

# VA Quality Enhancement Research Initiative

Everything You Need to Know  
About QUERI Non-research  
Protocols!

QUERI National Program Office  
VA Information Resource Center (VIREC)

VA



U.S. Department of Veterans Affairs  
Veterans Health Administration  
Office of Research & Development



# Agenda

- **VHA ORD Non-Research Guidance**
  - Amy Kilbourne, PhD, MPH
- **Operationalization of Non-Research Guidance**
  - Melissa Braganza, MPH
- **Non-Research Data Access**
  - Amanda Taylor, PhD
- **Project Documentation and Data Collection Requirements**
  - Kara Beck, PhD
- **Budget Guidance and Project Modifications**
  - Stefanie Gidmark, MPH
- **QUERI Resources**
  - Melissa Braganza, MPH

# VHA ORD Non-Research Guidance

*Amy Kilbourne, PhD, MPH*



# Key Characteristics of Non-Research Activities: [ORD Program Guide 1200.21](#): VHA Operations Activities That May Constitute Research

- **Issued by ORD on January 9, 2019 that includes criteria to assist in determining whether a VHA operations activity constitutes research.**
  - Replacement for VHA Handbook 1058.05 “VHA Operations Activities that May Constitute Research,” dated October 28, 2011.
  - Establishes procedures for verifying and documenting the non-research status of certain operations activities prior to publication of findings outside the Department of Veterans Affairs.
- **Primary purpose of quality assessment and quality improvement for internal VA purposes.**
  - The activity is designed and implemented for internal VA operational purposes (i.e., its findings are intended to be used by VA or by entities responsible for overseeing VA).
- **Not designed for generalizability beyond VA.**
  - The activity is not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field).
  - However, this does not mean that a research activity done solely within VA is not research if it is only conducted within VA.

# QUERI Non-Research Projects

- QUERI projects are non-research projects because of the **funding source** (medical administration, 0160 funds) and their focus on **improvement** within VA.
- Protocols involving data collection are non-research if the **data are fed back to providers or operations leaders** to directly improve care and/or other VA processes. The activity does not meet the definition of research.

# Examples of QUERI Non-research Protocols

- [Maintaining Implementation through Dynamic Adaptations \(MIDAS\): protocol for a cluster-randomized trial of implementation strategies to optimize and sustain use of evidence-based practices for VHA patients](#)  
ClinicalTrials.gov: [NCT05065502](#)
- [Getting to implementation: a protocol for a Hybrid 3 stepped wedge cluster randomized evaluation of using data-driven implementation strategies to improve cirrhosis care for Veterans](#)  
ClinicalTrials.gov: [NCT04178096](#)
- [Provision of peer specialist services in VA patient aligned care teams: protocol for testing a cluster randomized implementation trial \(Hybrid Type 3\)](#)  
ClinicalTrials.gov: [NCT02732600](#)
- [Comparing two implementation strategies for implementing and sustaining a case management practice serving homeless-experienced veterans: a protocol for a type 3 hybrid cluster-randomized trial \(Non-research determined per letter and MOU from national program office\)](#)  
ClinicalTrials.gov: [NCT05312229](#)

# Adding a Research Protocol

- In situations when a QUERI project wants to collect additional data beyond what is needed for informing improvement within VA, then a determination should be sought as to whether the project's activities constitute research.
  - In Program Guide 1200.21, this is called collecting “extra” data for systematic investigation to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study).
  - In contrast, data involving non-research activities are directly fed back to providers or operations leaders to improve processes in the VA.
- However, a research protocol involving extra data or other creation of generalizable knowledge can be “piggy-backed” on top of a QUERI non-research activity



# Examples with Elements of Research and Non-research

- Implementation and evaluation of the VA DPP clinical demonstration: protocol for a multi-site non-randomized hybrid effectiveness-implementation type III trial
  - DPP intervention rolled out by the national program office (non-research)
  - Patient, provider outcomes data ascertainment (research component)
- Enhancing Mental and Physical Health of Women through Engagement and Retention (EMPOWER)
  - Compare in-person, peer-led, or virtual Diabetes Prevention Program for women Veterans
  - Facilitating CVD risk screening and risk reduction for women Veterans
  - Tailored mental health collaborative care for women Veterans

All three involved implementation of evidence-based practices but ascertained extra data on patient, provider, and organizational factors to understand implementation impacts

Clinicaltrials.gov: [NCT02991534](#), [NCT02950961](#)



# Points of Contact

- For **QUERI-funded activities**, contact **Kara Beck**, QUERI Program Manager, at [kara.beck@va.gov](mailto:kara.beck@va.gov).
- For **ORD projects**, contact the **Scientific Program Manager** for the specific project with questions.
- For **ORD regulatory policy questions**, contact **VHA CO ORD Regulatory** [VHACOORDRegulatory@va.gov](mailto:VHACOORDRegulatory@va.gov) with regulatory questions.

# Operationalization of Non-Research Guidance

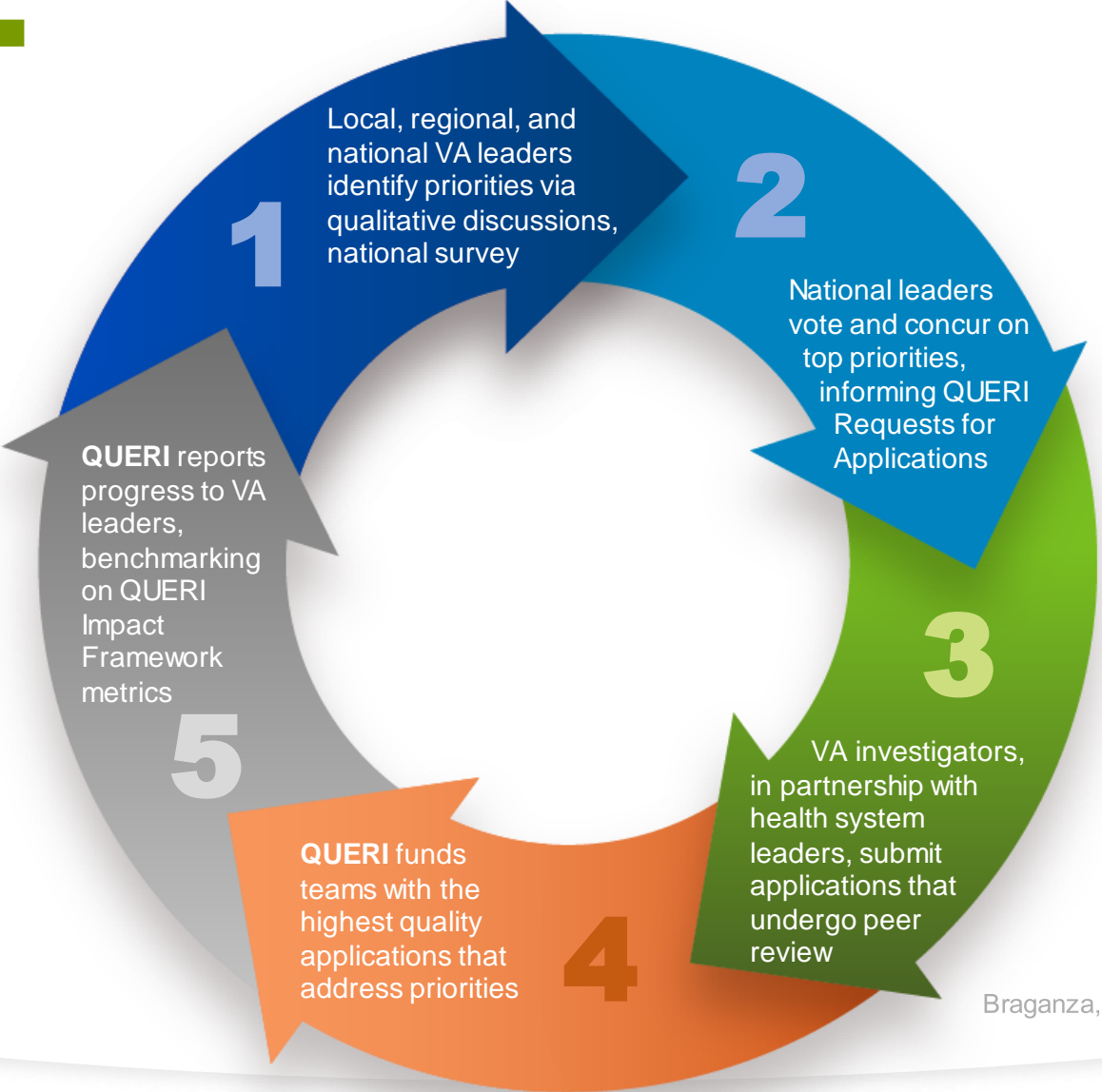
*Melissa Braganza, MPH*



# QUERI Addresses VHA Priorities

## QUERI activities driven by VHA operational needs

- ✓ Alignment with VHA priorities e.g., [VA Strategic Plan for FY2022-2028](#)
- ✓ QUERI Requests for Applications highlighting emerging priorities
- ✓ Reporting focused on impacts on Veterans, employees, and the health system



## Multiple rounds of review for non-research definition:

- ✓ Operations partner: non-research letter, letter of support
- ✓ Rigorous scientific merit review
- ✓ QUERI Central Office review

Braganza, Kilbourne et al., HSR 2022

# QUERI Impact Measures

## ACTION Impact Framework, Braganza, et al, JGIM, 2020

Domain	Measures
<b>A</b> lignment	Priorities, metrics, partners
<b>C</b> ommitment	Shared operational resources and financial support, evidence-based strategies and products
<b>T</b> ailoring to local context	Implementation sites, providers using effective practice, Veterans/family members/caregivers served
<b>I</b> nforming the field	Briefings with key decision-makers, publications, scale-up and spread
<b>O</b> bserving healthcare change and generating <b>N</b> ew projects	Sustainability, quality of care and health outcomes, policy, culture, employee engagement and new projects requests

# QUERI Non-Research Letter

- Describes how the project (and data collected during the course of the project) is designed for internal quality improvement purposes, as part of the agreed-upon protocol established with the VA operations partner
- Signed by the VA operations partner affiliated with the QUERI project
- QUERI Central Office developed a template, which is posted on the [QUERI SharePoint site](#)
- Helpful for communications with different groups and implementation sites, journals, data access

DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: \_\_\_\_\_

From: **Operational Leader Authorized to provide Non-Research Documentation Project**

Subject: **Project Title**

To: **Project PI**

1. The purpose of this letter is to confirm that the VA Quality Enhancement Research Initiative (QUERI) project entitled "**Project Title**" meets the criteria for classification as non-research. This project is being conducted at the **VA Medical Center** and is led by **Project PI**. The **implementation/evaluation** of **(describe project)** is designed to inform quality improvement efforts, as part of the agreed-upon protocol established with QUERI and **(operations partner)**.

