



 GOOD DATA PRACTICES SERIES

FY24 Session #: 2

Planning for Data Privacy for a New Research Protocol

May 1, 2024

Hosted by 

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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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



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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



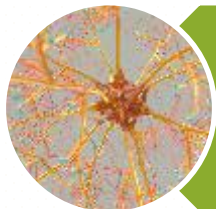
A written HIPAA authorization may be incorporated into an informed consent for participation in research



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 <i>Version Date: (XX/XX/XX)</i>
Participant Name:	_____ Last, First, MI suffix _____	Date: _____
Title of Study:	_____	
Principal Investigator:	_____	VA Facility: _____
<p>WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?</p> <p>This study about _____ <i>{insert concise, general description of study}</i>. It is being funded by <i>[the Department of Veterans Affairs; is unfunded; or is funded by add additional funding sources if necessary]</i>. By doing this study, we hope to learn _____.</p> <p><i>(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.)</i></p>		
<p>WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?</p> <p><i>Briefly describe the procedures to be followed in lay terms.</i></p> <p>Your participation in this research will last about <i>{state in hours, days, months, years}</i>.</p>		



Combined IFC/HIPAA

	Department of Veterans Affairs	RESEARCH CONSENT FORM
		<i>Version Date: (XX/XX/XX)</i>
Participant Name: _____ Last, First, MI suffix _____		Date: _____
Title of Study: _____		
Principal Investigator: _____		VA Facility: _____
<p>will have access to your research related health records. OR will not have access to your research related health records.</p> <p>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.</p> <p>Health Information Portability and Accountability Act (HIPAA)</p> <p>Include the following language in GREEN verbatim: {IF IMPAIRED DECISION MAKING INDIVIDUALS – REMOVE THIS WORDING AND SUBMIT A SEPARATE 10-4093 HIPAA AUTHORIZATION FORM}</p> <p>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.</p> <p>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.</p>		

IMPORTANT

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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.**



<input type="checkbox"/> Names	<input type="checkbox"/> Social security numbers or scrambled SSNs	<input type="checkbox"/> Device identifiers and serial numbers
<input type="checkbox"/> E-mail addresses	<input type="checkbox"/> Medical record numbers	<input type="checkbox"/> URLs (Universal Resource Locator)
<input type="checkbox"/> 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	<input type="checkbox"/> Health plan beneficiary numbers	<input type="checkbox"/> IP Addresses (Internet Protocol)
<input type="checkbox"/> Telephone numbers	<input type="checkbox"/> Account numbers	<input type="checkbox"/> 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.

- | | | |
|--|------------------------------------|------------------------------|
| <input type="checkbox"/> VistA/CPRS (Research project Sites) | <input type="checkbox"/> VINCI/CDW | <input type="checkbox"/> CMS |
| <input type="checkbox"/> Other data source(s)/database(s)
<i>Specify:</i> 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.

~~The Real SSN
Access Request
Memo~~



DART Privacy Request Entry Review

HIPAA Authorization *



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

- Yes
 No

2a. Is the Waiver of HIPAA authorization only for recruiting or determining subject's eligibility?

- Yes
 No

2b. Is the Waiver of HIPAA authorization for the entire study?

- Yes
 No

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.

