H7: A Dialogue With the Department of Veteran Affairs (VA)

December 6

1:45-2:45 PM ET

C. Karen Jeans, PhD, CCRN, CIP
Molly Klote, MD, CIP
Kristina Borror, PhD
Veterans Health Administration

PRIM&R

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C. Karen Jeans, PhD, CCRN, CIP

Charlotte K. Jeans, PhD, CCRN, CIP is the Director for Regulatory Affairs for the Office of Research Protections, Policy, and Education in the Office of Research and Development (ORD) at the Department of Veterans Affairs (VA) Veterans Health Administration (VHA). In her current VA position, she has primary responsibility for development of human subjects protections policies in VA research and facilitation of educational programs for VA researchers. She has served in multiple regulatory and education roles related to human subjects protections in VA for 20 years. She also maintains a position as an ICU nurse practitioner at the University of Arkansas for Medical Sciences (UAMS). Her current research focuses on development of a validation model for evaluating human research protection programs.

Molly Klote, MD, CIP

Dr. Molly Klote is Deputy Chief Research and Development Officer (CRADO) for Enterprise Support for the VHA Office of Research and Development. Responsible for VHA human subjects research policy, education, and support to the VA central institutional review board (IRB). Prior to this, as an active duty Army Colonel with 30 years of service, she oversaw all human research policy and education for the United States Army through the office of the Army Surgeon General. She has 10 years of expanding responsibilities over research and human subjects protection policy. She is a leader in effective, efficient, and compliant policy and education in human subjects research. Dr. Klote was awarded the Legion of Merit, the Defense Meritorious Service Medal, the Parachutist Badge, and the Expert Field Medical Badge.

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Kristina Borror, PhD

Dr. Kristina Borror is Director, Human Research Protections for the Office of Research Oversight (ORO) at the Veterans Health Administration (VHA), where she leads the Human Research Protections (HRP) Workgroup. ORO's mission is to promote the responsible conduct of Department of Veterans Affairs (VA) research for the protection of Veterans and others who volunteer in VA research, and for the benefit of all Veterans whose health and well-being are improved by the discoveries made through a sound and ethically grounded VA research program. Prior to coming to ORO, Dr. Borror was Director of Compliance Oversight at the Office for Human Research Protections, within the Department of Health and Human Services.

Disclosure: C. Karen Jeans

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

VHA Office of Research and Development, Director of Regulatory Affairs, ORPP&E

Disclosure: Molly Klote

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

VHA Office of Research and Development, Deputy Chief Research and Development Officer (CRADO) for Enterprise Support

PRIM&R PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

Disclosure: Kristina Borror

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

VHA Office of Research Oversight, Director, Human Research Protections

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Learning Objectives

1. Describe VA research initiatives, including the Office of Research and Development's (ORD) reorganization and enterprise-wide approach for supporting VA research facilities.
    - Restructuring of ORD Enterprise Update
    - Policy initiatives: current and future
    - Tools/technologies to facilitate VA Facility research programs
2. Identify key issues and solutions from both ORD and the Office of Research Oversight (ORO) associated with multi-site research activities
    - Successful implementation of utilizing external IRBs

ORD Initiative: Reorganization of ORD

Why is ORD Reorganizing?

- In the past 20 years, ORD has attempted two reorganizations of this complex national program office to meet changing needs of ORD and the Agency. Both of those attempts stalled and stopped.
- This third attempt is proceeding.
- Numerous entities within and outside ORD were consulted prior to the initiation of the formal planning phase, which began over a year ago.

The Why: The five values of the Research Enterprise

Unique Value Proposition: Leverage our position as the only Federal research entity devoted to Veterans' interests and being embedded in the nation's largest integrated healthcare system

Operational Excellence: Operates with streamlined processes, effective collaboration, high-quality customer service, and appropriate resources

Engaged People: Composed of a vibrant, diverse research community united in our mission to improve Veterans' well-being through research

Integration: Cultivate relationships and partnerships that accelerate our ability to achieve our mission

Real-world Outcomes: Define our success in terms of tangible real-world improvements in Veterans' health and well-being

