VIReC Database & Methods Cyberseminar Series

Session 2

Requesting Approval for Access to VA Data

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VA Information Resource Center

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VIReC
RESEARCHERS' GUIDE TO VA DATA

Poll #1: Your role as a data user

- What is your role in research and/or quality improvement?
  - Investigator, PI, Co-I
  - Data manager, analyst, or programmer
  - Project coordinator
  - Other – please describe via the Q&A function

Poll #2: Your experience with VA data

How many years of experience do you have working with VA data?

- 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

Today's objective

The purpose of this cyberseminar is to introduce concepts around VHA data access and resources for learning more.

Topics

“What are you using the data for?” - Data Access Categories in the VA

“Start with the data source.” - VHA Data Portal Data Source Pages

“*What are the rules?”* - VHA Policy on Data Access for Research

“*Retain, organize & label.”* - Tips for speedier access approvals

“Where did you say I could find that?” - Resources

Topics

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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 design has recently changed to help get you the information you need. Each one of the badges below links to access information and other relevant resources for a particular data use need, or use the new 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

Upcoming Events

VIReC Cyberseminars

Apr 17: MyHealtheVet (Smith, B)
May 07: Using VA DSS Lab Data for Research (Hung, A)
Sep 10: Comorbidity Measures Using VA & CMS Data (Hynes, D)

VINCI Happy Hour

3rd Wednesday Every Month at 3 PM ET
VINCI in its continuing efforts to assist VHA data users will be holding its VINCI Happy Hour open question and answer forum every 3rd Wednesday of the month from 3:00PM to 4:00PM ET to field questions from our customers on a range of topics. Click here to join the Lync meeting and call 855-767-1051 code 22265684.

News

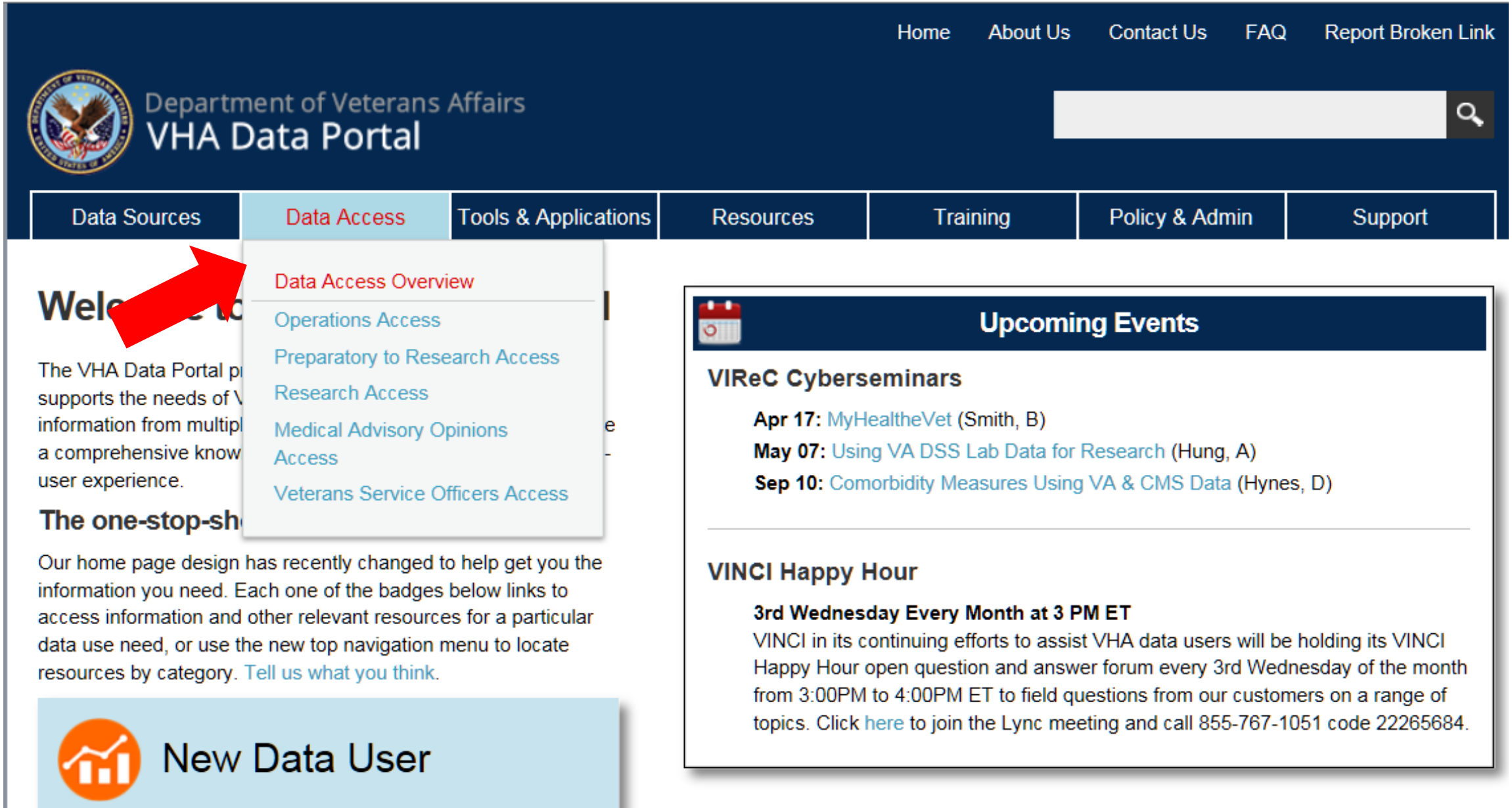
VINCI IT Services and Support Interruption Pending

The VA Informatics and Computing Infrastructure (VINCI) will undergo a change in contracted IT support beginning March 27th. At this time it is anticipated that there may be a gap between contracts during which time only limited support, data, and IT services will be available through VINCI@va.gov. New or existing project activities of granting VINCI Workspace and SAS/Grid access, folder creation, database creation, and data provisioning may be delayed until new contract staff are in place. We do not anticipate any interruption in VINCI system availability at this time. We appreciate your patience during this transition and apologize for any difficulty this may cause you and your study.

