



TRANSITION PROGRESS

A total of **97 sites** (+ Central IRB) are live on VA's instance of IRBNet

REMAINING SITES

- Palo Alto VA Health Care System
- Portland VA Health Care System
- Providence VA Medical Center
- San Diego VA Healthcare System
- San Francisco VA Health Care System
- Southern Nevada VA Health Care System

SNAPSHOT

TIER 3 START: 12 / 2020
 DEPLOYMENT END: 4 / 2021
 DEPLOYMENT DUR: 5 MONTHS

97 Sites, + Central IRB

DID YOU KNOW ?

Supplemental Guidance Document: Mini Energizer Announcement

When updating project-level information, three data fields are most omitted: project status, initial approval date, and project risk level. When pieces of information are omitted from your project records, ORD is unable to accurately project findings from our reporting dashboard. To mitigate this, please find a data fields energizer attached to reiterate the importance of updating the project-level fields.



Central IRB Reviewer Comments Memo

A new Reviewer Comments memo is now available in the Sandbox training.irbnet.org for all VA facilities! The Reviewer Comments Memo consolidates reviewer comments for the committee into one document. This allows you to create a PDF summary of the reviewers' comments so that they can be put up on a shared screen during a board meeting, copied into your Minutes, or published directly to a researcher. If you would like to enable the reviewer comments memo in the live site, or if you have any questions about the document, please contact IRBNet Support govsupport@irbnet.org.

REGISTRATION

VA Central IRB

CIRB researchers must register for an IRBNet account even if their affiliated site is not yet live in IRBNet. Once registered, notify the IRB Manager responsible for the project. The active study project shell will be transferred to the PI/LSI's account.

CIRB PROJECT SHELL

- For all active projects, use the newly migrated CIRB project shell for future submissions to the CIRB.
- If registered in IRBNet, the PI/LSI should have access to their CIRB project shell.
- The PI/LSI must grant access to the Study Coordinator, PM, and NSC using the sharing function in order for the study team to have access and work on submissions.

YOU SPOKE, WE LISTENED, WHAT WE ARE DOING

IRBNet Topics

CIRB Active Project: Q&A

Concerns: Local Oversight / Duplication

- Local site may lose all visibility of current CIRB project as oversight falls under both the Central IRB and the users local committees.
- Project duplication may occur on projects that have already been submitted prior to the CIRB VAIRRS transition.

Solutions:

- IRBNet has surveyed each VAIRRS site to identify the research office users that require access to the CIRB submissions for their site. To date, only 25% of the sites have responded. Please contact your IRBNet Gatekeeper for access to the CIRB workspace.
- The CIRB and IRBNet are developing an SOP to reconcile records where the local copy has completed reviews which involves:
 - withdrawing the CIRB record with the no history
 - submitting the record with the local approvals to the CIRB
 - linking the record to the multi-site study in IRBNet
- The team will be addressing the issue on a site-by-site basis as this is a complicated process. Please contact the IRB manager responsible for your project or VAIRRS@VA.gov to discuss reconciling your duplicate project records.

TEAM SPOTLIGHT

The VAIRRS Program would like to acknowledge the following VAMCs for sharing their IRBNet training documents and videos:

- Stratton VAMC, Albany, NY
Gregory Goodale, Administrative Officer (AO) / Director of Operations
- Milwaukee VAMC, Carlos Marquez, Biomedical Engineer
- Washington, DC VAMC, Bona Yoon, IRB Administrator

A very special thank you is due to the VAIRRS Program Mentors! The mentors volunteer their time to assist transitioning VAIRRS sites with resolving process issues and questions.

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|---------------------------|--------------------------|
| Daniel Edwards | Nashville, TN |
| Amy Flowers | Columbia, SC |
| Gregory Goodale | Albany, NY |
| Luann Graves | White River Junction, VT |
| Heather Hall | Syracuse, NY |
| Jeannie Helton | Memphis, TN |
| Tiffani Lacasse | White River Junction, VT |
| Amy Lallier | Little Rock, AR |
| Sheri Lindsay | Chicago, IL |
| Charmain O'Brien | Nashville, TN |
| Jennifer Ordano | Hines, IL |
| Ixia Ortiz-Serrano | Orlando, FL |
| Joni Wagner | Little Rock, AR |

HELP DESK SUPPORT AND 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, first 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 next study event as soon as possible.*

LEARNING CORNER

VAIRRS Library Updates

The following library updates are posted to the VAIRRS SharePoint portal for review. The revised documents will be published within 14 days. Please review the changes and update your instructions accordingly.

- Local requirements section added to the R&DC and IRB Reviewer Checklists.
- PI name field added to all IRB Reviewer Checklists.
- IRB Information Sheet: Page – Subject Groups Information, 'N/A – Exempt Study' added as a response option for the Informed Consent question.
- Updated signature block field, where applicable, to support electronic signatures. Thanks to Laura Jones at the Mather VAMC for the suggestion.
- 7.3A Separate ICF – Updated page numbering and added version date.
- 7.16A Amendment Request Form – Updated ERDSP guidance.
- SRSS Personnel Form – Updated checkboxes. Thanks to Dawn Biddulph at the Lexington VAMC for drafting the revised version.

We are forming a focus group to discuss the potential of developing an enterprise Tissue Repository initial and CR form. Thanks to Susan Loess-Perez at the Jesse Brown VAMC for contributing sample forms. If you are interested, please email VAIRRS@va.gov.

The VAIRRS Change Control Board is forming a subcommittee of five field representatives. One subcommittee member will sit on the Board for a six-month term. If you are interested in joining the subcommittee, please email VAIRRS@va.gov.

CSP Webinars

Thank you to all CSP NSCs, PMs, and Study Coordinators that attended the March 31st and April 8th ORPP&E webinars, VA CIRB New Submission Platform. Topics included registration for an IRBNet account, IRBNet support for Central Teams, and information around access to packages.

If you would like to learn more, please visit the [ORPP&E Webinar Archive](#) to access a recording of the CSP webinar and other ORPP&E hosted webinars. To access the handout please link to [VHA ORPPE SharePoint](#).



Looking Ahead

- More on Macros: Automated Insight Report formatting
- TMS integration
- New VAIRRS webinars