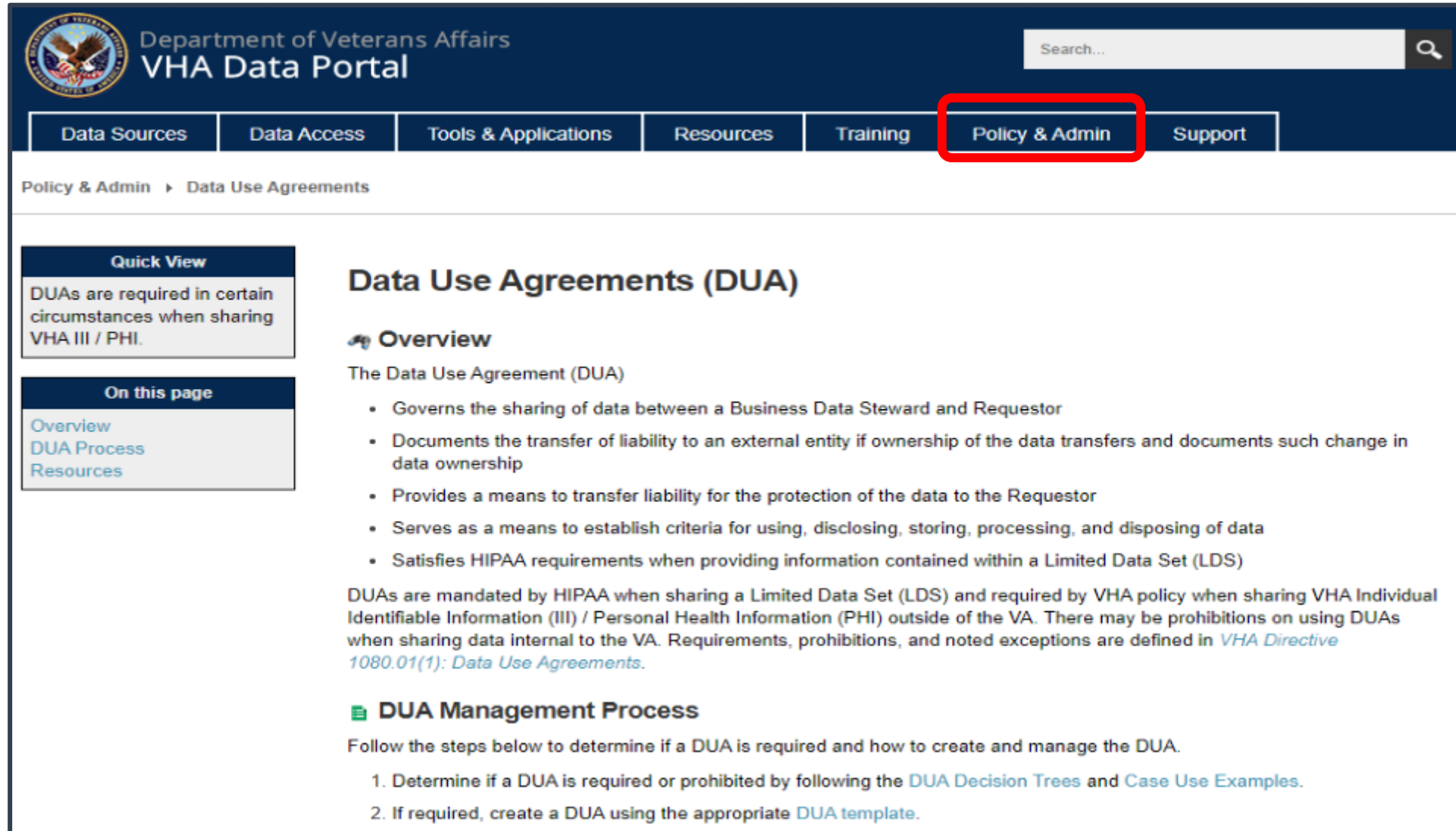


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VHA Data Portal: Data Use Agreements (DUA)



Department of Veterans Affairs
VHA Data Portal

Search...

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

Policy & Admin > Data Use Agreements

Quick View

DUAs are required in certain circumstances when sharing VHA III / PHI.

On this page

[Overview](#)
[DUA Process](#)
[Resources](#)

Data Use Agreements (DUA)

Overview

The Data Use Agreement (DUA)

- Governs the sharing of data between a Business Data Steward and Requestor
- Documents the transfer of liability to an external entity if ownership of the data transfers and documents such change in data ownership
- Provides a means to transfer liability for the protection of the data to the Requestor
- Serves as a means to establish criteria for using, disclosing, storing, processing, and disposing of data
- Satisfies HIPAA requirements when providing information contained within a Limited Data Set (LDS)

DUAs are mandated by HIPAA when sharing a Limited Data Set (LDS) and required by VHA policy when sharing VHA Individual Identifiable Information (III) / Personal Health Information (PHI) outside of the VA. There may be prohibitions on using DUAs when sharing data internal to the VA. Requirements, prohibitions, and noted exceptions are defined in [VHA Directive 1080.01\(1\): Data Use Agreements](#).