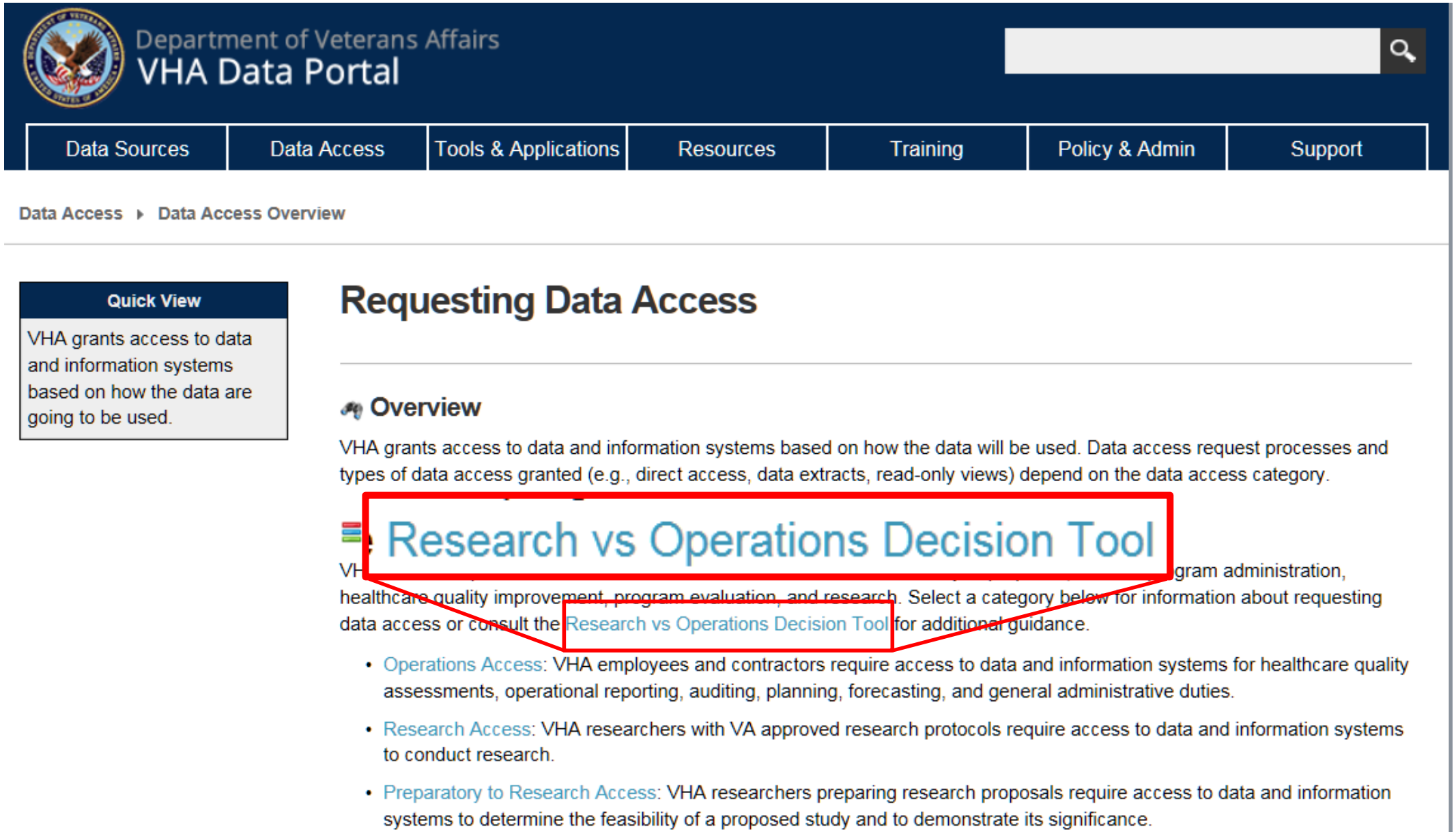
DART Data Request Memo Changes

Information Security Officers (ISOs) are no longer required to sign DART preparatory to research and research data request memos due to changes based on the Acting Assistant Secretary for OI&T, Chief Information Officer's memo, VAIQ 7808858. The DART request memo templates have been updated to reflect this change and are available from the DART Preparatory to Research Request Process and DART Request Process pages.