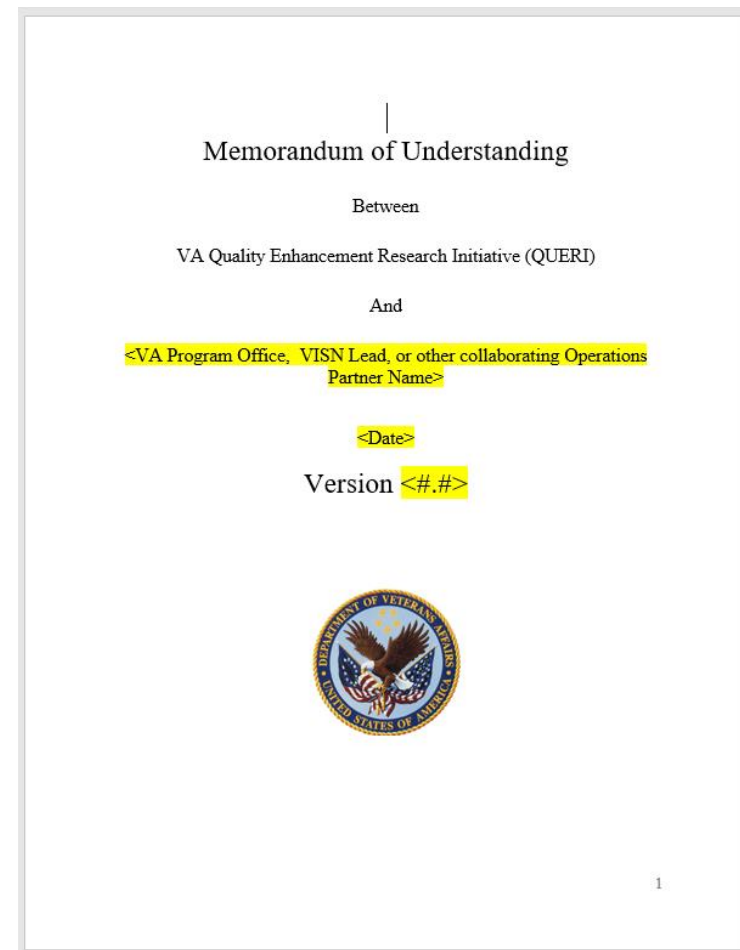
2. The purpose of this project is to support internal implementation and evaluation efforts to **(describe aims of project)**. The project will involve use of secondary and **(if applicable) primary VA data** collected using assessments that are part of routine care and/or clinical management. This project will be collecting information that is designed for quality improvement initiatives, as described in [Program Guide 1200.21](#), for the purposes of program **implementation/evaluation**.

3. These activities are designed and implemented for internal VA purposes and findings are intended to be used to better inform care in the VA. This project is not designed to inform activities beyond VA, produce information that expands the knowledge base of a scientific discipline or other scholarly field, and does not involve collecting additional data or performing analyses that are not needed for the purposes of this internal implementation.

**Signature and title of VA operational leader from program office authorized to sign off on non-research projects**

# MOU for RRTs, EBPs, PEI Extensions

- Promotes shared goals, approach, metrics
- Includes non-research template language from non-research letter to reduce duplication
- Two [different MOU templates](#), depending on the QUERI mechanism:
  - QUERI Partnered Evaluation Initiative and RRT MOU Template
  - QUERI Evidence-based Policy Evaluation Center MOU Template
- Helpful for communications with different groups and sites, staff turnover, journals, data access



# Participating Site Agreements

- When implementing evidence-based practices/programs and/or conducting data collection at a site, it is important to **notify the facility leadership and ACOS/R at the implementation sites** before conducting any surveys or interviews.
  - If the implementation/evaluation initiative has a research component, contact [vacoqueri@va.gov](mailto:vacoqueri@va.gov) for a template to help with communications with key personnel at the site to clarify which activities are considered research and non-research.
- Some sites may request information about how the activity does not constitute engagement in (human subjects) research, and in these cases, consider adapting the participating site agreement for those specific situations, even if the project fully meets the definition of non-research.



# Key Points to Keep in Mind

- Non-research projects should register as a clinical trial via Clinicaltrials.gov or ISRCTN if they meet the ORD definition of a clinical trial (ICMJE/WHO):  
*“Any study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”*
- Data collection in the course of a non-research project require reviews similar to other ORD work (e.g., union notification, OAC review)
- Publication of protocols and results is highly encouraged

**CyberSeminar:  
Everything You Need  
to Know About VA  
Non-research  
Protocols**

[Link to Recording](#)

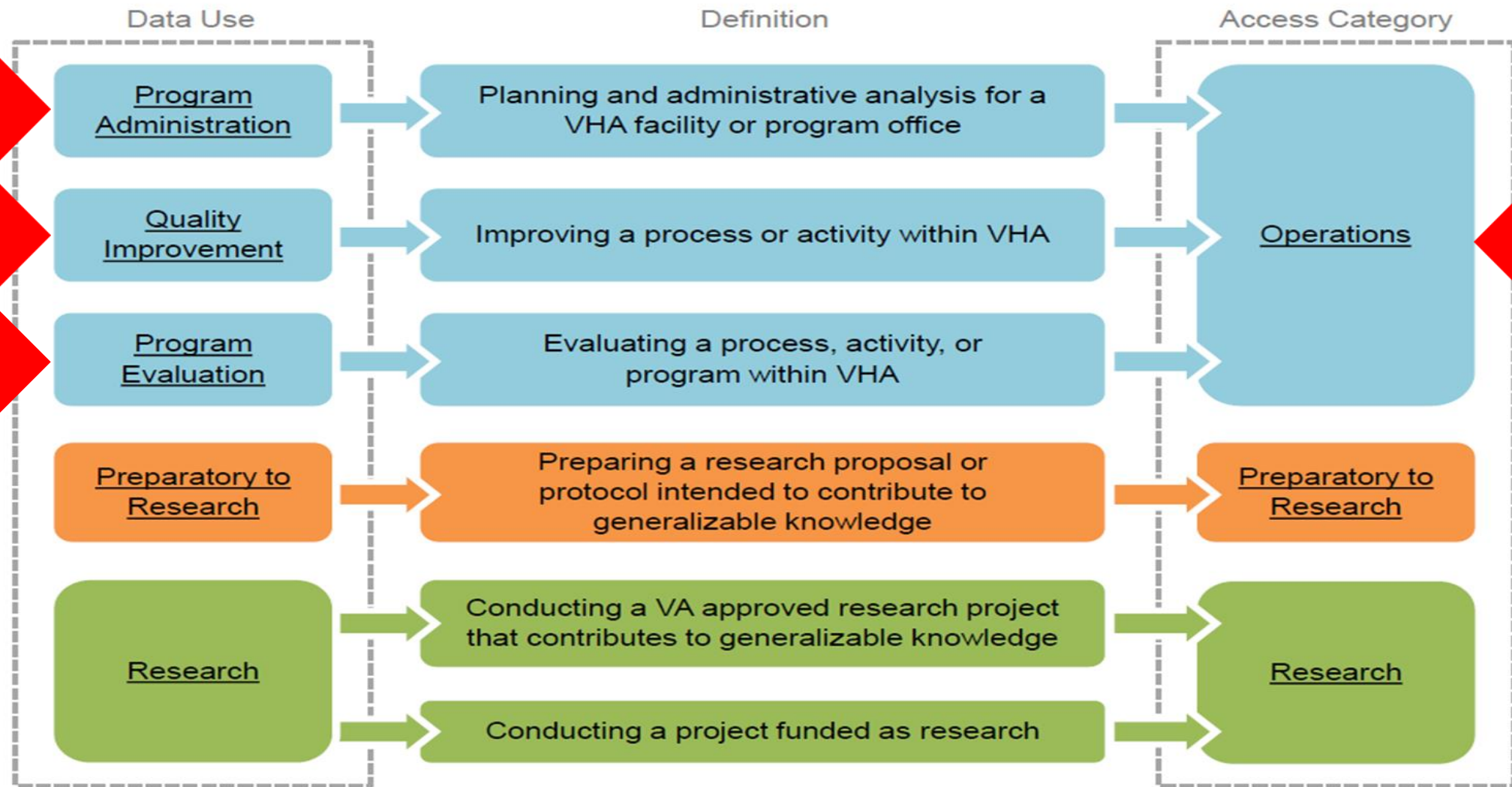
# Non-Research Data Access

*Amanda Taylor, PhD*



# Access Category Finder Tool

<https://vaww.virec.research.va.gov/Access/Research-vs-Operations-Decision-Tool.pdf?pdf=Decision-Tool>





# VIREC GOOD DATA PRACTICES: ACCESS TO VA DATA SERIES

Session #3

[Operations Access to VA Data](#)

April 25, 2022

**Angela Jannotta, BA, Data Policy and Access Specialist**

**Linda Kok, MA, Senior Analyst for Data Policy and Access**

**VA**



U.S. Department of Veterans Affairs  
Veterans Health Administration  
Office of Research & Development



VHA Data Portal

Your best source  
for learning  
about VA data  
sources and how  
to request access.

