What is VINCI and how do they help Researchers?

Tim Trautman

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DART and VADDRT Program Manager

VA Informatics & Computing Infrastructure

What is VINCI?

The VA Informatics and Computing Infrastructure (VINCI) is an Office of Research & Development (ORD) Resource that provides researchers a nation-wide view of high value VA patient data. VINCI is a research and development partnership and operational platform for health services research, epidemiology, decision support, and business intelligence.

VINCI Central web site

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

What does VINCI provide?

- Computing resources
  - Virtual computers
  - File shares
  - Databases
  - SAS/Grid
  - Data security
  - Server maintenance
  - Data backups
- Analytical software
- Productivity software
- Data sets
- Data provisioning
- Data services
- Data access requests
- SP Collaboration sites
- Data exploration tools
- VINCI Services
  - Data Needs Assessments
  - Feasibility assessments
  - Cohort development
  - Patient Lists
  - Study setup assistance
  - Training
  - VINCI Concierge help

VINCI

FREE! FREE! FREE! FREE!

Focus on using VINCI Resources

This presentation will focus on studies that will be:

- Conducting IRB Research
- Using VINCI services
- Requesting data access with DART
- Using VINCI/CDW data
- Using the VINCI Workspace

Basic Steps of a VINCI Study

1. Feasibility Assessment (optional)
2. Create your Protocol
3. IRB approvals
   a. IRB Letter (VAEDA and VAIRRS)
   b. HIPAA Waiver and/or Informed Consent
   c. Real SSN Access (if needed)
4. Data Needs Assessment (optional)
5. R&D Committee approval
6. Research Request Memo
7. Request data access with DART
8. VINCI data and project provisioning
9. Use the VINCI Workspace
10. Create Project Collaboration Site (optional)

A VINCI Concierge can assist at any time by contacting VINCI@va.gov with your request

1. Feasibility Assessment

- A Feasibility Assessment is a ***FREE*** VINCI service and is done prior to starting a protocol or study
- It is for determining if enough patients exist to conduct the study you want
- To request a Feasibility Assessment, send the following to VINCI@va.gov:
  - Put “Feasibility Assessment” in the email Subject line
  - Primary Investigator Name
  - Phone number and email address

1. Feasibility Assessment

- Inclusion/exclusion criteria
  - **Location** - nationwide or specific location(s)
  - **Time frame**
  - **Age/gender/other limitation**
  - **Diagnosis** - ICD9/10 codes – *Note: VA has used ICD10 codes since October 2015. If time frame exceeds 8 years, please provide both.*
  - **Procedures** - CPT codes or/and ICD-PC
  - **Lab tests** - topography, units, range
  - **Medications** - list of all generic and brand names, strength and route of administration

2. Create your Protocol

- Introductory paragraph
- Statement of the Problem
- Purpose
- Significance of the Study
- Research Questions and/or Hypotheses and/or Null Hypotheses
- Background
- Methodology
- Procedure and time frame
- Analysis plan
- Scope and limitations
- Use the most up to date Protocol

3a. Institutional Review Board (IRB) Letter

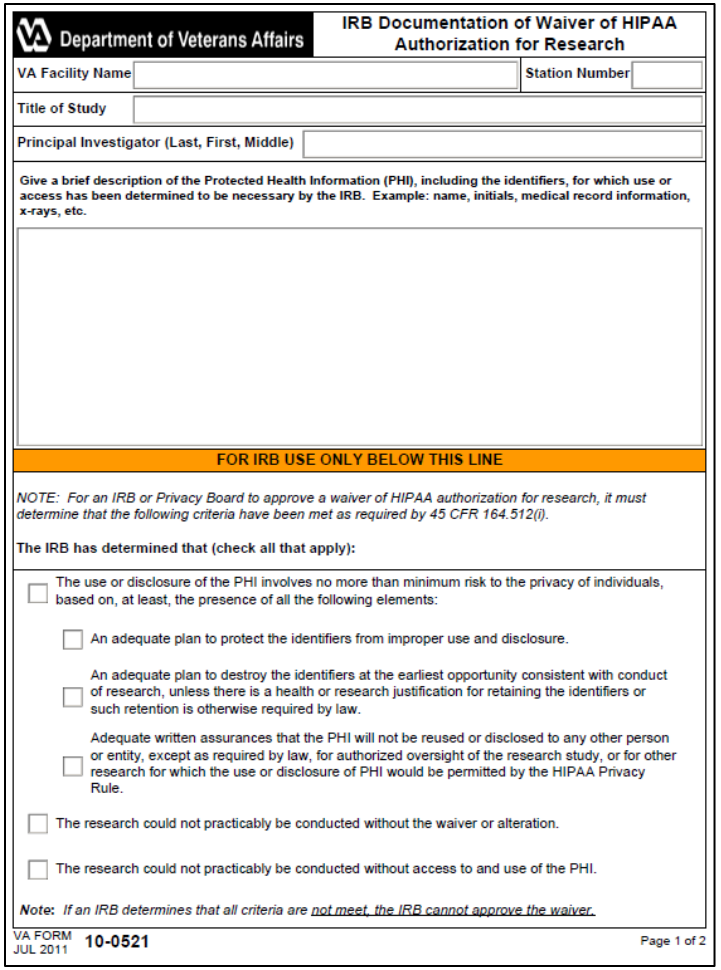
Prior to IRB submission, use **VA Electronic Determination Aid (VAEDA).** This is a regulatory decision support tool designed to help standardize the process by which VA makes preliminary project determinations of "not-research" vs "research that meets the definition of the common rule (38 CFR 16)."

VA Electronic Determination Aid (VAEDA)

3a. Institutional Review Board (IRB) Letter

- ***Generally, you will need an IRB Letter from each location where an investigator is involved***
- It can come from the Central IRB, local VAMC, or University Affiliate
- Use the **VA Innovation and Research Review System (VAIRRS)** to submit your IRB request. Contact your local IRB or Research Office for access as it is location specific.
- Use *VINCI Description for IRBs* and *VINCI Information Security Description* in IRB request

3b. Waiver of HIPAA Authorization



Department of Veterans Affairs

IRB Documentation of Waiver of HIPAA Authorization for Research

VA Facility Name | Station Number

Title of Study

Principal Investigator (Last, First, Middle)

Give a brief description of the Protected Health Information (PHI), including the identifiers, for which use or access has been determined to be necessary by the IRB. Example: name, initials, medical record information, x-rays, etc.

FOR IRB USE ONLY BELOW THIS LINE

NOTE: For an IRB or Privacy Board to approve a waiver of HIPAA authorization for research, it must determine that the following criteria have been met as required by 45 CFR 164.512(i).

The IRB has determined that (check all that apply):

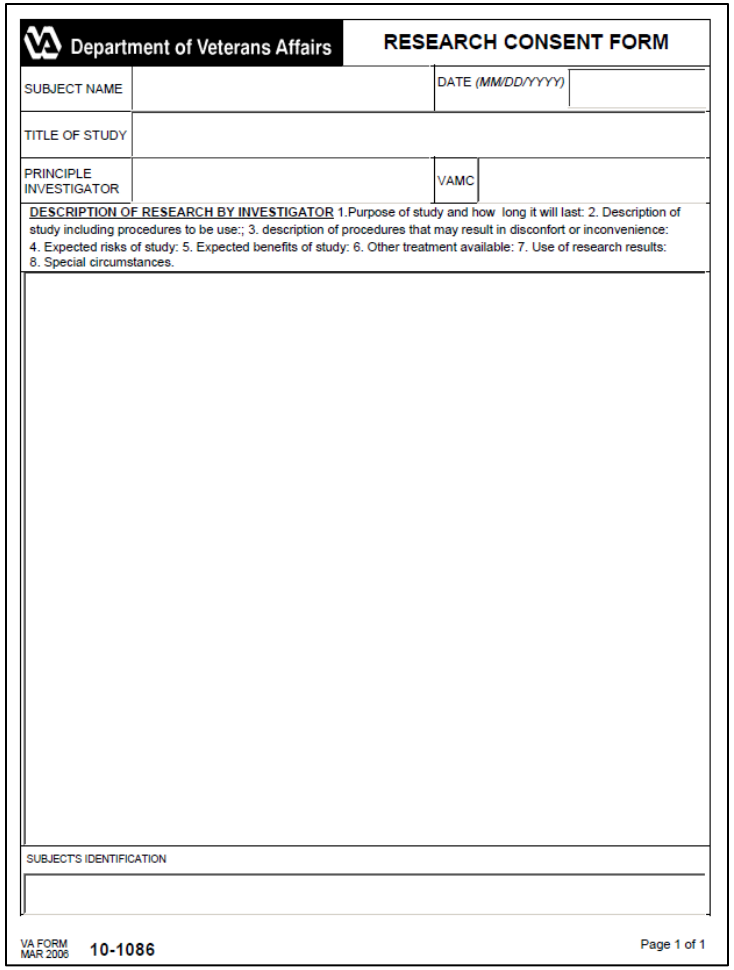
- ☐ The use or disclosure of the PHI involves no more than minimum risk to the privacy of individuals, based on, at least, the presence of all the following elements:
  - ☐ An adequate plan to protect the identifiers from improper use and disclosure.
  - ☐ An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
  - ☐ Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.
- ☐ The research could not practicably be conducted without the waiver or alteration.
- ☐ The research could not practicably be conducted without access to and use of the PHI.

