



 GOOD DATA PRACTICES SERIES

FY2024 Session #: 4

Planning for Data at Project Close

June 12, 2024

Hosted by 

Susan Salas, MLIS

Linda Kok, MA

VA Information Resource Center (VIReC)

GOOD DATA PRACTICES CYBERSEMINAR SERIES

Informational seminars to help VA researchers access VA databases.

Topics Include:

Planning for Data for a New Research Protocol

Planning for Data Privacy for a New Research Protocol

Notes to Your Future Self: The Living Protocol

Planning for Data at Project Close



GOOD DATA PRACTICES SESSIONS

First session 12:00pm-1:00pm ET, remaining sessions 2:00pm-3:00pm ET

Date	Topic
4/3/24	Planning for Data for a New Research Protocol
5/1/24	Planning for Data Privacy for a New Research Protocol
5/29/24	Notes to Your Future Self: The Living Protocol
6/12/24	Planning for Data at Project Close

Visit the [VIReC Cyberseminars](#) page for more information & registration links.

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



Where can I
download a
copy of the
slides?



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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Polls #3 and #4

Have you ever prepared research data for reuse?

1. Yes
2. No

Are you working on or planning a project that will produce data that might be reused?

1. Yes
2. No

Agenda

- GDP Cyberseminar Series Recap
- Current closure and data use policies
 - VA and external
- Closing a research project
 - VA records retention & disposition for research investigator records
- Reuse of research data
 - Prepare for reuse of data & documentation



Agenda

- **GDP Cyberseminar Series Recap**
- Current closure and data use policies
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Sarah Krein

Planning for Data for a New Research Protocol

- Where to find study data
- How to be specific about your data reuse plan in your protocol
- How to determine and obtain legal authority to reuse
- What are the types of de-identification



Tomica Jefferson

Planning for Data Privacy for a New Research Protocol

- Plan consent and authorization language with data reuse in mind
- Understand full waiver of consent & authorization
- Levels of de-identification



Matt Maciejewski

Notes to My Future Self: The Living Protocol

- Document as you go
- Capture data decisions in Living Protocol
- Document and clarify programming code with comments
- Easier manuscript writing, reviewer questions & valid reuse



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Current VA Policy on Records Retention & VA Data Reuse at Project Close

VA Records Management policy requires submission of a records inventory for each project, removal of data access, retention per Records Control Schedule 10-1 at project close

ORD data reuse policy requires research generated or transformed data available for reuse to be stored in a research data repository

VHA and HIPAA privacy policy requirements govern what Personally Identifiable Information (PII) and Protected Health Information (PHI) may be disclosed

VA data security policy requirements govern release of VA sensitive information outside the VA firewall

Note: Applicable VA & VHA Directives linked on Reference slide



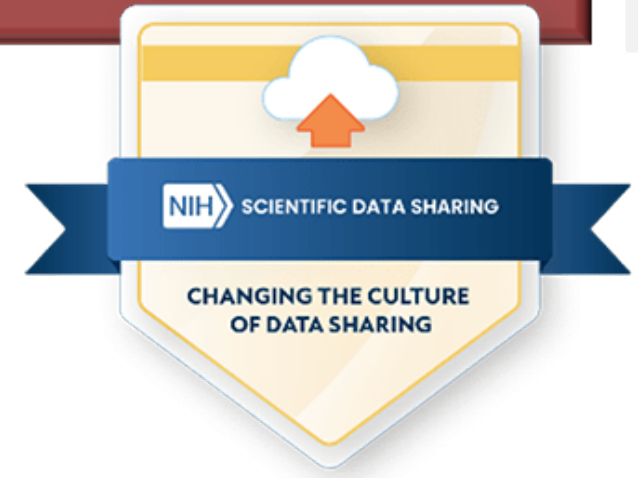
Current NIH Priorities

Under the DMS policy (DMSP), NIH expects investigators and institutions to:

- Plan and budget for the managing and sharing of data
- Submit a DMS plan for review when applying for funding
- Comply with the approved DMS plan