[http://vaww.vha  
dataportal.med.v  
a.gov/](http://vaww.vha<br/>dataportal.med.v<br/>a.gov/)



The screenshot shows the VHA Data Portal website. At the top right, there is a navigation menu with links for Home, About Us, Contact Us, FAQ, and Report Broken Link. Below this is a search bar. The main header features the Department of Veterans Affairs logo and the text "Department of Veterans Affairs VHA Data Portal". A secondary navigation bar contains tabs for Data Sources, Data Access, Tools & Applications, Resources, Training, Policy & Admin, and Support.

### Welcome to the VHA Data Portal

The VHA Data Portal promotes a knowledge-sharing culture that supports the needs of VHA data users. The Portal integrates information from multiple sources into a single location to promote a comprehensive knowledge base and to facilitate a positive end-user experience.

**The one-stop-shop for data users' needs.**

Our home page is designed to help get you the information you need. The badges below link to access information and other relevant resources for a particular data use need. Check out the top navigation menu to locate resources by category. [Tell us what you think.](#)



-  **New Data User**
-  **Research**

### COVID-19


The [COVID-19 Shared Data Resource](#) is a new data domain containing information related to COVID-19 in and outside of VA. It is comprised of data from various sources and uses case definitions, concept definitions, VA data mappings, and other information that are collected, validated, and updated collaboratively across VA.

COVID-19 information and resources for VA research administrators, investigators, and staff including funding opportunities, links to webinars, and other resources are available from the [ORD COVID-19 for the VA Research Community](#) SharePoint site and [COVID-19 Resources for the HSR&D Research Community](#) web page.

### Upcoming Events

-  [Cyberseminars](#)
-  [VINCI Training Hour](#)

### News







Data Sources

Data Access

Tools & Applications

Resources

Training

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Support

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### News



# Department of Veterans Affairs VHA Data Portal

Data Sources

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Tools & Applications

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New Data User



Research

- Data Access Overview
- Operations Access
- Preparatory to Research Access
- Research Access
- Veterans Service Officers Access



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## News







- Data Sources
- Data Access
- Tools & Applications
- Resources
- Training
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- Support

Data Access > Operations Access

### On This Page

- Overview
- Requesting Access
- Data Sources
- Tools

### Did You Know?

Operational Access request include users who require access for Treatment, Payment, and/or Healthcare Operations. Operations access and Non-Research access is synonymous.

### Tips for Requestors

The ePAS NDS User Guide will provide step-by-step instructions on requesting Operational access.

## Operations & Quality Improvement Access

### Overview

VA or VHA employees or contractors who require broader access to data in the performance of their official duties under the treatment, payment, and/or healthcare operations provisions of the Health Insurance Portability and Accountability Act (HIPAA) can request access to the data required to perform their jobs. This includes quality assessment and improvement, operational reporting, auditing and general administrative duties.

**Note:** The following resources provide information on determining whether a VHA operations activity constitutes research.

- [Research vs Operations Decision Tool](#)
- [Program Guide 1200.21: VHA Operations Activities That May Constitute Research](#) (Jan 2019)
- [Operations Data Access Policy](#)

### Requesting Access

Access to data sources and data access tools is available through several request processes.

- [NDS Healthcare Operations Request Process](#)
- [Patient Care Services \(PCS\) Request Process](#)
- [Pharmacy Benefits Management \(PBM\) Request Process](#)
- [Local National Social Security Database \(NSSD\) POC Request Process](#)
- [Medicare and Medicaid Analysis Center \(MAC\) Request Process](#)
- [VINCI Workspace Request Process](#)

Determining which process to use for requesting access depends on the data source or data access tool:

- Expand a source or tool in the lists below for an outline of its access request process.
- [+ View Terms and Definitions](#) used in the these outlines.

**Note:** Operational data users generally receive direct access to VHA data.

### **Data Source Request Processes**

Expand or select a data source in the list below to view an outline of its data request process.

[▶ Assistant Deputy Under Secretary for Health \(ADUSH\) Enrollment Files](#)

[▶ Care Assessment Need \(CAN\) Scores](#)

[▶ Clinical Assessment Reporting and Tracking \(CART\) Program Data](#)

[▶ Corporate Data Warehouse \(CDW\) Data](#)

[▶ COVID-19 Shared Data Resource](#)

[▶ Electronic Quality Measures \(eQM\) Data](#)

[▶ Health Economics Resource Center \(HERC\) Cost Data](#)

[▶ Homeless Registry](#)

[▶ Home Based Primary Care \(HBPC\) Masterfile](#)

[▶ Managerial Cost Accounting National Data Extracts \(MCA NDEs\)](#)

[▶ Managerial Cost Accounting \(MCA\) Web Reports](#)

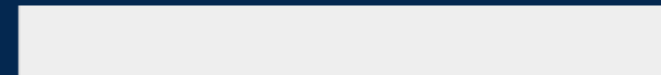
[▶ Medical SAS Inpatient & Outpatient Data Sets](#)

- [Traumatic Brain Injury \(TBI\) Screening and Evaluation Data](#)
- [United States Veterans Eligibility Trends and Statistics \(USVETS\)](#)
- [VACMS Data for Operations](#)
- [VA Surgical Quality Improvement Program \(VASQIP\) Data](#)
- [Veterans Services Network Corporate Mini Master \(VETSNET\) File](#)
- [VHA Support Service Center \(VSSC\) Web Reports](#)
- [VINCI Natural Language Processing \(NLP\) Output – Left Ventricular Ejection Fraction \(LVEF\)](#)
- [Vital Status File](#)

### **Tools Request Processes**

Expand or select a data access tool in the list below to view an outline of its access request process.

- [CAPRI](#)
- [CPRS](#)
- [Joint Legacy Viewer \(JLV\)](#)
- [SAS/GRID](#)
- [VA Network Server Workspace \(Local and Regional\)](#)
- [VINCI Workspace](#)



### Do you already have data access?

Visit the [Access & Permissions Lookup Tools page](#) to check your current access and permissions before submitting a data request.

### Tips for Requestors

Detailed, step-by-step instructions on submitting a request are available from the [NDS ePAS User Request Guide](#).

## NDS Healthcare Operations Request Process

Overview

Submitting a Request

Request Metrics

Resources

### Overview

The [National Data Systems \(NDS\)](#) Healthcare Operations (HCO) Request Process is used for requesting permission to access VHA data for operations/non-research. Several [data sources](#) and [tools](#) can be requested through this process. Here is a list of those that are available for request. Select a data source for a description of its contents and tips for requesting access. Be sure to [determine if a request is needed](#) before submitting your request.

- [ADUSH Enrollment Files](#)
- [Care Assessment Need Score \(CAN Score\)](#)
- [Clinical Assessment Reporting and Tracking \(CART\) Program Data](#)
- [CAPRI](#)
- [Corporate Data Warehouse \(CDW\)](#)

[Healthcare Operations Request Process \(va.gov\)](#)






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# NDS Healthcare Operations Request Process


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## Submitting a Request

This is a general overview of the process for submitting a NDS Healthcare Operations request in VA's Electronic Permission Access System (ePAS). Data source specific tips and essential information for request access are available from each [data source page](#). The [NDS ePAS User Request Guide](#)  provides detailed, step-by-step instructions.

### Step 1. Determine if a Request is Needed

Do not submit a new ePAS form to request your current CDW, VSSC Web Reports, MCA Web Reports, or Mainframe Access privileges for a new project. Check on the status of your existing NDS managed data access privileges using the [Access & Permissions Lookup Tools page](#) to avoid submitting an unnecessary, duplicate request.

Go to step 2 and submit an NDS ePAS form to

- Request a data source listed in the [Overview](#) for the first time.
- Request CAPRI/JLV access for a new project.
- Modify existing data access privileges, e.g. adding CDW "Privileged Read Patient Access" when you previously only had "Basic Read Access" or modifying VSSC access from VISN to national.

## Step 2. Submit the NDS Access Form for Health Operations

Note: requests may be submitted only by the person who needs access. NDS will deny requests submitted on behalf of someone else.

- a. Launch the [VHA NDS Access Form for Health Operations](#) form in ePAS.
- b. Select **Create Document**.
- c. Complete the Request tab.
  - i. Fill out all fields highlighted in yellow.
  - ii. Select one or more **purpose(s) of use**.
  - iii. Select **only the data source(s) you need** in the Data Sources section. A tab will appear at the top of the document for each data source you select, except for the Operation Enduring Freedom/ Operation Iraqi Freedom/ Operation New Dawn Roster.
  - iv. Affirm you have read and understood the acknowledgment.
- d. Complete each data sources tab at the top of the document.
- e. Select **Save and Submit** and digitally sign the form.

Once you sign, your supervisor will receive an email notification to approve your request. Once your supervisor has approved and signed the access form, your request will automatically be routed to NDS for processing.

### [VHA NDS Access Form for Health Operations](#)

For questions contact [NDS.OperationalAccessRequests@va.gov](mailto:NDS.OperationalAccessRequests@va.gov)

# Accessing Operational Data on VINCI Workspace



**VINCI Central**

Home \ VINCI University \ OPS QI Study How To

Workspaces Applications My VINCI Dashboard VINCI University Services Support Quick Links

Send by email

Operations & Quality Improvement How-To

## Operation Project Data Access

VA or VHA employees or contractors who require broader access to data in the performance of their official duties under the treatment, payment, and/or healthcare operations provisions of the Health Insurance Portability and Accountability Act (HIPAA) can request access to the data required to perform their jobs. This includes quality assessment and improvement, operational reporting, auditing, and general administrative duties.