Note: *If an IRB determines that all criteria are not meet, the IRB cannot approve the waiver.*

VA FORM JUL 2011 **10-0521** Page 1 of 2

- HIPAA Waivers are not standardized across the VA
- Your local IRB may have their own language and format
- VA Form 10-0521 is available for use
  - VA Facility Name
  - Title of Study
  - PI Name
  - Brief description of PHI used

3b. Sample Informed Consent & HIPAA Authorization



Department of Veterans Affairs

RESEARCH CONSENT FORM

SUBJECT NAME		DATE *(MM/DD/YYYY)*	
TITLE OF STUDY			
PRINCIPLE INVESTIGATOR		VAMC	

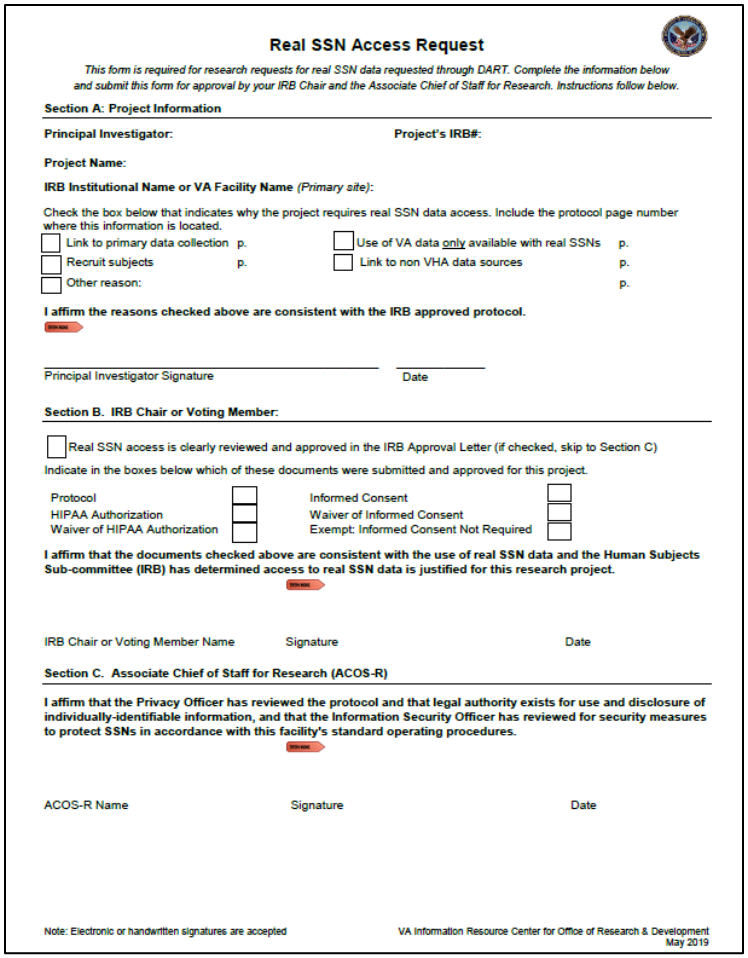
DESCRIPTION OF RESEARCH BY INVESTIGATOR 1.Purpose of study and how long it will last: 2. Description of study including procedures to be use:; 3. description of procedures that may result in disconfort or inconvenience: 4. Expected risks of study: 5. Expected benefits of study: 6. Other treatment available: 7. Use of research results: 8. Special circumstances.

SUBJECT'S IDENTIFICATION

VA FORM MAR 2006 **10-1086** Page 1 of 1

- Used to inform potential study participants and gain their consent to participate
- Informed Consent forms are not standardized across the VA
- Your local IRB may have their own language and format
- VA Form 10-1086 is available for use
  - Subject Name (leave blank)
  - Title of Study
  - PI Name
  - Description of research by Investigator (8 sections)

3c. Real SSN Access



Real SSN Access Request

This form is required for research requests for real SSN data requested through DART. Complete the information below and submit this form for approval by your IRB Chair and the Associate Chief of Staff for Research. Instructions follow below.

Section A: Project Information

Principal Investigator: **Project's IRB#:**

Project Name:

IRB Institutional Name or VA Facility Name *(Primary site)*:

Check the box below that indicates why the project requires real SSN data access. Include the protocol page number where this information is located.

- ☐ Link to primary data collection p.
- ☐ Recruit subjects p.
- ☐ Other reason:
- ☐ Use of VA data only available with real SSNs p.
- ☐ Link to non VHA data sources p.

I affirm the reasons checked above are consistent with the IRB approved protocol.

Principal Investigator Signature Date

Section B. IRB Chair or Voting Member:

☐ Real SSN access is clearly reviewed and approved in the IRB Approval Letter (if checked, skip to Section C)

Indicate in the boxes below which of these documents were submitted and approved for this project.

- Protocol ☐
- HIPAA Authorization ☐
- Waiver of HIPAA Authorization ☐
- Informed Consent ☐
- Waiver of Informed Consent ☐
- Exempt: Informed Consent Not Required ☐

I affirm that the documents checked above are consistent with the use of real SSN data and the Human Subjects Sub-committee (IRB) has determined access to real SSN data is justified for this research project.

IRB Chair or Voting Member Name Signature Date

Section C. Associate Chief of Staff for Research (ACOS-R)

I affirm that the Privacy Officer has reviewed the protocol and that legal authority exists for use and disclosure of individually-identifiable information, and that the Information Security Officer has reviewed for security measures to protect SSNs in accordance with this facility's standard operating procedures.

ACOS-R Name Signature Date

Note: Electronic or handwritten signatures are accepted

VA Information Resource Center for Office of Research & Development
May 2019

- This form is for justifying use of Real SSN
- You will need a Real SSN Access Request form signed by your ACOS-R
- More information is available on the VIReC Real SSN Data Request Process page.

4. Data Needs Assessment (DNA)

- This ***FREE*** VINCI service helps you discover the data you need to conduct your study and how to get access approvals
- It is not for Preparatory to Research where you explore the data yourself
- A DNA will deliver a list of data sources mapped to CDW and other sources for your DART request

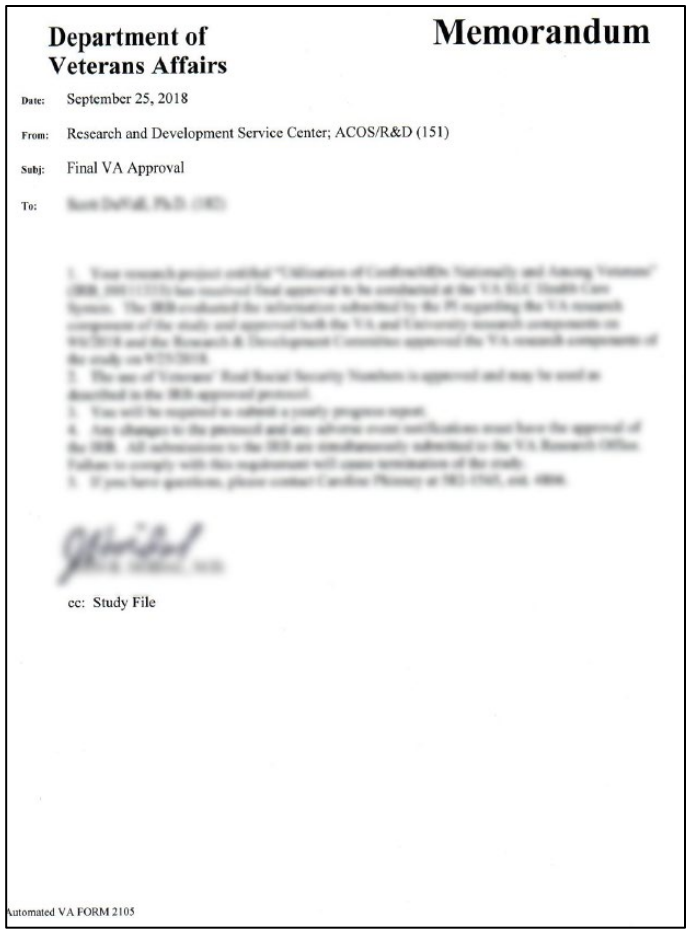
4. Data Needs Assessment

- To request a DNA, send an email to VINCI@va.gov with the following:
  - Put “DNA” in email Subject line
  - Your study protocol if you have one or similar study information
  - An extensive description of what kind of data you are looking for – a prior Feasibility request helps

