From: Veterans Health < veteranshealth@messages.va.gov>

Sent: Tuesday, November 23, 2021 11:04 AM

Subject: November Update: VAIRRS Project Cover Sheet Due Dec. 15



WIZARD COMPLETION CAMPAIGN - 22 DAY COUNTDOWN!

The deadline to complete the Project Cover Sheet Wizard for your project is fast approaching.

All active and new studies must complete the Project Cover Sheet Wizard by December 15, 2021.

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!

PROGRESS METER



To date, **5,788 Project Cover Sheets are completed**, accounting for 32.3% of the 17,938 Active Projects.

COVID-RELATED RESEARCH

ORD is transitioning its COVID-19 research data into VAIRRS by including a question related to COVID-19 in the Project Cover Sheet. As of November, 802 active projects identified themselves as being related to COVID-19. ORPP&E is currently in the process of identifying additional studies in VAIRRS.

DID YOU KNOW?

Field Level Dashboards

The first iteration of field-level dashboards was released for testing by the VAIRRS Dashboard Focus Group on November 15th.

All feedback is due by November 30th.

Privacy Officer Guidance

The VHA ORPP&E, Washington, DC – Documents for Human Subjects
Researchers library contains the most current (04/29/2021) VHA Privacy
reviewed "2.1 – Request for Waiver of HIPAA Authorization" form. This form
provides a single source for requesting and documenting the IRB or Privacy
Board outcome regarding the waiver request.

2. The most often missed identifier in a data set is "All elements of dates (except year) and any age over 89." This identifier refers to any date accessed, collected, used and/or disclosed. A common missed date is the blood collection date on the sample labels. Check your submitted documents to complete the identifiers section.

VAIRRS AMBASSADOR - ATLANTA

Throughout the VAIRRS transition, the Atlanta VA has been recognized as a top-performing VAIRRS site - serving as a great model for others to follow.

Kallie Medbery, the R&D Coordinator at the Atlanta VA, reported on the site's experience, challenges, and success throughout the VAIRRS implementation process.

The Atlanta VAHCS has an extensive research program with over 400 studies, including 300+ studies conducting human research. As one of the first sites to get on board, Atlanta was a part of the Tier 1 sites to transition to VAIRRS and is currently conducting all local research committee



reviews and facility PO and ISSO reviews within the IRBNet system.

Medbery stated, "We found success during the transition by starting with a phased rollout and regularly communicating with our investigators as we implemented each new element of the software."

The site created a dedicated space on their facility webpage to store all communications and guidance documents for easy reference (Research-
IRBNet/VAIRRS Guidance - Atlanta VA Health Care System) to facilitate employee experience throughout the transition. In addition to the guidance documents, Atlanta created submission checklists for each of their external IRBs, which they store in their local libraries in IRBNet. According to Medbery, the site "found these checklists to be instrumental in assisting the investigators with tracking the varying requirements and procedures for each IRB."

We applaud your commitment to VAIRRS & encourage other sites to follow suit to optimize all that IRBNet has to offer!

LEARNING CORNER

The Office of Research Protections, Policy, and Education (ORPP&E) is pleased to announce a webinar scheduled for Thursday, January 13, 2022.



Topic: IRBNet 101 for Central IRB Coordinators and Investigators - FY 22 Qtr. 2

Date: Thursday, January 13, 2022

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

Purpose: Refresher of CIRB submission process in IRBNet

Lead Presenter(s):

Angela Foster, VAIRRS Program Manager Jessica Kroll, VA Central IRB Administrator Don Workman, VA IRB Network Director

Target Audience: Investigator and study team members and research office staff

Details and registration: Stay tuned... registration will open after the holidays!

VAIRRS Library Update

<u>Click here to access the revised IRB Information Sheet wizard</u> published on October 29, 2021.

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	 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 	activity at your site, all actions, including
IRB Information Sheet	PI	 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	 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 	

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 <u>VAIRRS@va.gov</u>. 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 <u>VAIRRS SharePoint</u> 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

- Project Cover Sheet Wizard Guide Deadline: December 15, 2021
- IRBNet Training: January 13, 2022

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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