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- [Program Guide 1200.21: VHA Operations Activities That May Constitute Research \(Jan 2019\)](#)
- [Research vs Operations Decision Tool](#)

## Resources

- [Ops on VHA Data Portal](#)
- [VIReC](#)
- [VHA Directive 1200.05 - Requirements for the Protection of Human Subjects in Research](#)
- [VHA Handbook 1605.01 - Privacy and Release of Information](#)
- [VHA Handbook 1200.12 - Use of Data and Data Repositories in VHA Research](#)

## [Operations & Quality Improvement How-To \(va.gov\)](#)

VA



U.S. Department of Veterans Affairs  
Veterans Health Administration  
Office of Research & Development





# Accessing Operational Data on VINCI Workspace, con't

**All team members** for the project must be approved for the same healthcare operations data access if you intend to use any identifiable data in your VINCI Workspace Operations folder.

After **all team members** needing access receive their approvals through ePAS, you can apply for VINCI Workspace access and a project folder. **Only one request per project is needed.**

## Applying for VINCI Workspace access and folder

- Apply through the [BaseCamp](#) application.
  - Select Operations under Workgroup Type
  - Select VINCI under default environment
  - Make sure to fill out all of the fields, including VA sponsor (likely Program Office or QUERI)

## What happens next?

1. The request is reviewed for completeness and accuracy by CDW staff.
2. The project is approved.
3. In most cases the file folder is created within 24 hours but it can take days depending on workload.
4. Customer is notified by VA email once the file folder has been created.

# VINCI Workspace:

## Operational Data not requested through ePAS

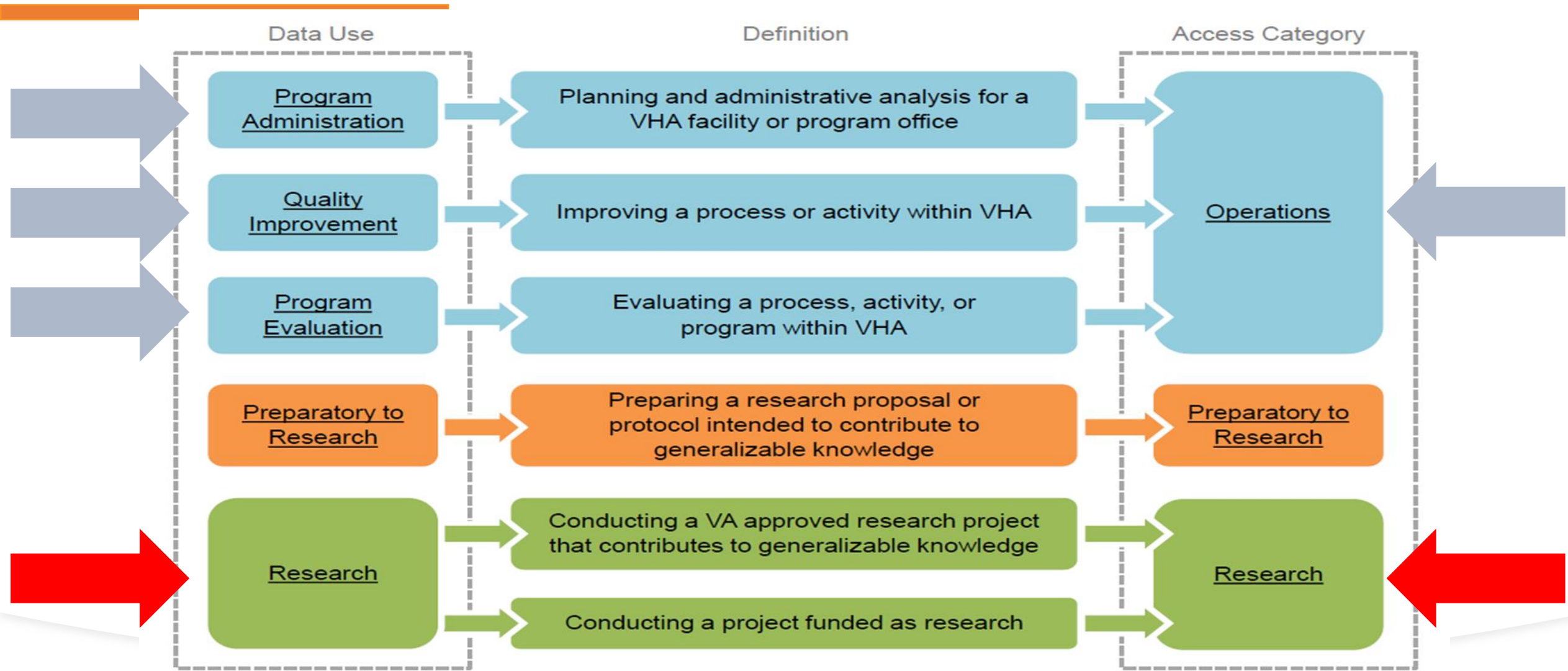
It may be possible to access data for operations use in the VINCI environment that is not requested through ePAS, for example data created by a specific program office.

If you wish to access this type of operational data in VINCI Workspace Operations folder you must have first **permission from the data steward** to do so.

After obtaining approval from the data steward you should contact the VINCI Concierge Desk at [VINCI@VA.gov](mailto:VINCI@VA.gov) to find out if it is possible for the data to be accessed via a VINCI Workspace Operations folder.

# Access Category Finder Tool

<https://vaww.virec.research.va.gov/Access/Research-vs-Operations-Decision-Tool.pdf?pdf=Decision-Tool>





# Department of Veterans Affairs VHA Data Portal

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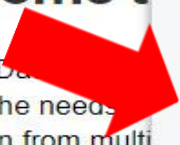
Policy & Admin

Support

## Welcome to

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## Upcoming Events

- + [Cyberseminars](#)
- + [VINCI Training Hour](#)



## News





# Staying in the Appropriate Data Access Lane

VA data can only be accessed for its **approved use**, i.e., Operations **OR** Research.

Projects with research and non-research components:

- Access approval for **operations (e.g., non-research) data** use cannot be used to access data for **research** or to **prepare a research protocol**.
- **Separate** data access requests and approvals are needed for operations and research data use.
- Data for the research and operations project components must be stored & accessed **separately**.
- Data for the two components **can not** be **combined** or **stored** in the same folder.
- **Operations access** cannot be used to identify or pull a cohort for a research project.

# Data Tools and Software

## Digital Voice Recorders (DVRs)

- Philips Voice Tracer DVT1160 Digital Recorder
- Olympus 9500 Voice Recorder
- Philips Pocket Memo Voice Recorder DPM8000

## How can I look up what recording tools are permitted for use in the VA?

To determine if a VA digital camera, audio recorder or video camera is approved for use in the VA, search the [OIT Solution Delivery, Security Engineering Research Analysis \(SERA\)](#) documents to determine if your device has been approved or submit a ticket to [OIS VHA Regulatory Research Cybersecurity Guidance Request Process](#) in ServiceNow (YourIT).

## How can I determine what software is approved in the VA?

The VA Investigator or applicable VA individual can check the [TRM Technology/Standard List](#) to determine if the software is approved. When reviewing the software's TRM entry, special attention should be paid to the **Decision** tab. This tab discusses the decision, constraints on the use of the software, and the software versions that are approved for use in VA.

If the device's software is not approved by TRM, the VA Investigator or applicable VA individual must submit the software to TRM for approval using the [TRM Content Request Form](#).

# Guidance and Resources for Data Access

- VIREC's Cyberseminars
  - [Navigating VA Data Access: An Overview of the Process for Requesting Permission to Use VA Data](#)
  - [Good Data Practices: Access to Data Series](#)
- [VHA Data Portal](#)
- [VINCI Concierge Desk](#) or email [VINCI@VA.gov](mailto:VINCI@VA.gov)
- For questions, contact:
  - [VIREC HelpDesk](#)
  - Amanda Taylor ([Amanda.Taylor2@va.gov](mailto:Amanda.Taylor2@va.gov)), VIREC QUERI Liaison
  - Linda Kok ([Linda.Kok@va.gov](mailto:Linda.Kok@va.gov)), VIREC Senior Analyst for Data Policy and Access