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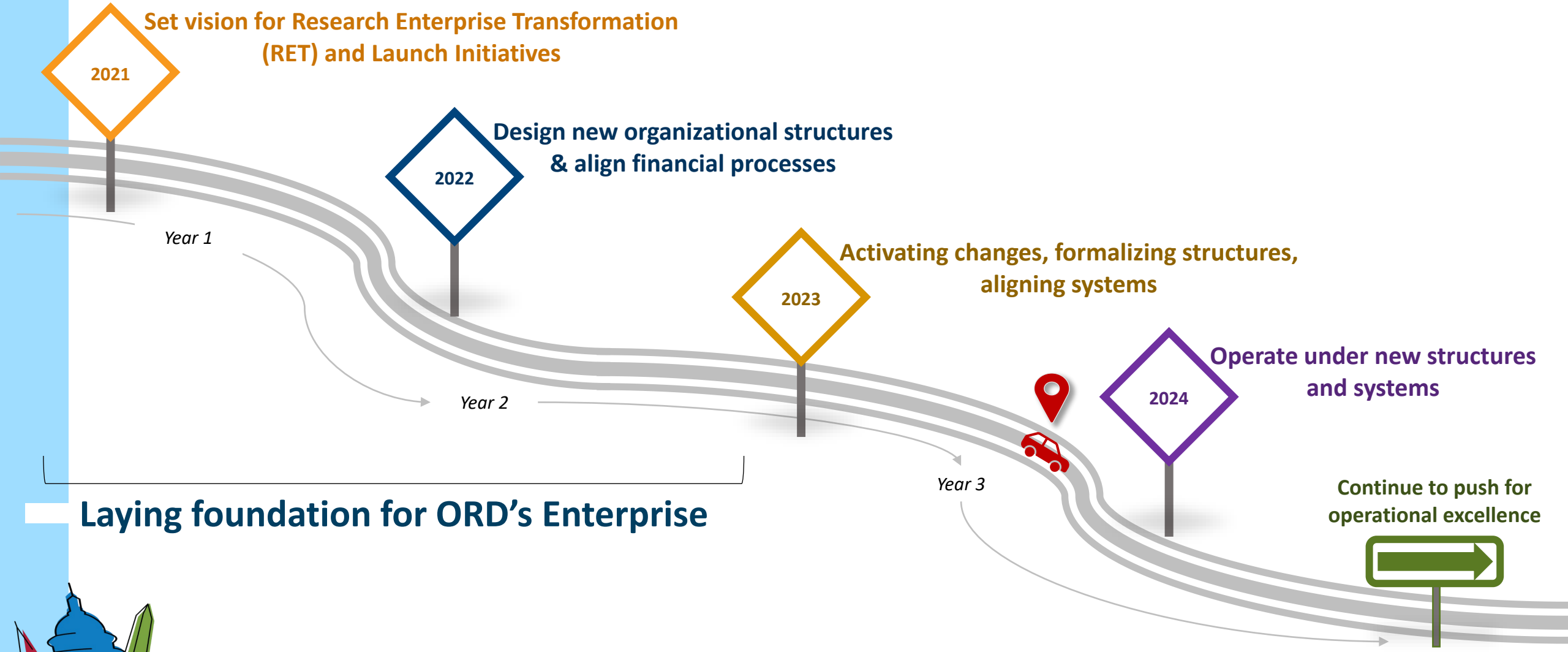
In the last 2 years, the foundation for the future of ORD's Research Enterprise was built



Laying foundation for ORD's Enterprise

The How: The Research Enterprise Transformation begins FY24 with three* initiatives whose goals will aid in achieving the Priorities

FY24 Initiatives' goals and how those goals will be achieved…

Investigators, Scientific Review, and Management (ISRM)

Finalize the transition from research Services to Portfolios in the new ISRM structure, including staffing

- **Hire new ISRM and portfolio leadership**
- **Create ISRM operational SOPs**
- **Launch and operationalize Portfolios**

Organizational Alignment

Strengthen and staff the new ORD organizational structure to better serve the Enterprise

- **Build out org structures and develop all new positions**
- **Scale the enterprise functions from the centers to central office**
- **Align and document staff duties**

