



# DATABASE & METHODS CYBERSEMINAR SERIES

Session #: 3

## Navigating VA Data Access: An Overview

December 5, 2022



Hosted by  **VIRec**

Linda Kok, MA

Senior Analyst, VA Information Resource Center



# DATABASE & METHODS CYBERSEMINAR SERIES

*Informational seminars to help VA researchers  
access and use VA databases.*

## Topics covered

- VA data sources & data access systems
- Application of VA data to research and quality improvement questions
- Limitations of secondary data use
- Resources to support VA data use



## UPCOMING DATABASE & METHODS SESSIONS

First Monday of the month | 1:00pm-2:00pm ET

Date	Topic
1/9/23	Geriatrics and Extended Care Data Analysis Center Residential History File (GECDAC RHF)

Visit the VIREC [Database & Methods Cyberseminar](#) page for more information & registration links.

Visit [HSR&D's VIREC Cyberseminar Archive](#) page to watch previous sessions.

Where can I  
download a  
copy of the  
slides?

VA HSR&D

CYBERSEMINARS



## SAMPLE EMAIL

**A Practical Approach to Working with VA-Purchased Community Care Data**

Thursday, October 13, 2022

2:00 PM | (UTC-04:00) Eastern Time (US & Canada) | 1 hr

Please download today's slides

~~Please click here for today's live captions~~

Join webinar

More ways to join:

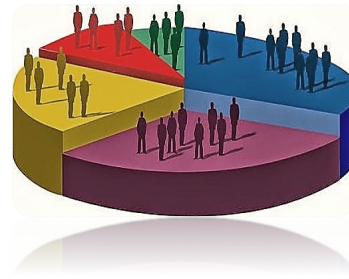
Join from the webinar link

<https://veteransaffairs.webex.com/veteransaffairs/j.php?>

## Poll #1:

*What is your primary **role** in projects using VA data?*

- Investigator, PI, Co-I
- Statistician, methodologist, biostatistician
- Data manager, analyst, or programmer
- Project coordinator
- Other – please describe via the chat function



## Poll #2:

*How many years of experience working with VA data?*

- None – I'm brand new to this!
- One year or less
- More than 1, less than 3 years
- At least 3, less than 7 years
- At least 7, less than 10 years
- 10 years or more



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# Terms and Acronyms Used in this Presentation

## Data source

- A file or group of files managed as an entity

## Data steward

- The office responsible for managing data and/or data access authorization

## DART

- Data Access Request Tracker

## ePAS

- Electronic Permissions Access System

## NDS

- National Data Systems

## VAEDA

- VA Exempt Determination Application

## VAIRRS

- VA Innovation and Research Review System (IRBNet)

## VINCI

- VA Informatics and Computing Infrastructure



# Learning Objectives

To enable you to

- Embody the principles of the VA ethics framework in data access & use
- Explain the difference between VA research, preparatory to research, and operations data uses
- Comply with regulatory requirements for accessing and using VA data for all types of data use
- Identify data access processes for commonly used data sources and where to find data access request information about others



# Session roadmap

- Ethics Principles Guiding Access & Use of Veteran Data
- Categories of data use
- Common VHA data access requirements for each category
- Data steward-specific access requirements for each category
- Resources

# Session roadmap

## Ethics Principles Guiding Access & Use of Veteran Data

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# Principle-based Ethics Framework for Access to and Use of Veteran Data

- [The National Center for Ethics in Health Care \(NCEHC\)](#)
  - Honor Veterans' values, goals, and preferences by driving healthcare ethics standards and nurturing strong healthcare ethics communities
- [AR52-Final Rule-Principle-Based Ethics Framework for Access to and Use of Veteran Data](#)
  - Final rule effective as of July 7, 2022

Questions: [vhaethics@va.gov](mailto:vhaethics@va.gov)

# In brief, the Principle-based Ethics Framework for Access to and Use of Veteran Data

- **Principle 1.** The primary goal for use of veteran data is for the good of veterans. Veteran data is personal and sensitive.
- **Principle 2.** Veteran data should be used in a manner that ensures equity to veterans.
- **Principle 3.** The sharing of veteran data should be based on the veteran's meaningful choice.
- **Principle 4.** Access to and exchange of veteran data should be transparent and consistent.
- **Principle 5.** De-identified veteran data should not be reidentified without authorization.
- **Principle 6.** There is an obligation of reciprocity for gains made using veteran data.
- **Principle 7.** All parties are obligated to ensure data security, quality and integrity of veteran data.
- **Principle 8.** Veterans should be able to access to their own information.
- **Principle 9.** Veterans have the right to request amendments to their own information.