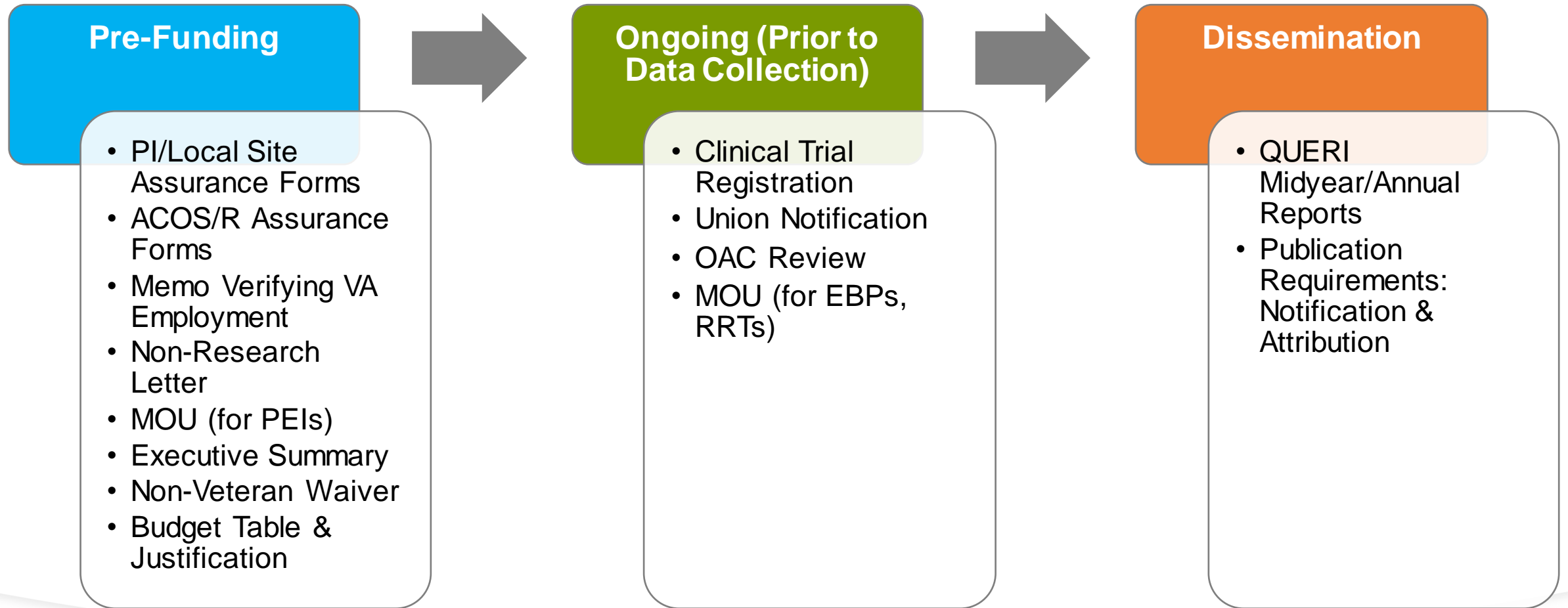


# Project Documentation and Data Collection Requirements

*Kara Beck, PhD*

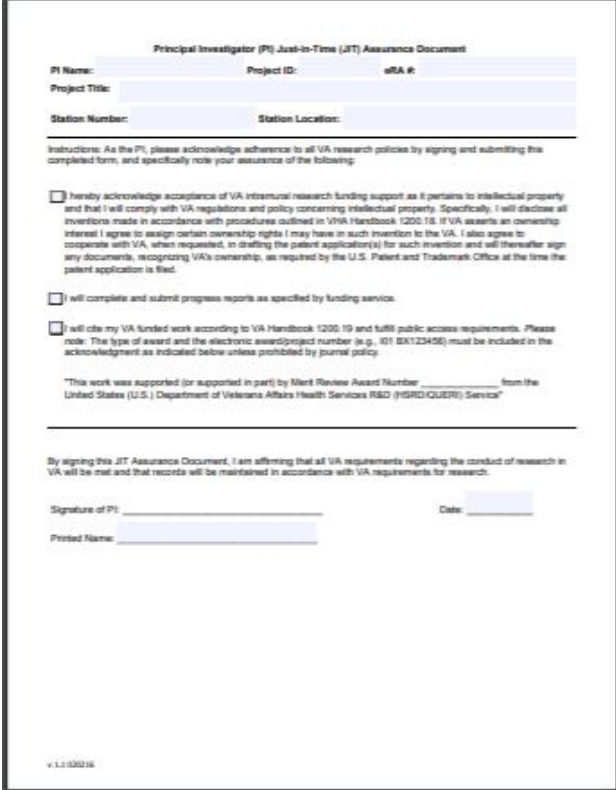


# QUERI Project Requirements



# PI and Local Site Investigator Assurance Forms

- PI and Local Site Investigator Assurance Forms attest to the PI and local site investigator's agreement to comply with VA policies.
- The PI must agree to comply with VA regulations and policies concerning intellectual property, complete and submit progress reports as specified by QUERI, and cite the VA support of the work in all publications, in accordance with VA Handbook 1200.19.



The image shows a form titled "Principal Investigator (PI) Just-in-Time (JIT) Assurance Document". It contains several fields for PI Name, Project ID, eRA #, Project Title, Station Number, and Station Location. Below these fields are instructions and three checkboxes for the PI to acknowledge and agree to: 1) acknowledge acceptance of VA intramural research funding support and intellectual property regulations; 2) complete and submit progress reports; 3) cite VA funded work according to VA Handbook 1200.19 and public access requirements. The form also includes a signature line for the PI and a date field.

# Memo Verifying VA Employment

- A Memo Verifying VA Employment from the Medical Center Director, stating that the awardee has, at this time, a VA-paid appointment which will extend continuously through the duration of the Merit Review award.
- State the fractional VA effort (8ths) for this awardee. For appointments less than 5/8ths, an eligibility waiver or project modification form signed by the Director, QUERI is required.
- Generally included as part of application submission.

# ACOS Assurance Forms

- **Non-Research ACOS Assurance Form** affirms the research office's awareness and support of the QUERI project, as well as the PI's eligibility to receive VA funding based on VA employment status.
  - Needs to be completed for all sites that are receiving QUERI funds.
  - The project lead is the site PI for that site.
- Describes how QUERI funds are medical administration (0160) funds and how all QUERI funds sent to the facility receive VERA credit at the same level as other ORD-funded projects, see the VERA Research Support Back-Up Data and Allocations table posted [here](#).
- Even if a project site is not receiving QUERI funds, local site investigators are encouraged to notify their local research office of their participation in a QUERI project.

**Associate Chief of Staff for Research and Development (ACOS/R) Acknowledgement and Assurance Document for QUERI-Funded Non-Research Activities**

Project Lead Name: \_\_\_\_\_

Project ID: \_\_\_\_\_ eRA#: \_\_\_\_\_

Project Title: \_\_\_\_\_

Station Number: \_\_\_\_\_ Station Location: \_\_\_\_\_

The ACOS/R is responsible for signing the completed assurance form. No other supporting documentation for these requirements (Eligibility Verification) is needed unless indicated.

**A. Non-Research Determination Acknowledgement.** Please check whether the non-research letter signed by a VA operations leader authorized to provide documentation of non-research has been completed. Note: QUERI funds are medical services (1060) funds, and all QUERI funds sent to the facility receive VERA credit at the same level as other ORD-funded projects, see the VERA Research Support Back-Up Data and Allocations table posted [here](#).

The project is a non-research project by virtue of its QUERI funding and because a determination has been made by an entity or individual who has the capacity to make a non-research determination.

**B. Verification that the Project Lead is eligible to receive QUERI funding.** Please check one box below:

Project Lead is eligible to receive funds due to a current 5/8ths or greater VA paid appointment.

Project Lead is eligible to receive funds due to an ORD-issued waiver from the 5/8ths or greater VA paid appointment.

Project Lead will be eligible to receive funds once VA hiring or promotion is complete. Project start date will not be set until Project Lead is hired.

Reminder: Contract employees are not eligible to serve as a Project Lead on VA-funded projects.

**C. By signing this ACOS/R Acknowledgement and Assurance Document for QUERI Funded Non-Research Activities, I am affirming my awareness that the above-named QUERI project will be initiated at this station and acknowledging that the project has been determined to be a non-research activity. As an ORD-administered project, this QUERI project will have access to the administrative resources of the Research Service and, if applicable, its affiliated HSR&D program.**

Signature of ACOS/R&D: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name of ACOS/R&D: \_\_\_\_\_



# Non-Research Documentation by Ops Partner

- Non-research letter or (combined) letter of support with non-research language
  - Newly funded peer reviewed initiatives, usually included as part of the application
  - PEI extensions
- MOU with non-research language
  - PEI extensions
  - Rapid Response Team projects
  - Evidence-based Policy Center evaluations

# Memorandum of Understanding: PEIs, RRTs

- **MOU** is required for QUERI Partnered Evaluation Initiatives (PEIs) and Rapid Response Team (RRT) projects.
  - Describes the context of the work, the scope of the work to be done, the project milestones and timeline, and the reporting cadence.
  - PEI MOUs also state the funding commitment by the operations partner and QUERI.
  - Template is provided on the [QUERI SharePoint site](#).
- Prior to gathering signatures, the draft MOU needs to be sent to the QUERI Center for Evaluation and Implementation Resources (CEIR; [ceir@va.gov](mailto:ceir@va.gov)). After CEIR has reviewed the MOU, it can be circulated for operations partner signatures prior to being sent to [vacoqueri@va.gov](mailto:vacoqueri@va.gov) for the QUERI Director's signoff.

<Project Name> MOU

**<Project Name>**

This Memorandum of Understanding (MOU) sets forth the terms and understanding between the VA Quality Enhancement Research Initiative (QUERI, 14RDH), the <Operations Partner Name (e.g., VA Program Office, VISN, or other partner)> and <name of Partnered Evaluation Initiative or Rapid Response Team Project>.

*Overall goal of project*

<Provide 2-3 sentences describing the overall project goal and what the expected outcome of the project will be.>

*Documentation of non-research status of project*

The <name of Partnered Evaluation Initiative or Rapid Response Team Project> meets the criteria for classification as non-research. This project is being conducted at the <name of VA Medical Center> and is led by <name of lead PI>. The implementation/evaluation of <describe Partnered Evaluation Initiative or Rapid Response Team Project> is designed to inform quality improvement efforts, as part of the agreed-upon protocol established with QUERI and <Operations Partner Name (e.g., VA Program Office, VISN, or other partner)>.

The purpose of this project is to support internal implementation and evaluation efforts to <insert goals/objectives/aims>. This project will be collecting information that is designed for quality improvement initiatives, as described in [Program Guide 1200.21](#), for the purposes of program implementation/evaluation.

These activities are designed and implemented for internal VA purposes and findings are intended to be used to better inform care in the VA. This project is not designed to inform activities beyond VA, produce information that expands the knowledge base of a scientific discipline or other scholarly field, and does not involve collecting additional data or performing analyses that are not needed for the purposes of this internal implementation.

**1. Background**

<Briefly describe why this partnership is important.> Relevant information to consider for inclusion: current state of the problem area, impact of problem on areas of national VA priority, intervention/strategy to address problem, evidence to support intervention/strategy as a good match to the problem.

**2. Purpose**

This MOU will <purpose/goals of partnership>. Relevant information to consider for inclusion: information to be collected, planned application of intervention/strategy to address problem, evaluation strategy, potential application of lessons learned from

1

# Memorandum of Understanding: EBP Evaluations

- **MOU** is required for QUERI-funded Evidence-Based Policy (EBP) center evaluations.
  - Similar content but briefer than PEI/RRT MOU.
  - No requirement to include operations partners commitment or garner operations partner signatures.
  - PEPRc-approved evaluation plan included as an addendum.
- After approval of the evaluation plan by PEPRc, the MOU can be drafted, signed by the EBP center leads, and sent to [vacoqueri@va.gov](mailto:vacoqueri@va.gov) for review.

