

VA



U.S. Department
of Veterans Affairs

Office of Research Oversight (10R)

Operational Transformation

February 16, 2016

Effective March 1, 2016



Current ORO Structure & Function

Significant Accomplishments Since ORO Created:

- Dramatic Reductions in Noncompliance
- Dramatic Improvements in Research Oversight

Frequent ORO Findings 2003-2005:

- Incomplete Research Pharmacy Files
- IRB noncompliance with fundamental VA requirements on expedited reviews and waivers of informed consent
- No procedures for reporting SAEs, UPRs, Noncompliance suspensions
- Noncompliance with FDA regulations
- Committee Chairs and members lack knowledge of regulations, policy requirements
- Protocol approvals without quorum, email protocol approvals
- Informed consents lack required elements
- Failure to obtain written informed consent
- Failure to obtain R&DC and IRB approvals prior to initiating research
- Failure to maintain records
- Incomplete committee minutes and protocol files



Why Is ORO Changing?

Why “Transform” ORO??

- 1. Expanded Mission** - Impossible to conduct intensive review in **all five subject matter areas** on a reasonable, recurring schedule
 - R&D Oversight and Research Administration , Human Research, Research Safety and Security, Laboratory Animal Welfare, Research Information Security
- 2. Expanded Mission** – Identify and address **system-wide risks** in addition to facility noncompliance
- 3. Fiscal and Political Realities** require **increased value** in the face of **decreasing resources**
 - Current Routine Reviews require **significant time, energy, and resources** but findings are increasingly limited to less serious regulatory noncompliance
 - Maintain current compliance levels while increasing focus and priority on most significant vulnerabilities



ORO Transformation Strategy & Goals

TRANSFORMATIONAL STRATEGY:

Identify and target **facility-specific** and **system-wide** research compliance vulnerabilities to strengthen protections for Veterans and other VA research subjects, research investigators, and research animals. Prioritize ORO operations based on **risk**.

SPECIFIC GOALS:

1. Conduct a standardized **REVIEW** of each facility's **INFRASTRUCTURE** for protecting human subjects, investigators, and animals in research at least every fifth year.
2. Achieve more efficient resource utilization by prioritizing focused, subject matter reviews and technical assistance activities through **ON-GOING RISK ASSESSMENT**.
3. Achieve more standardized oversight of research programs and increase ability to identify emerging **SYSTEMIC RISKS** by integrating functions and increasing communication and collaboration among all ORO staff.