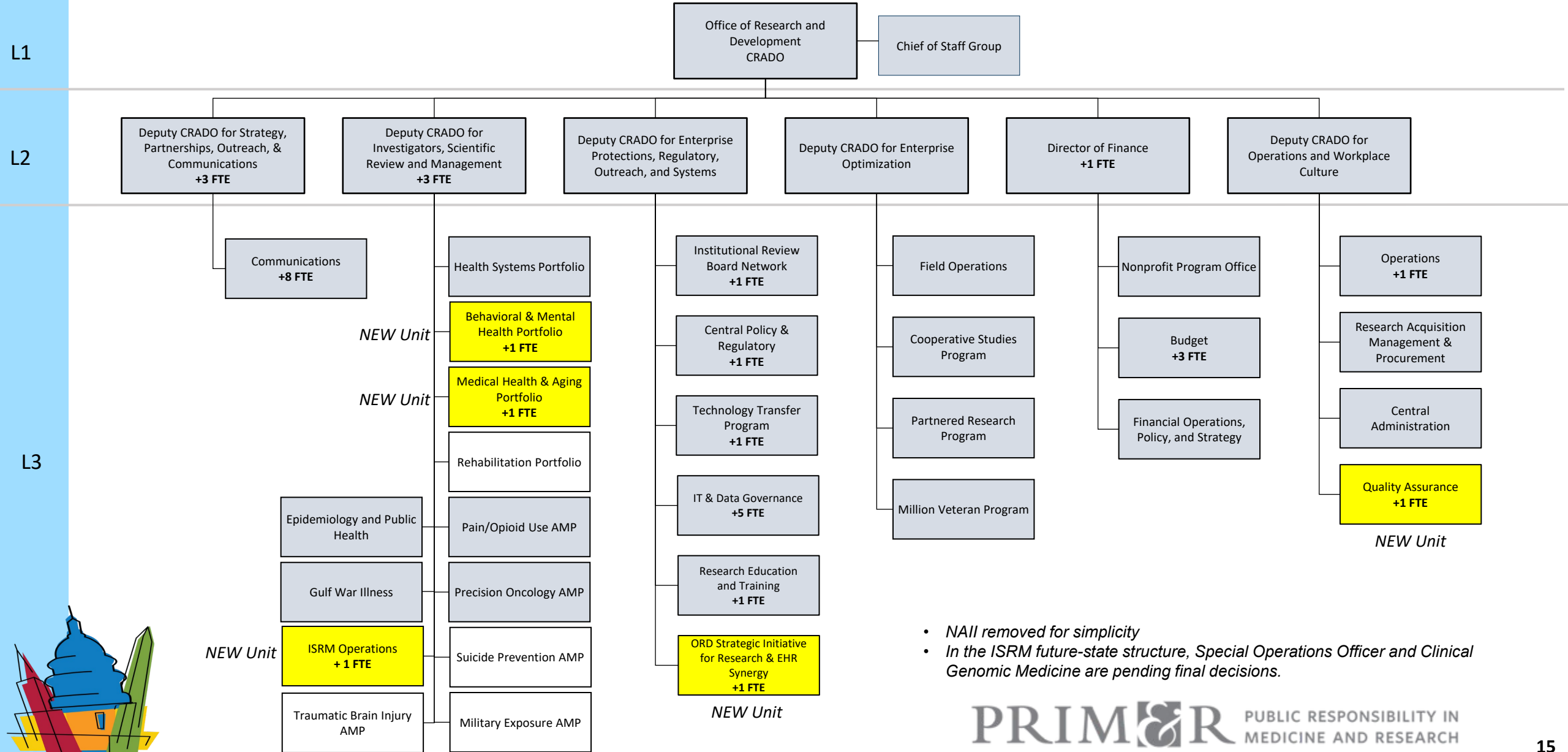
Finance Process

Finalize and implement One Stream software, align Budgeting Operating Plan with new ORD and Portfolio structure, and improve processes and training for the field

- **Implement new processes and training curriculum for field staff and make resources available**
- **Align new budget operating plans with new structure**

*Additional initiatives are to continue and stand up in the New Year

Interim Phase 3 + Future-State ORD Organization



- *NAII removed for simplicity*
- *In the ISRM future-state structure, Special Operations Officer and Clinical Genomic Medicine are pending final decisions.*

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How Will ORD's Reorganization Benefit VA Facility Research Offices and VA Investigators?