4. Explore the Data Yourself

- VHA Data Portal
- VINCI Data Sources
- CDW Metadata Reports Page on the CDW Production Data on the CDW Site
- CDW-Raw Domains Page on the CDW site
- VIReC's CDW Documentation
- VINCI's Dim Data Viewer (Explore CDW Dim Table)
- VINCI's Meta Data Viewer (Explore CDW Meta Data Table)

5. R&D Committee Approval



Department of Veterans Affairs

Memorandum

Date: September 25, 2018

From: Research and Development Service Center; ACOS/R&D (151)

Subj: Final VA Approval

To: [redacted]

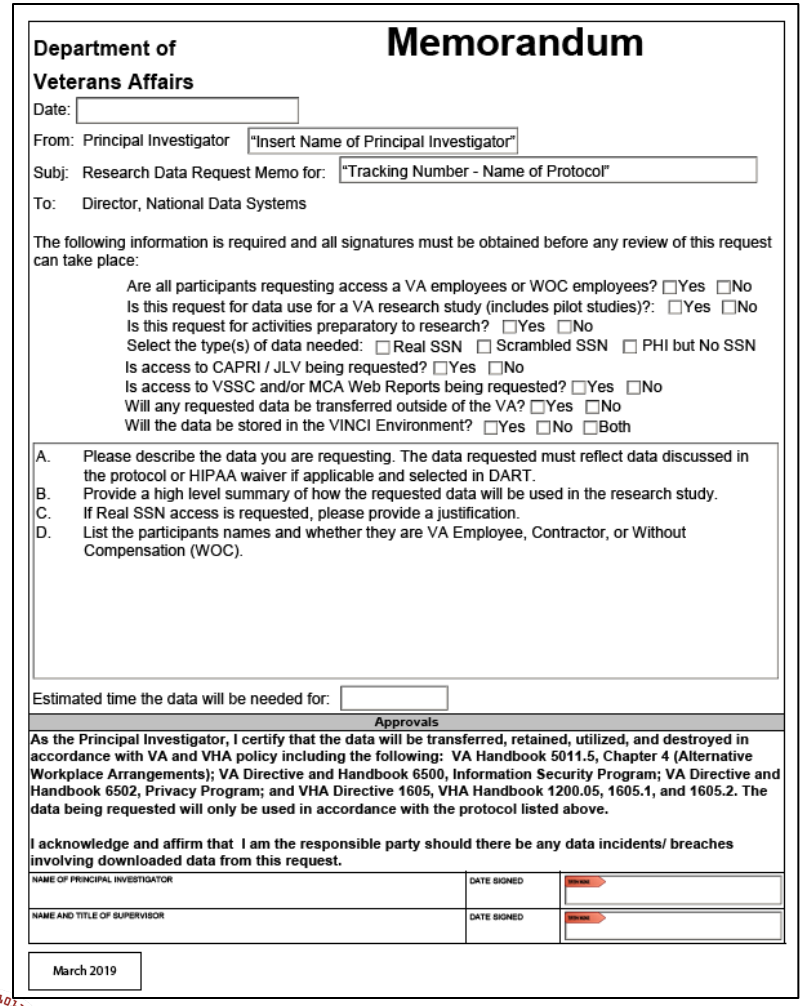
[redacted]

cc: Study File

Automated VA FORM 2105

- Each VA facility has a local Research and Development Committee
- All IRB Approved or exempt Research studies in DART must have and R&D approval letter for each location participating in the study
- Per VHA Directive 1200.01(1)

6. Research Request Memo



Department of Veterans Affairs

Memorandum

Date:

From: Principal Investigator "Insert Name of Principal Investigator"

Subj: Research Data Request Memo for: "Tracking Number - Name of Protocol"

To: Director, National Data Systems

The following information is required and all signatures must be obtained before any review of this request can take place:

Are all participants requesting access a VA employees or WOC employees? ☐Yes ☐No
Is this request for data use for a VA research study (includes pilot studies)?: ☐Yes ☐No
Is this request for activities preparatory to research? ☐Yes ☐No
Select the type(s) of data needed: ☐Real SSN ☐Scrambled SSN ☐PHI but No SSN
Is access to CAPRI / JLV being requested? ☐Yes ☐No
Is access to VSSC and/or MCA Web Reports being requested? ☐Yes ☐No
Will any requested data be transferred outside of the VA? ☐Yes ☐No
Will the data be stored in the VINCI Environment? ☐Yes ☐No ☐Both

A. Please describe the data you are requesting. The data requested must reflect data discussed in the protocol or HIPAA waiver if applicable and selected in DART.
B. Provide a high level summary of how the requested data will be used in the research study.
C. If Real SSN access is requested, please provide a justification.
D. List the participants names and whether they are VA Employee, Contractor, or Without Compensation (WOC).

Estimated time the data will be needed for:

Approvals

As the Principal Investigator, I certify that the data will be transferred, retained, utilized, and destroyed in accordance with VA and VHA policy including the following: VA Handbook 5011.5, Chapter 4 (Alternative Workplace Arrangements); VA Directive and Handbook 6500, Information Security Program; VA Directive and Handbook 6502, Privacy Program; and VHA Directive 1605, VHA Handbook 1200.05, 1605.1, and 1605.2. The data being requested will only be used in accordance with the protocol listed above.

I acknowledge and affirm that I am the responsible party should there be any data incidents/ breaches involving downloaded data from this request.