Data Access Overview



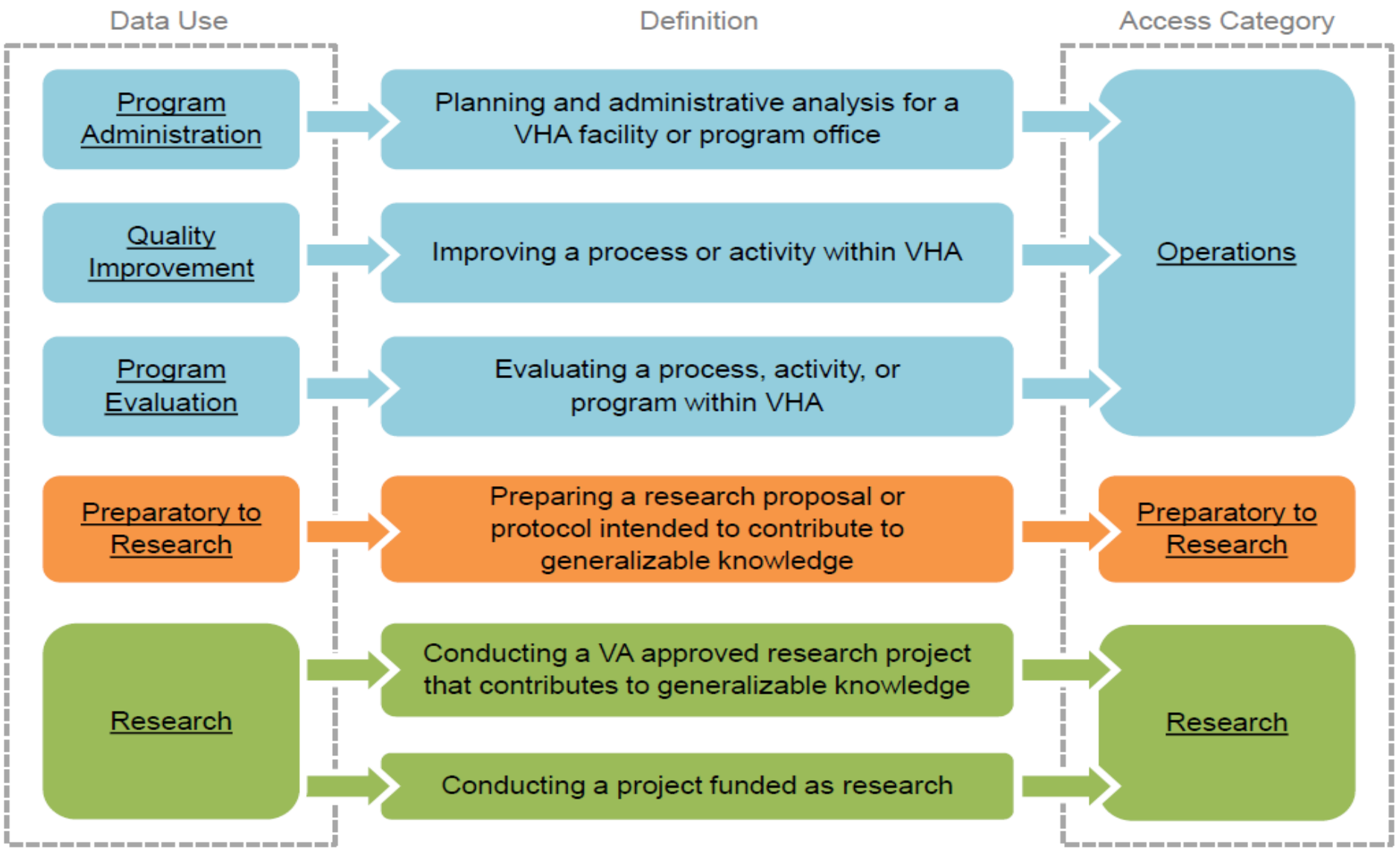
Data Access Overview



Research vs Operations Decision Tool

[3]

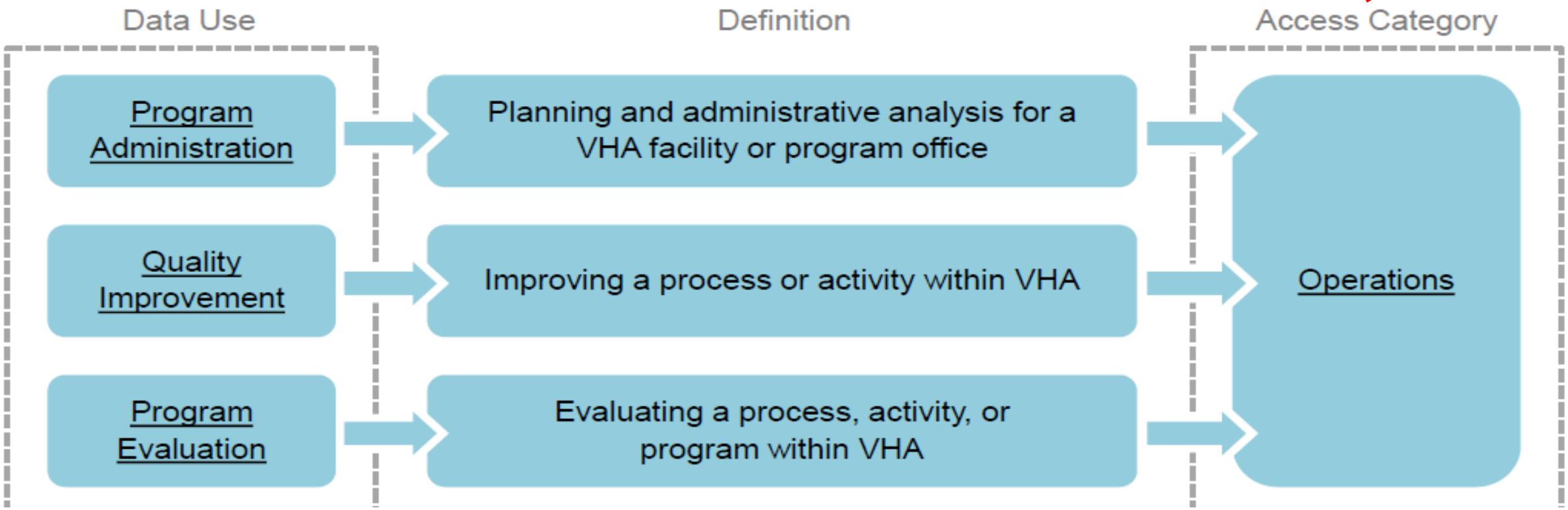
Access Category Finder



Research vs Operations Decision Tool

[3]

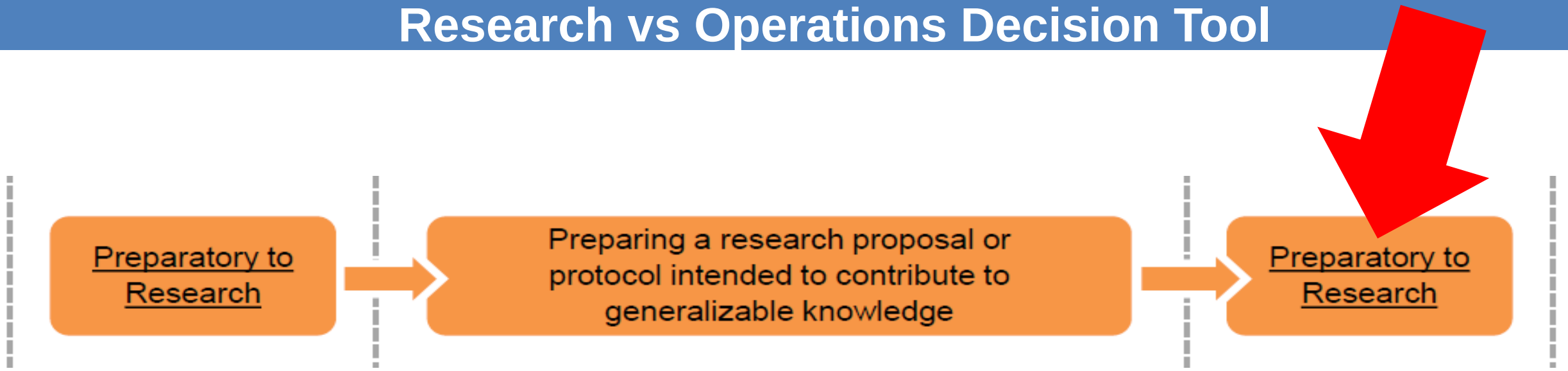
Access Category Finder



To publish findings of non-research data activities, intramural and extramural see Appendix:

https://www.research.va.gov/resources/policies/ProgramGuide-1200-21-VHA-Operations-Activities.pdf