<Project Name> MOU

<Project Name>

This Memorandum of Understanding (MOU) sets forth the terms and understanding between the VA Quality Enhancement Research Initiative (QUERI, 14RDH), and <Name of Evidence-based Policy Evaluation Center.>

**Overall goal of project**

<Provide 2-3 sentences describing the overall evaluation goal and what the expected outcome of the evaluation will be.>

**Documentation of non-research status of project**

The <Name of the Evaluation> meets the criteria for classification as non-research. This evaluation is being conducted at the <Name of VA Medical Center> and is led by <Name of Evaluation Lead>. The evaluation of <describe evaluation> is designed to inform quality improvement efforts, as part of the agreed-upon protocol established with QUERI and <Name of Evidence-based Policy Evaluation Center.>

The purpose of this evaluation is to support internal implementation and evaluation efforts to <insert goals/objectives/aims>. This evaluation will be collecting information that is designed for quality improvement initiatives, as described in [Program Guide 1200.21](#), for the purposes of program implementation/evaluation.

These activities are designed and implemented for internal VA purposes and findings are intended to be used to better inform care in the VA. This evaluation is not designed to inform activities beyond VA, produce information that expands the knowledge base of a scientific discipline or other scholarly field, and does not involve collecting additional data or performing analyses that are not needed for the purposes of this internal implementation.

**1. Background**

<Briefly describe why this evaluation is important >

*Relevant information to consider for inclusion: current state of the problem area, impact of the problem on areas of national VA priority, existing work in this area and complementary initiatives, intervention/strategy to address problem, evidence to support intervention/strategy as a good match to the problem.*

**2. Purpose**

This MOU will <summarize the purpose/goals of the evaluation>.

1

# Executive Summary

- **Executive Summary** presents an overview of the project for a non-research audience.
  - Instructions and template found on the [QUERI SharePoint site](#).
  - Updated version with impacts submitted every six months as part of annual/midyear reporting.
  - Summaries posted on the QUERI website to disseminate QUERI impacts to various groups.
  - Content supports QUERI presentations to different groups, including VA leaders.
- Examples can be found on the QUERI website:
  - [Function QUERI Program](#)
  - [LEARN Evidence-Based Policy Evaluation Center](#)
  - [Health Equity Partnered Evaluation](#)
  - [Randomized Evaluation of Caring Letters](#)

The screenshot displays a document template with several key elements:

- Title and Subtitle:** Shows "Title Small" and "Title Large" styles for headers, and a "Subtitle" area for the header.
- Introductory Paragraph:** A paragraph of text demonstrating font size and type (Georgia).
- Heading 1:** A section header example.
- Smart Art:** A graphic example with a blue background and white text.
- Icons:** A list of icons (grid, envelope, refresh) with corresponding text instructions.
- Body Text:** A paragraph of text demonstrating font size and type (Georgia).
- Callout Header:** A callout box with a white background and blue border, containing text and a quote.

# Non-Veteran Waiver

- Projects that involve individuals who are not Veterans, such as VA providers, should submit a **Non-Veteran Waiver**. The template can be found on the [QUERI SharePoint site](#).
- The waiver requires a strong justification for including non-Veterans in the project.

**Memorandum**

**Department of Veterans Affairs**

Date: \_\_\_\_\_

From: Principal Investigator Name: \_\_\_\_\_  
Thru: ACOS for Research and Development (151) \_\_\_\_\_  
VAMC Station Name and Location: \_\_\_\_\_

Subj: Waiver for non-Veteran Enrollment in QUERI Sponsored Project

To: Director, Quality Enhancement Research Initiative (QUERI) (14RDH)

1. I am the principal investigator on the proposed QUERI project entitled:  
\_\_\_\_\_

2. I am requesting authorization to enroll non-Veterans in this QUERI project.

3. I understand that projects funded by QUERI must be focused on improving the quality of healthcare/well-being of Veterans and/or ailments specifically affecting the Veteran population served by VHA. For greater than minimal risk projects, I understand that you require a written risk assessment from the Principal Investigator (i.e., for purposes of this waiver, risk pertains to non-Veterans). My justification (and risk assessment as applicable) for enrolling non-Veterans in this protocol is described below.  
  
\_\_\_\_\_

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Associate Chief of Staff for Research Signature

Enrollment of non-Veterans in this study is: APPROVED  DISAPPROVED

VACO Comments if disapproved:  
\_\_\_\_\_

\_\_\_\_\_  
for Amy Kilbourne, PhD, MPH  
Director, QUERI (14RDH)



# Required Submissions After Project Begins

- Clinical Trial Registration
  - ORD requirement for initiatives that meet the ICMJE/WHO definition
  - Helps ensure results are publishable
- Primary Data Collection among VA Employees
  - Union notification: interviews, surveys
  - OAC review: large surveys
  - See [HSR&D website](#) for additional information

# Clinical Trials Registration

- ORD Definition (ICMJE/WHO):

**“Any study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”**

- QUERI-funded studies that meet this definition can register at either [Clinicaltrials.gov](https://clinicaltrials.gov) or Biomed Central (BMC).

[Huang et al, Contemp Clin Trials 2017](#)

# Clinicaltrials.gov vs. ISRCTN



## Clinicaltrials.gov

No fee

Biomedical focused  
reporting requirements

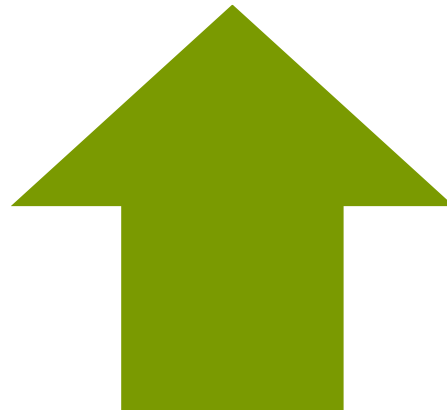
To initiate the clinical trial registration process through Clinicaltrials.gov, please email the ART Program ([ART@va.gov](mailto:ART@va.gov)). ART will usually set up the clinical trial the same day they receive the information.



## ISRCTN

~£250 registration fee

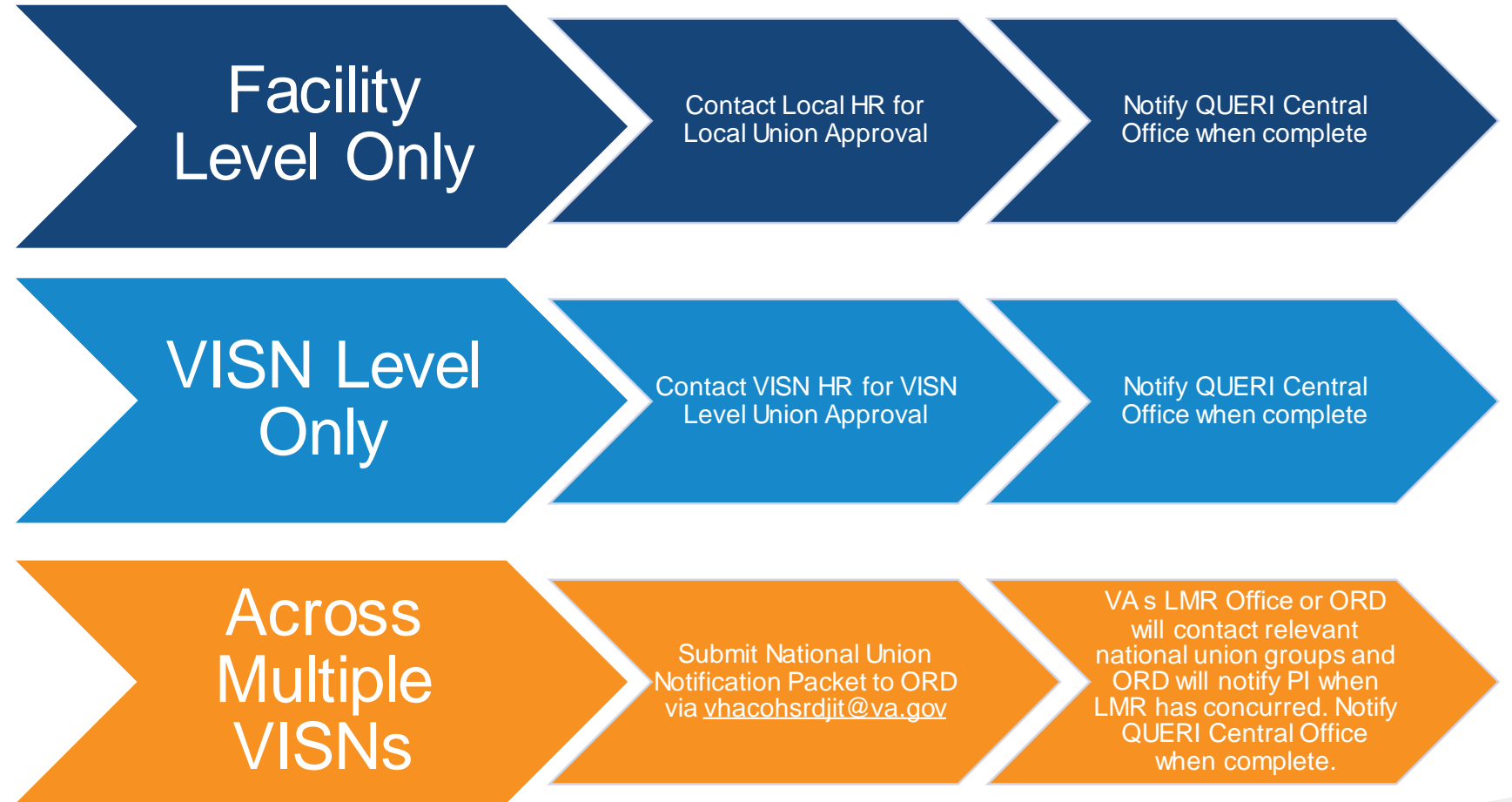
Implementation trials  
focused



If you prefer to register using ISRCTN, submit your trial [here](#). Guidance on making BMC payments is found on the [QUERI SharePoint site](#).

