GOOD DATA PRACTICES SERIES

FY24 Session #1:

Planning for Data for a New Research Project

April 3, 2024

Hosted by VIReC

Sarah L. Krein, PhD, RN
VA HSR&D Research Career Scientist

UPCOMING 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 Privacy for a New Research Protocol
5/1/24	Planning for Data Security for a New Research Protocol
5/22/24	Notes to Your Future Self: The Living Protocol
5/29/24	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.

GOOD DATA PRACTICES CYBERSEMINAR SERIES

Informational seminars to help VA researchers access VA databases.

Topics Include:

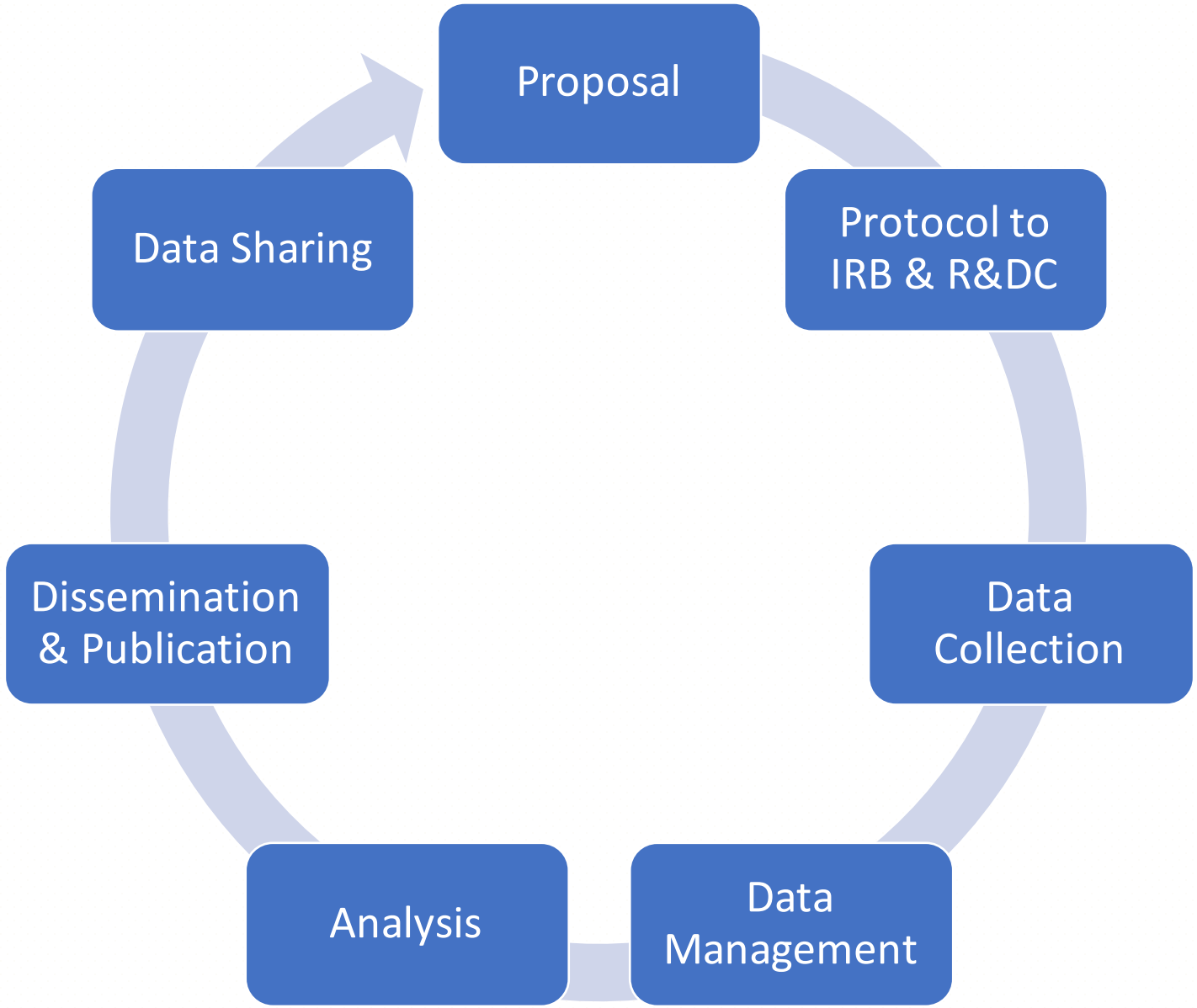
Planning for Data for a New Research Protocol

Planning for Data Privacy for a New Research Protocol

Notes to Your Future Self: The Living Protocol

Planning for Data at Project Close

Research Project Data Lifecycle



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

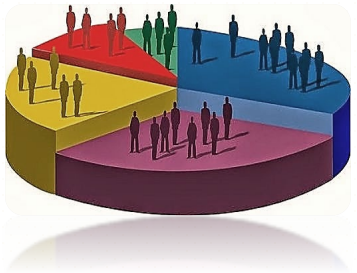
More ways to join:

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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Roadmap for today's session

1. Identify factors that influence data needs

2. Discuss data-related questions that need to be answered early in protocol development

3. Describe special considerations for conducting VA research, including privacy and security, data use and sharing

Why is advance planning related to data important?