NAME OF PRINCIPAL INVESTIGATOR	DATE SIGNED	
NAME AND TITLE OF SUPERVISOR	DATE SIGNED	

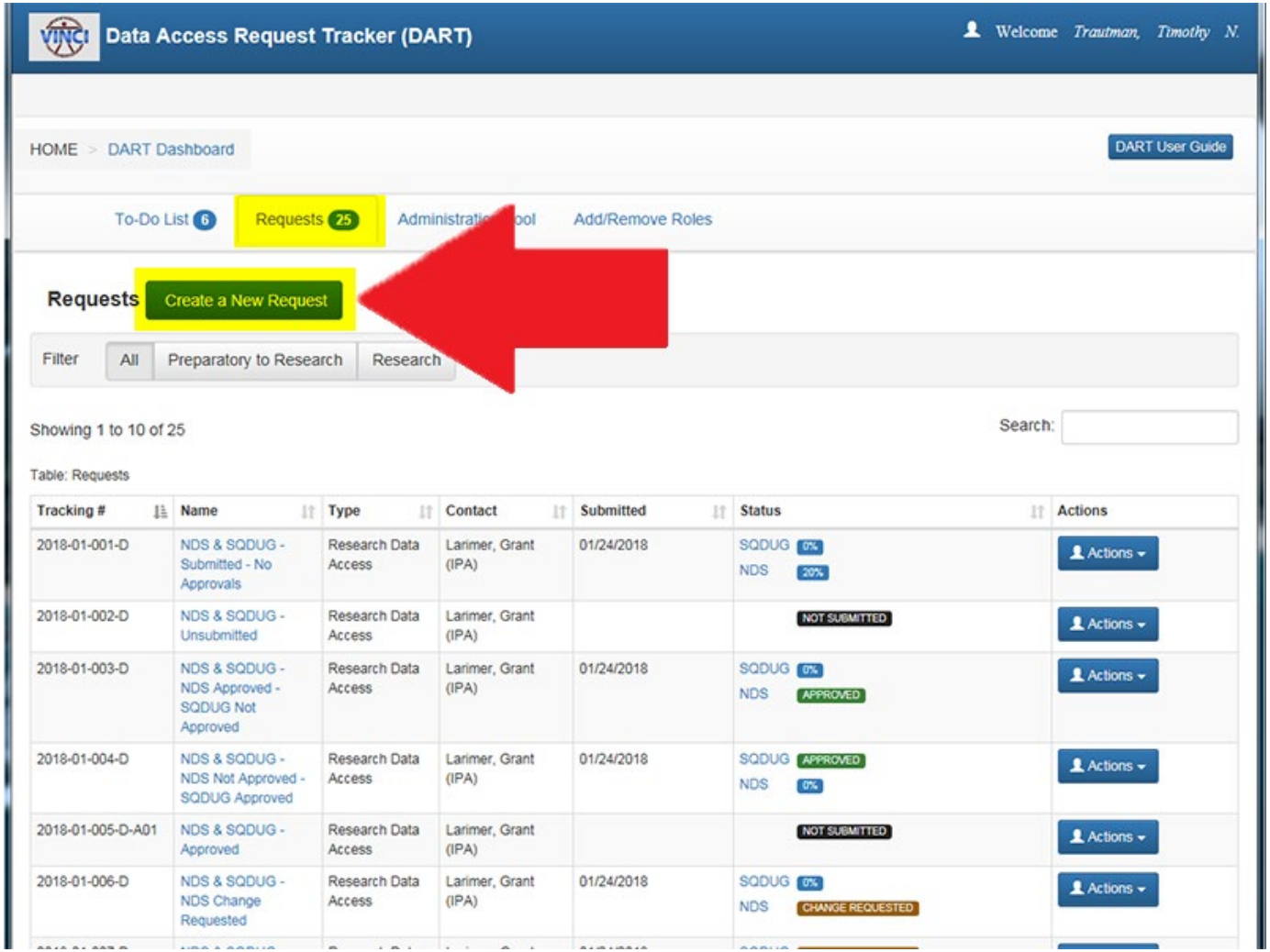
March 2019

- Research Request Memo
- Instructions are in Appendix A of the DART User Guide
- Initiate your DART request to obtain your DART Tracking Number for the memo's Subject line

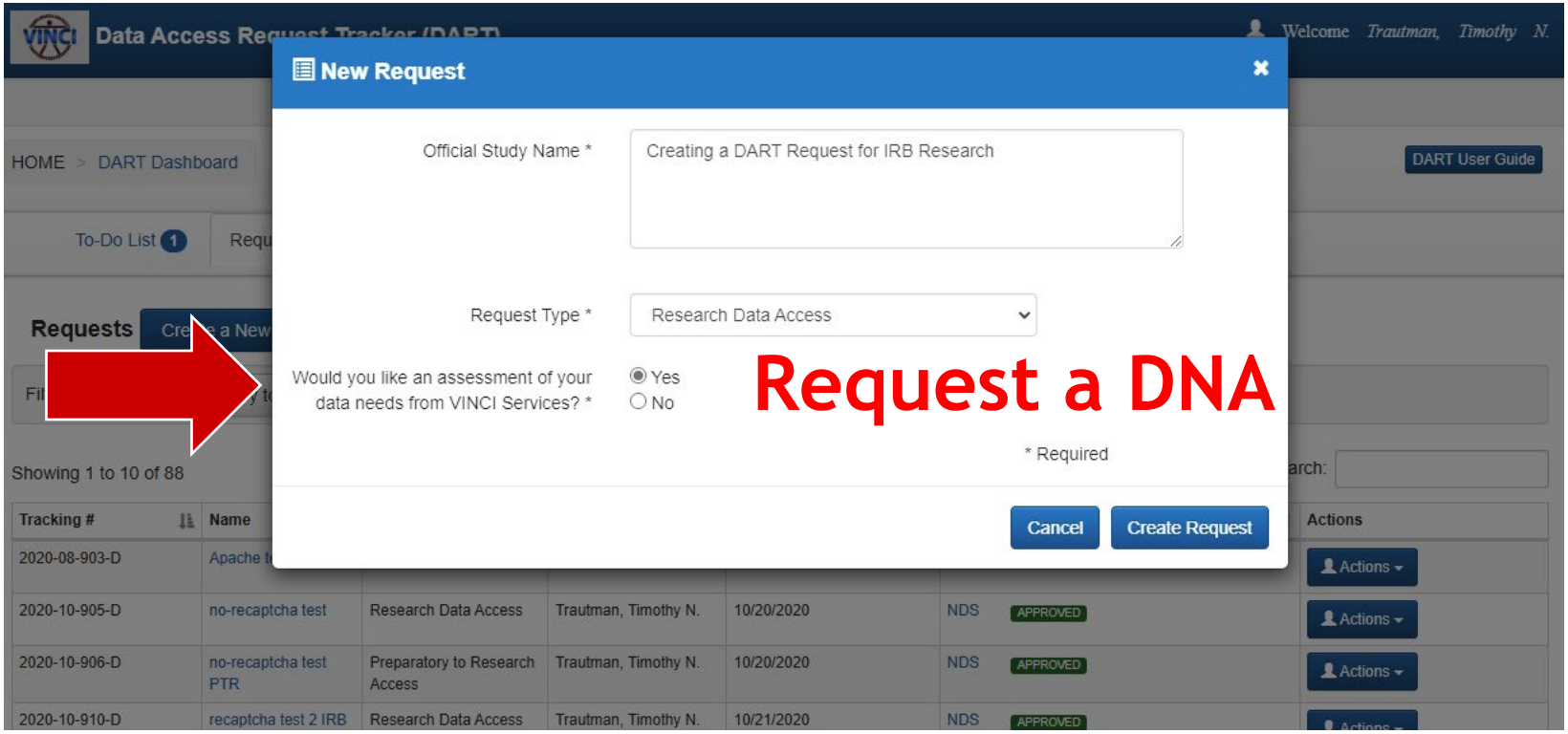
7. Request data access with DART

- DART is VINCI's Data Access Request Tracker online application used by National Data Systems (NDS) and other data stewards to approve access to various data sources including CDW/VINCI data
- Collects study information and documentation via a 4-screen "Wizard"
- Determines required documentation based on Wizard entries
- Distributes the request to approving authorities who approve online
- See DART Research Request Process page

DART Demo – Create a New Request



DART Demo - Create a New Request



Official Study Name is exact Protocol Name

DART Demo - Initiated Email

DART Test .NET DART 2023-09-003-D has been Initiated - Please Read Before Submitting This Request - Do Not Reply

Reply | Reply All | Forward

D dart@va.gov

To Trautman, Timothy N. (VINCI)

Thu 9/7/2023 3:37 PM

DART_Considerations.pdf
151 KB

Greetings DART User,
You are receiving this email because you initiated a new Dart Request Request Tracker (DART) request:

- DART Tracking Number: 2023-09-003-D
- Study/Protocol Name: Creating a DART Request for IRB Research

It is important that you read the attached PDF document in order for you to understand the process. Please note that only IRB approved research and Preparatory to Research requests should be submitted through DART. Operational access is requested through other processes.