# Data Collection Involving VA Employees

Prior union notification is required for **all data collection (e.g., interviews, surveys) involving VA personnel** when asking about conditions of employment of bargaining unit employees. See [HSR&D website](#) for more details on the process for union notification.



# Large Multi-Site Surveys of VA Employees

- **Organizational Assessment Committee (OAC) Review** is needed for all surveys that involve VA employees and that also meet at least one of the following criteria:
  - **Surveys 10,000 or more VA employees**
  - **Surveys VA employees across 20 or more sites**
- OAC review is needed so that the survey does not overlap with other National VA surveys.
- OAC has no jurisdiction over surveys to Veterans.
- OAC only has authority to review surveys (paper and pencil or web based) and not interviews.
- See the [HSR&D website](#) for more information and the process for submission.



# Dissemination of Results/Impacts: Reporting

- QUERI midyear/annual reports provide an overview of QUERI center goals, activities, and key impacts achieved, to date.
  - Submitted every six months via VA Redcap.
  - Guidelines and templates are updated and sent out via email 4-6 weeks before the deadline (midyear due end of April, annual due end of October) and are posted on the [QUERI SharePoint site](#).
- Information from reports is utilized for multiple purposes, including:
  - Conveying the value of QUERI impacts on Veteran care across diverse groups, including leadership, frontline providers, and Veterans
  - Supporting VA's enterprise approach to evaluation and the development of deliverables required as part of the Foundations for Evidence-Based Policymaking Act of 2018 (Public Law 115-435).
  - Responding to external requests (e.g., requests for information from Congress)
  - Recognizing and disseminating information to the public (e.g., QUERI website)

# Publication Requirements: Notification & Attribution

- Written attestations (from Appendix A of [Program Guide 1200.21](#) for non-research publications) are **not** required for QUERI-funded work.
- Notify HSR&D via the ORD PubTracker Website (<https://vaww.pubtracker.research.va.gov>) as soon as you have an article accepted for publication.
- Make sure to acknowledge VA QUERI support in articles, presentations, interviews, and other professional activities in which the results of QUERI-funded work are publicized or recognized.
- For more information on the notification process, attribution, and disclaimer, see the [HSRD website](#).

# Budget Guidance and Project Modifications

*Stefanie Gidmark, MPH*



# QUERI Budget Overview

QUERI SUMMARY BUDGET TABLE													
Corresponding PI: Last Name, First Name, Degree(s)			Project Duration: XX/XX/20__ - XX/XX/20__					Date: XX/XX/20__					
Project ID: XXX-XX-XXX		Project Title:											
								FY 20	FY 20	FY 20	FY 20	FY 20	
Primary Site VA Personnel	Degree	Primary Site	Role	Title 38 Clinical Appointment	Grade	Step	% Effort	Salary+Fringe	Salary+Fringe	Salary+Fringe	Salary+Fringe	Total	
Last Name, First Name		City, State		Y/N								0	
												0	
												0	
												0	
								0	0	0	0	0	
Site Subtotal								0	0	0	0	0	
Additional Site VA Personnel	Degree	Additional Site	Role	Title 38 Clinical Appointment	Grade	Step	% Effort	Salary+Fringe	Salary+Fringe	Salary+Fringe	Salary+Fringe	Total	
Last Name, First Name		City, State		Y/N								0	
												0	
												0	
												0	
								0	0	0	0	0	
Site Subtotal								0	0	0	0	0	
Project Total for Personnel								0	0	0	0	0	
Consultant(s)	Degree	Site		Licensed in U.S.				Year 1	Year 2	Year 3	Year 4	Year 5	Total
Last Name, First Name		City, State		Y/N									0
													0
													0
Equipment (total per site; do not itemize)								Year 1	Year 2	Year 3	Year 4	Year 5	Total
City, State													0
City, State													0
Supplies (total per site; do not itemize)								Year 1	Year 2	Year 3	Year 4	Year 5	Total
City, State													0
City, State													0
Project Travel (total from Budget Justification Travel Table; do not itemize)								Year 1	Year 2	Year 3	Year 4	Year 5	Total
City, State													0
City, State													0
Other (IPA, contract, transcription, other items and payments)	Degree (for IPA)	Site		Licensed in U.S. (for IPA)			% Effort	Year 1	Year 2	Year 3	Year 4	Year 5	Total
IPA: Last Name, First Name		City, State		Y/N									0
Service Contract		City, State											0
Transcription Services		City, State											0
Participant Payments		City, State											0
Publication Costs		City, State											0
Other		City, State											0
Project Total								0	0	0	0	0	0

- QUERI funds are one-year funds and do not roll over to the next fiscal year and unused funds will be swept at end of FY
  - Notify QUERI as soon as possible regarding expected unused funds
  - Budget Modifications should match approved FY amounts, not only overall project budget
- QUERI participates in VERA ([VERA Support Table](#); [VERA EDM](#))
- QUERI budget guidance and templates available on the [QUERI SharePoint site](#).

Totals by Site - FY 20__					
Site	Station Number	Site PI	Salary (Salary+Fringe for Personnel)	All Other (Consultant + Supplies + Equipment + Other + Travel)	Total per Site
City, State	XXX	Last Name, First Name			
City, State	XXX	Last Name, First Name			
Total Across Sites			0	0	0

# Itemized Budget Table: Personnel

- Project Budget divided into FYs, not project years
- Personnel should be grouped by site, with the site PI listed first
  - Include TBN positions
- MPI and Site Investigator Requirements
  - ePromise account
  - Doctoral Degree and 5/8ths VA
    - **UNLESS** approved by QUERI Central Office
- Title 38 Clinical Appointment
- Salaries must be within OPM approved salary rates
  - 2% allowable COLA/year
  - May include anticipated personnel actions (e.g., within grade increases), but must be explained in the budget justification

								FY 20	FY 20	FY 20	FY 20	FY 20	
Primary Site VA Personnel	Degree	Primary Site	Role	Title 38 Clinical Appointment	Grade	Step	% Effort	Salary+Fringe	Salary+Fringe	Salary+Fringe	Salary+Fringe	Salary+Fringe	Total
Last Name, First Name		City, State		Y/N									0
													0
													0
													0
													0
							Site Subtotal	0	0	0	0	0	0
Additional Site VA Personnel	Degree	Additional Site	Role	Title 38 Clinical Appointment	Grade	Step	% Effort	Salary+Fringe	Salary+Fringe	Salary+Fringe	Salary+Fringe	Salary+Fringe	Total
Last Name, First Name		City, State		Y/N									0
													0
													0
							Site Subtotal	0	0	0	0	0	0
Project Total for Personnel								0	0	0	0	0	0
Consultant(s)	Degree	Site		Licensed in U.S.				Year 1	Year 2	Year 3	Year 4	Year 5	Total
Last Name, First Name		City, State		Y/N									0
													0
													0



# Budget Justification: Personnel

## Budget Justification

Primary Site: New Castle, ST

### Personnel

**Snow White, Ph.D.**, Project Director/Principal Investigator, (2.4 cal mos, GS 14/3, 5/8<sup>th</sup> VA, salary \$21,874/yr, fringe \$9,374/yr, years 1-4.) Dr. White will oversee all aspects of the project. She will hire, train, and supervise all study personnel at the New Castle site and organize and lead the initial training for personnel at both study sites in Year 1. She will provide oversight of all aspects of participant recruitment, enrollment and retention, intervention delivery, data collection, analysis and dissemination.

**Happy G. O'Luckee, Ph.D.**, Co-Investigator (0.4 cal mos, GS 14/4, 5/8<sup>th</sup> VA, no salary requested in years 1-4.) Dr. O'Luckee is a licensed Clinical Research Psychologist based at the MIRECC affiliated with the Veterans Affairs Medical Center in Castle Rock, where she specializes in research on family interventions. She will assist Dr. White and her team in the creation and implementation of treatment strategies for adapting standard family communication training to accommodate emotion processing deficits.

# All Other: Equipment and Supplies

Equipment (total per site; do not itemize)	Year 1	Year 2	Year 3	Total
New Castle, ST	0	0	0	0

- If equipment sounds like IT, please note in justification that you have already consulted with local IT and confirmed that item is non-IT.

Supplies (total per site; do not itemize)	Year 1	Year 2	Year 3	Total
New Castle, ST	1,500	500	200	2,200

- Audio recorders should be categorized as supplies.
  - VA Microsoft TEAMS and VA WebEx may be used for interviews as long as all ORD human subject policy requirements regarding informed consent and applicable privacy regulations and policies are met. Zoom is not approved for interviews at this time.

# All Other: Travel Budget Justification

Traveler	Purpose	Destination	Days/ date	Lodging	Per diem	Transportation	Miscellaneous (taxi, tip...)	Estimated Total Cost

- Travel costs should be itemized per trip for hotel and transportation and listed in a table in the justification. Please include FY of projected travel.
  - Conference fees should be categorized as Other expenses, not travel.
- Travel is not authorized for non-VA employees; travel should be rolled into the contract or IPA mechanism with instructions to follow GSA and the VA's travel policies.

# All Other: Other Personnel Categorization

- An IPA is not a contract. It is an agreement with a University or Federal Agency. An IPA must name an individual.
  - VA employees cannot be paid as IPAs
- Contracts are **for services, not people**, and must go through contracting.
  - Describe the service; do not identify the individual(s) who will provide the service.
  - Contracting for clinical services is not permitted.
- Consultant costs are limited to \$500 per consultation and \$2,500 per annum.
  - Clearly explain the involvement of each consultant with regard to the proposed project, and the nature of the service to be provided.