Research vs Operations Decision Tool



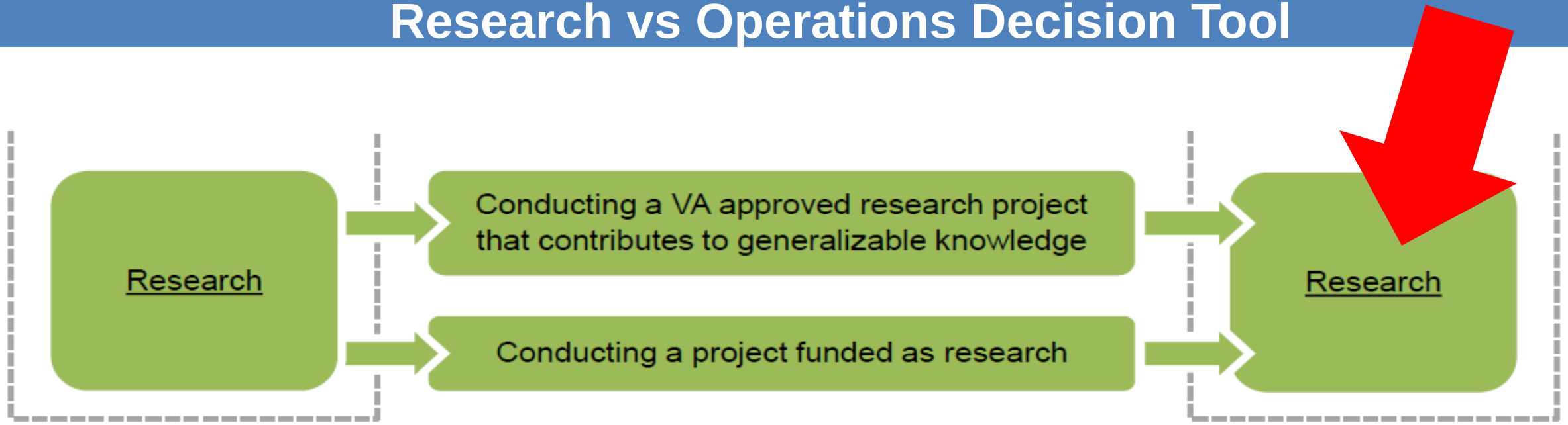
VA Guidance – Prep to Research

Data access ends with protocol is submitted to IRB.

Personal identifiable information may not be retained

Only aggregate data (tables and charts) may be retained for later use.

Research vs Operations Decision Tool



VA Guidance – Research

Projects can receive funding from ORD and not be research.

Example: QUERI projects funded by ORD with an operational purpose may be classified as operations not research.

Approval for operations access

cannot be used to

access or obtain data for research

or to prepare a research protocol.

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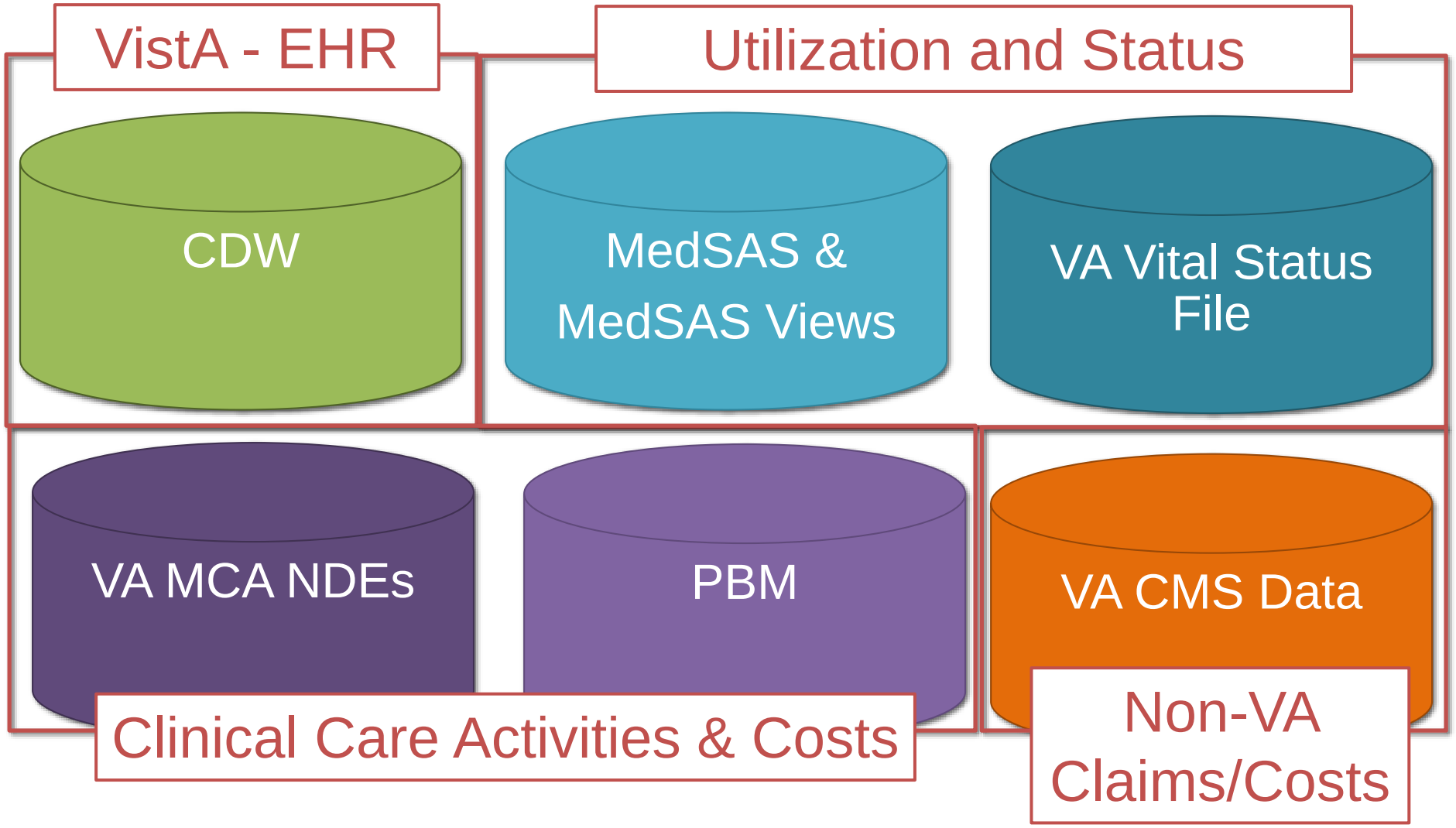
“*Retain, organize & label.*” - Tips for speedier access approvals

“Where did you say I could find that?” - Resources

Reminder: Commonly used VA data sources



Department of Veterans Affairs
VHA Data Portal

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New Data User

Research

Upcoming Events

Cyberseminars

Upcoming

Oct 16: Events Associated with Changes in Reliance on VHA Among Medicare-Eligible Veterans (HERC)

Nov 4: Requesting Approval for Access to VA Data (VIReC)

Nov 14: How to Conduct a Research Study in VINCI (VINCI)