# In brief, the Principle-based Ethics Framework for Access to and Use of Veteran Data

- **Principle 1.** The primary goal for use of veteran data is **for the good of veterans**. Veteran data is personal and sensitive.
- **Principle 2.** Veteran data should be used in a manner that ensures **equity to veterans**.
- **Principle 3.** The sharing of veteran data should be based on the veteran's **meaningful choice**.
- **Principle 4.** Access to and exchange of veteran data should be **transparent and consistent**.
- **Principle 5.** De-identified veteran data **should not be reidentified** without authorization.
- **Principle 6.** There is an **obligation of reciprocity** for gains made using veteran data.
- **Principle 7.** All parties are obligated to **ensure data security, quality and integrity** of veteran data.
- **Principle 8.** Veterans should be able to access to their own information.
- **Principle 9.** Veterans have the right to request amendments to their own information.



# Session roadmap

■ Ethics Principles Guiding Access & Use of Veteran Data

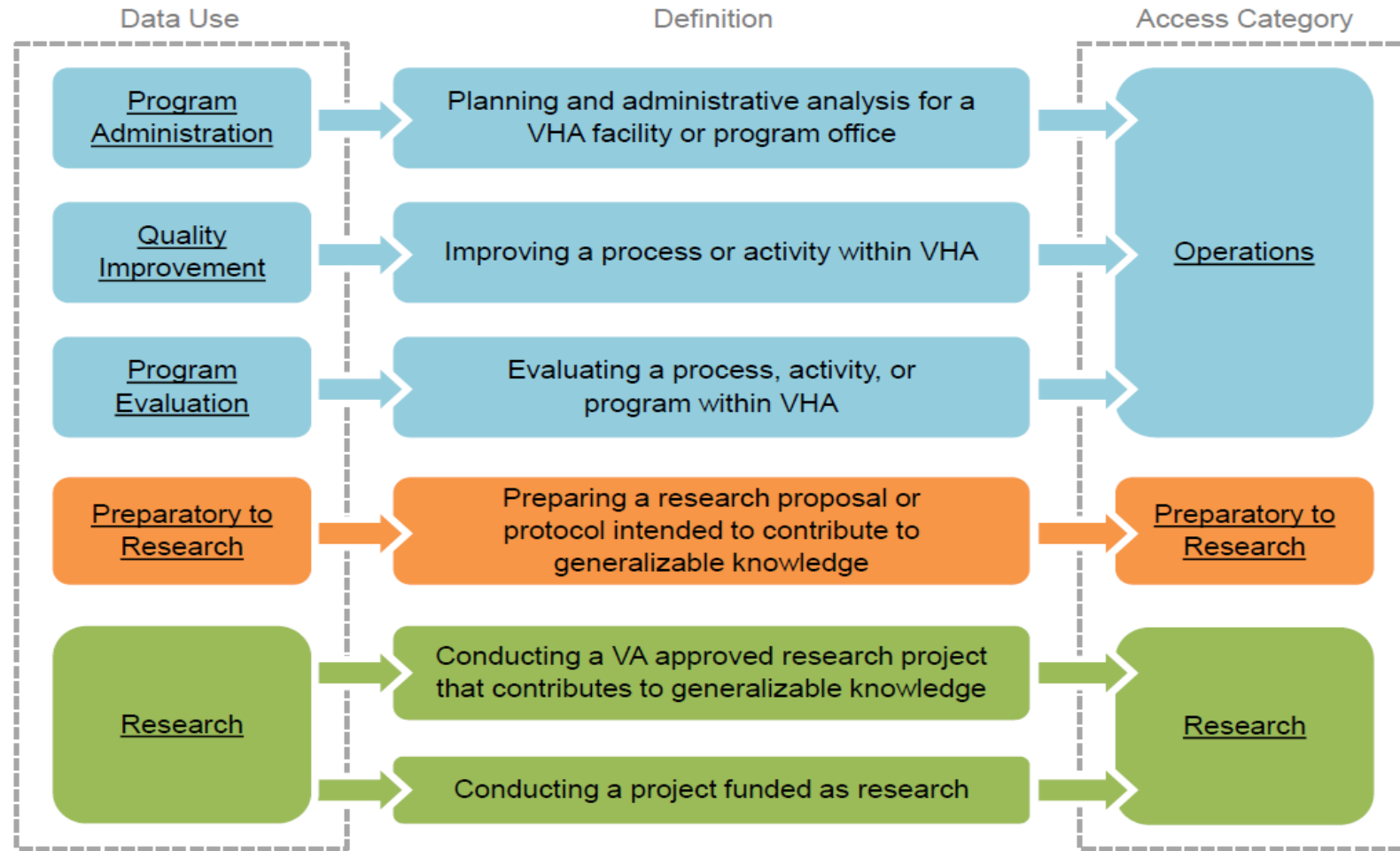
■ Categories of data use

■ Common VHA data access requirements for each category

■ Data steward-specific access requirements for each category

■ Resources

## Access Category Finder



Adapted from: [ORD Program Guide 1200.21 : VHA Operations Activities That May Constitute Research](#)  
 Location: [VHA Data Portal – Data Access - Research vs Operations Decision Tool and Access Category Finder](#)





# VAEDA – VA Exempt Determination Application

- Created by VA Office of Research and Development (ORD)
- Accessible to VA employees and appointees
- Produces a preliminary determination summary based on information you provide about your project
- Provides answers to questions like these
  - Is it quality improvement?
  - Is it research?
  - Is it human subjects research?
  - Is it human subjects research that is exempt from requirements of 38 CFR 16 including initial IRB review?
- Indicates next steps for your project