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Benefits to VA Facility Research Offices and VA Investigators

- Shift to an integrated model that improves collaboration and increases effectiveness of VA Research through
  - Central coordination of key business functions related to field research operations;
  - Standardization of processes to reduce variability across VA research facilities; and
  - Reduction of unnecessary redundant processes that contributes to loss of productivity and creates confusion and frustration.

What is the Intended Result of ORD's Enterprise Transformation?

ORD's intended result is to shift to an integrated model that improves collaboration and increases effectiveness of VA Research by ensuring that the appropriate resources are available to complete our research mission.

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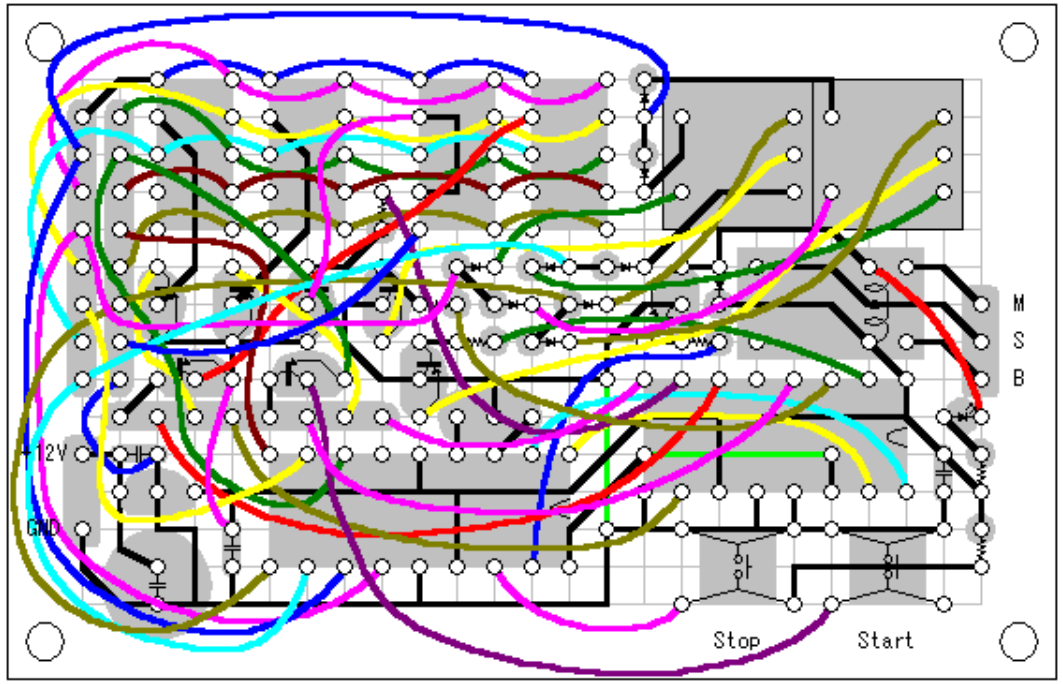
Policy Updates: Revisions to Existing Policies and New Directives

Creating and Revising Policy is Complicated



There is no such thing as simply putting in a statement in a policy and obtaining approval in less than three months based upon ORD's experiences.

ORD Policies Currently in Active Revision:

VHA Directive 1200.05(3): Requirements for the Protection of Human Subjects in Research

- Technical amendments

VHA Directive 1200.02(1): Research Business Operations

- Major revision for recertification

VHA Directive 1200.17: VA Nonprofit Research and Education Corporations Authorized b Title 38 (U.S.C_. Sections 7361 Through 7366

- Major revision for recertification

Technical Amendment #3 to VHA Directive 1200.05(3): Exclusion of the Paperwork Reduction Act (PRA) for VHA Research

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Exclusion of VHA Research from the Paperwork Reduction Act

- The Cleland-Dole Act was signed into law on December 29, 2022, under Division U of the Consolidated Appropriations Act of 2023 (P.L. 117-328).
- Section 181 of the Cleland-Dole Act specifies that the PRA "...shall not apply to the voluntary collection of information during the conduct of research by the Veterans Health Administration, including the Office of Research and Development, or individuals or entities affiliated with the Veterans Health Administration."
- VHA Directive 1200.05(3) issued on July 13, 2023 created the implementing policy with associated published guidance.
- ORD has published a guidance document (July 19, 2023) titled, "ORD Guidance Document: Applicability of the Exclusion of VHA Research From the Paperwork Reduction Act" located at Applicability-of-the-Exclusion-of-VHA-Research-from-the-PRA.pdf (va.gov) and in Find Pro.