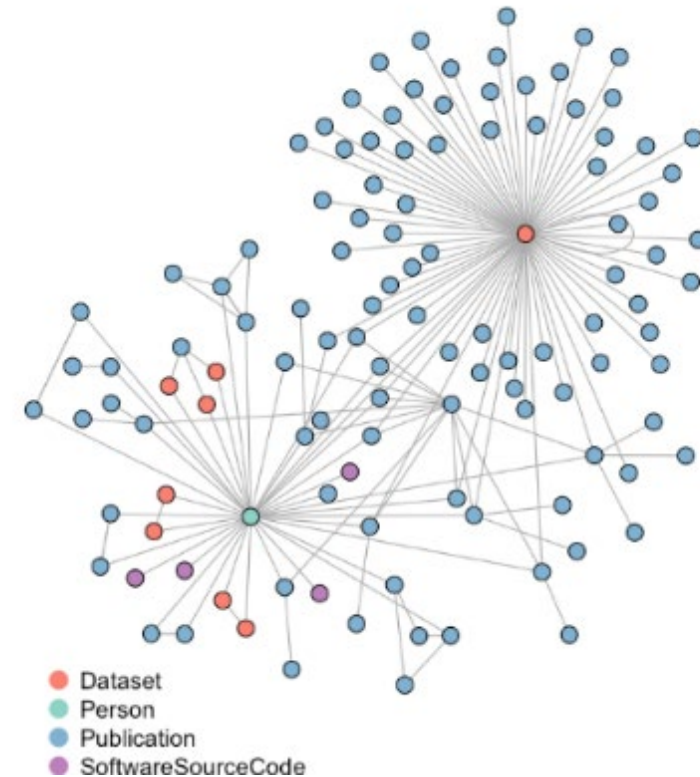
Data should be:

- Widely & freely available
- With timely release and sharing
- While protecting patient/subject privacy



Publisher Requirements

- Which publishers suit your work?
- Understand data management policies
 - Mandatory sharing vs. recommended sharing
 - Repository requirements
 - Embargoes



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Records Policy Documents

➤ VA Directive 6300 Records Management

– 6300.6 Research Investigator Files

➤ VHA Records Control Schedule (RCS 10-1)

– Item 8300.6 - Research Investigator Files

- Research records maintained by the investigator that span the entire project lifecycle
- Records required by regulations such as the investigator's regulatory file



What are records?

- Books, papers, maps, photographs, machine readable materials (project data), or other documentary materials, regardless of physical form or characteristics (including texts, emails, social media posts, etc.)*
- Made or received in connection with the transaction of public business (VA research) and appropriate for preservation by that agency
- Evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the government (VHA)

Specific to research:

- Unique data generated/transformed during or by research that contributed to the research findings and associated documents.

*See NARA bulleting 2023-02 on the Resources slide



What are non-records?

Examples

- Informational materials preserved solely for purposes of reference
- Extra copies of materials preserved only for convenience – official copies have been retained elsewhere
- They do not represent significant basic steps in the preparation of record copies of documents
- They are not circulated or made available to employees other than the creator
- They do not contain unique information that aids in the understanding of VA business that has not been made part of the official record
- Letters of transmittal that do not add information to that contained in the other preserved project records
- Other material determined to be non-record based on the appraisal procedures or material used in preparing official copies, e.g., word processing, shorthand notes



Records Management and Inventory

A records inventory should include:

- Initial proposal documents (protocol, approvals, funding applications, oversight committee documentation, etc.)
- Correspondence with oversight officials
- Subject records, including consent documentation and adverse events
- Data analyses, code and keys
- Reports or other publications
- See 6300.6 for full list

Note: All records remain with the VA upon investigator departure



New VHA Data Portal Closure Page

Home About Us Contact Us FAQ Report Broken Link

Department of Veterans Affairs
VHA Data Portal

Search...

Data Sources Data Access Tools & Applications Resources Training Policy & Admin Support

Data Access > Closing a Research Project

On this page

- Overview
- Records Retention Policy
- Closing Project
- Resources

Closing a Research Project

Overview

Once your research project is complete, your study team will initiate the process of closing the project. Note: You may no longer access the study data after the project has been closed.

Records Retention Policy

Research records must be retained in accordance with [VA Records Control Schedule \(RCS\) 10-1](#) and [Directive 6300, Records Management](#). The current RCS specifies that research investigator files are retained for six years after the cutoff date (i.e., the end of the fiscal year after completion of the research project) or longer if required by other Federal regulations, such as Federal Drug Administration governed clinical trials.