# Getting started with VAEDA



- Navigate to the VAEDA site in your browser.
- Access using your VA-issued credentials.
- First-time users complete and save a profile page.
- VAEDA presents an ordered set of questions with branching logic based on VA and ORD policy.
  - Input: You answer each question as it appears in the process
  - Output: Preliminary Determination Document

<https://vhacdwdwhvda01.vha.med.va.gov/vaeda/home#/>



 U.S. Department of Veterans Affairs

**Electronic Determination Aid**  
 (Send Questions To: [VAEDAsupport@va.gov](mailto:VAEDAsupport@va.gov))

Determinations My Profile Logout

### My Determinations

	Date ▼	Project Title ⇅	Created By ⇅			
	mm/dd/yyyy ×	project title ×	created by ×			

# VAEDA Preliminary Determination Document



NOT an approval letter authorizing you to begin your project



Retained in VAEDA indefinitely



Save a copy for your project records



Present to the facility research office, quality office, or other offices or committees when requested



Submit with your initial VAIRRS package



For assistance, contact the VAEDA support team at [VAEDAsupport@va.gov](mailto:VAEDAsupport@va.gov)

## When not to use VAEDA:



You already know your research project needs IRB approval (e.g., clinical trial)

Skip VAEDA and submit the project to VAIRRS/IRBNet

You are a local site of a multi-site project

The project lead at the primary site should share the final project VAEDA determination with all local site leads

Your project involves live animals or animal specimens, requiring IACUC review

Skip VAEDA tool and submit your project in VAIRRS

## Definition: Operations Activities

- Administrative, financial, legal, public health, quality improvement and quality assurance efforts necessary to support VHA's missions
- Designed and implemented for internal VA purposes
- Not designed to produce information to expand the knowledge base of a scientific discipline or other scholarly field
- Requires support or approval from VA director, administrator, or supervisor, e.g., a letter from the VHA program office or facility sponsoring the operations project

