GOOD DATA PRACTICES SERIES

FY24 Session #: 2

Planning for Data Privacy for a New Research Protocol

May 1, 2024

Hosted by VIReC

Tomica Jefferson, MSM

Management & Program Analyst, National Data Systems (NDS)

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 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.

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

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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Session roadmap

- Documentation Overview
- How to Meet Federal Requirements
  - Combined IFC/HIPAA Authorization
  - HIPAA Authorization
  - HIPAA Waiver
  - Data Use Agreement (DUA)
  - VHA Data Portal

Session roadmap

- **Documentation Overview**
- How to Meet Federal Requirements
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  - HIPAA Waiver
  - Data Use Agreement (DUA)
  - VHA Data Portal

Documentation Overview

- Research Request Memo
- IRB Approval Letter
- R&D Approval Letter
- Informed Consent
- Stand Alone HIPAA Authorization 10-0493/10-3203
- Combined Informed Consent/HIPAA Authorization
- HIPAA Waiver
- Data Use Agreement

Session roadmap

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How to Meet Federal Requirements

Must have Research and Development (R&D) Committee approval

Must have legal authority to collect, use, and disclose patient information

Research will always require either an Authorization, HIPAA Waiver, Data Use Agreement or a combination of the above when collecting, using, or disclosing patient information

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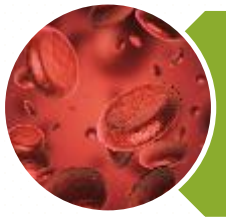
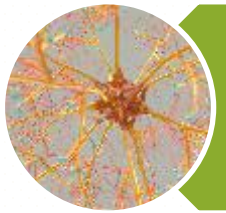
Combined IFC/HIPAA Authorization

A written HIPAA authorization may be incorporated into an informed consent for participation in research

Because VA subjects may revoke HIPAA authorizations, when the HIPAA authorization is combined with the informed consent, the document must clearly indicate whether revocation of the HIPAA authorization is also withdrawal of informed consent



VA Investigators may use and disclose the requested data only in a manner consistent with the approved research protocol and as indicated in the written HIPAA authorization from the subject or waiver of HIPAA Authorization.



When the HIPAA authorization is combined with the informed consent form, the VA Investigator may use and disclose the requested data consistent with the informed consent

Combined IFC/HIPAA Authorization

Unconditioned/optional components are present, such as optional tissue banking, or the subjects have diminished decision-making capacity and informed consent will be obtained from the subject's legally authorized representative

Using the Combined IFC/HIPAA Authorization when standalone Authorization is needed

Removing required language in template

Combined IFC/HIPAA

Combined IFC/HIPAA: What you need to know!

Informed Consent Template with HIPAA Authorization Elements

DIRECTIONS TO USE THIS TEMPLATE:

- Do not use this form if there is an **optional** future storage of identifiable data/specimens. If not optional you may use this form.
- **Do not adjust the bottom margin or use the footer**; it has been reserved for use by the IRB.
- Follow the italicized guidelines in **red** print and complete as applicable for your project. Words in **black** print or Green are generally expected be used without modification; those in **blue** print are examples/optional. Please **delete the template guidelines and unwanted text** after the document is completed.
- The consent form should include all the section headings indicated in the template unless otherwise indicated.
- The headings of this consent form are generally phrased as questions from the participant; the content of each section is generally written as the response from the study team. The form should provide information that a reasonable person would want to have in order to make an informed decision about whether to participate or not.
- The consent form may **not** contain exculpatory language through which the participant is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator or the Institution from liability for negligence. Phrases such as "I understand..." or "You understand..." are not appropriate as they can be interpreted as suggestive and can constitute coercive influence over a participant.

Combined IFC/HIPAA

Department of Veterans Affairs

RESEARCH CONSENT FORM

Version Date: (XX/XX/XX)

Participant Name: Last, First, MI suffix Date:

Title of Study:

Principal Investigator: VA Facility:

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study about _____{insert concise, general description of study}. It is being funded by [the Department of Veterans Affairs; is unfunded; or is funded by add additional funding sources if necessary]. By doing this study, we hope to learn _____.