VA Requirements for Closing a Research Project

- Follow the funder's guidance for any final report requirements.
- Submit a project closure request to the primary oversight committee for the project (Institutional Review Board, Research and Development Committee, or both) in accordance with your local facility's standard operation procedures.
- Work with your Research Records Liaison and the facility Privacy and Records Officers to ensure you follow all policies for
 - Documenting your data
 - Verifying which files are considered records
 - Destroying files that are not records
 - Determining appropriate records disposition type
 - Updating your project's record inventory, e.g., categories of project records, current location of paper records, and server and folder name where electronic records are stored, including the VINCI project workspace name
 - Retaining or archiving paper and electronic records stored on your local server
 - Removing access to study data

Note: Ask Research Service for the Research Records Liaison's and facility Privacy Officer's contact information. View the [VHA Records Officer Roster](#) to find the Records Officer for your facility.

- Close the project in the Data Access Request Tracker (DART) and archive it on the VA Informatics and Computing



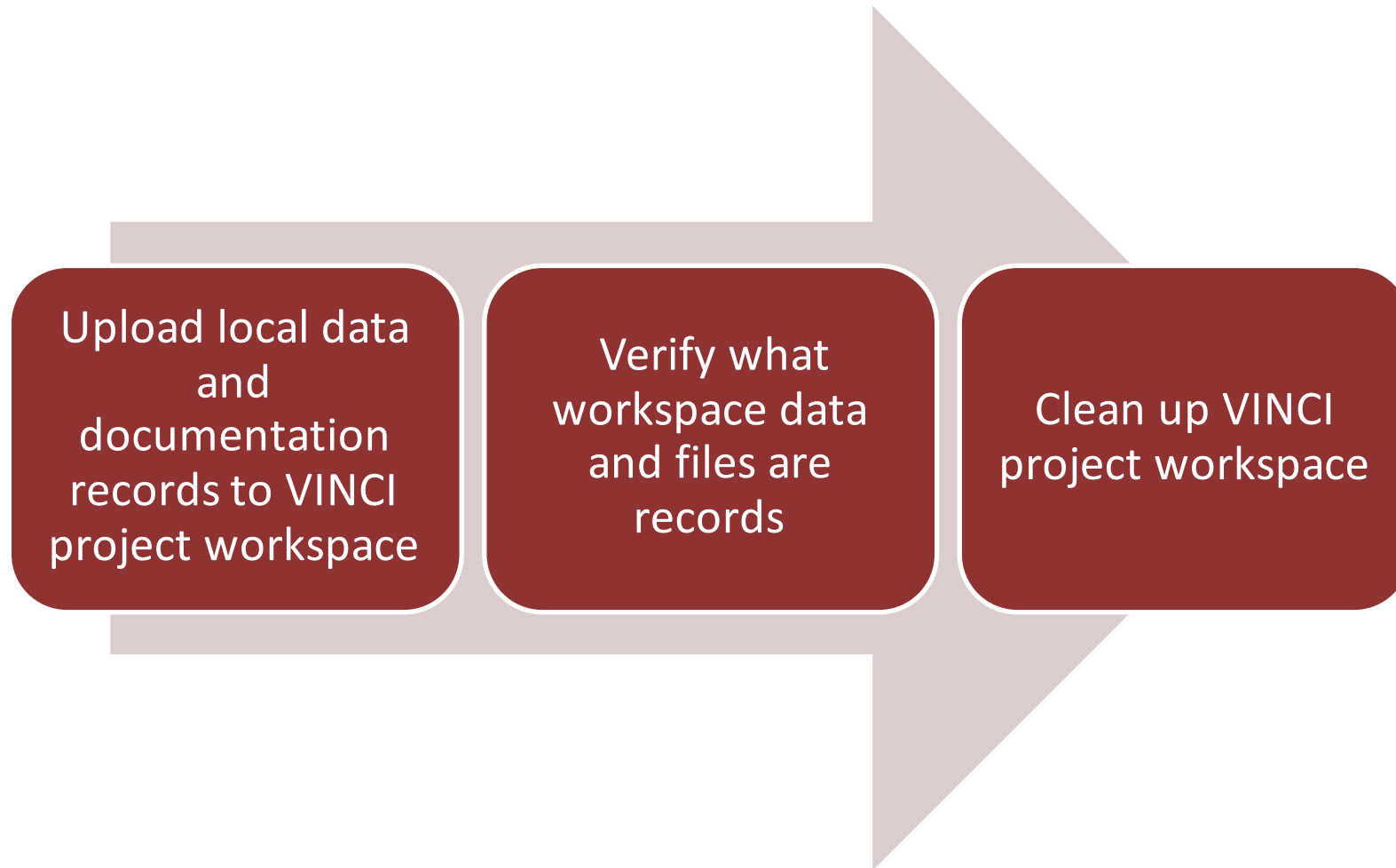
Research Protocol Closure Process

- ✓ Notify & consult local Research Records Liaison (RRL) and/or Records Officer (RO)
 - To submit a copy of the project's records inventory
 - For help determining what is and isn't a record
 - To confirm the required records retention schedule
- ✓ Request approval for project closure from the IRB and/or R&D Committees
- ✓ After closure approval, notify local AD/PAC or OIT to remove access to data stored locally