# Examples of Operations Activities

Quality assurance, quality improvement, program evaluation, and public health endeavors necessary to support VHA's missions

National, VISN, VAMC, hospital, and CBOC management and administration

Finance and business operations such as strategic analysis, planning, and forecasting



# Note: Findings From Operations Projects May Be Published

## Guidance & Form

[ORD Guidance 1200.21 Appendix A:](#)  
*Sample Format for Documentation of  
Non-Research Activities For Publications Outside the VA*

## Approval

Designated Official attestation that project was not  
research





## Definition: Research Activities

A systematic investigation, including research development, testing, and evaluation designed to

- develop or contribute to **generalizable** knowledge
- produce information to expand the knowledge base of a scientific discipline or other scholarly field of study

Note: Systematic investigation, in and of itself, does not define research.

# Examples of Research

## Always research

- Activities funded or otherwise **supported as research** by ORD or any other sponsor
- **Clinical investigations** as defined under Food and Drug Administration (FDA) regulations

## Likely to be research

- Double-blind interventions, use of placebo controls, and prospective patient-level randomization to clinical interventions not tailored to individual patient benefit

**Note:** Pilot studies are research activities- not preparatory to research

**Definition:**  
Preparatory  
to Research  
(PTR)

- Access to data is granted solely for preparing
- Research grant application, i.e., funding proposal
  - A new VA research protocol for submission to VAIRRS

# Typical Reasons to Access Data Preparatory to Research

Feasibility study

Statistical power analysis



# PTR Access

PTR access may not be used for research-like analyses or pilot studies

PTR access may not be used for collecting contact information for subject recruitment

PTR person-level data may not be downloaded from VINCI

PTR person-level data may not be removed from VHA



# PTR Access Limitations

Aggregate PTR data may be downloaded from VINCI **only** if all cell-sizes have more than 10 individuals or meet NDS limits

PTR access to data ends when the protocol is submitted to an IRB or R&D Committee or VAIRRS

Notify all data stewards, e.g., DART, as soon as your protocol is submitted to VAIRRS



# Session roadmap

- Ethics Principles Guiding Access & Use of Veteran Data
- Categories of data use
- Common VHA data access requirements for each category
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- Resources



# Common VHA Requirements for Data Access

- ▀ **Operations** –Documentation of supervisor's approval
- ▀ **Research** - Documentation of supervisor's and facility research regulatory approval
- ▀ **Preparatory to research** – Documentation of supervisor's approval and investigator's affirmation to comply with HIPAA and ORD policies

# Operations Requirements

Access requests are submitted via email or electronic tool

For example, NDS uses the Electronic Permissions Access System (ePAS)" electronic platform

Program offices often use email to receive data access requests, e.g., Rehabilitation, Prosthetics, and Dental

# Research Data Access Requirements

At each facility with staff\* involved in the research project using PHI data:

- Protocol (or protocol summary information) as submitted to the primary site
- IRB approval or Exempt Determination document, as applicable
- For **non-exempt** projects, documented IRB approval of informed consent, a waiver of documentation of consent, or a waiver of informed consent
- Documented IRB or Privacy Board approval of a HIPAA authorization, waiver of HIPAA authorization for part of the project, e.g., screening, or a waiver of HIPAA authorization for the entire project
- Research and Development Committee approval document

\* Facility employee or Without Compensation (WOC) appointee or contractor

# Preparatory to Research Requirements

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IRB and facility R&DC approval are not required – PTR data access happens before there is a research protocol

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Approval of HIPAA authorization or waiver of authorization is not required

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Researcher must attest to understanding and commit to complying with all requirements governing PTR access in a memo to the project file for DART PTR requests, and perhaps other request processes



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## Data Stewards of Commonly Used Data

National Data Systems

Medicare Analysis Center

VIReC

Pharmacy Benefits Management

Mortality Data Repository VA/DoD Board of Governors

Patient Care Services Office

# Data Steward: National Data Systems

## Operations access requests

- **Request submission via:** [NDS Healthcare Operations Request Process](#)
- **Application:** Electronic Permissions Access System (ePAS)
- **Approval level:** Individual
- **Affirmation:** Access will not be used to provide data access for research
- **Organizational approval:** Requestor's supervisor