What About VHA Handbook 1200.12: Use of Data and Data Repositories in VHA Research?

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New Policies

- VHA Directive XX: Research Financial Conflict of Interest
- VHA Notice XX: Outside Compensation for Performance of VA Research

Implementation of ORD Enterprise Initiatives to Facilitate Research Programs

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COMING SOON

Gathering Pre-Study Information

- Both ORD funded and through NPCs
  - *New*Data Access Management Plan
    - Revisions to get specific on retention and storage
    - Registry/Repository
    - Size of files
  - IT dollar needs
  - Software and Hardware needs
    - Information security implications
  - Research Scientific Computing Devices
  - Analytic computing needs
    - On premise vs cloud
  - Conflict of commitment

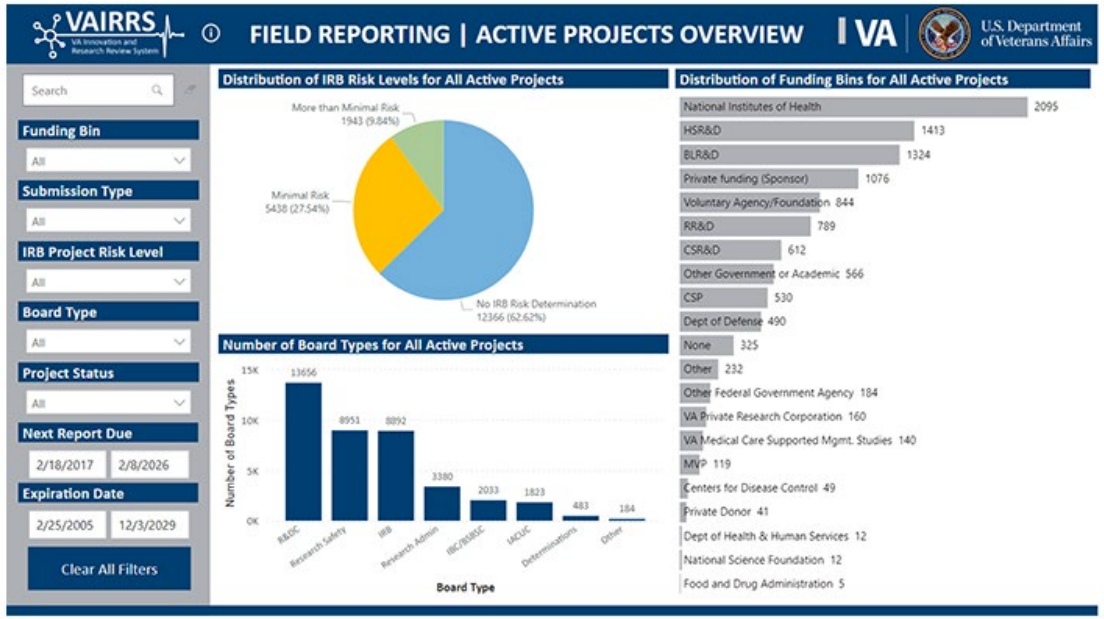
The VA Innovation and Research Review System (VAIRRS) provides researchers with greater visibility and understanding of enterprise studies

Research Dashboards

National Researcher Dashboard

Visual tool to search the national VAIRRS dataset for active research projects and to help connect researchers working on similar topics.

Field Staff Dashboard



Facility-level dashboard and analysis to support management and understanding of local research programs and to help providers identify studies for their patients.

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VA Box.com

- Conventional Box.com and Dropbox are not permitted due to security issues.
- VA has set up a secure VABox.com and is available for use, specifically for larger data.
- VABox.com does external sharing.
- Can upload files as large as 150 GB.
- Files in VABox will be retained for seven years after use.
- Cannot use VA Box to bypass IRB, ISSO or PO rules.

