VAIRRS at
VA Boston Healthcare System

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Overview of the VA Boston Healthcare System (VABHS) Research Program

Located on 3 campuses and 5 Outpatient Clinics

Jamaica Plain

West Roxbury

Brockton

Overview of the VABHS Research Program

- **Over 800 total studies**

- **Often the largest or second largest VA research program in the country**
  - Total FY21 was $127,438,533 (Largest VA Funded program)
  - FY 21 VERA Expenditures: $130,144,109 (#1 in VA)

- **Relatively small committee administrative staff for the size of the program**
  - 2 IRB administrators
  - 1 R&DC administrator
  - 1 IACUC administrator
  - 1 Safety/Biosafety administrator

- **Additional support personnel**
  - Regulatory person to help investigators with submissions
  - 2 AOs
  - 2 Deputy ACOS/R&D – 1 animal/bench and 1 HRPP

Overview of the VABHS Research Program

Affiliated with 2 local academic institutions:
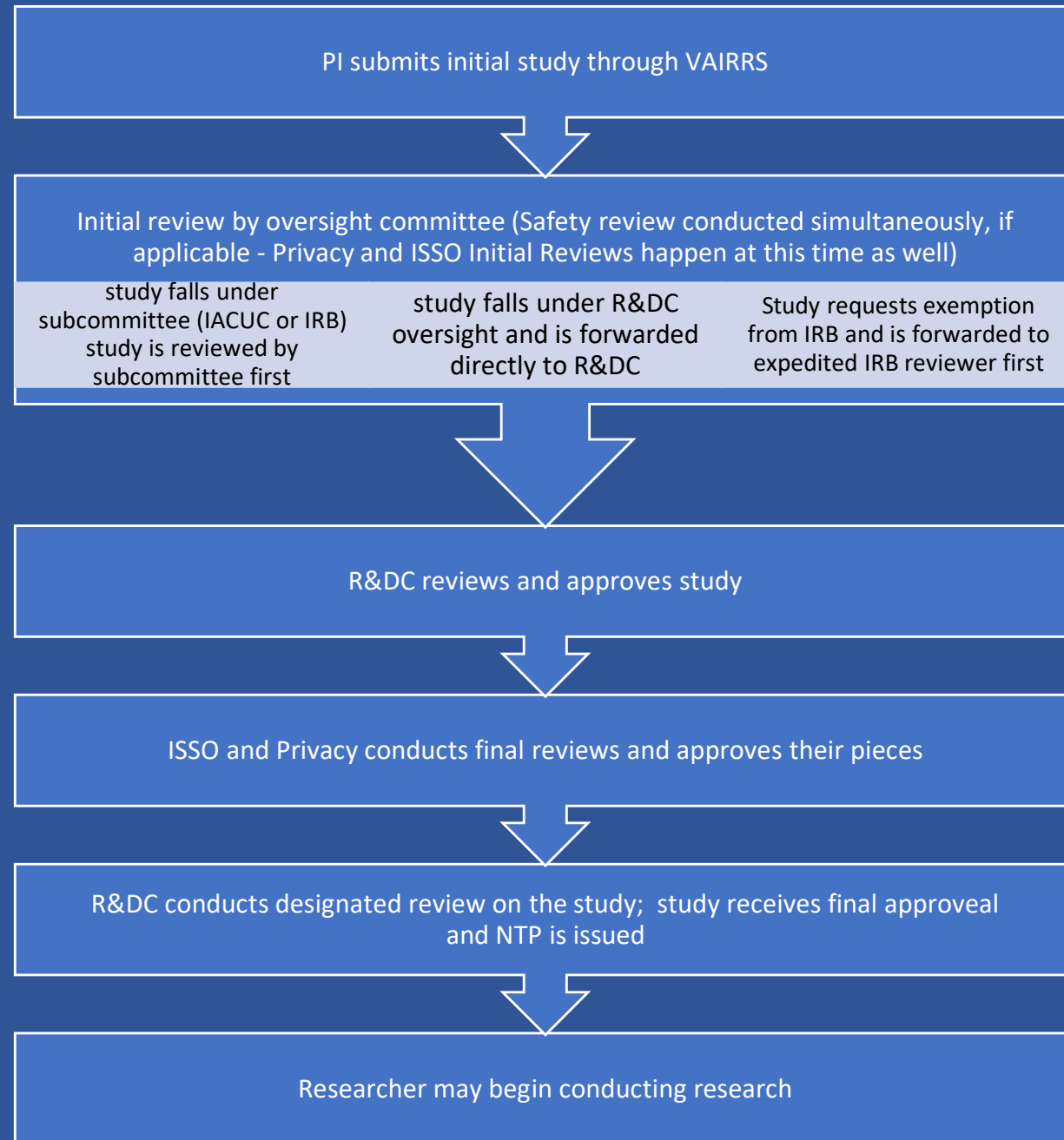- Boston University School of Medicine
- Harvard University Medical School

