govsupport@irbnet.org for technical issues and questions related to IRBNet. First, for regulatory queries 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 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

- Field-Level Dashboards
- TMS Integration
- Future Training Opportunities

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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