# Data Steward: National Data Systems – ePAS Process

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

Complete all required elements



Select the data sources needed



Look for new tabs at the top to complete



Select supervisor from list



Affirm, sign & submit



# Data Steward: National Data Systems

## Research access requests

- **Request submission:** [DART Research Request Process](#)
- **Application:** Data Access Request Tracker (DART)
- **Approval level:** Research project and project team members listed
- **Pre-submission requirements:** VA Facility IRB/R&DC approval, HIPAA document approval, PI's supervisor's approval
- **DART approvals:** NDS, Privacy, Security, ORD (depending on data source, venue, identifiers)



# Data Steward: National Data Systems – Research Continued

In DART

(Select Filter: Research)

Complete all elements on Information and Participants Screens

On Data screen

Indicate data use location(s)

Select record identifier(s)

Select the data sources needed

On Documents screen

Upload all required documents

Verify request completeness

Submit

# Data Steward: National Data Systems

## Preparatory to research access requests

- **Request submission:** [DART Preparatory to Research Request Process](#)
- **Approval Level:** PI and any staff assisting on data work for protocol
- **Pre-submission requirement:** PI's supervisor's approval, HIPAA affirmation
- **DART approvals:** NDS, Privacy, Security, ORD (depends on data source, venue, identifiers)



# Data Steward: National Data Systems – PTR Continued

**In DART**

(Select Filter: Preparatory to Research)

Complete all elements on Information and Participants Screens

On Data screen

Indicate data use location(s)

Select record identifier(s)

Select the data sources needed

On Documents screen

Upload all required documents

Verify request completeness

Submit

# Data Steward: Medicare Analysis Center (MAC)

## Operations access requests for CMS data use

- **Pre-request data consultation**
- **Access forms**
  - Petition to Become a CMS Data User
  - MAC Data Request form
  - Individual users sign Rules of Behavior
  - Data Use Agreement (DUA) Required
- **Project Manager/Supervisor approval**



# Data Steward: VA Information Resource Center (VIReC)

## Research access requests for CMS data use

- **Pre-request consultation – before getting facility official's approvals**
- **Research regulatory documents**
  - R&DC approval letters
  - IRB approval or Exempt determination letters
- **Access forms signed by PI & facility officials**
  - Project Information & Authorization Form – ACOS-R
  - Data Security Compliance Form - ISSO
  - Data Description Form - Privacy Officer
  - VA/CMS Rules of Behavior - Individuals with access to data



# Data Steward: Pharmacy Benefits Management System Data

## Operations and research access requests

**Step 1 Temporary process:** Email [Nikia Griffith](#) for a copy of the Memorandum.  
Watch HSRData list serv for updates

**Step 2** Read and complete the form in the VHA Pharmacy Benefits Management ,  
Policy Memorandum 119 (R-1) Updated June 2020

**Step 3** Attach a copy of the R&DC approval letter and abstract/narrative  
proposal/protocol with the completed Memorandum and email to [Nikia Griffith](#)





# Data Steward: VA/DoD Mortality Data Repository (MDR): Board of Governors (BoG)

## Operations & research access requests

- [Mortality Data Repository](#): Provides requestors with dates of birth and death, gender, state, and cause of death from National Death Index
- *Data available through December 31, 2020*
- Request access: [VHACANMDRDataRequests@va.gov](mailto:VHACANMDRDataRequests@va.gov) for application materials & submission assistance
- The VA/DoD BoG is responsible for the MDR and reviews all applications.
- Upon approval, requestors will be asked to submit a search (finder) file for match
- Mortality data are available for VA-approved studies at no additional cost
- Results are typically returned within one month