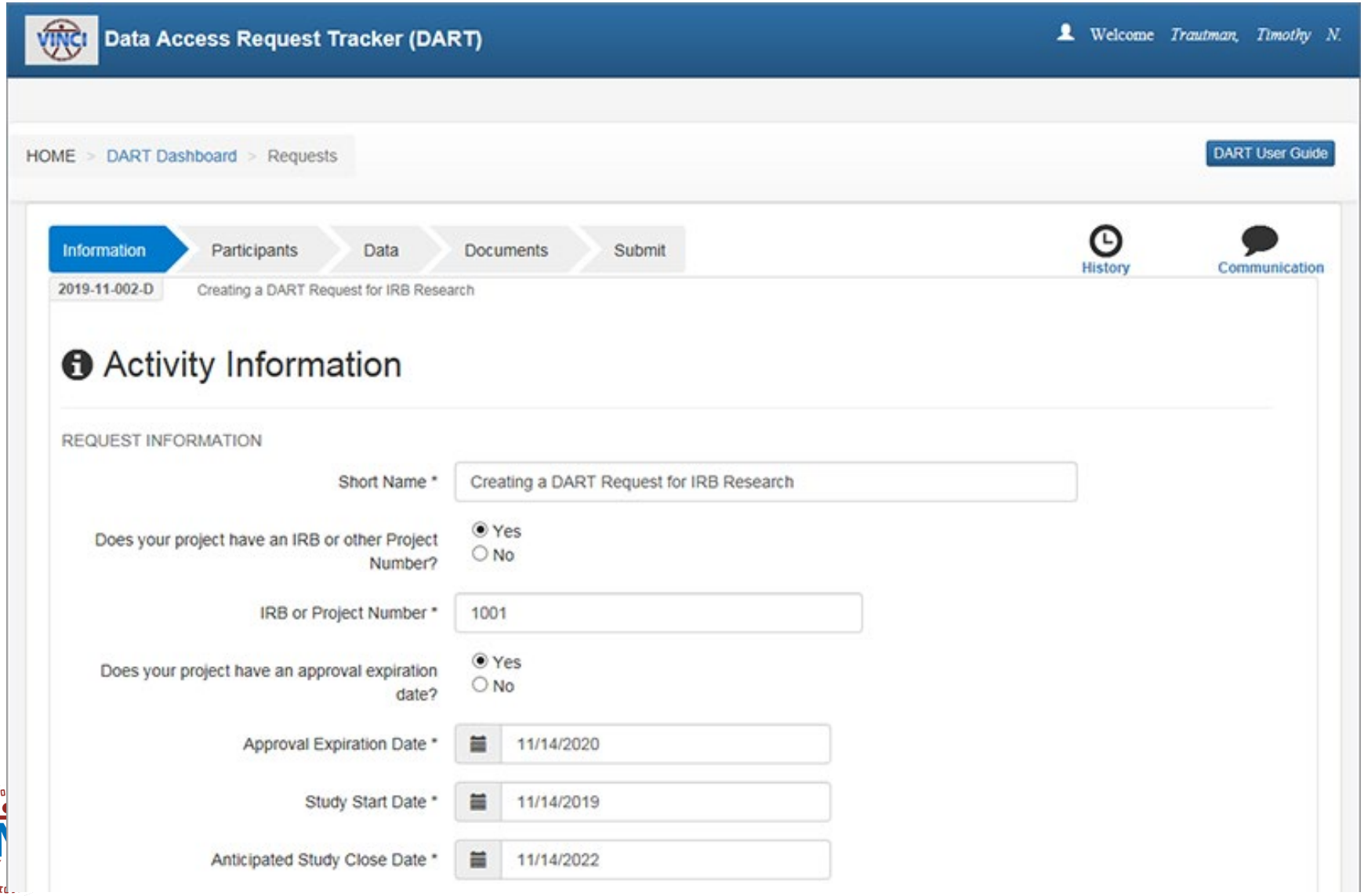
The attached document provides links to helpful resources, considerations to take into account when requesting data access, and what to expect. The DART User Guide provides complete details about how to use DART. If you need assistance with completing the DART request or have questions, please contact the VINCI Concierge Service at VINCI@va.gov or NDS.ResearchAccessRequests@va.gov. Do not reply to this email as it is system generated.

Data Needs Assessment
You declined assistance from VINCI Services on your cohort development. If you change your mind and decide you would like assistance, please contact VINCIServices@va.gov.

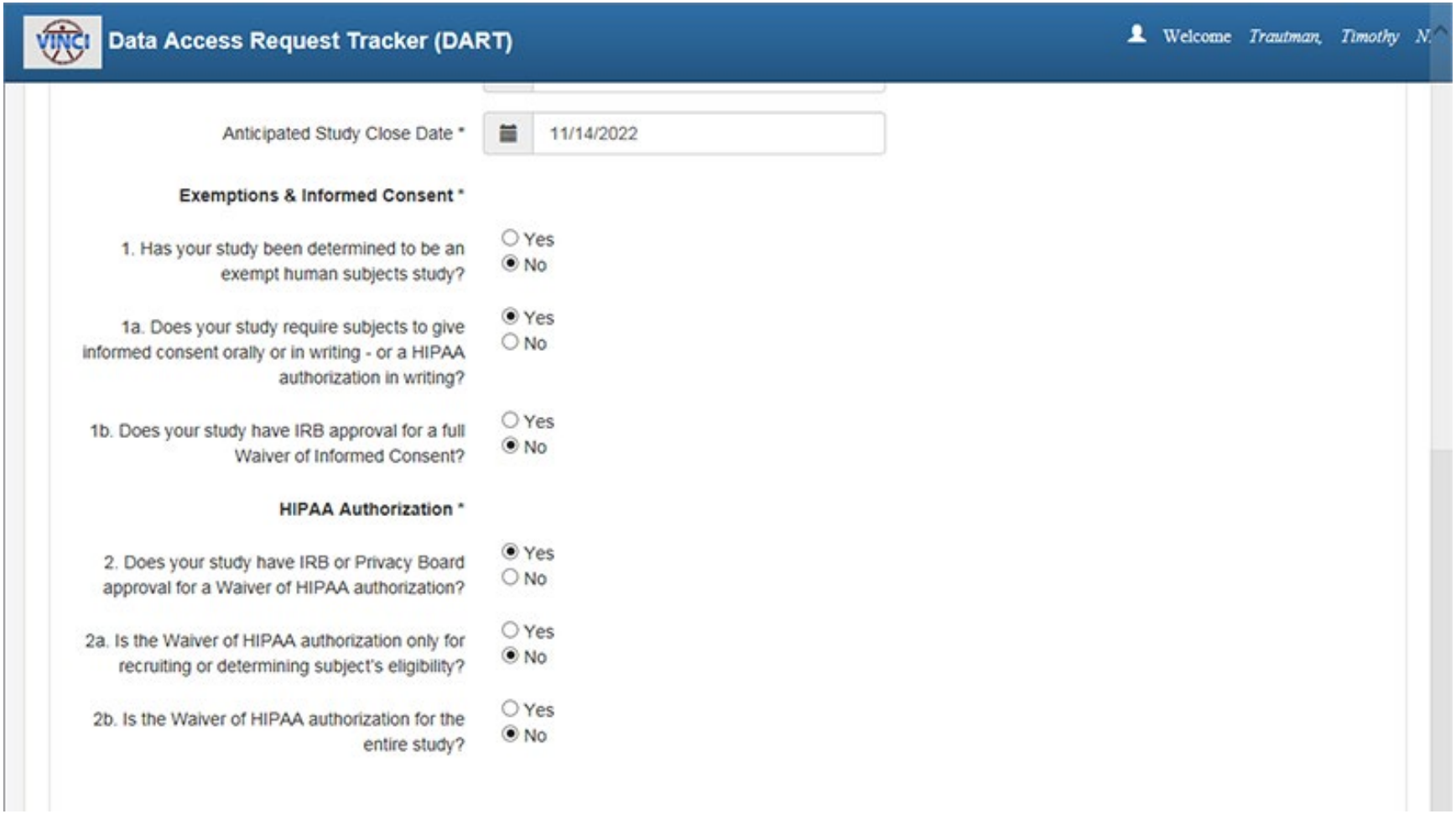
Remember, please take time to read the DART User Guide.