Affiliated with 7 other medical centers:
- Beth Israel Deaconess Medical Center
- Boston Medical Center
- Brigham and Women's Hospital
- Massachusetts Eye and Ear Infirmary
- Massachusetts General Hospital
- Tufts Medical Center
- Spaulding Rehabilitation Hospital

Reliance agreements with 7 other IRBs:
- VA Central IRB
- Advarra
- All of Us
- DOE ORISE
- NCI
- Western IRB
- CDC

Overview of Initial Submission Process

PI submits initial study through VAIRRS

Initial review by oversight committee (Safety review conducted simultaneously, if applicable - Privacy and ISSO Initial Reviews happen at this time as well)

| study falls under subcommittee (IACUC or IRB) study is reviewed by subcommittee first | study falls under R&DC oversight and is forwarded directly to R&DC | Study requests exemption from IRB and is forwarded to expedited IRB reviewer first |

R&DC reviews and approves study

ISSO and Privacy conducts final reviews and approves their pieces

R&DC conducts designated review on the study; study receives final approveal and NTP is issued

Researcher may begin conducting research

Receiving an Initial Submission

- Study team submits submission materials

- Submission goes to Research Administration (R-Admin)

- Administrator goes into R-Admin and tags each study for the appropriate committee of oversight

- Administrator forwards the package to the committee of oversight

- Once the package is routed to the committee of oversight, the administrator sends the original submission from the R-Admin space to a cornfield with the action of Forwarded
  - There is a cornfield for each committee

Some administrative challenges of using VAIRRS and VA Boston solutions:

- Resubmission of items during pre-review or committee review

- Minutes

Things VA Boston does to help investigators and research staff:

- What forms do I need?   What trainings do I need?
- Weekly office hours
- Posted local training sessions and VAIRRS energizers to local shared drive
- Send out newsletters

VAIRRS and ORO combined program review:

- Use tags!

Administrative challenges of using VAIRRS and VA Boston solutions

- Resubmission of changes required during pre-review, committee review or for PO/ISSO review

- Minutes

Changes required during Pre-Review

- The committee administrator does a pre-review

- If changes are needed the administrator unlocks the package and communicates with the study team regarding what is needed to forward the package to the committee for review

- Study team makes necessary corrections/additions, etc. then locks the package

- The process is repeated until all documents are correct and ready for full review

- The package is added to the next agenda, or a designated reviewer is notified to review the package

Changes required <u>after being reviewed by committee</u>

- The committee administrator downloads all the files from the package that was reviewed by the committee

- These files are placed into a zip file and uploaded into the reviewer comments, thus keeping a copy of the reviewed materials within the VAIRRS system

- The package is then unlocked so that the study team can make the requested changes/additions, etc.