ORO Transformation: Overview

REDESIGNED REVIEW PROGRAM

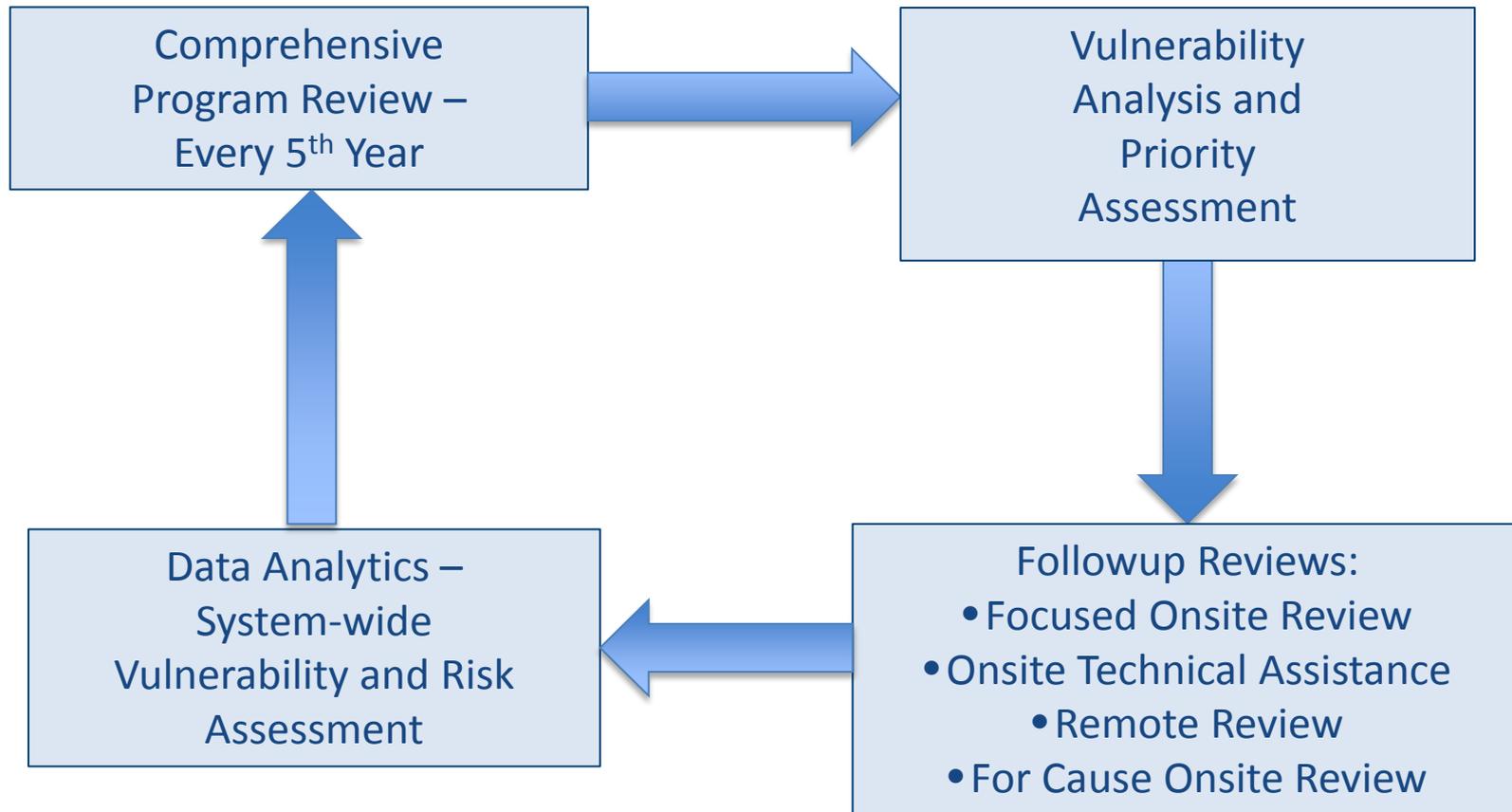
1. Regularly scheduled **Comprehensive Program Reviews (CPRs)** (every 5th year)
 - **Virtual** and **Limited Onsite** Components
 - **Holistic Integrated Review:** R&DC and Research Admin, HRPP, ACUP, RSSP, RISP
 - **Streamlined Report** to Facility
2. Followup reviews based on **Prioritized Area(s) of Vulnerability**
 - **Focused** Onsite Reviews
 - Onsite **Technical Assistance** Reviews
 - **Remote** Followup Reviews
3. Continue **For-Cause** Onsite Reviews as needed

NEW ORGANIZATIONAL STRUCTURE

REDESIGNED FACILITY INTERFACE => “CATS”



ORO Transformation: Overview





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Subject Matter Workgroups Rather than Regional Offices:

- **Human Research Protections (HRP)**
 - Mr. Richard D'Augusta, Director
- **Research Safety and Animal Welfare (RSAW)**
 - Dr. Jim Trout, Director
- **Research Information Security (RIS)**
 - Dr. Brendan Keegan, Director
- **Comprehensive Research Oversight Workgroup (CROW)**
 - Ms. Cindy Paulsen, Director
 - Comprehensive Program Reviews (CPRs)
 - R&DC and General Research Administration Follow-up
 - Facility Liaisons



ORO Transformation: Overview

Reorganized ORO Workgroup:

- **Policy and Education (P&E) – Director, TBD**
 - RCO education and oversight
 - Policy Coordination and Management

New ORO Workgroups:

- **Informatics and Data Analytics (IDA) – Dr. Yen Nguyen**
 - Risk Assessment Modeling
 - Facility Director Certification
 - Quality Improvement – System Level Risk Assessment – Annual Report
 - Data, Records, and Information (DRI) Administration
- **Review Management and Integrity – (RMI) Dr. Ben Gao**
 - Priority setting, coordination, and scheduling of onsite reviews
 - Onsite Review Quality Control
 - Research Misconduct Oversight