Recent

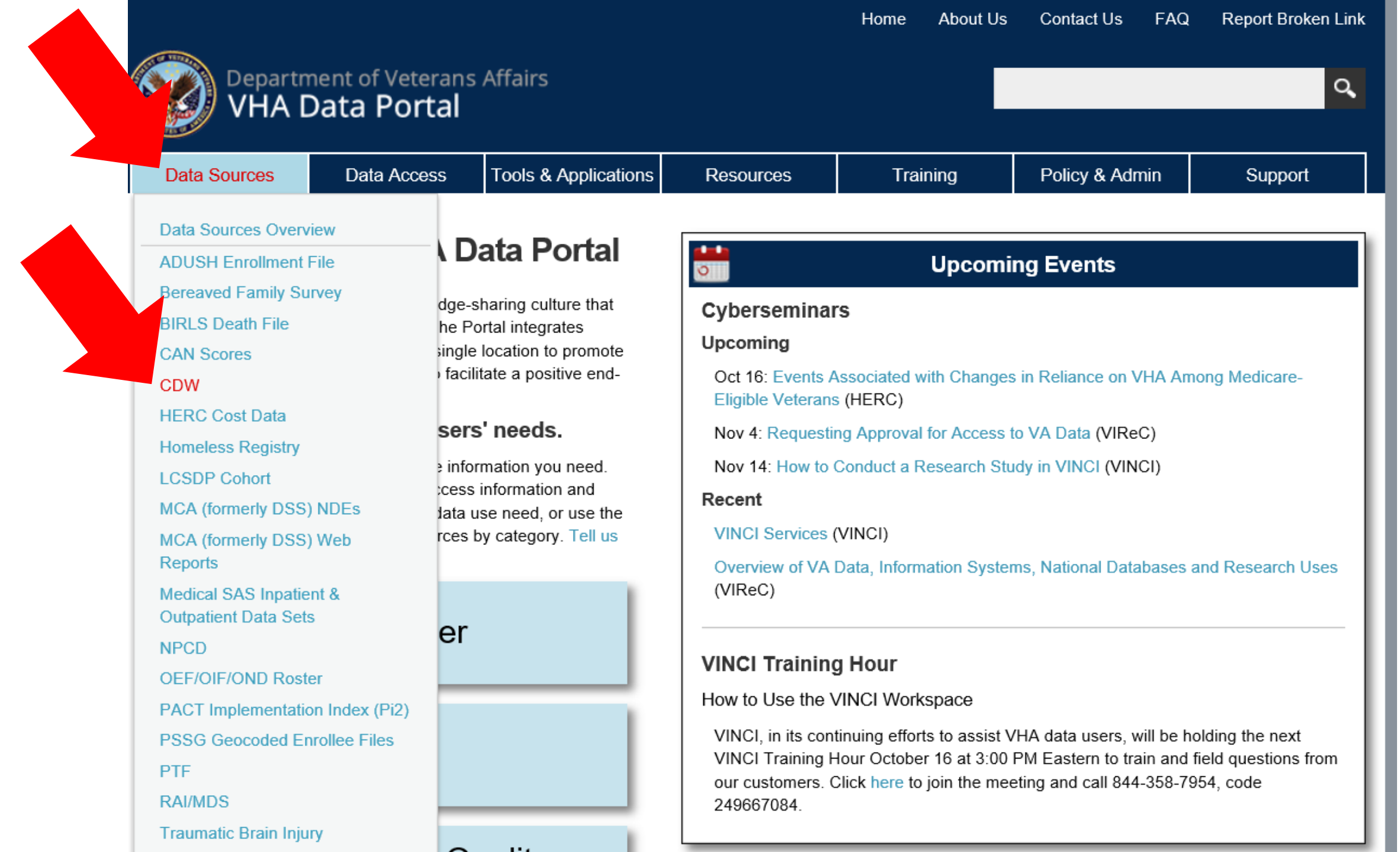
VINCI Services (VINCI)

Overview of VA Data, Information Systems, National Databases and Research Uses (VIReC)

VINCI Training Hour

How to Use the VINCI Workspace

VINCI, in its continuing efforts to assist VHA data users, will be holding the next VINCI Training Hour October 16 at 3:00 PM Eastern to train and field questions from our customers. Click here to join the meeting and call 844-358-7954, code 249667084.


Home
About Us
Contact Us
FAQ
Report Broken Link
Department of Veterans Affairs
VHA Data Portal
Data Sources
Data Access
Tools & Applications
Resources
Training
Policy & Admin
Support
Data Sources Overview
ADUSH Enrollment File
Bereaved Family Survey
BIRLS Death File
CAN Scores
CDW
HERC Cost Data
Homeless Registry
LCSDP Cohort
MCA (formerly DSS) NDEs
MCA (formerly DSS) Web Reports
Medical SAS Inpatient & Outpatient Data Sets
NPCD
OEF/OIF/OND Roster
PACT Implementation Index (Pi2)
PSSG Geocoded Enrollee Files
PTF
RAI/MDS
Traumatic Brain Injury
A Data Portal
dge-sharing culture that
he Portal integrates
single location to promote
facilitate a positive end-
sers' needs.
information you need.
ccess information and
data use need, or use the
rces by category. Tell us
er
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Quick View

CDW is an evolving repository of national VHA data. It is a physical implementation of a logical data model at the enterprise level for VHA.

CDW

Corporate Data Warehouse (CDW)

Overview

VHA's Corporate Data Warehouse (CDW) is a national repository comprising data from several VHA clinical and administrative systems. The objective of CDW is to facilitate reporting and data analysis at the enterprise level by incorporating data from multiple data sets throughout the VHA into one standard database structure. CDW provides data and tools to support management decision making, performance measurement, and research objectives.

Content

CDW is an evolving repository of national VHA data containing clinical, enrollment, financial, administrative, utilization, Veteran benefits information and more. Data are available from October 1999 to present. Visit the CDW SharePoint site and VINCI-CDW Data Sources page for more information about CDW data.

CDW Production Data Domains - Allergy, Appointment, Consult, CPRS Orders, Dental, Dimensions (CDW), Health Factors,

Content

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CDW Production Data Domains - Allergy, Appointment, Consult, CPRS Orders, Dental, Dimensions (CDW), Health Factors, Immunization, Inpatient, Lab Chemistry, Lab Microbiology, Mental Health Assessment, Outpatient, Patient, PCMM, Pharmacy BCMA (Bar Code Medication Administration), Pharmacy Outreach, Purchased Care (Fee), SPatient, Staff, SStaff, and Vital Signs.