Note: Contact your facility's AO for assistance in identifying an RRL

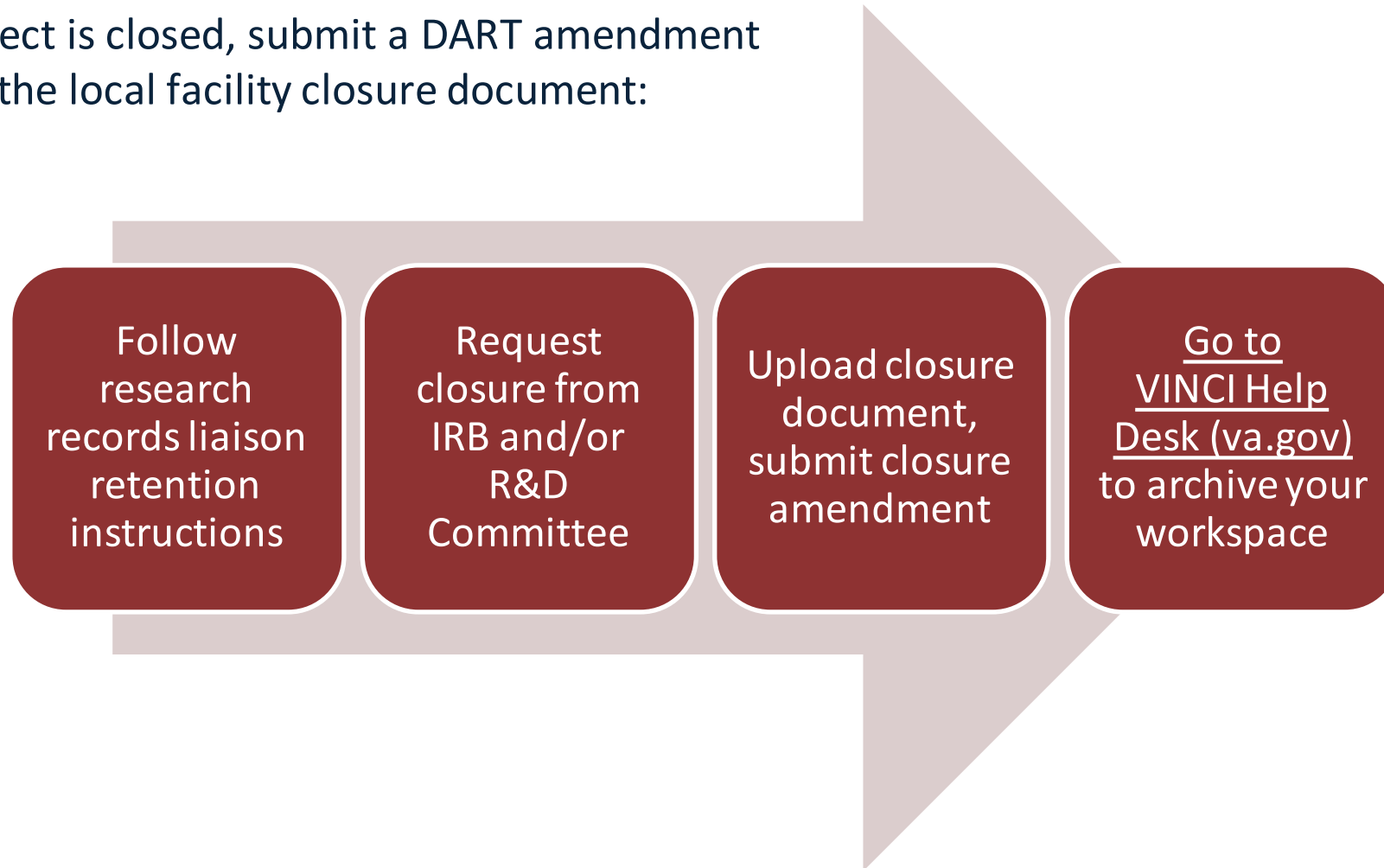


Tip: If data are on VINCI and on a local server, consider consolidating data and documentation records on your VINCI project workspace



DART Closure

Once project is closed, submit a DART amendment including the local facility closure document:



My Requests View or edit your existing requests	Dev Workspace Request a virtual machine environment for your project	Standard Workspace
Vinci Help Access issues and DART related problems	Data Archive Project is finished or suspended	Additional Space Additional storage for folders, databases, etc...
Software Suggest software not currently available in VINCI	New Project New to VINCI or if you would like to request a new project.	