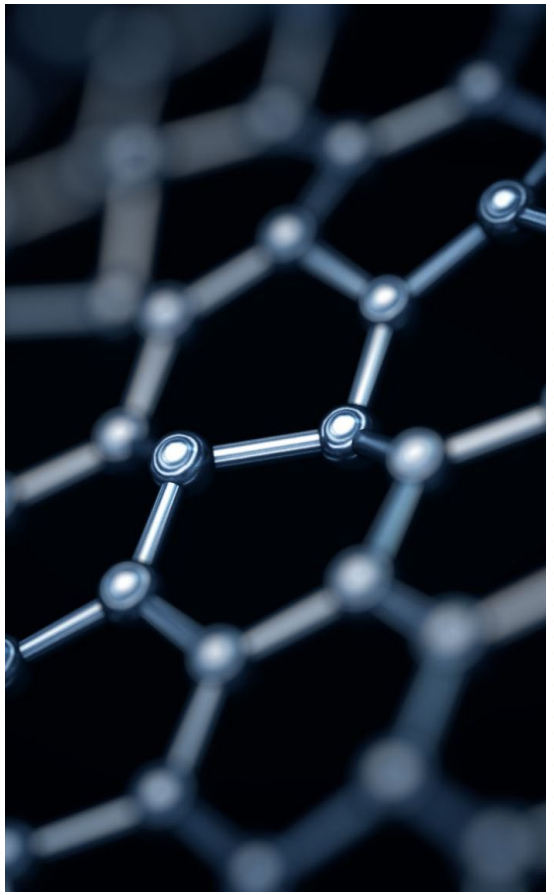
- Project feasibility
- Necessary for developing study protocol
- Identify potential issues before you start
- Study team composition
- Budgeting
- Timeline

Factors that Influence Data Needs

GOALS

DESIGN

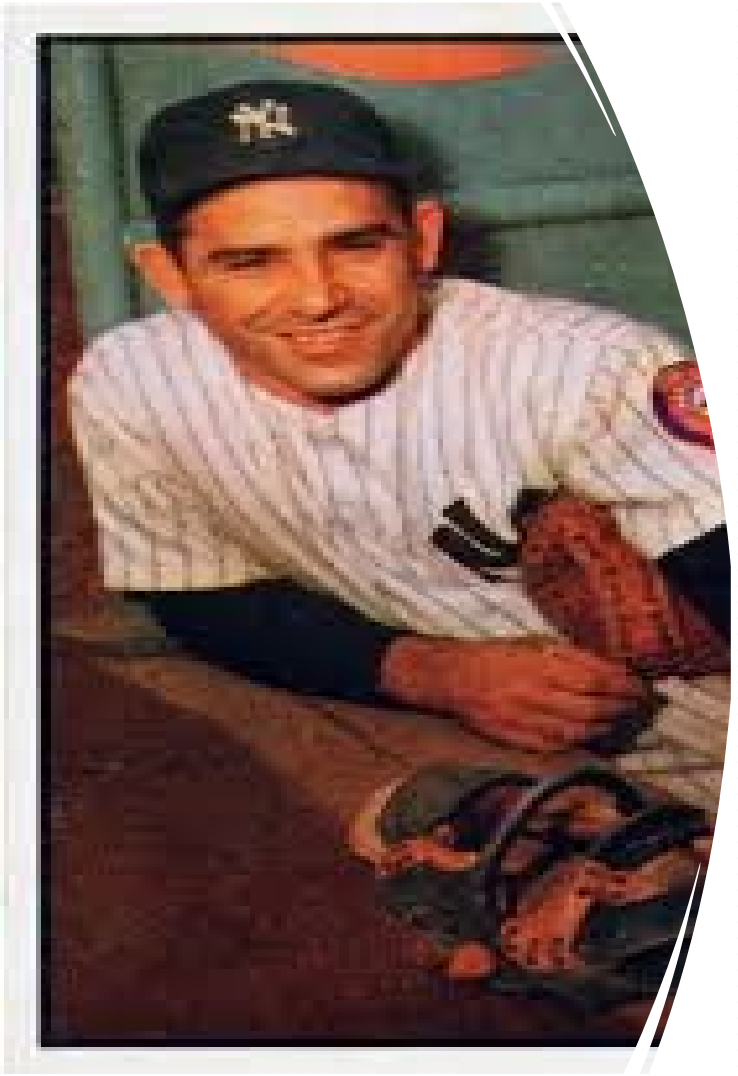
RESOURCES



Advance Planning Questions

- What are my study goals and proposed design?
- Can I use existing data sources?
  - What are potential data sources?
  - Are the data feasible for addressing my study aims?
- Do I need to collect data directly?
  - What type of data? From whom?
- How will I obtain the data (secondary and/or primary)?
- How will I analyze my data?
- Who do I need on my study team?
- How will I store & manage my data?
- What are my plans for data sharing?
- What is the required study budget & timeline (i.e., is it affordable)?