Home - VA Box.com Requests (sharepoint.com)

DocuSign, Qualtrics and Redcap

DocuSign is available for Research (electronic signature capture)

DocuSign Requests - Home (sharepoint.com)

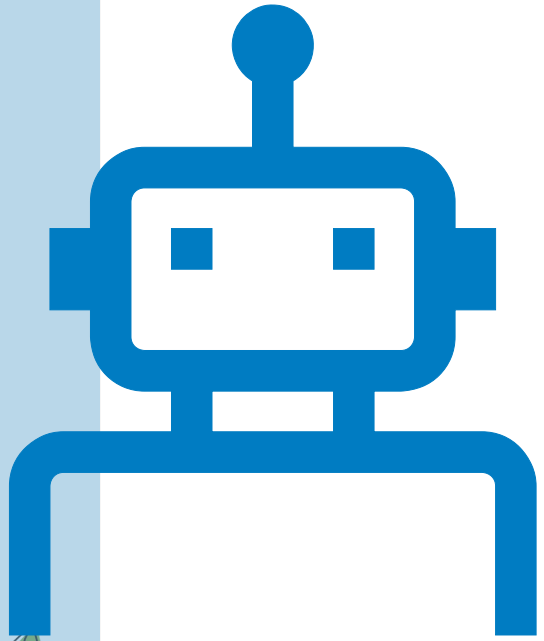
Qualtrics VHA ORD Qualtrics Portal - Home (sharepoint.com)

Survey Software
Licenses available

VA Redcap

Clinical Trials Software
Now can have PII/PHI
Now has external use and public face via url

VA Electronic Determination Aid (VAEDA)



What is VAEDA?

The VA Electronic Determination Aid (VAEDA) is a decision support tool created to:

- **Increase standardization** in regulatory preliminary determinations for proposed research, quality improvement, program evaluation, and innovation projects.
- **Decrease** administrative burden on research offices and research regulatory review committees.

The VAEDA tool intends to harmonize and standardize project (research/not research) classifications for all VA facilities. However, its use is voluntary by VA Facilities and VA Program offices.

NOTE: Activities that are known to be research (e.g., clinical trials, animal studies) or not research (e.g., case report of a single patient) should not go through the VAEDA process by the project owner.

VAEDA
VA Electronic Determination Aid

U.S. Department of Veterans Affairs

VAEDA STATISTICS

As of November 27, 2023

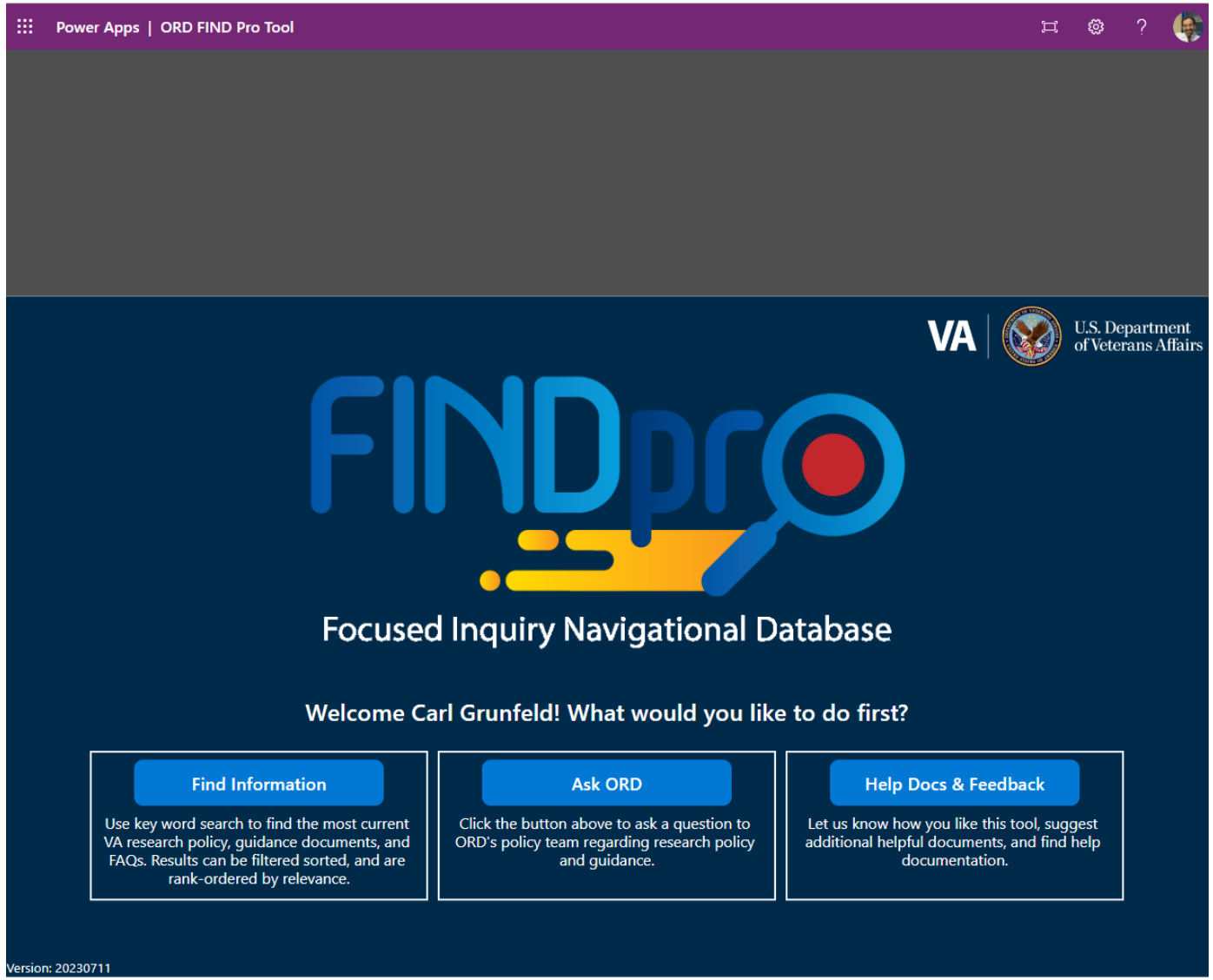
- How many total determinations – ***2022***
  - How many not research determinations – ***842***
  - How many research determinations – ***911***
    - How many exempt determinations – ***269***
- Estimated total time saved: ***> 2,000 person hours***
- Estimated frustration saved: **PRICELESS!**