(If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness include the following: The purpose of this research is to gather information on the safety and effectiveness of _____ *{state name of drug, device, etc.}. Indicate if the drug, device, or biologic is FDA-approved and whether it is being used in the study for an alternate use or consistent with labeling indications.)*

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

***Briefly** describe the procedures to be followed in lay terms.*

Your participation in this research will last about *{state in hours, days, months, years}*.

Combined IFC/HIPAA

Department of Veterans Affairs

RESEARCH CONSENT FORM

Version Date: (XX/XX/XX)

Participant Name: Last, First, MI suffix Date:

Title of Study:

Principal Investigator: VA Facility:

will have access to your research related health records.
OR
will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care
and will not affect your right to have access to the research records after the study is completed.

Health Information Portability and Accountability Act (HIPAA)

Include the following language in GREEN verbatim: {IF IMPARIED DECISION MAKING INDIVIDUALS – REMOVE THIS WORDING AND SUBMIT A SEPARATE 10-4093 *HIPAA AUTHORIZATION FORM}*

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as **{MODIFY AS APPROPRIATE}** medical history, allergies, lab results, HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

IMPORTANT

Session roadmap

- Documentation Overview
- How to Meet Federal Requirements
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  - **HIPAA Authorization**
  - HIPAA Waiver
  - Data Use Agreement (DUA)
  - VHA Data Portal

VA Form 10-0493
Standalone HIPAA Authorization

If the authorization is for VA research purposes, VA Form 10-0493 must be used when not combined with the Research Informed Consent Form

If there are 3rd Party Disclosures, an authorization is needed. However, it is not a requirement to use the Combined IFC/HIPAA Authorization, but always required to use 10-0493

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HIPAA Waiver

If there is no prior signed, written HIPAA authorization, VHA individually identifiable health information involving non-employee research subjects may be used by a VA Investigator for research purposes when there is an IRB or Privacy Board waiver of HIPAA authorization in accordance with 45 C.F.R. § 164.512(i)

A waiver requires that the IRB or Privacy Board appropriately document that it has determined that the waiver of HIPAA authorization satisfies the criteria stated in Directives 1605.01 and 1200.05

HIPAA Waiver

- HIPAA: This study is subject to HIPAA. A waiver of Authorization was granted. All criteria for waiving HIPAA authorization were met.
- The Privacy Officer reviewed this research project on XX/XX/XXXX and found that the proposed research complies with VA Privacy Requirements.
- The IRB has approved a waiver of the requirement for signed authorization as outlined in the HIPAA Privacy Rule regulations at 45 CFR 164.512(i), which states that an IRB may approve a waiver or alteration of the authorization requirement provided that the following criteria are met (1) the PHI use or disclosure involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the requested waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI. A waiver of HIPAA authorization is granted for this retrospective chart review.
- The IRB also determined that the criteria for a waiver of HIPAA Authorization were also met 45 CFR 164.512. The HIPAA waiver request was approved.

HIPAA Waiver

IV. Justification for Waiver

The PI must provide a response for each of the items listed below. Separate the plans for PHI as described in the protocol if the submitted project has multiple phases (e.g., Phase I, Phase II, or Aim 1, Aim 2, etc.), if applicable.