Do not reply to this email as it is system generated.
Sincerely,
The DART Team

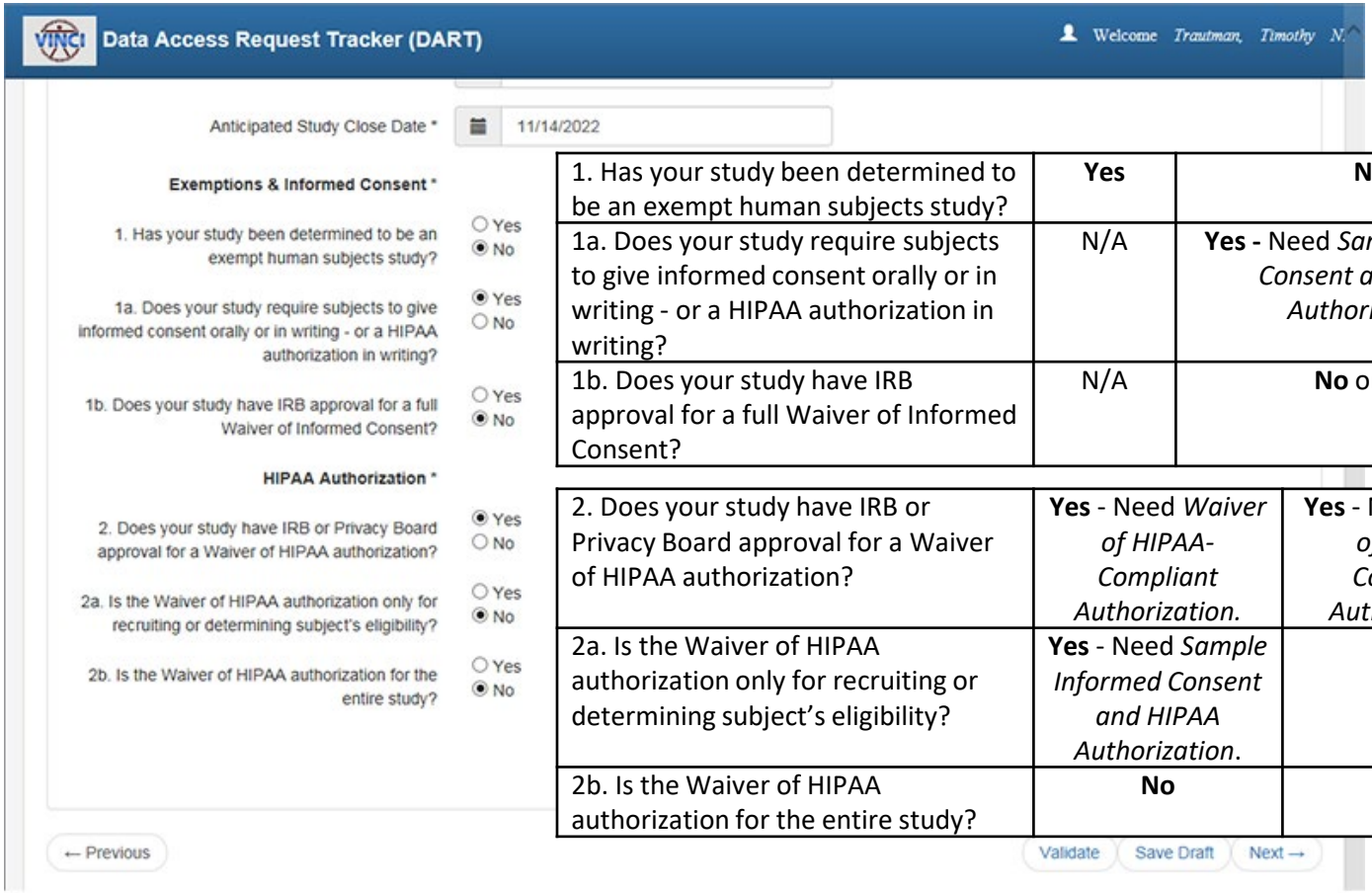
DART Demo- Activity Information



DART Demo- HIPAA Questions



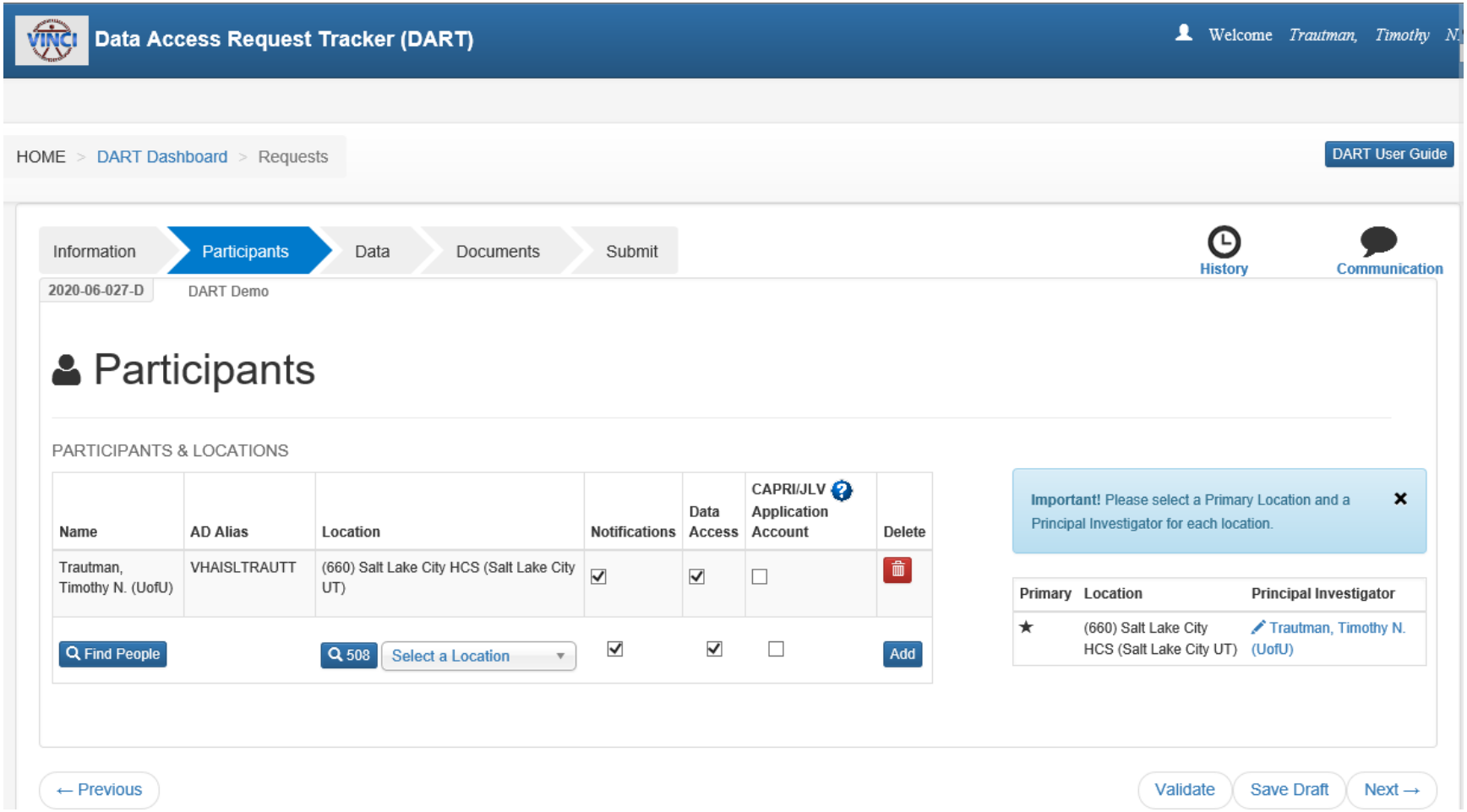
DART Demo- HIPAA Questions



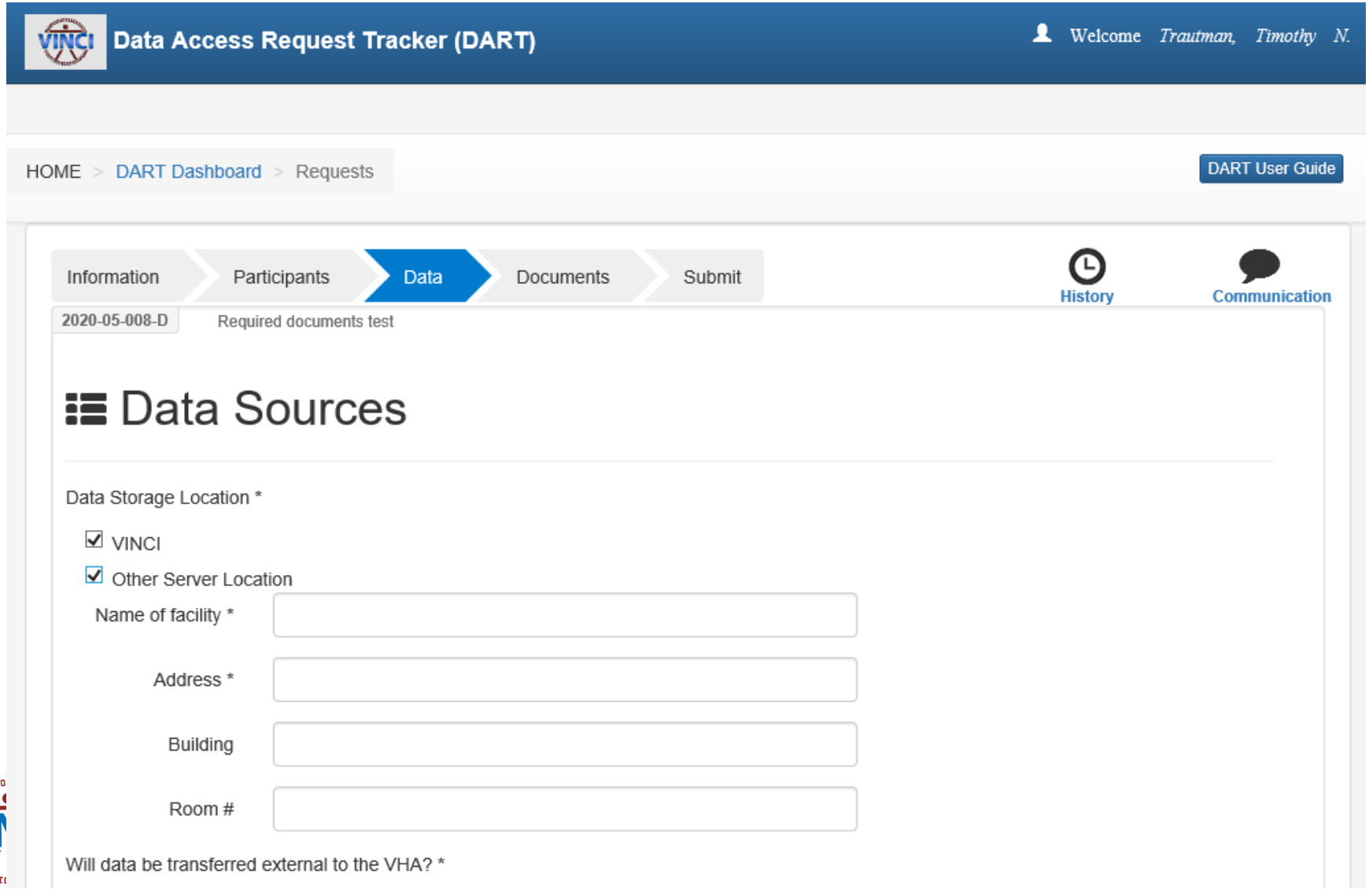
1. Has your study been determined to be an exempt human subjects study?	**Yes**	**No**	**No**
1a. Does your study require subjects to give informed consent orally or in writing - or a HIPAA authorization in writing?	N/A	**Yes -** Need *Sample Informed Consent and HIPAA Authorization*.	**No**
1b. Does your study have IRB approval for a full Waiver of Informed Consent?	N/A	**No** or **Yes**	**No** or **Yes**