# Data Steward: Patient Care Services (PCS): Data Request Process

## Operations and research access requests

For PCS datasets not available through DART, such as

- National Prosthetics Patient Database (NPPD)
- Podiatry
- Dental

Access supported with Data Transfer Agreement (DTA) for

Program Evaluation : Program Office, PCS Database Steward approval

Quality Improvement: Program Office, PCS Database Steward approval

Research: R&DC Chair/Medical Center Director or Chief Consultant approval



SharePoint

<https://dvagov.sharepoint.com/sites/VHAOSPM/default.aspx>

BROWSE PAGE

- Pharmacy Data Dictionaries
- SWS Data Dictionary
- Rehab Data Dictionaries
- Primary Care Data Dictionary
- Diabetes Data Dictionary
- Podiatry Data Dictionary
- Rehab Data Dictionary
- Geriatrics Data Dictionary
- Geriatrics DD
- MRSA DATADictionary
- HBPC

(Att I)

DTAExtension(Att E)	June 18, 2014
DTAProgramEvaluation (Att C)	August 26, 2015
DTAQIRequest(fillable) -Att B	May 20, 2016
DTAResearchRequest(Att A)	May 20, 2016
FTE VA Appointment forResearch(Fillable)	February 9, 2016
ftee	April 10, 2009
Leaving	March 27, 2009
PCS DTA amendment form (ar042209)	September 19, 2016
PCS DTA Policy(032309)	May 25, 2016

Email to: [VHA10P4CorrespondenceActionGroup@va.gov](mailto:VHA10P4CorrespondenceActionGroup@va.gov)

Strickland, Julie A

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- Ethics Principles Guiding Access & Use of Veteran Data
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# Best sources for access information

## ■ VHA Data Portal

Department of Veterans Affairs  
VHA Data Portal

Home About Us Contact Us FAQ Report Broken Link

Data Sources Data Access Tools & Applications Resources Training Policy & Admin 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 User Tools, examples

- Data Sources
- Data Access
- Tools & Applications
- Resources, examples
  - CIPHER
  - Data Reports
  - Data Services
  - Research User Guides
  - SQL Code Snippets
  - Data.gov
  - VA Systems Inventory (VASI)

- VIREC Good Data Practices: *Access to VA Data Series*, Angela Jannotta, BA, Data Policy and Access

# VIReC GOOD DATA PRACTICES: *ACCESS TO VA DATA* SERIES

- Angela Jannotta, BA, Data Policy and Access Specialist

## Session #1

- [Research Access to VA Data](#)
- March 28, 2022

## Session #2

- [Preparatory to Research Access to VA Data](#)
- April 11, 2022

## Session #3

- [Operations Access to Data](#)
- April 25, 2022



THANK YOU!  
Questions?



# CONTACT INFORMATION

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VA Information Resource Center  
Hines VA Hospital

[Linda.kok@va.gov](mailto:Linda.kok@va.gov)







## DATABASE & METHODS CYBERSEMINAR SERIES

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Next session:

January 9<sup>th</sup>, 2023 at 1 pm Eastern

Geriatrics and Extended Care Data Analysis Center  
Residential History File (GECDAC RHF)



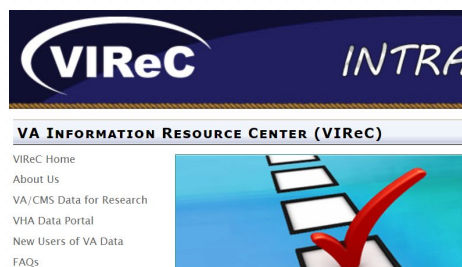


# Database & Methods BONUS SLIDES



# Resources for VA Data Users

Select image to visit page



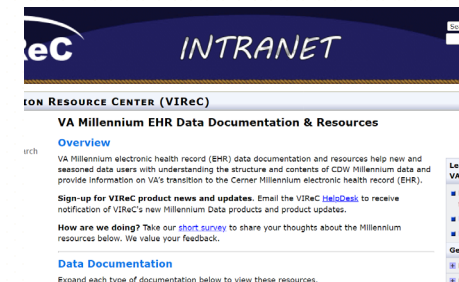
VA Information Resource Center (VIREC) (VA Intranet)



VHA Data Portal (VA Intranet)