Table Summarizing HSR&D/QUERI Budgetary Guidelines - Services Rendered by Individuals

	VA			Non-VA			
	Non-clinicians	Clinicians		Non-clinicians	Clinicians		
Licensed Medical Professionals		MD	Licensed Medical Professionals		MDs and Dentists <u>NOT</u> licensed in the US and providing NON-CLINICAL services	MD licensed inside US (including residents)	
<b>Personnel Section</b>	OK	OK if GS employee or if Title 38 Waiver granted by CRADO for services beyond usual care	OK, if time is contributed; Physicians and Dentists who are not licensed to practice in the US may request salary, but they must be clearly identified as such in the budget justification section.	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not allowed</i>
<b>IPA Section</b>	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not allowed</i>	OK	OK if budget justification states no clinical responsibilities	OK if not licensed in US and has no clinical responsibilities	<i>Not allowed</i>
<b>Contract Section</b>	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not Allowed. Contracts should be with the entity/agency providing the service who will then assign their employees. Contracts are for services, not individuals.</i>			
<b>Consultant Section</b>	<i>Not allowed; Should be listed under personnel</i>	<i>OK if no salary compensation</i>	<i>Ok if no salary compensation.</i>	OK	OK only if stated as performing non-clinical services	OK, can be paid consultant fee	OK if no consultant fee.

# Other Direct Costs

Other (IPA, contract, transcription, other items and payments)	Degree (for IPA)	Site	Licensed in U.S. (for IPA)	% Effort	Year 1	Year 2	Year 3	Total
IPA: Grimm, Wilhelm	LCSW	New Castle, ST	N	0/0/30	0	0	16,050	16,050
Service Contract (University of Oz)		New Castle, ST			10,000	10,000	10,000	30,000
Transcription Services		New Castle, ST			1,000	0	0	1,000
Participant Payments		New Castle, ST			5,700	5,400	5,400	16,500
Publication Costs		New Castle, ST			0	0	3,000	3,000
Other (Conference Registration Fees)		New Castle, ST			500	500	0	1,000

- HSR&D/QUERI is an intramural program; it is expected that any contracted services and/or IPAs will not exceed 30% of the proposed budget (COIN sites) or 40% (non-COIN sites).
- Contracts cannot be for clinical services.
- If devices, such as laptops or tablets, are intended for patient use only, they can be considered patient medical devices and can be a non-IT purchase (allowable cost).
  - If the devices will be used by both patients and personnel, then they are considered an IT purchase and cannot be purchased using QUERI funds



# Other Direct Costs: Participant Payments

Year 1: 90 assessments @ \$30 each = \$2,700

Plus compensation for participants screened but not enrolled = \$300 total or \$30 per Veteran

Year 2: 180 assessments @ \$30 each = \$5,400

Year 3: 180 assessments @ \$30 each = \$5,400

Year 4: 90 assessments @ \$30 each = \$2,700

*Total participant payments at this site: \$16,500*

- Participant Payments should be listed under the Other section.
- If the project plans to compensate VA employees for participation, the investigator team needs to contact their local OGC STAR (Specialty Team Advising Research).
- Payments to residents or other clinical trainees not authorized.
- The justification should include a list or table that clearly shows how the total amount was calculated.

# Final Steps: Summary Budget Site Table

Totals by Site FY 20__					
Site	Station Number	Site PI	Salary (Salary+Fringe for Personnel)	All Other (Consultant + Supplies + Equipment + Other + Travel)	Total per Site
City, State	XXX	Last Name, First Name			
City, State	XXX	Last Name, First Name			
<b>Total Across Sites</b>			0	0	0

- Double check addition and formulas and ensure the Corresponding PI has reviewed the budget for accuracy.
- Check that the budget justification, the itemized table, and the site-level tables match.
- Confirm that the budget does not exceed the total amount requested in the original application for each FY – not only the total requested amount.

# Software Purchases

- QUERI funds cannot be used for IT. Consult your local IT on any items that could be considered IT to confirm they are not and state that this has been confirmed explicitly in your justification.
- Atlas software is considered scientific computing and can be purchased. List under Other Direct Costs.
- GoToMeeting: Must be approved by local CIO before funds can be provided. Explicitly note approval in budget justification.
- SPSS, SAS, and Stata: [See ORD FAQs and Guidance](#)
- Qualtrics: See the [ORD Qualtrics Portal](#) to request access or contact [VHAORDQualtricsSupport@va.gov](mailto:VHAORDQualtricsSupport@va.gov) to transition an existing license to the ORD license.
- NVivo: Follow your local process for software installation to install from [this link](#).

# Requesting Funds Transfers

- QUERI funds are distributed directly to project sites according to the approved budget.
- If funds need to be redistributed **among existing project sites in the same fiscal year**, please submit an email request to [VACOQUERI@va.gov](mailto:VACOQUERI@va.gov).
  - Please include in the email the sending and receiving site PIs, the location and station numbers, the amount and type of funds that need to be transferred, and the reason for the request (e.g., fund research assistant salary).
- Note that the deadline for submitting requests for fund transfers may be as early as 10 weeks before the end of the fiscal year.

# Project Modifications

Submission of a [project modification form](#) is needed for:

- No-cost extensions
- Budget changes, including redistribution of funds between study sites for **future** fiscal years
  - Note: A **revised project budget table and justification** for all project years needs to be attached in the project modification form.
- Addition, replacement, or closing of study site(s)
- Changes in the corresponding PI, MPI, or site PI effort or eighths
- Changes in the corresponding PI, MPI, or site PI receiving funds or a PI station transfer
  - Note for Personnel Changes: The corresponding PI, MPI, or site PI receiving funds must be at least **5/8 VA**, have a **doctoral degree**, and be in **ePromise** at that site.
  - Please confirm this explicitly in the project modification form and provide an updated CV, budget table, and budget justification when adding/changing any MPIs or site PIs.



# Other Requests

Project Modification Forms are **not** needed for:

- Redistribution of funds between *existing* study sites in the **same** fiscal year
- Returning funds during the fiscal year
- Adding Salt Lake City CTSP to provide transcription services

Requests of this nature should be submitted to [vacoqueri@va.gov](mailto:vacoqueri@va.gov) with the following information:

- Project ID
- Corresponding PI
- Fiscal Year
- Funding category (salary or all other)
- Sending station number
- Sending station PI
- Receiving station number
- Receiving station PI
- Amount
- Brief explanation

# QUERI Resources

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*Melissa Braganza, MPH*



# CEIR

VA QUERI Center for Evaluation  
and Implementation Resources

# PEPReC

Partnered Evidence-based Policy Resource Center  
A VA QUERI Center



Health Economics Resource Center



## HSR&D/QUERI Resources

- Selecting and assessing fidelity to implementation strategies: QUERI's Center for Evaluation and Implementation Resources ([ceir@va.gov](mailto:ceir@va.gov))
- Aligning evaluations and implementation projects with legislative mandates, including the Evidence Act and MISSION Act: QUERI's Partnered Evidence based Policy Resource Center (PEPReC)
- Cost/economic analyses and evaluation appropriate for the selected strategies and training on data science/organization: HSR&D's Health Economics Resource Center (HERC)
- VA data resources and considerations regarding Cerner implementation: HSR&D's VA Information Resource Center (VIReC)
- Reviews of medical and health care evidence: Evidence Synthesis Program (ESP)

# QUERI Implementation Roadmap

[Link for QUERI Implementation Roadmap Guide](#)

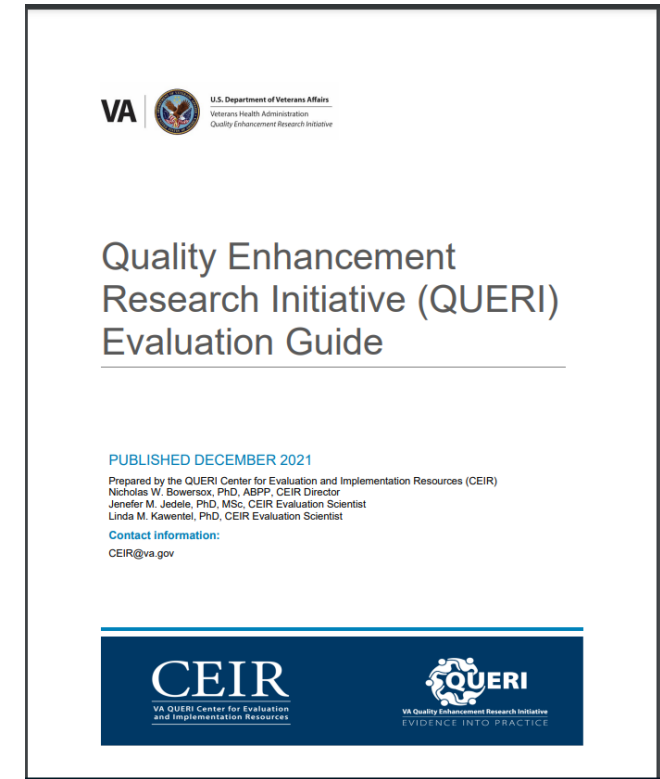


**CyberSeminar: The QUERI Implementation Roadmap: A Framework to Guide Partnered Implementation and Quality Improvement Efforts in a Learning Health System**

[Link for recording](#)  
[Link for slide deck](#)

# QUERI CEIR Evaluation Guide

- Designed to support the development, planning, and implementation of rigorous evaluations.
- Provides references, examples, and targeted materials that may be used side-by-side in designing an evaluation.
- Audience: VA employees, investigators, leaders.
- Posted on the [QUERI website](#).





# Points of Contact

- Contact Kara Beck, QUERI Program Manager, at [kara.beck@va.gov](mailto:kara.beck@va.gov) for questions re:
  - Request for Applications (RFAs), proposal ideas
  - Non-research and data collection requirements
  - Clinical trial registration
- Contact Stefanie Gidmark, QUERI Program Specialist, at [Stefanie.Gidmark@va.gov](mailto:Stefanie.Gidmark@va.gov) for questions re:
  - Midyear/Annual reporting
  - Project modifications, including extensions, budgets
  - Prefunding documents

# QUERI VA Central Office Team



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## Questions?

**We are happy to answer any additional questions! Please submit questions using the chat.**

**For questions that arise after the cyberseminar, please feel free to reach out to our office at [vacoqueri@va.gov](mailto:vacoqueri@va.gov).**