- The package is locked

- The package is placed on the next agenda, or a designated reviewer is notified to review the package

Example of why we work within the same package

Review Details: | Add Another Agenda Date |

Agenda		Review Type		Action	Effective Date	Expiration Date	Report Due	
▼ 10/18/2021 01:00 PM	📄	Full Committee Review	📝	Deferred	10/18/2021	12/22/2021		✕
▼ 12/06/2021 01:00 PM	📄	Full Committee Review	📝	Deferred	12/06/2021	12/22/2021		✕
▼ 12/20/2021 01:00 PM	📄	Full Committee Review	📝	Tabled without Action	12/20/2021	12/22/2022		✕
▼ 01/10/2022 01:00 PM	📄	Full Committee Review	📝	Deferred	01/10/2022	12/22/2022		✕
▼ 02/28/2022 01:00 PM	📄	Full Committee Review	📝	Approved with Conditions	02/28/2022	12/22/2022	03/28/2022	✕
▼ Unassigned		▼ Unassigned	📝	Pending Review				✕

Click on the paper and pencil icon for each action to see the minutes from the meeting where it was reviewed

Changes required for Initial submissions
after conditional approval by R&DC contingent on ISSO and PO review

- If ISSO or PO changes are minor and do not affect participant-facing documents or participant protection:

  - Documents backed up by R&DC administrator and package unlocked

  - Once updated documents are uploaded, the ISSO/PO reviews/approves

  - During final designated review by R&DC chair all modified documents are reviewed and documented

Challenges related to Minutes

Solution for Challenge of Minutes Tracking

- Created a minutes agenda project that is shared amongst all committees

- All administrators are listed as study staff so they have access to all the minutes

Solution for Challenge of Minutes Tracking

- Project History

  - Can view all minutes and know exactly...

    - Where certain meeting minutes are

    - Which minutes are corrected from a specific meeting

    - If they have been approved yet

Ways We Helped Researchers with VAIRRS when Boston first went Live

- We posted all the VAIRRS Energizers on our Boston Research SharePoint site

- Conducted several live remote trainings – one of the trainings was recorded and posted on the Research SharePoint site

- Created, sent out and posted Tips and Reminders and FAQs

Ways We Continue to Help Researchers with VAIRRS

- Weekly "Open Office Hours" – 2 hours per week during which all committee administrators are on Teams – can share screens and can go into private rooms to go over specific submissions

- Created a spreadsheet for each library in VAIRRS of what forms from the library are needed for each type of submission

- Created a spreadsheet of what trainings are needed for Human Research Studies

- Created a local CIRB Guidebook with requirements and processes

- Every month or two send out an *HRPP Newsletter* of changes, reminders, and helpful tips

- When appropriate send out a *VAIRRS Newsletter* of changes, reminders, and helpful tips

- Created a position for a person to help researchers with preparing submissions

What Forms Do I need? - IRB

Forms	Initial submission (non-Exempt)	Annual Continuing Review	Amendment	Serious Adverse Event or Unanticipated Problem involving Risk to Subject or Others	Protocol Deviation/Self-identified non-compliance	Study closure
🟢 = Required 🔶 = may be necessary						
Abstract		🟢				🟢
Amendment Request			🟢	🔶	🔶	
Amendment Request - Personnel Required only if changing PI or adding/removing investigator(s) or study personnel named in approved documents			🔶			
Brief Screening Agreement for Recruitment template	🔶		🔶			
Conflict of Interest (FCOI OGE Form 450 Alternative-VA) Send via encrypted email to committee administrator. DO NOT UPLOAD IN VAIRRS	🟢	🟢				
Consent for Picture or Voice	🔶		🔶			
Continuing Review		🟢				
Data Management Access Plan (DMAP)	🟢		🔶			🟢
	🔶		🔶			

What Forms Do I need? - Determinations

Form	Status	
Service Impact Form	🔶	
VAEDA- Determination Request Complete the VAEDA form at https://vhacdwdwhvda01.vha.med.va.gov/vaeda/ Uploade VAEDA Determination in VAIRRS	🟢	
NON-VAIRRS FORMS REQUIRED FOR SUBMSSIONS:		
*Cover Memo - no template in library but please include a cover memo for all Initial submissions, amendments and re-submission of deferred items	🟢	
Budget	🟢	
Full grant	🟢	
Be sure most current Trainings are uploaded in VAIRRS for all Intial and Continuing Review packages	🟢	
SOPs for Repository (see VHA Handbook 1200.12)		