1. Provide a specific description for each aspect of the research project for which the waiver is being sought:
   ☐ N/A
2. Describe why the research could not be practicably conducted without the waiver.
3. Describe why the research could not practicably be conducted without access to, and use of, the PHI.
4. Indicate below the specific individual identifiers required as part of the research effort. ***Check all the identifiers that will be accessed, collected, used and/or disclosed.***

☐ Names	☐ Social security numbers or scrambled SSNs	☐ Device identifiers and serial numbers
☐ E-mail addresses	☐ Medical record numbers	☐ URLs (Universal Resource Locator)
☐ All elements of dates (except year) and any age over 89 Dates may include dates of birth, dates of treatment, procedures, death, etc. *Specify:* Date of diagnosis and months of survival	☐ Health plan beneficiary numbers	☐ IP Addresses (Internet Protocol)
☐ Telephone numbers	☐ Account numbers	☐ Biometric Identifiers including finger and voice print

HIPAA Waiver

VAIRRS | **Request for Waiver of HIPAA Authorization**

a. If SSNs will be used, describe all of the following: ☐ N/A

1. Type of SSN to be used: ☐ Real ☐ Scrambled ☐ Last 4 digits
2. Specific use: for each type of SSN to be used:
3. Security measures in place for protecting the SSNs:

b. Indicate the "specific" health information (past, present, or future physical or mental health or condition of the individual) that will be accessed, collected, and/or used in addition to the above identifiers:

5. Indicate by name, and location if applicable, the database(s) from which information will be obtained.

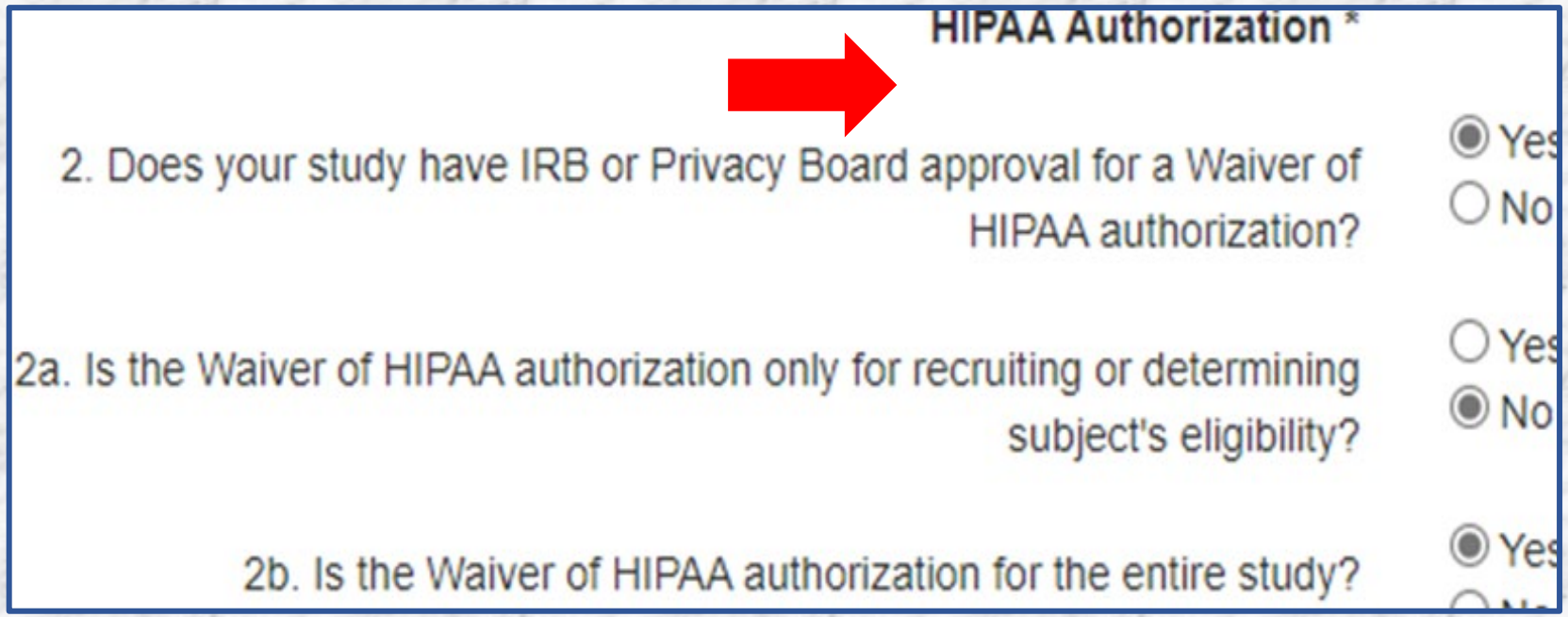
☐ VistA/CPRS (Research project Sites)	☐ VINCI/CDW	☐ CMS
☐ Other data source(s)/database(s) *Specify:* Ohio Cancer Incidence Surveillance System		