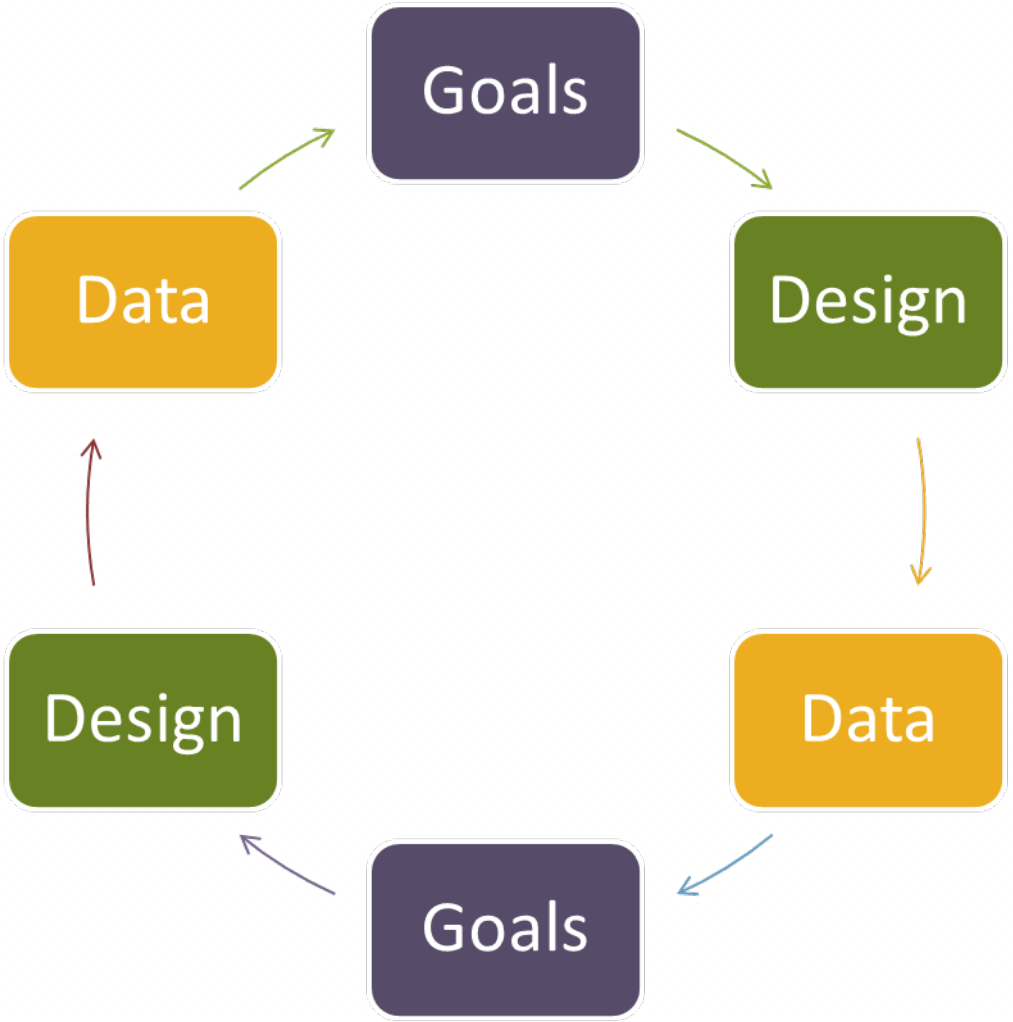
What are my study goals?



. . . .if you don't know where you're going, you might not get there.

-- Yogi Berra

Process of Identifying Data Needs



Can I use existing data sources?

VA or non-VA

National, regional, local

Level/unit of analysis

Timeframe

How will I obtain my data?

Secondary data
Existing database/data warehouse
Manual extraction (chart abstraction)

How will I identify data sources to answer my question?

Search

the literature

Talk

with colleagues

Post

inquiry on listservs or

Join

mailing lists

Where can I find information about VA data sources?