Tips of What Administrators have Developed to Help with VAIRRS

- Created "blurbs"
  - Standardized instructions for most common mistakes to use in unlock messages
  - Saves time for administrators and keeps instructions consistent
    <u>Example</u>:
    Please make sure that all study staff have been assigned VAIRRS access and that everyone's training certificates are uploaded into USER PROFILE

- IRB uses admin tags to keep up with what's still outstanding

- R&DC uses "fake" agendas to track what is outstanding

- Make use of "Review Complete" for post-meeting tracking

Ways VAIRRS can help with an ORO Combined Program Review (CPR)

- The CPR was new to us (October 2021)

- All encompassing review of the entire research program including IRB, R&DC, HRPP, IACUC, Safety, Privacy, Information Security, Police, etc.

- VAIRRS was very useful in being able to assign ORO reviewers to specific protocols

- Were able to use IRBNet reports to obtain some information - easily finding studies in each workspace

Ways VAIRRS can help with an ORO Combined Program Review (CPR)

- We had just started using VAIRRS about a year prior to the ORO CPR review

- VAIRRS was somewhat helpful, but much of what was requested was still in the old system (paper and scanned pdfs!)

    - We were having to look for documents in 2 systems

    - Should be more helpful to others who are fully transitioned to VAIRRS for a longer time prior to an ORO CPR

- Dashboards were not yet available at the time of our ORO CPR

Tag, tag, tag and then tag some more!

- As of now we have:
  - 55 tags for IRB
  - 55 tags for R&DC
  - 22 tags in Determinations space
  - 27 tags for IACUC
  - 20 tags for IBC
  - 36 tags for Safety
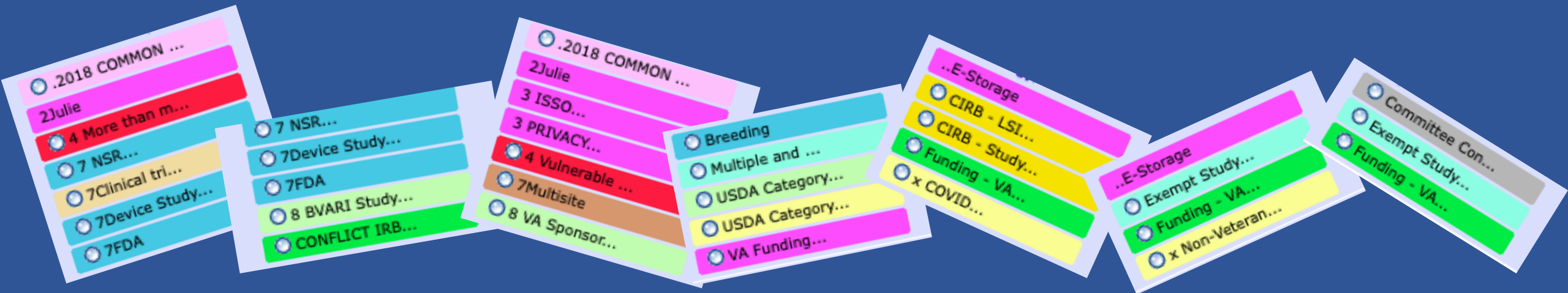
Advice for those who have not yet had an ORO CPR

Tag, tag, tag and then tag some more!