DUA Management Process

Follow the steps below to determine if a DUA is required and how to create and manage the DUA.

1. Determine if a DUA is required or prohibited by following the [DUA Decision Trees](#) and [Case Use Examples](#).
2. If required, create a DUA using the appropriate [DUA template](#).



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

The screenshot shows the VHA Data Portal homepage. At the top, there is a search bar and a navigation menu with categories: Data Sources, Data Access, Tools & Applications, Resources, Training, Policy & Admin, and Support. The main content area features a welcome message, a description of the portal's purpose, and a 'one-stop-shop' for data users. Below this are two prominent buttons: 'New Data User' and 'Research'. On the right side, there are three featured sections: 'VA Millennium EHR Data', 'Upcoming Events' (listing Cyberseminars and VINCI Training Hour), and 'News' (highlighting the VINCI Precision Medicine Prostate Cancer Data Core).

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**

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.

- [VINCI Precision Medicine Prostate Cancer Data Core](#) [released Mar 2024]



THANK YOU!
Questions?



CONTACT INFORMATION

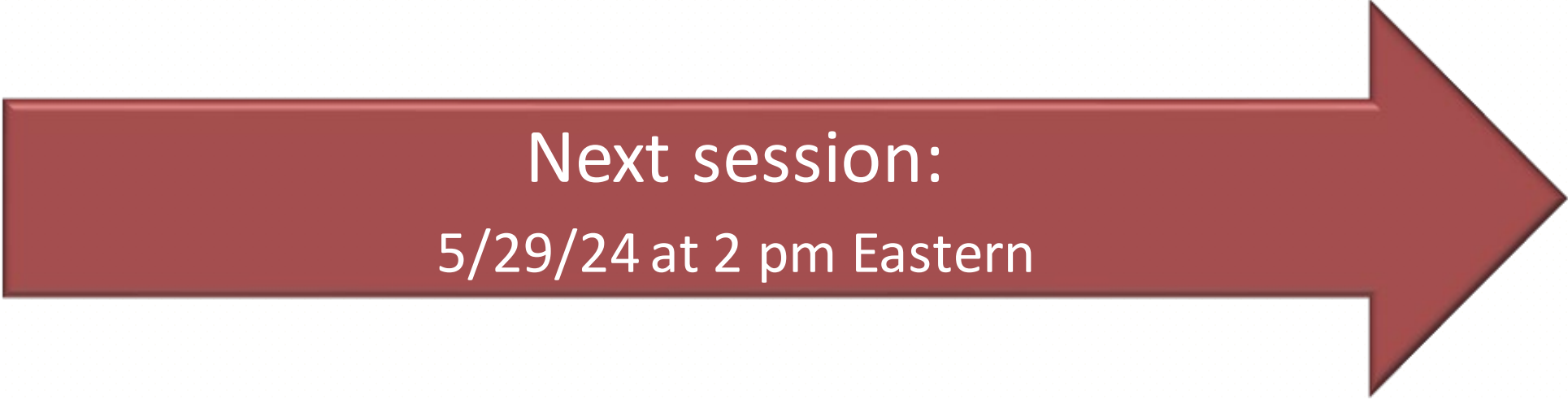
Tomica Jefferson, MSM

Management & Program Analyst
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

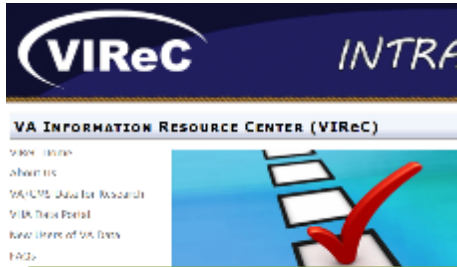


GOOD DATA PRACTICES BONUS SLIDES



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)