VA Information Resource Center

Health Economics Resource Center

VA Office of Research and Development
VHA Program Offices

Home
About Us
Contact Us
FAQ
Report Broken Lin
Department of Veterans Affairs
VHA Data Portal
Search...
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
Operations & Quality Improvement
Access Policy & Administrative Tools
Quick Links Library
VA Millennium EHR Data
As part of the Electronic Health Record Modernization (EHRM) initiative, VA is migrating to the new VA Millennium EHR developed by Oracle Cerner. While the implementation of the EHR at new facilities is paused for a reset, data generated at facilities already using this new EHR are now available for use in research and operations projects. Visit the VA Millennium EHR page to learn about these data, how to request access, and for links to data documentation and resources.
Upcoming Events
Cyberseminars
VINCI Training Hour
News
What's new on the VHA Data Portal?
Learn about these data sources and how to request access.
Patient-Generated Health Data [released Feb 2024]
GECDAC Core Files [released Feb 2024]
All-Payer Claims Data [released Dec 2023]
Community Care Data [released Dec 2023]
Patient-Level Quarterly Area Deprivation Index [released Sep 2023]
Integrated Veteran Care Consolidated Data Sets [released Aug 2023]
NDS wants your feedback!
National Data Systems (NDS) has released a customer satisfaction questionnaire to understand our strengths and also to highlight areas for improvement. Ultimately, your participation will allow NDS to develop and implement strategies to better serve your needs. Your participation is voluntary.
Please click the link below to participate.
NDS Customer Satisfaction Questionnaire

VINCI Central
Krein, Sarah
Home
Workspaces
Applications
My VINCI Dashboard
VINCI University
VINCI Data
Search this site
Please sign up for VINCI Outage and Maintenance Alerts HERE!
Announcements
See all
Announcement
Welcome to the VA Informatics and Computing Infrastructure
We are here to assist you in all your Preparatory to Research and IRB Research needs.
VINCI provides numerous consultation services throughout the life-cycle of your research project. When you are thinking medical research, think of VINCI first. We can guide you through every step of the process.
VA
U.S. Department of Veterans Affairs
Feedback | Site Map | Privacy Policy | VHA Data Portal | VIReC | HSR&D | HSRData-L Listserve | Section 508 Accessibility

VINCI Services

Data Needs Assessment	Data requirements are gathered from your study protocol, other project documentation, and discussions with a VINCI Concierge. The standardized Data Needs Assessment, an Excel workbook, maps project variables to VINCI/CDW data source, domain, schema and table, and captures cohort inclusion and exclusion criteria.
Feasibility Assessment	Provides aggregate counts for researchers during the preparatory to research phase. The deliverables result in summarized counts to assist in grant and IRB applications. Feasibility results cannot be used for any publication. No regulatory documents are required.
Clinical Trial Recruitment Patient List	A CTR uses the Electronic Medical Record (EMR) to supplement traditional patient recruiting methods by leveraging patient data stored in the VA EMR. This requires an IRB approved research study plan and VA DART approval.

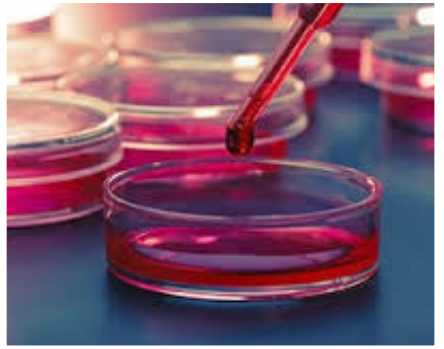
Where can I find information about non-VA data sources?

Data.CMS.gov

Centers for Medicare & Medicaid Services

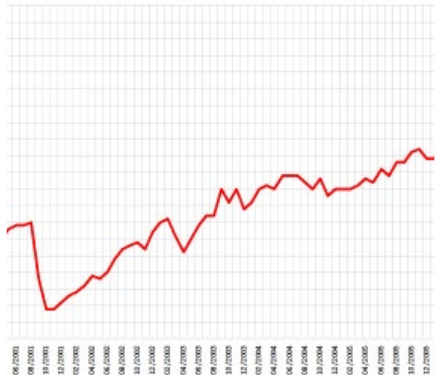
Do I need to collect data directly?