- Ended up backtracking and tagging all types of studies that were requested
- Tags are only as good as the tagging that is done

- Recommend using the Facility Director's Report and some of the ORO audit tools as a starting point for tagging studies
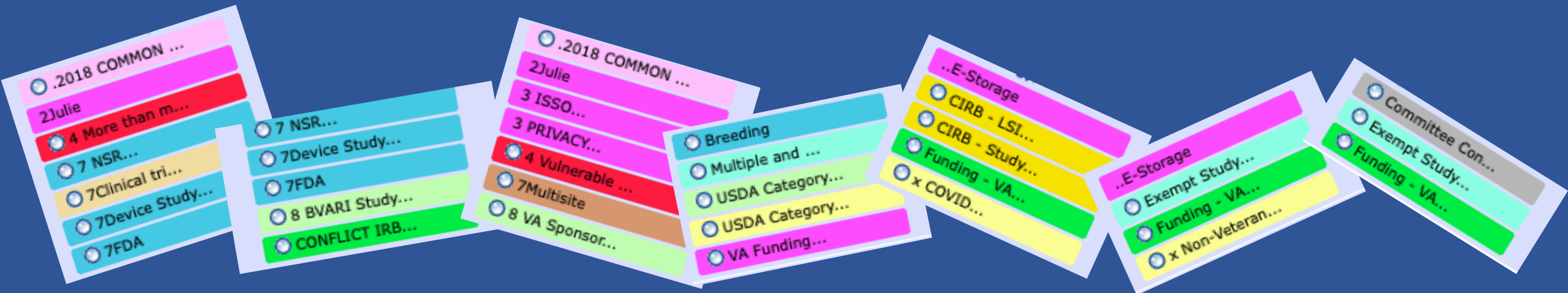
Questions?

Transition to VAIRRS
Successful Practices and Developing Solutions

NAVREF/ACOS Meeting
September 13, 2022

Angela Foster, Program Manager, Enterprise Research Data Systems
Protections, Policy, and Education
Office of Research and Development

VAIRRS
VA Innovation and Research Review System

- **The VA Innovation and Research Review System (VAIRRS) is VA's online submission and and review system, the enterprise instance of IRBNet.**

- VAIRRS is deployed at all VA medical centers with research programs and will provide an enterprise platform to support the management of research regulatory committees. As of July 2022, 106 sites have implemented VAIRRS.

- **VAIRRS Mission:** VAIRRS supports management of the research enterprise and processes of research-related stakeholders in VA.

- **VAIRRS Vision:** VAIRRS seeks to be the trusted review platform and data source for all research-related stakeholders.

DID YOU KNOW?

VAIRRS has over 32,000 registered users, more than 298,000 packages and more than 600,000 documents submitted into the system.

Choose VA

VA | U.S. Department of Veterans Affairs

Successful Practices - VAIRRS Strategic Advisory Council and Change Control Board

VAIRRS Strategic Advisory Council (VSAC)

The VSAC is an advisory group of field representatives that reviews quarterly initiatives of the VAIRRS program, relays feedback from users and serves as the voice of the field for consideration as VAIRRS makes decisions.

The primary goals of the VSAC are to (1) ensure end users' needs are being met and (2) guarantee strategic initiatives on the field are understood and considered prior to implementation.

The VSAC includes a group of 15 standing members, 2 nonvoting members and 2 ORD advisors. All representatives within the VSAC were selected from various roles within the VA research community, from administrative officers to investigators, and represent all sizes of research programs.

The VSAC meets quarterly, with a goal of reviewing upcoming quarterly initiatives. Most recently, the VSAC reviewed the VAIRRS Strategic Goals from FY22-FY24 and is currently weighing in on the programmatic revision of the VAIRRS mentor program.

VAIRRS by the Numbers

As of July 2022, the VAIRRS team has conducted 7 webinars. Recordings and webinar materials can be found [here](#).

To date, the VAIRRS team has responded to over 1,800 inbox inquiries.

The VAIRRS team has provided short- and long-term administrative to 6 facilities, with plans to expand site support as milestones are achieved.

Opportunities for Growth

Training Review

Improvements in Training include:

Through the VAIRRS Field Gap analysis, we identified a gap within our training resources that have been offered to the field. Although VAIRRS offers an abundance of training resources in its online learning library, users were having a hard time locating the right resources to meet their needs.