VAEDA
VA Electronic Determination Aid

U.S. Department of Veterans Affairs

FINDpro

- Allows you to find resources
- Research Policy
- Guidance Documents
- FAQ
- Type in word(s) to find
- Can also submit queries
- ORD FIND Pro Tool – PowerApps



Summary

- The changing needs of our Veterans and VA research demand innovative approaches.
- VA research must continue to evolve to meet those demands.
- ORD is committed to working with the VA research community to successfully create and implement an enterprise model

Contact Information

- Dr. Molly Klote: molly.klote@va.gov
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Please send regulatory questions to the FindPro “Ask ORD” site located at FIND Pro (va.gov).

References

- Box (VA): Home - VA Box.com Requests (sharepoint.com)
- DocuSign (VA): DocuSign Requests - Home (sharepoint.com)
- FIND Pro (va.gov)
- ORD Guidance Document: Applicability of the Exclusion of VHA Research From the Paperwork Reduction Act"(July 19, 2023)
- Qualtrics VHA ORD Qualtrics Portal - Home (sharepoint.com)
- VAEDA Homepage: https://www.research.va.gov/programs/orppe/vaeda.cfm
- VAEDA Tool: VINCI VAEDA – Home
- VHA Directive 1200.01(1): Research and Development Committee at VHA Publications
- VHA Directive 1200.05(3): Requirements for the Protection of Human Subjects in Research at VHA Publications

ORO Organizational Chart

Key Responsibilities in SOPs for working with external IRBs

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SOPs for working with external IRBs – Responsibilities of External IRB

- How does VA get access to the IRB SOPs?
- What submission/tracking system is used?
- Does the IRB Platform permit direct access by the VA Investigator?
- Does the IRB provide exempt determinations?
- How will VA specific language be incorporated into the Informed Consent Document and HIPAA Authorization?
- What are the IRB reporting requirements?

SOPs for working with external IRBs --Responsibilities of the Institutional Official (Facility Director)

- Signs the Signatory Institution Authorization Agreement/MOU.
- Appoints, in writing, the Signatory Institution Primary Contact(s) if required by the IRB.
- Ensures the facility complies with review and reporting of any reportable events to the IRB as required by VA policy to ORO and external federal agencies or oversight bodies.
- Updates and signs the FWA and VA Addendum.