Qualitative



Direct Measurement

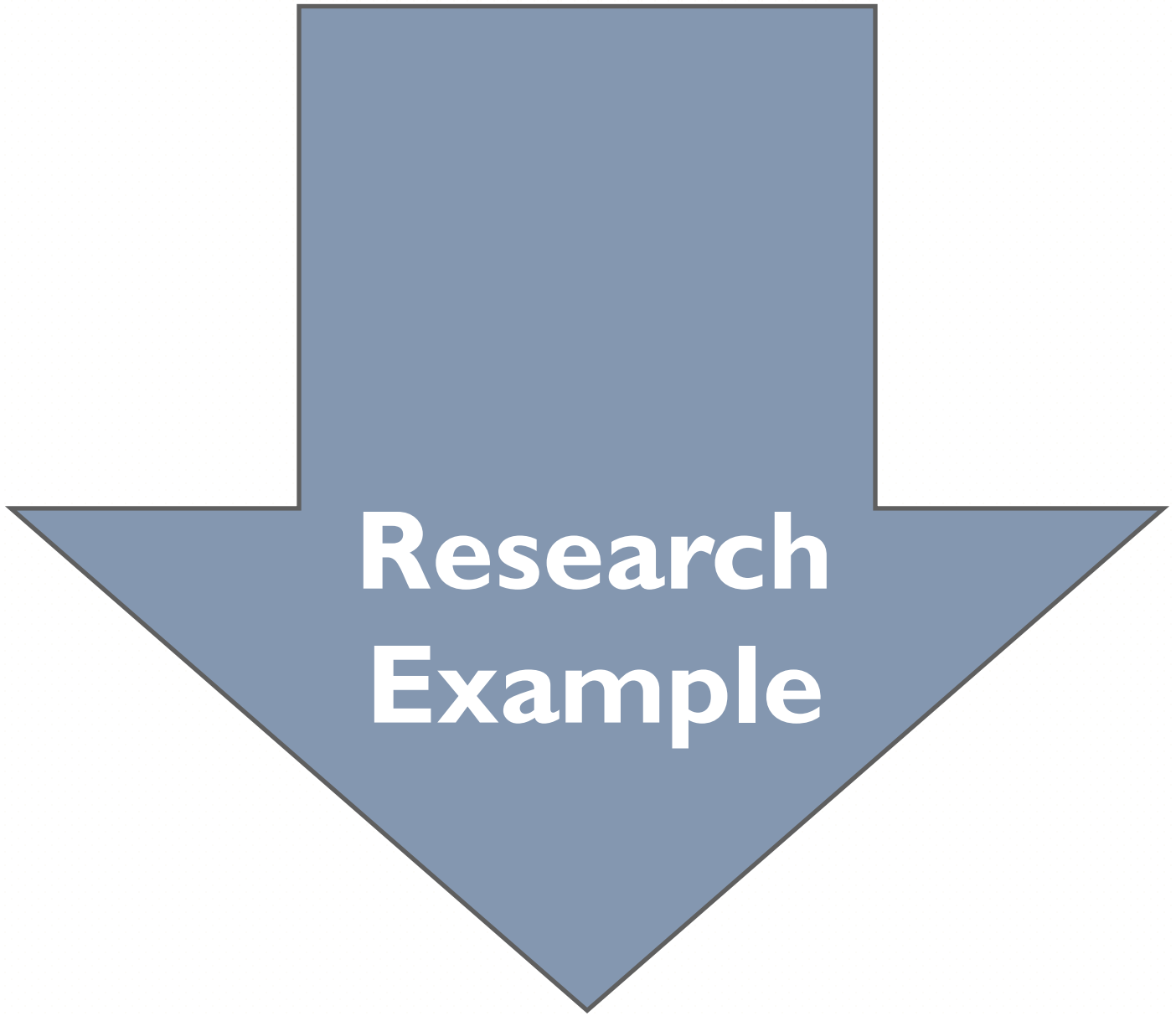
Surveys



Data Frequency

How will I obtain my data?

Primary data
Sample identification
Method(s) (software/personnel)
Equipment/tools


Research
Example

Peripherally Inserted Central Catheter (PICC)

- Increasing utilization
- Use is highly variable
- Not always appropriate
- Associated with complications

Example Research Questions

1. What is the volume of PICC use at VAMCs?

2. What factors influence PICC use, care and management at VAMCs?

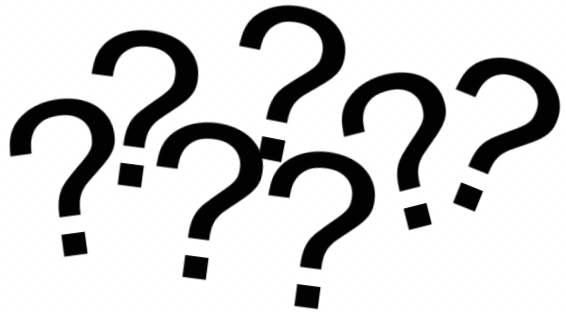
3. What are staff perceptions and practices related to PICC use in VHA?

4. What is the Veteran experience related to PICC use in VHA?

What would be your choice of data to answer RQ1?

1. What is the volume of PICC use at VAMCs?

a) Existing VA data
b) Survey of VAMCs
c) Create new data repository
d) Other



My likely answer – RQ1

1. What is the volume of PICC use at VAMCs?

a) Existing VA data
   - Procedures
   - Products
   - Association with infectious complications

Data Sources for Answering RQ1

1. What is the volume of PICC use at VAMCs?

a) Existing VA data
   - VIReC website & VHA Data Portal
     - Corporate Data Warehouse (CDW)
   - VHA Program Offices
     - Inpatient Evaluation Center (IPEC)

"Preparatory to Research" Data Access

- A provision of the
  - HIPAA Privacy Rule
  - VHA Handbook 1200.05
- Allows VHA to provide personal health information for development of a VHA research protocol without:
  - the patient's authorization or
  - a waiver or an alteration of authorization by an Institutional Review Board (IRB)
- VHA prohibits using preparatory to research data to contact or recruit subjects.

On this page

» Overview
» Requesting Access
» Data Sources
» Tools

Did You Know?

CMS and USRDS cannot be accessed preparatory to research. VIReC provides cohort size estimates through its Pre-Request Consultation Service for researchers intending to use these data.