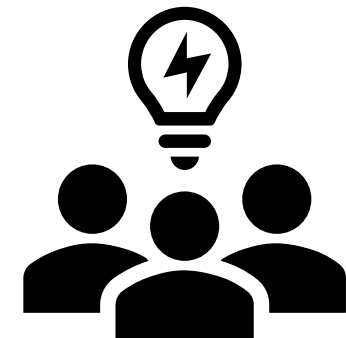
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Data Reuse Benefits

- ✓ Encourage innovation, new approaches
- ✓ Hasten scientific discovery, create new knowledge
- ✓ Allow for meta-analyses
- ✓ Ensure accuracy of research findings
- ✓ Increase trust in findings
- ✓ Reduce data collection/preparation effort & costs
- ✓ Provide a return on taxpayers' investment
- ✓ Further health research equity efforts



Why make your data available for reuse?

- Save data prep time and \$\$\$ on your next project
- Promote your research
- Enable new discoveries with your data
- Find collaborators
- Publisher requirement
- Increase citations of your publications



VA Data Reuse Policies

Identifiable data in approved VHA research data repository

- ✓ Self and project team
- ✓ VA-approved research

Disclosure outside the VHA

- ✓ De-identification approved by VHA Privacy Office
 - Safe harbor
 - Expert determination
- ✓ Aggregate tables/figures – cell size restriction

Approval of Under Secretary for Health or their Designee



VHA Handbook
1200.12
Use of Data and
Data
Repositories in
VHA Research

VA-Approved Research Data Repository: Policy

- Contains data generated or transformed during a research protocol that are maintained after the completion of the research protocol for future use
- The protocol may be a primary research project designed to prove or disprove a specific hypothesis or specifically designed to collect data for the repository



Approvals Affecting Data Reuse

IRB-approved written informed consent and HIPAA authorization that allow reuse

IRB-approved full waiver of HIPAA Authorization and informed consent

IRB-approved protocol that specifies data reuse

Privacy office approval of data reuse





Recent Standards and Initiatives for Data Sharing



It's Dangerous to Curate Alone...



Use existing resources and best practices:

- LibGuides
- Checklists
- Publications
- Toolkits

Example Documentation Checklist for Reuse

- Titles and authors of protocol and datasets
- Preferred citation
- Study aims and design
- Data sources used
- Data collection, cleaning & management decisions
- Decision changes and rationale
- Methods for creating the analytic dataset
- Analytic methods and tools used
- Data limitations and other issues discovered
- Final project records inventory created
- VA criteria applied for allowing reuse
- Secure method established for sharing the data



FAIR Data



FAIR data must be:

Findable: searchable online with a persistent identifier

Accessible: machine-readable and downloadable (with permissions detailed)

Interoperable: data in standard or commonly-available formats; study materials use controlled vocabularies/CDEs

Reusable: documentation and data are easy to understand and sufficiently descriptive



THANK YOU!
Questions?



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GOOD DATA PRACTICES BONUS SLIDES



Resources

[Records Control Schedule](#)

[VHA Directive 6300](#)

[VHA Data Portal Project Closure Instructions](#)

[Closing a VINCI Workspace](#)

[NIH Data Management and Sharing Policy](#)

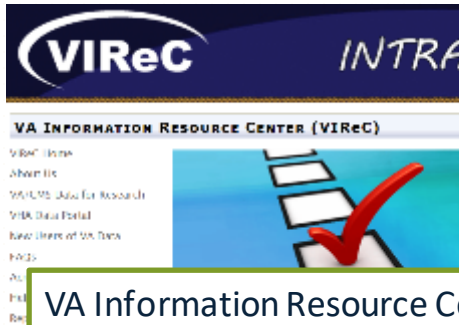
[FAIR Data](#)

[Records Officer Roster](#)

[Office of Research Oversight](#)

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
- ~1,800 VA data users
- Researchers, operations, data stewards, managers
- Subscribe by visiting 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 (VA Intranet)