- Role based curriculum maps within the online learning library
- An extended library of Navigational Guides to serve as just-in-time training resources
- An improved VAIRRS Mentor Program to assist facilities that require advisory support from a subject matter expert within VA research
- Regular maintenance of our learning library and calendar
- Collection and dissemination of best practices from the field

External Conflict of Interest (COI) Review

In development:

- Process improvement and efficiency for 23,000+ VA researchers and administrators

- Harmonized processes and standards across VA

- Improved visibility, auditability, enforcement and oversight

How will it work?

- OGC-Approved 450 Alt VA Smart Form integrated into IRBNet

- Complete workflow support for investigators and VAMC COI administrators

- Secure visibility for research compliance boards and reviewers

- Comprehensive access control to protect private information

The Future of VAIRRS

The Future of VAIRRS

Revamped Mentor Program

- Structured framework for requesting and providing mentor services

- Paid mentor time

- Increase in number of mentors

- Matches based on specific needs of mentee site

Data Integrity

- Ongoing analysis of enterprise data set to identify data inconsistencies and level of completeness.

- Leverage findings to improve training and establish best practices

COI MODULE

- Fully integrated tool set within the IRBNet GovCloud Conflict of Interest solution

- Collaboration with Office of General Counsel (OGC)

- Electronic COI smart form

VAIRRS Dashboards

- Increased functionality for Field Dashboard

- Support for ORD Actively Managed Portfolios (AMP) and other stakeholders

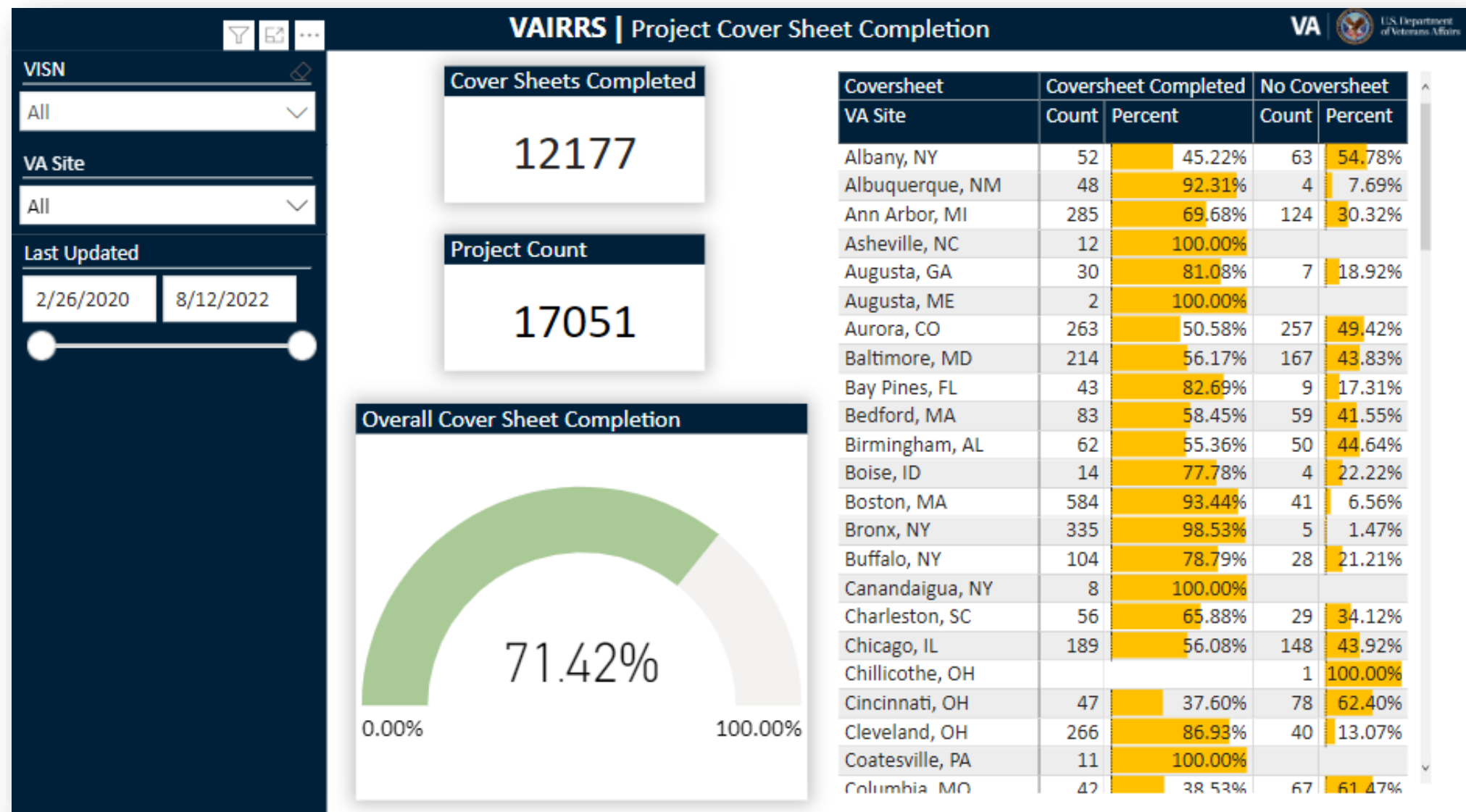# VAIRRS Dashboards – Transforming Data into Knowledge