Tips for Requestors

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

Preparatory to Research Access

Overview

The term "preparatory to research" refers to a provision of the HIPAA Privacy Rule. This provision and VHA policy allow a covered entity (e.g., VHA) to provide personal health information (PHI) to a VHA researcher for the purpose of developing a VHA research protocol without the patient's authorization or a waiver or an alteration of authorization by an Institutional Review Board (IRB).

Under the HIPAA Privacy Rule and VHA policy, VHA must obtain from the researcher representations that

- the use is requested solely to prepare a research protocol or for similar purposes preparatory to VHA research,
- the PHI will not be removed from the covered entity, and
- the PHI for which use or access is requested is necessary for the research purpose.

VHA prohibits using preparatory to research data to contact or recruit subjects. Authorization to use data preparatory to research ceases once the protocol has been submitted to the IRB and the Research and Development (R&D) Committee for review. VHA Directive 1200.05 provides more information.

Note: Pilot studies are not considered preparatory to research activity and require IRB approval.

Requesting Access

Access to data sources and data access tools is available through several request processes, including:

- Data Access Request Tracker (DART) Preparatory to Research Request Process
- Patient Care Services (PCS) Request Process
- Pharmacy Benefits Management (PBM) Request Process
- Local National Social Security Database (NSSD) POC Request Process

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

Data for Answering RQ1

1. What is the volume of PICC use at VAMCs?

- CPT codes (PICC specific): 0 to > 900
- ICD-9 procedure codes (all CVCs): 0 to > 3000
- Event Capture: 0 to > 800

Preparatory to Research Conclusion – RQ1

Example Research Questions

1. What is the volume of PICC use at VAMCs?

2. What factors influence PICC use, care and management at VAMCs?

3. What are staff perceptions and practices related to PICC use in VHA?

4. What is the Veteran experience related to PICC use in VHA?

How would you obtain/collect data to answer RQ3?

3. What are staff perceptions and practices related to PICC use in VHA?

a) Use existing VA data?

b) Conduct a survey?

c) Use qualitative methods (interviews, focus groups)?

d) Other?

My likely answer – RQ3

3. What are staff perceptions and practices related to PICC use in VHA?

b) Conduct a survey?

c) Use qualitative methods

Special Considerations: Conducting VA Surveys or Interviews

- Who?
  - VA Employees
- How?
  - Electronic, REDCap
- Regulatory considerations
  - Union notification, Organizational assessment committee (OAC) review

Requirements for Surveys & Interviews (Projects Conducted for Research & Operational Purposes)

Overview

The chart below summarizes the general requirements for surveys and interviews conducted within the VA system. Please see the relevant section(s) for additional detail. (Section IV provides information regarding approved platforms for web-based surveys.)

Requirement	Participants	Modality	Criteria
OAC Review *Section I*	VA Employees	Surveys	>10,000 participants or >20 sites
Union Notification *Section II*	VA Employees	Surveys & Interviews	Local, VISN, or National (not based on # of employees)

How will I analyze my data? Who do I need on my study team?

	Qualitative	Quantitative
Software	√	√
Personnel	√	√

Information Security

Department of Veterans Affairs
Office of Research Reviews (ORR)

Cybersecurity Guidelines for Technical Reference Model (TRM)

Overview:

This knowledge article provides guidance on the use of the Technical Reference Model (TRM) when conducting Department of Veteran Affairs (VA) Institutional Review Board and Research & Development (R&D) Committee approved research. This guidance is applicable to research projects requiring the use of new software. The target audience for this guidance is VA research stakeholders: (e.g., Researchers, VA Investigators, Research Staff, Research Compliance Officers (RCO), Information System Security Officers (ISSO), and Information System Security Managers (ISSM)).

End User Solution:

The purpose of VA's TRM is to identify approved software for use within VA. Generally, the TRM only assesses Commercial-off-the-Shelf (COTS) software products that are to be used on the VA production Network.

Software purchased or acquired for installation on a VA network-connected device must be approved by the TRM. Compliance with TRM is required to ensure VA systems use software that has been both evaluated and approved for use.

Approved Software: For a list of TRM-approved software, see the TRM Technology/Standard List. Users are advised to pay close attention to the **Decision** tab of any software planned for use in a VA research project. The **Decision** tab lists the status of the software (Approved, Approved w/Constraints, Unapproved, Divest, and Prohibited), approved version, and constraints placed on the software's usage. Research projects should not use software that is unapproved, in divest status or prohibited.

How will I store & manage my data?