6. Describe the overall plan to protect the identifiers from improper use or disclosure.

7. Describe the plan to destroy the identifiers at the earliest opportunity in accordance with the VHA's Records Control Schedule (RCS 10-1). If there is a health, research, or other justification for retaining the identifiers, please provide such justification below.

8. Indicate any non-VA collaborators or service providers such as a transcription company, academic collaborators, etc. who are covered under this waiver.

DART Privacy Request Entry Review



Select the responses applicable to the approved project.

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Date Use Agreements

VHA is required to enter into a DUA under certain data-sharing circumstances, such as when a limited data set (LDS) is used.

An LDS is not de identified information under the HIPAA Privacy Rule and therefore HIPAA regulations still apply.

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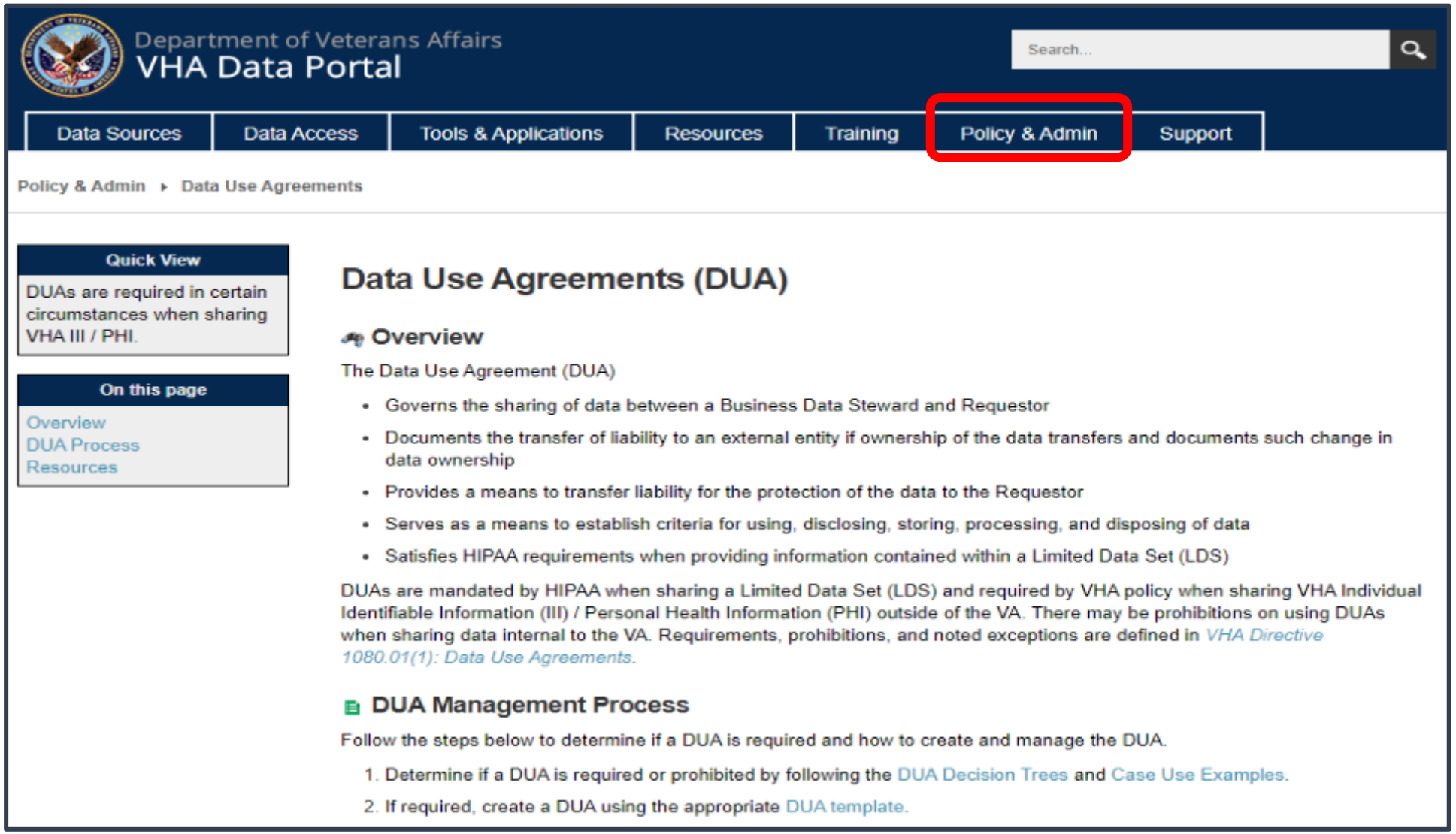
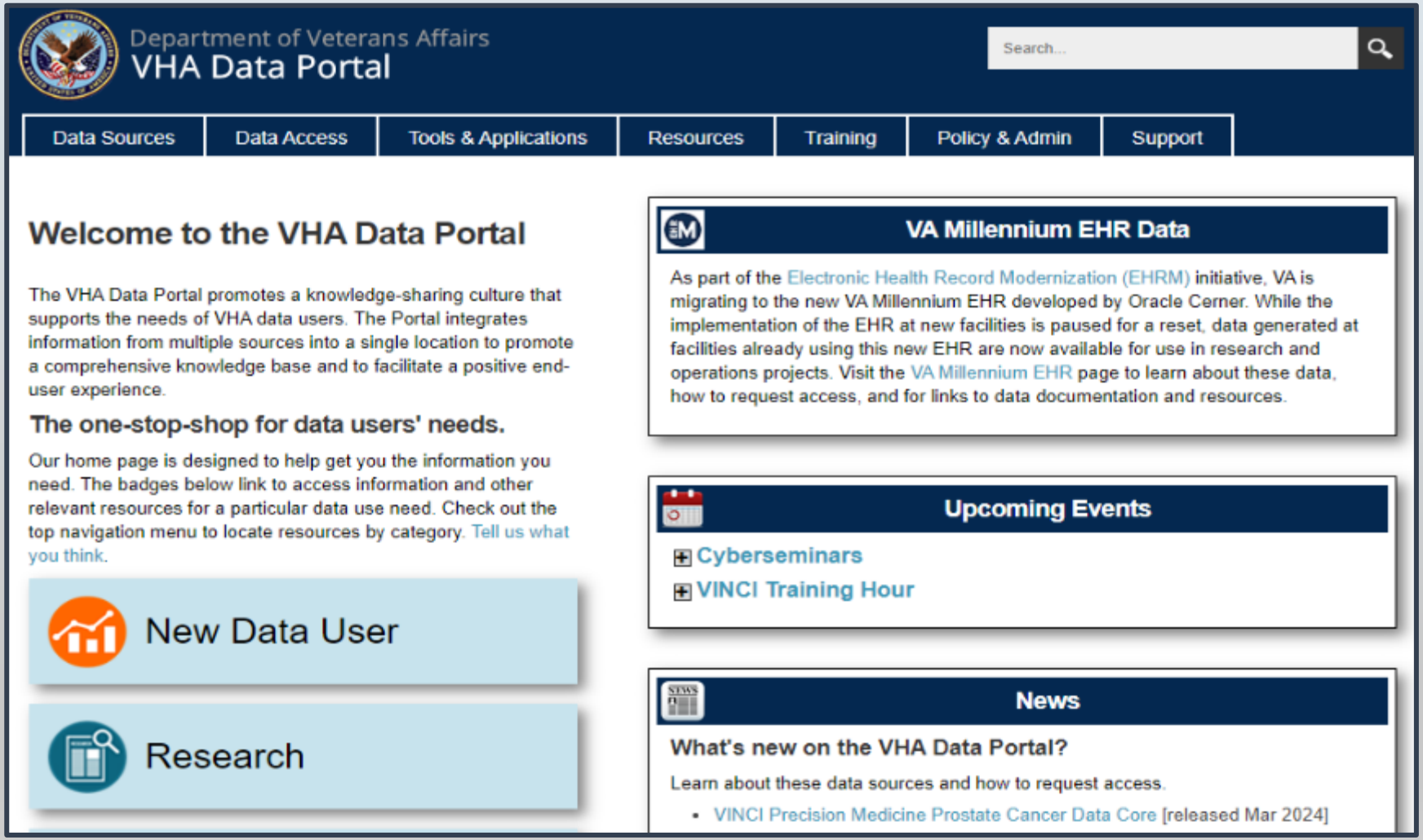
VHA Data Portal: Data Use Agreements (DUA)