VAIRRS CRADO Dashboard
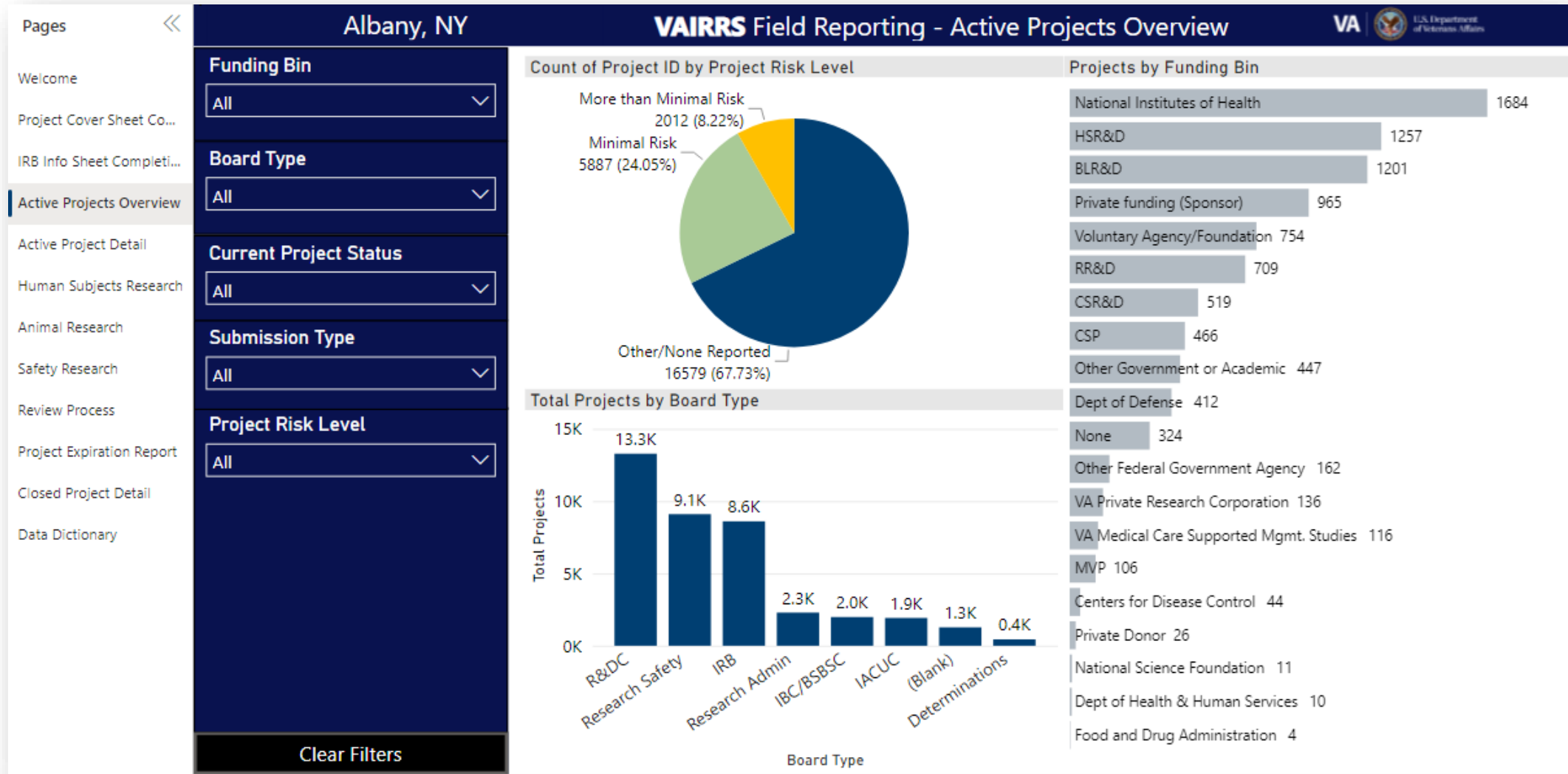

VAIRRS | Project Cover Sheet Completion

Cover Sheets Completed

12177

Project Count

17051

Overall Cover Sheet Completion

71.42%

0.00% — 100.00%

VISN: All
VA Site: All
Last Updated: 2/26/2020 – 8/12/2022

Coversheet	Coversheet Completed		No Coversheet	
VA Site	Count	Percent	Count	Percent
Albany, NY	52	45.22%	63	54.78%
Albuquerque, NM	48	92.31%	4	7.69%
Ann Arbor, MI	285	69.68%	124	30.32%
Asheville, NC	12	100.00%		
Augusta, GA	30	81.08%	7	18.92%
Augusta, ME	2	100.00%		
Aurora, CO	263	50.58%	257	49.42%
Baltimore, MD	214	56.17%	167	43.83%
Bay Pines, FL	43	82.69%	9	17.31%
Bedford, MA	83	58.45%	59	41.55%
Birmingham, AL	62	55.36%	50	44.64%
Boise, ID	14	77.78%	4	22.22%
Boston, MA	584	93.44%	41	6.56%
Bronx, NY	335	98.53%	5	1.47%
Buffalo, NY	104	78.79%	28	21.21%
Canandaigua, NY	8	100.00%		
Charleston, SC	56	65.88%	29	34.12%
Chicago, IL	189	56.08%	148	43.92%
Chillicothe, OH			1	100.00%
Cincinnati, OH	47	37.60%	78	62.40%
Cleveland, OH	266	86.93%	40	13.07%
Coatesville, PA	11	100.00%		
Columbia, MO	42	38.53%	67	61.47%

VAIRRS Field Dashboard

VAIRRS Resources

❑ Recorded training videos are available on the VAIRRS SharePoint portal. The training videos are categorized by role (e.g., researcher, administrator, committee member perspectives).

❑ Training energizers are available on the VAIRRS SharePoint portal. The energizers, which serve as guides for the end-user, are also categorized by role.

❑ Answers to Frequently Asked Questions (FAQs) about VAIRRS are available on the VAIRRS website.

❑ The VAIRRS Newsletter is published bi-monthly. A VAIRRS Program Update is published on the alternative months. Any user can subscribe to the publications.

❑ VAIRRS Website: https://www.research.va.gov/programs/orppe/vairrs/

❑ VAIRRS SharePoint Portal: https://dvagov.sharepoint.com/:f:/r/sites/VHAORPPE/VAIRRS/

❑ Subscribe here: https://public.govdelivery.com/accounts/USVHA/subscriber/new?topic_id=USVHA_1952

❑ Contact VAIRRS Program: VAIRRS@VA.gov

Questions?