Local server

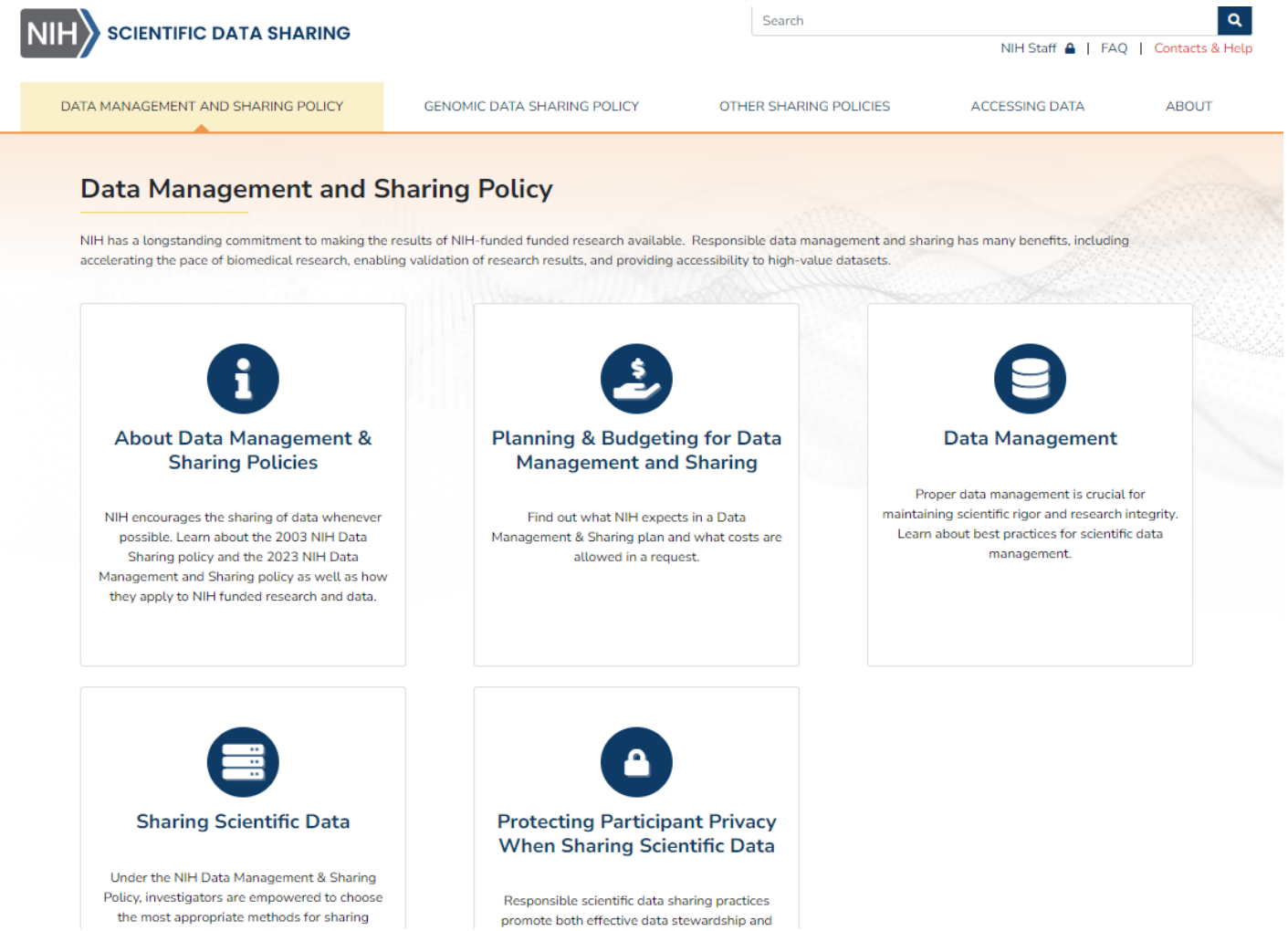
Centralized data repository

Level of security

Physical storage

Accessibility to collaborators, co-Is

What are my plans for data sharing?



OFFICE OF INFORMATION AND TECHNOLOGY

Amendment 2 dated 1/27/22:
Section 2: Data Classification Table has been updated.

Enterprise Research Data Security Plan (ERDSP) User Guide

Privacy, Security and Human Subjects Resources

VHA Handbook 1200.05 -- *Requirements for the Protection of Human Subjects in Research*

Office of Research & Development Website
https://www.research.va.gov/resources/policies/human_research.cfm

FINDpro
Focused Inquiry Navigational Database

Local research office RDC/IRB coordinator(s), chair, committee member, PO, ISSO

Advance Planning Questions

- What are my study goals and proposed design?
- Can I use existing data sources?
  - What are potential data sources?
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- How will I store & manage my data?
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- What is the required study budget & timeline (i.e., is it affordable)?

fry's
State Farm

THANK YOU!
Questions?