CDW Raw Data Domains - Beneficiary Travel (CBO), Bill Claims (CBO), Compensation & Pension Exam, Echocardiogram, Emergency Dept. Int. Software (EDIS), Equipment Inventory, IFCAP, Intravenous Meds (IV), Unit Dose, MyHealthe Vet, Non-VA Meds, Oncology, Paid, Prosthetics, Radiology, and Surgery.

Structure

CDW uses multiple servers to store data. Data on these servers are stored in relational databases organized into data domains. Each domain comprises logically or conceptually related sets of data tables. Domains generally indicate the VistA application from which most of the data elements originate (e.g., Vital Signs or Mental Health Assessment).

CDW SQL databases are categorized as production or raw.

- **CDW Production** – Data on the CDW-prod servers are mostly uploaded from VistA with no filtering of records, editing, or business rules applied. These data are modeled and indexed to promote efficient querying.
- **CDW Raw** – CDW-Raw refers to the test and evaluation database. CDW-RAW data are extracted directly from the data source (e.g., VistA). These data are not modeled, standardized, or indexed and include MCA (formerly DSS) NDEs in SQL tables and other SAS-to-SQL tables. When the domain is developed for production it is removed from Raw. CDW Raw data has not been verified or had business rules applied. It may not be current and there is limited documentation for users. Requests for CDW Raw data require additional time for creating data extracts and it is more difficult for studies to

Note: The CDW environment also includes these data sources. Visit each data source page for more information.

- Beneficiary Identification Records Locator Subsystem (BIRLS) Death File
- Managerial Cost Accounting National Data Extracts (MCA NDEs)
- Medical SAS Inpatient and Outpatient Data Sets
- Veterans Services Network Corporate Mini Master File (VETSNET File)
- Vital Status File

Requesting Data Access

VHA grants access to data based on how it will be used. These uses are organized into data access categories, which determine the appropriate process for requesting permission to access data. Select a category below for information on requesting access privileges to the CDW production and raw databases. If you're not sure which option to choose, visit the Data Access Overview page for additional guidance.

⊞ Operations/ Non-Research

⊞ Preparatory to Research (PTR)

⊞ Research

Operations/ Non-Research

CDW data are available for operations use. Visit the NDS Healthcare Operations Request Process page for instructions on submitting a data request through the VHA NDS Access Form for Health Operations in ePAS.

Use the CDW Permissions Crosswalk for information on what level of permissions should be requested for a given data set. For example, if you need access to [GeoCodedAddress] then you would request [CDW_SStaff] level access.

Important steps for filling out your ePAS request...

1. Check **Corporate Data Warehouse (CDW)** under Data Sources.
2. Select the **CDW tab** that appears at the top of the form.
3. Check **CDW SQL Datasets**.
4. Select one or more of the following privileges:

   - **Basic Read Access (CDW_Full)**
     Permits access to every extracted table on CDW except for SPatient.Spatient, SPatient.Spatient Address, SStaff.SStaff production tables.
   - **Privileged Read Patient Access (CDW_SPatient)**
     Permits access to every extracted table on CDW including SPatient.Spatient and SPatient.Spatient Address tables. Note: Does not permit access to CDW Production table SStaff.SStaff.
   - **Staff Real SSN Access (CDW_SStaff)**
     Permits access to every extracted table on CDW Production and CDW-RAW, including the CDW Production SStaff.SStaff table.

Note: VHA Scrambled SSNs and Real SSNs for patients are available only in the SPatient table.

Preparatory to Research (PTR)

Use the Data Access Request Tracker (DART) to request access to CDW data for preparing a research protocol. Visit the DART Preparatory to Research Request Process page for instructions on how to submit a request, including links to documents and forms you may need.

Important tip for filling out your DART request...

- Be sure to select **CDW Production Domains** or **CDW Raw Domains** under "Corporate Data Warehouse (CDW)" in the Data Sources section.

Research

Use the Data Access Request Tracker (DART) to request access to CDW data for research cohorts. Visit the DART Research Request Process page for instructions on how to submit a request, including links to documents and forms you may need.

Important tips for filling out your DART request...

- Be sure to select **CDW Production Domains** or **CDW Raw Domains** under "Corporate Data Warehouse (CDW)" in the Data Sources section.
- DART will prompt you to upload the CDW Domain Checklist and other required documents and forms.
- When completing the Checklist for production domains, be sure to select at least one of these domains depending on the identifiers you will need:
  - **Patient Domain** – does not include real or VHA Scrambled SSNs
  - **SPatient Domain** – includes real and VHA Scrambled SSNs
  - **SStaff Domain** – includes employee real SSNs

⊞ Operations/ Non-Research

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Resources

- The CDW SharePoint site contains information on newly released and missing data, an up-to-date list of data domains, structural documentation, and more.
- VIReC provides several resources supporting the use of CDW:
  - CDW Factbooks describe of tables, columns, and values in select CDW Domains and include domain-specific SQL "starter language" for those new to CDW, relational databases, and SQL.
  - Issues of *The Researcher's Notebook* describe methodological approaches to working with CDW data.
  - *Getting Started with CDW Data Cyberseminars* provide an introductory foundation aimed at making CDW and relational data less intimidating.
  - *CDW Statistical Snapshot: Patient Demographics* provides a summary of patient demographics found in the CDW.
  - The CDW Domain Layout workbook lists schemas and tables for each CDW domain.
  - The CDW Domain Descriptions resource includes a high-level summary of content found in most CDW production domains.
- BISL CDW Data Profiling Reports provide statistical reports about selected underlying fact tables in CDW views.
- Learn more about using a VINCI Workspace to store and analyze CDW data.
- VINCI applications for exploring CDW data tables: Meta Data Viewer and Dim Data Viewer.