2. Does your study have IRB or Privacy Board approval for a Waiver of HIPAA authorization?	**Yes** - Need *Waiver of HIPAA-Compliant Authorization.*	**Yes** - Need *Waiver of HIPAA-Compliant Authorization.*	**No** - Need *Sample Informed Consent and HIPAA Authorization*.
2a. Is the Waiver of HIPAA authorization only for recruiting or determining subject's eligibility?	**Yes** - Need *Sample Informed Consent and HIPAA Authorization*.	**No**	N/A
2b. Is the Waiver of HIPAA authorization for the entire study?	**No**	**Yes**	N/A

DART Demo- Participants



DART Demo - Data Sources



DART Demo – Data Sources

Will data be transferred external to the VHA? *

NDS cannot approve a research request that would include disclosing data requested through DART to entities outside of VHA unless the disclosure complies with VHA Privacy Office and Office of Research and Development (ORD) policy. ORD policy requires VHA research investigators to apply data use agreements (DUAs) when transferring research data external to VHA.

For example:

The HIPAA Privacy Rule permits the transfer of Limited Data Sets for research purposes, without obtaining an Authorization or documentation of Waiver of Authorization with a DUA.

If "finder" files are to be sent out to Federal or state agencies for the purpose of a Federal or state agency disclosing information on the individual back to VA per SOR 34VA12, a DUA between the PI and the external agency must be submitted with the DART application.

- ○ No
- ◉ Yes (DUA is required)

Name of Company/Agency*

Street *

City *

State *

Zip Code *

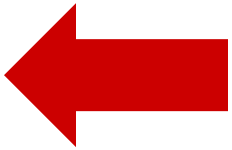
Data Access Systems

- ☐ SAS Grid

IDENTIFIERS (More about identifiers)

- ☐ Real SSN
- ☐ Scrambled SSN
- ☐ Identifiable data but no real or scrambled SSNs