CONTACT INFORMATION

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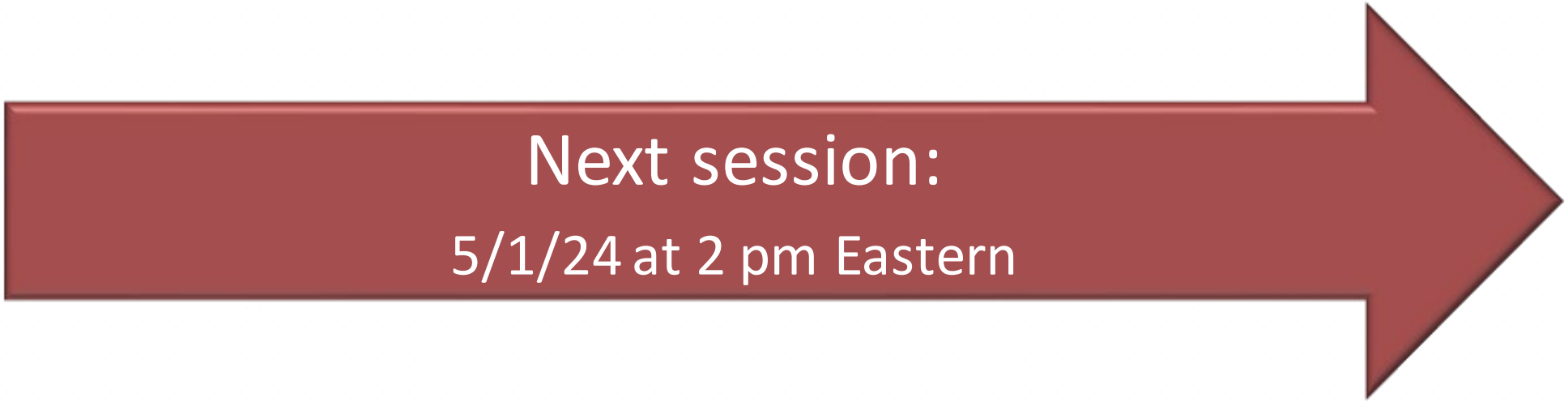
VA HSR&D Research Career Scientist

sarah.krein@va.gov

GOOD DATA PRACTICES CYBERSEMINAR SERIES



Planning for Data Privacy for a New Research Protocol

GOOD DATA PRACTICES
BONUS SLIDES

VA Data Information Resources

VIREC website
https://www.virec.research.va.gov/

HERC website
http://www.herc.research.va.gov/

VHA Data Portal
http://vaww.vhadataportal.med.va.gov/

VINCI
https://vincicentral.vinci.med.va.gov/

Office of Research & Development website
https://www.research.va.gov/

VHA Program Offices websites
http://vaww.va.gov/health/programs.asp

Non-VA Data Information Resources

Centers for Medicare and Medicaid Services (CMS)
https://data.cms.gov/

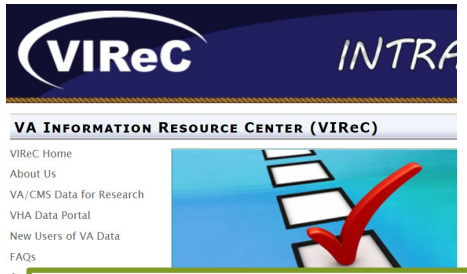
Agency for Healthcare Research & Quality (AHRQ)
https://www.ahrq.gov/research/data/index.html

Centers for Disease Control & Preventions (CDC)
https://data.cdc.gov/

Optum
https://www.optum.com/en/business/life-sciences/real-world-data/claims-data.html

Resources for *VA Data Users*

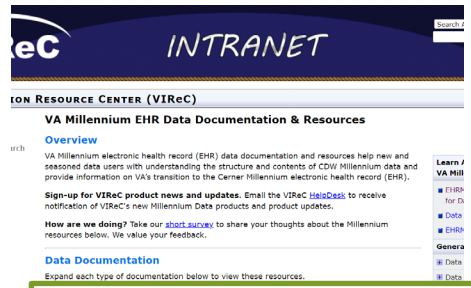
Select image to visit page



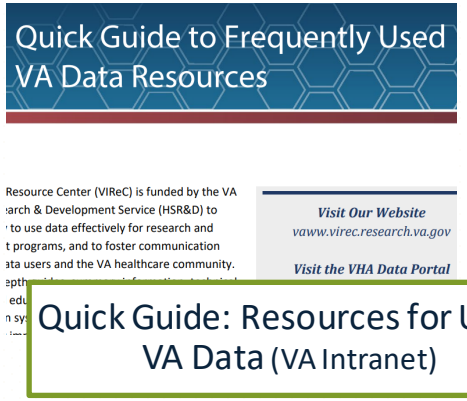
VA Information Resource Center (VIReC) (VA Intranet)

VHA Data Portal (VA Intranet)

VIReC Cyberseminars

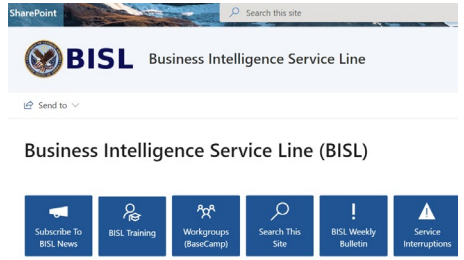


VA Millennium EHR Data Documentation (VA Intranet)



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 (VA Intranet)

VIReC HelpDesk

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