PCS Data Requests

Patient Care Services (PCS) Research Data Requests

Home - VACO Patient Care Service (PCS)- Office of Strategic Planning and Measurement (OSPM)

And select one of these

- DTA Program Evaluation Request*
- DTA QI (Quality Improvement) Request
- DTA Research Request

*DTA = Data Transfer Agreement

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

PBM Data Requests

Documents
Clinical Guidance
Directives, Policies and Information Letters
Education
Emergency Pharmacy Service EPS
ISMP
National Formulary
Other Documents and Resources
Pharmaceutical Compounding and Management Standards
Special Handling Drugs
VA Center for Medication Safety
Workload Capture
State Prescription Monitoring Program Requirements
Prescription Labels, Patient Centric
Opioid Safety Initiative

Pharmacy Benefits Management Services
Research Data Request

The following must be done to obtain PBM v.3 pharmacy data for research purposes:

1. Mail a copy of the IRB approval form and a summary of the study protocol to the following address:

Attn: Nikia Griffith (10P4P)
Pharmacy Benefits Management
1st Ave. - 1 Block N. of Cermak Rd.
Bldg. 37 Rm. 139
Hines, IL 60141

2. Complete and submit the form that appears when you click the following Link:

Complete Form

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Federal Policy Governing Information Access

Health Insurance Portability and Accountability Act Privacy Rule

- Aka: HIPAA
- Governs access to personal protected health information (PHI)
- Applies to use of PHI by VA healthcare operations, prep to research and approved research projects

Department of Veterans Affairs: 38 CFR Part 16 Federal Policy for the Protection of Human Subjects

- Aka: The Common Rule
- Governs human subject protections in research
- Requires Institutional Review Board review of non-exempt research
- New exemption categories with 2018 Common Rule Revisions *

* Handout: Exemption Category Tool – U of KY

Things you should know before requesting data

Exemptions & Informed Consent

1. Has your study been determined to be an exempt human subjects study?

1a. If no, does your study require subjects to give informed consent orally or in writing - or a HIPAA authorization in writing?

1b. If no, does your study have IRB approval for a full Waiver of Informed Consent?

HIPAA Authorization

2. Does your study have IRB or Privacy Board approval for a Waiver of HIPAA authorization

2a. If yes, is the Waiver of HIPAA authorization only for recruiting or determining subject's eligibility?

2b. If yes, is the Waiver of HIPAA authorization for the entire study?

Requirements for Data Access for Research

Research Approvals

- IRB approval for human subjects protection or Exempt Determination Letter verified by local Research Service for projects meeting exempt criteria
  - If not exempt, approval of informed consent language or waiver of informed consent approval
  - If Protected Health Information, approval of HIPAA authorization or waiver of HIPAA authorization
- Research and Development Committee approval of research project
- Associate Chief of Staff for Research approval to begin research

Data Steward Requirements

- May include documentation of some or all of the above
- Source specific data access forms, e.g., CDW Domain Checklist, Vital Status Rules of Behavior
- Identifier specific request forms e.g., Real SSN Access Request

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Tips for speedy approval of data requests #1

Naming

- Use the same standard document naming convention and organization for all projects you are responsible for.
- Examples for approval documents names
  - Include approval date - don't depend on "date last modified."
  - Include "initial," "revision," "amendment," "continuing review."

Combining and organizing documents

- PDF documents together based on purpose, e.g., amendments separate from continuing review.
- Add the most recent version to the top of the PDF.
- Retain data access forms submitted in sub-folders by data steward, e.g., DART requests, PCS requests, PBM requests, etc.

Tips for speedy approval of data requests #2

Protocol and IRB/R&DC Submissions

- Keep a copy of all approved protocols.
- PDF each version of your protocol separately.
- Retain a copy of your IRB submissions to show you what you requested, e.g., waiver of informed consent or HIPAA waiver, data sources.

Research approval documents

- In your project folder, maintain a folder for research documents and a separate folder for data access documents
- Use sub-folders for each type of document, e.g., IRB letters, Exemption letters, R&DC letters, HIPAA

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"Where did you say I could find that?"

Office of Research and Development Links

- Human Research
- ORD VHA Directive, Handbooks, and Program Guides -- 1200 series
- Office of Research Protections, Policy, and Education
  - Fall 2019 - Myths about VHA Research

“Where did you say I could find that?”

VHA Data Portal

- NDS Healthcare Operations Request Process (ePAS)
- DART Preparatory to Research Request Process
- DART Research Request Process

Patient Care Services Data Access Request Forms

Pharmacy Benefits Management Systems Request Process

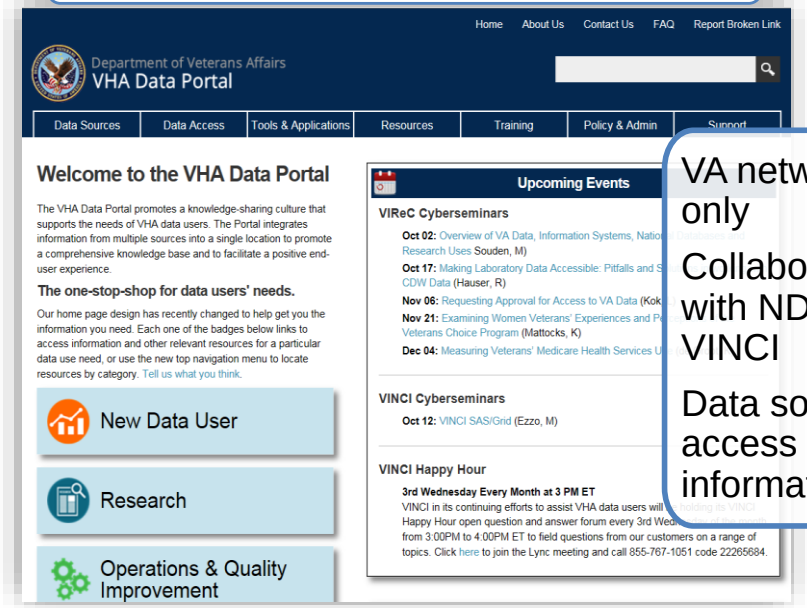
Additional Resources

vaww.virec.research.va.gov

VA network only

News & new resources

Resources for working with data



VA network only

Collaborative with NDS & VINCI

Data source & access information

www.virec.research.va.gov

Public-facing

VIReC overview

Publications & events

Cybersemina rs

VIReC options for specific questions

HelpDesk

- Individualized support

virec@va.gov

(708) 202-2413

HSRData Listserv

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

Quick links for VA data resources

Quick Guide: Resources for Using VA Data
https://vaww.virec.research.va.gov/Toolkit/QG-Resources-for-Using-VA-Data.pdf

VIReC: https://vaww.virec.research.va.gov/Index.htm (VA Intranet)

VIReC Cyberseminars: https://www.virec.research.va.gov/Resources/Cyberseminars.asp

VHA Data Portal: https://vaww.vhadataportal.med.va.gov/Home.aspx (VA Intranet)

VINCI: https://vaww.vinci.med.va.gov/vincicentral/ (VA Intranet)

Health Economics Resource Center (HERC): http://vaww.herc.research.va.gov (VA Intranet)

CDW: https://vaww.cdw.va.gov/Pages/CDWHome.aspx (VA Intranet)

Archived cyberseminar: What can the HSR&D Resource Centers do for you?
http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=101

Take Away

Understand the distinction between operations and research.

Be aware of the rules for research use of data.

Research data access is granted for **one** purpose/project, no other use is permitted unless you submit a new request to the data steward.