VHA Data Portal

Includes:

- All data sources
- Detailed resources to assist with data use
- Links to useful resources elsewhere, such as the VIReC and VINCI websites



THANK YOU!
Questions?

CONTACT INFORMATION

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National Data Systems (NDS)

Email: Tomica.Jefferson@va.gov

GOOD DATA PRACTICES CYBERSEMINAR SERIES

Next session:

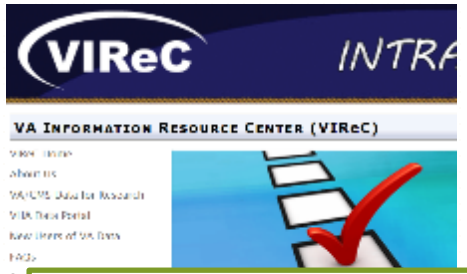
5/29/24 at 2 pm Eastern

Notes to Your Future Self: The Living Protocol

GOOD DATA PRACTICES
BONUS SLIDES

Resources for *VA Data Users*

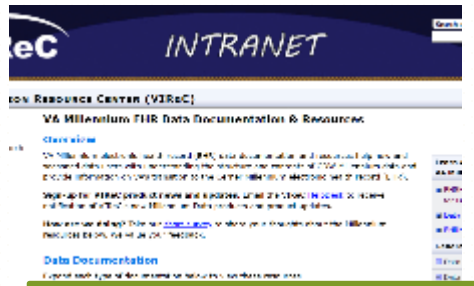
Select image to visit page



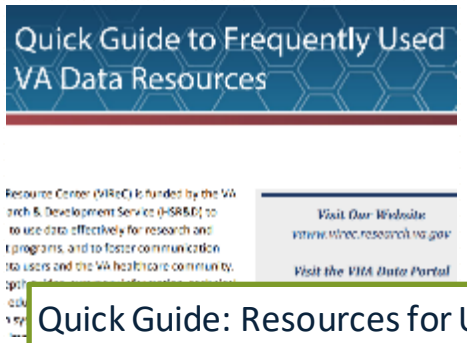
VA Information Resource Center (VIReC) (VA Intranet)

VHA Data Portal (VA Intranet)

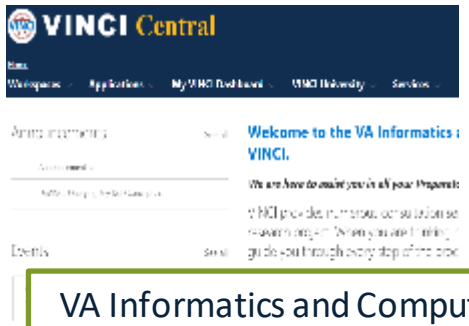
VIReC Cyberseminars



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
- ~1,800 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)