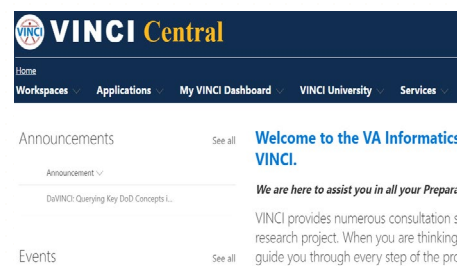
VIREC Cyberseminars



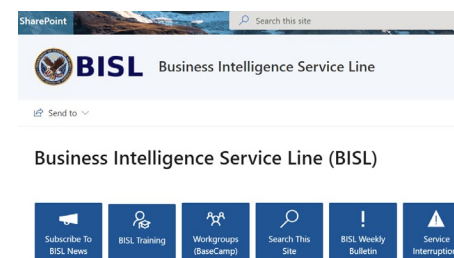
VA Millennium EHR Data Documentation (VA Intranet)



Quick Guide: Resources for Using VA Data (VA Intranet)



VA Informatics and Computing Infrastructure (VINCI) (VA Intranet)



BISL/CDW (VA Intranet)



Health Economics Resource Center (HERC) (VA Intranet)



## Questions about using VA Data?

### HSRData Listserv

- Community knowledge sharing
- ~1,400 VA data users
- Researchers, operations, data stewards, managers
- Subscribe by visiting  
[vaww.virec.research.va.gov/Support/HSRData-L.htm](http://vaww.virec.research.va.gov/Support/HSRData-L.htm) (VA Intranet)

### VIReC HelpDesk

- Individualized support
- Request Form:  
[varedcap.rcp.vaec.va.gov/redcap/surveys/?s=KXMEN77LXK](http://varedcap.rcp.vaec.va.gov/redcap/surveys/?s=KXMEN77LXK) (VA Intranet)



## Navigating VA Data Access **BONUS SLIDES**

- Additional Tips on Data Access/Use Requirements
- VHA Data Portal: Data Source & Access Information



# Tips for faster research data access approvals

- In research protocol:
  - Provide a clear description of protocol aims and planned measures for each
  - Describe the types of identifiers & key variables needed and how (why) they will be used for each aim. It could reduce delays & save time later
  - Learn about the available data and describe in your protocol how your planned data choices fit the proposed analyses. For example, if you will need access to CAPRI/JLV, be sure to say that in the protocol. If you need a large amount of data, explain why this is necessary to reduce delays
- Use VAEDA to determine the review and data use categories, and what facility reviews are needed to reduce delays. If your site has adopted VAEDA, upload the preliminary determination to the initial VAIRRS package
- Maintain regulatory documents in orderly fashion to facilitate data access request submissions



# Research Data Access Requests

- Understand required local facility research approvals
  - Requirements if you are a primary site or a secondary site
  - Facility protocol reviews for exempt vs non-exempt
  - Submit initial and most current research approvals for new requests and relevant approvals with amendments to support changes in staff, data, location
- Request only the data needed for your research project – refine your research cohort inclusion and exclusion criteria
  - Many data stewards will apply your cohort criteria and save you time - ask if you're not sure
- Access only the data approved by the data steward for your project
- Never use or allow others to use operational data access permissions to access data for your research project



# Compliance Tips on Access and Project Close

- Access only the data approved by the data steward for the project
  - Use the data only for the purpose access was granted
    - PTR access cannot be used for research activities including recruitment or screening
    - Operations access cannot be used to access or obtain data for (anybody's) research
- Submit a data request amendment if you need additional data, to add staff, or to add locations
- End data access when the work is done:
  - Request removal of PTR data access when the protocol submitted to VAIRRS
  - Submit project closure request to all data stewards and notify facility Research Records Liaison when research project is closed
  - Notify Records Officer for your facility or office when operations project is completed





# Notes on Preparing a Data Request for a new Project

- Know where to find request process instructions & identify the data steward for each data source
- Select the least risky record identifier (SSN, ICN, scrSSN) available
- Use the most up-to-date request forms. They're available on the VHA Data Portal for DART requests
- Identify the platform/venue where you will use the data
- Confirm where and how you'll receive/access the data once request is approved