Use the VHA Data Portal Data Source pages to find the process for requesting common data sources.

You can make the approval process faster by retaining, organizing & labelling your regulatory documents.

Final Tips

Determine what facilities will be included in project: local only, VISN only, or national.

Know where to find the request process for each data source.

Know the format of data sources requested, e.g., SQL, SAS.

Identify the platform/venue where you will manage and analyze data.

Select a record identifier (SSN, ICN, scrSSN) e.g., JLV access requires real SSNs.

Know where and how you'll receive your data.

Questions?

For more about VIReC Resources

Join us here December 9

DBM #3: *Meet VIReC*

https://www.hsrd.research.va.gov/cyberseminars/catalog-upcoming-session.cfm?UID=3696

Acronyms for Popular Data Sources

- **CAPRI:** Compensation and Pension Record Interface (EHR viewer)
- **CDW:** Corporate Data Warehouse production domain data
- **JLV:** Joint Legacy Viewer (DoD and VA EHR viewer)
- **MCA NDEs:** Managerial Cost Accounting System National Data Extract
- **MedSAS:** Medical SAS datasets
- **PCS:** Patient Care Services data
- **TUI Notes:** Text Integrated Utilities – Progress and other clinical notes
- **VA/CMS Data:** Data from the Centers for Medicare and Medicaid Services used in the VHA
- **VSF:** Vital Status File

Acronyms for More Data Sources

- **ADUSH Enrollment Files:** Assistant Deputy Under Secretary for Policy and Planning Enrollment Files
- **CAN Scores:** Care Assessment Need Scores
- **CAPRI:** Compensation and Pension Record Interface (EHR tool)
- **CART:** Clinical Assessment Reporting and Tracking (CART)
- **RAI/MDS:** Community Living Center Resident Assessment Instrument/Minimum Data Set
- **DaVINCI:** DoD and VA Infrastructure for Clinical Intelligence
- **OMOP –** Observational Medical Outcomes Partnership, Common Data Model
- **NPPD –** National Prosthetics Patient Database
- **PSSG –** Planning Systems Support Group Geo-coded Enrollee Data
- **VASQIP –** VA Surgical Quality Improvement Program Data
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VHA Data Stewards, Access Managers

- **CUPS POC** – Customer User Provisioning System Point of Contact (often your facility ISO)
- **DART** – Data Access Request Tracker
- **ePAS** – Electronic Permission Access System
- **MAC** – Medicare Analysis Center: VA/CMS Data for Operations
- **NDS** – National Data Systems
- **PCS** – Patient Care Services
- **PBM** – Pharmacy Benefits Management System
- **VIReC** – VA Information Resource Center: VA/CMS Data for Research

Acronyms for Research

- **IRB** – Institutional Review Board
- **R&DC** – Research and Development Committee
- **ACOS-R** – Associate Chief of Staff for Research
- **ORD** – Office of Research and Development
- **ORRP&E** –
- **ORO** – Office of Research Oversight

Other Data Access Acronyms

- **VINCI** – VA Informatics and Computing Infrastructure (a secure platform with tools for research data use)

University of Kentucky Office of Research Integrity Exemption Categories Tool

- Subpart B: Studies Involving Pregnant Women, Fetuses & Neonates are Eligible for Exempt Under All 8 Categories
- Subpart C: Exemptions Do Not Apply to Research Involving Prisoners Except "for Research Aimed at Involving a Broader Subject Population that Only Incidentally Includes Prisoners"
- Subpart B: Children are allowed in categories 1,4,5,6,7, & 8; Limitations & Exclusion of Children in Category 2 & 3

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
1	**104(d)(1)**	**Research in Established or Commonly Accepted Education Settings that Involves Normal Educational Practices**	N/A	**Not Likely to Adversely Impact Students' Opportunity to Learn or Assessment of Educators Providing Instruction**
2	**104(d)(2)**	**Research only includes interactions involving Educational Tests, Surveys, Interviews, Public Observation if at least ONE of the following criteria met:**	N/A	**Data Collection Only;** **May include visual or auditory recording;** **May NOT include Intervention;** **Only includes Interactions**
		(i) Recorded information cannot readily identify the subject (directly or indirectly/linked); **OR**	N/A	**Surveys & Interviews: No Children;** Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
		(ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR**	N/A	**Surveys & Interviews: No Children;** Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
		(iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	NO Children
3	**104(d)(3)(i)**	**Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of following met:**	N/A	**NO Children;** **May Not include Medical Interventions;** **Subject prospectively agrees;** **(ii)BBI must be:** • **Brief in Duration** • **Painless/Harmless** • **Not Physically Invasive** • **Not Likely to Have a Significant Adverse Lasting Impact on Subjects** • **Unlikely that Subjects Will Find Interventions Offensive or Embarrassing** **(iii)No deception unless participant prospectively agrees**
		A. Recorded information cannot readily identify the subject (directly or indirectly/linked): **OR**	N/A	
		B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR**	N/A	
		C. Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
4	**104(d)(4)**	**Secondary Research for Which Consent is Not Required: Use of Identifiable Information or Identifiable Biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if ONE of following criteria met:**		**No Primary Collection from subjects for the research;** **Allows Both <u>Retrospective and Prospective Secondary Use</u>**
		(i) Biospecimens or Information is Publically Available; **OR**	N/A	Must be publically available
		(ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects; **OR**	N/A	PI does not contact: Will not re-identify
		(iii) Collection and Analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"; **OR**	N/A	HIPAA still applies; HIPAA protections include authorization or waiver of authorization; Does not include Biospeciments (only PHI); Federal guidance needed on how to apply this criterion
		(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities	N/A	If research generates identifiable private information it is subject to specified federal privacy laws (see iv for list)
5	**104(d)(5)**	**Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study…improve… public benefit or service programs.**	N/A	**Must be posted on a Federal Web Site**
6	**104(d)(6)**	**Taste and Food Quality**	N/A	
7	**104(d)(7)**	**Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research For Which Broad Consent Is Required**	-Broad consent is obtained --Documented or documentation waived - If there is a change made for research purposes in the way material stored or maintained, Privacy and confidentiality review	**All requirements for Broad Consent Met;** **MUST TRACK REFUSALS –as the IRB may not waive consent for use of identifiable material for any individual who refuses**
8	**104(d)(8)**	**Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required**	-Privacy and confidentiality review & -research is within the scope of the broad consent & -PI does not plan to return research results	Privacy and Confidentiality protections adequate; Broad consent was obtained**;** Documented or documentation waived **No plan to return research results;** **MUST TRACK REFUSALS as the IRB may not waive consent for use of identifiable material for any individual who refuses**