SOPs for working with external IRBs -- Responsibilities of the R&D Office

- Complete and submit the worksheets/forms required by the IRB.
- Ensures a process in place to allow ISSO and PO access to study materials for project review prior to study submission.
- Manage evaluation of financial conflict of interest, ensures current training and qualification.
- Provide tracking for protocols and correspondence.
- Promptly update SOPs for changes in the IRB requirements and inform researchers.
- Maintain current FWA and access to IRB Rosters.

SOPs for working with external IRBs -- Responsibilities of the R&D Committee

- Ensures that the investigator and study personnel have the resources, experience and training needed to conduct the research.
- Ensure ISSO and PO review is complete before the study is approved.
- Ensures that the external IRB is provided with current state law requirements.
- Reviews all determinations by the external IRB of any reported incidents or unanticipated problems and/or serious or continuing noncompliance for acceptance or further action.
- Determine if non-Veterans should be enrolled in a study at their facility.
- Conducts an annual review of the IRB and submits to the VA MFD.

SOP for working with external IRBs -- Responsibilities of the Investigator

- Ensure that study staff have been appropriately credentialed and privileged as applicable and have completed all required VA training.
- Comply with all IRB and Facility requirements related to the protection of human subjects and adhere to responsibilities detailed in VHA Directive 1200.05 investigator section.
- Maintain a regulatory file for each study under IRB purview as per local institution and sponsor policy.
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects.
- Report apparent UPIRTSOs, apparent S/C noncompliance, any termination or suspension of research; and privacy or information security incidents related to VA research.

Elements of an effective SOP for working with external IRBs --Responsibilities of the RCO

- Conduct audits to ensure compliance with applicable federal, VA and local policy.
- Report any apparent UPIRTSO and/or apparent S/C noncompliance.
- Submit audit reports to the R&D Committee and IRB.
- Determine the method to be used by the RCO to report to the IRB, i.e., obtain an IRB account or report through the Investigator or IRB primary contact

Flexibilities for Reporting Requirements

- If the procedures of a non-VA operated committee differ from, or the timeframes exceed those of, VHA Directive 1058.01, the medical facility Director must consult with ORD and ORO as to the adequacy of those procedures.
- Consultation with ORO and ORD should occur when requesting formal permission to rely upon the non-VA IRB, or upon learning that a non-VA RRC's SOPs have changed such that the procedures and/or timeframes no longer comport with VHA Directive 1058.01.
- For example, the NCI Central IRB and the NIH All of Us IRBs do not accept RCO audit reports with no findings.

1058.01 § 5.g.(2)

Questions that ORO has received about using external IRBs

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Question 1

- **Q: Do the external commercial IRB MOU's have a standard requirement for minutes to be shared with local RDCs for the annual evaluation by the R&DC?**
- A:While the external commercial IRB MOUs executed between the VA Facility and the commercial IRBs do not contain specific statements regarding access to IRB minutes, ORD-approved commercial IRBs are required to enter into a master service agreement in which the requirements apply to any VA Facility entering into a reliance agreement with the applicable ORD-approved commercial IRB. The master service agreement executed with any ORD-approved commercial IRB explicitly requires that ". . . applicable IRB meeting minutes will be delivered to the Institutions within 10 business days of written request to the IRB." Individual VA Facility research offices can request the minutes. ORD requests to be copied if possible. If there are issues with obtaining IRB minutes, please inform ORD.

Question 2

- **Q: VA medical facility personnel identify that a Principal Investigator is using commercial IRB-approved consent forms that appear to be missing some of the elements required by the Common Rule. For example, key information is not provided up front, information is missing about compensation for injury, etc. What is the local site's responsibility when this is identified?**
- A: It isn't the role of the R&D Committee to do a re-review of an IRB-approved consent form, but if something is missing and/or there is a question, it needs to be sent to the commercial IRB. The IRBs have been provided the VA specific requirements, so if there is something missing, that needs to be brought to their attention. Also, were these required by national policy or were only locally?

Question 3

- **Q: My facility has a protocol that is subject to the single IRB review requirement. How do facility personnel determine whether or not the study was reviewed by a sIRB or that an exception to the sIRB requirement has been granted?**
- A: ORD maintains a list of exceptions granted by ORD. You should contact the research team or the liaison for the external IRB at your facility.

Contact Information

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Office of Research Oversight Home (va.gov)

Questions?

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