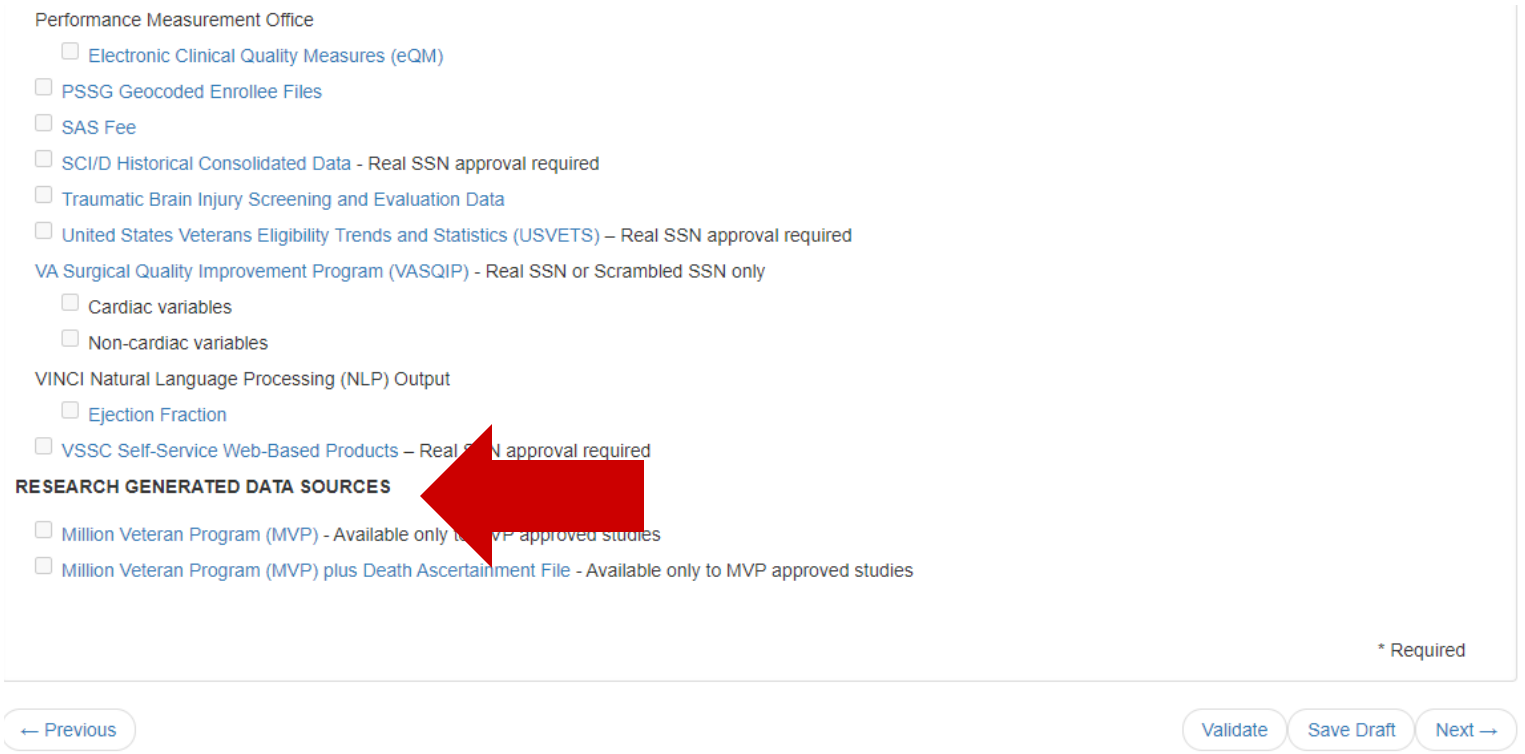
DART Demo - Data Sources



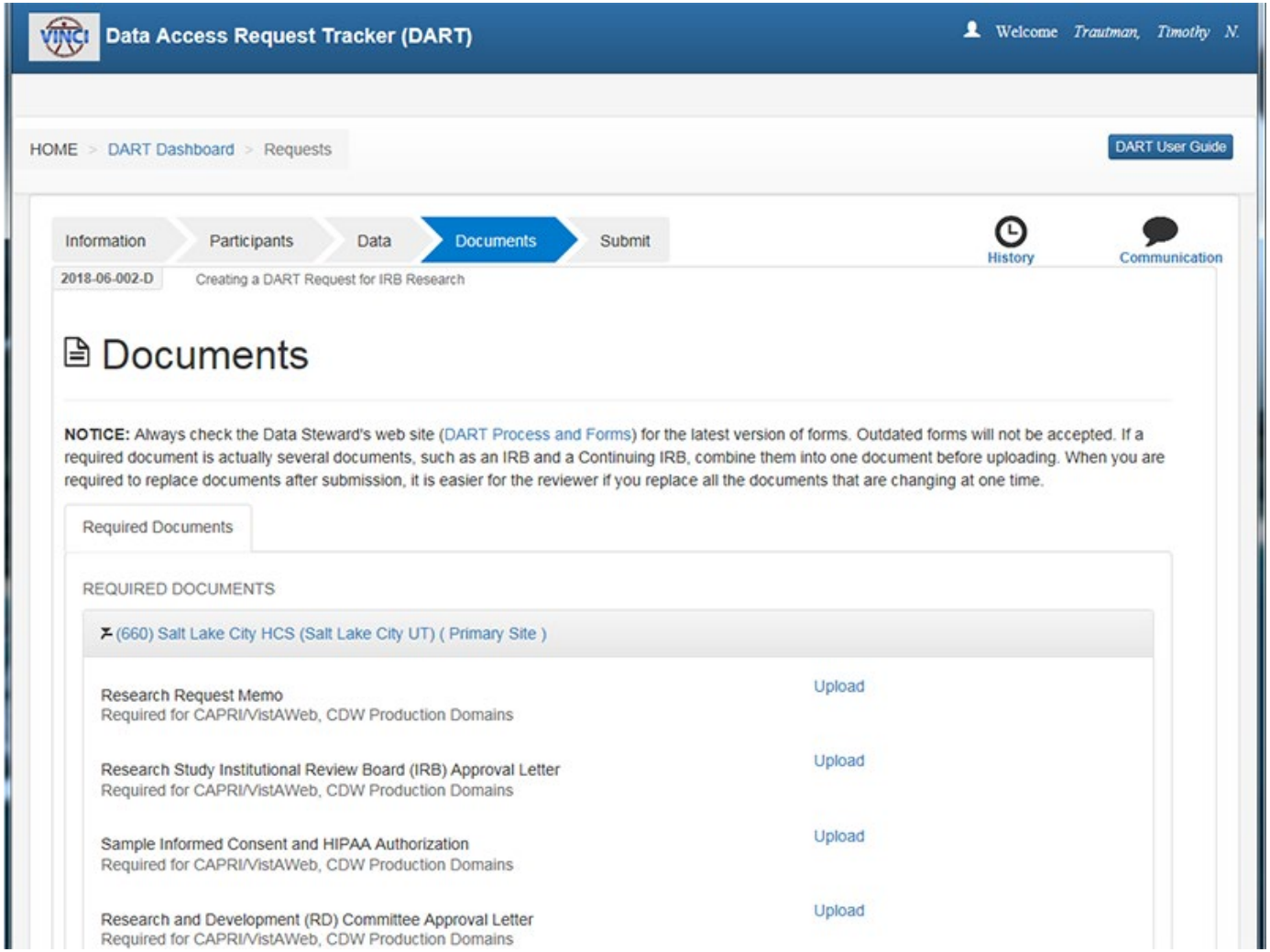
HEALTHCARE OPERATIONS GENERATED DATA SOURCES

- ☐ ADUSH Enrollment Files
- ☐ Bereaved Family Survey
- ☐ CAPRI & Joint Legacy Viewer (JLV) - Individuals needing system access are selected on the Participants page and require Real SSN approval
- ☐ Care Assessment Need Score (CAN Score) - Scrambled SSN approval required
- ☐ Clinical Assessment Reporting and Tracking (CART) CV (Disclaimer)
- Corporate Data Warehouse (CDW)
  - ☐ Production Domains
  - ☐ Raw Domains
  - ☐ VA Millennium
  - ☐ Text Integration Utility (TIU) Text Notes
- ☐ COVID-19: Shared Data Resource
- ☐ Death Ascertainment File (DAF) – CDW SQL tables
- ☐ DoD-VA Infrastructure for Clinical Intelligence (DAVINCI)
- Geriatrics and Extended Care (GEC)
  - ☐ GECDAC Health Care Risk Measures
  - ☐ Home Based Primary Care (HBPC) Masterfile
  - ☐ RAI/MDS
- ☐ Health Economics Resource Center (HERC) Cost Data - Includes Average Cost Data, V21 and Nosos Risk Scores, and Discharge Data Sets with Subtotals
- ☐ Homeless Veterans Registry (Disclaimer)
- ☐ IVC Consolidated Data Sets - Real SSN approval required
- ☐ Lung Cancer Screening Demonstration Project (LCSDP) Cohort
- Managerial Cost Accounting (MCA)
  - ☐ National Data Extracts (NDEs)
  - ☐ Web Reports - Real SSN approval required
- ☐ Medical SAS Files & VETSNET File - CDW SQL tables

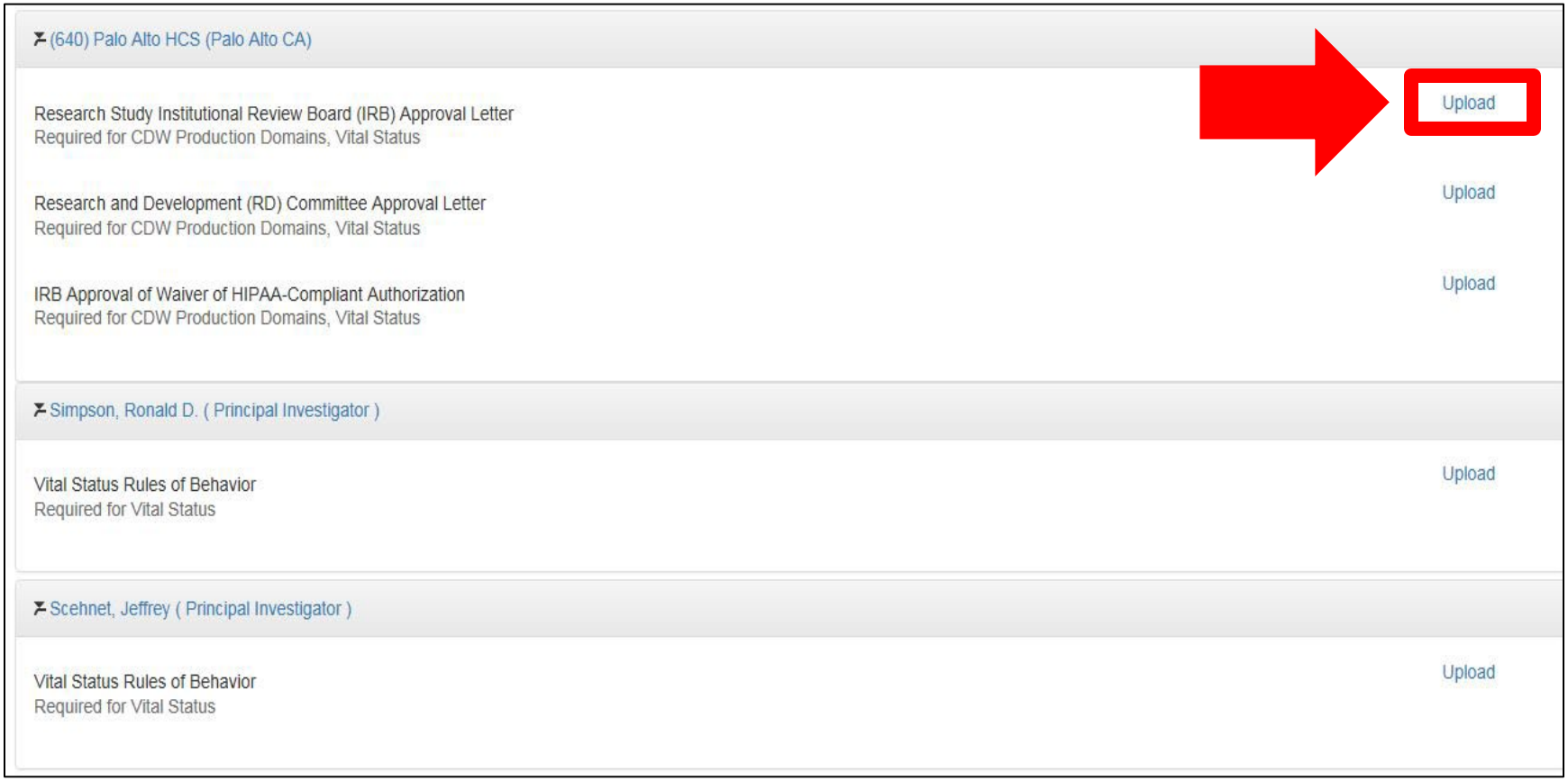
DART Demo - Data Sources



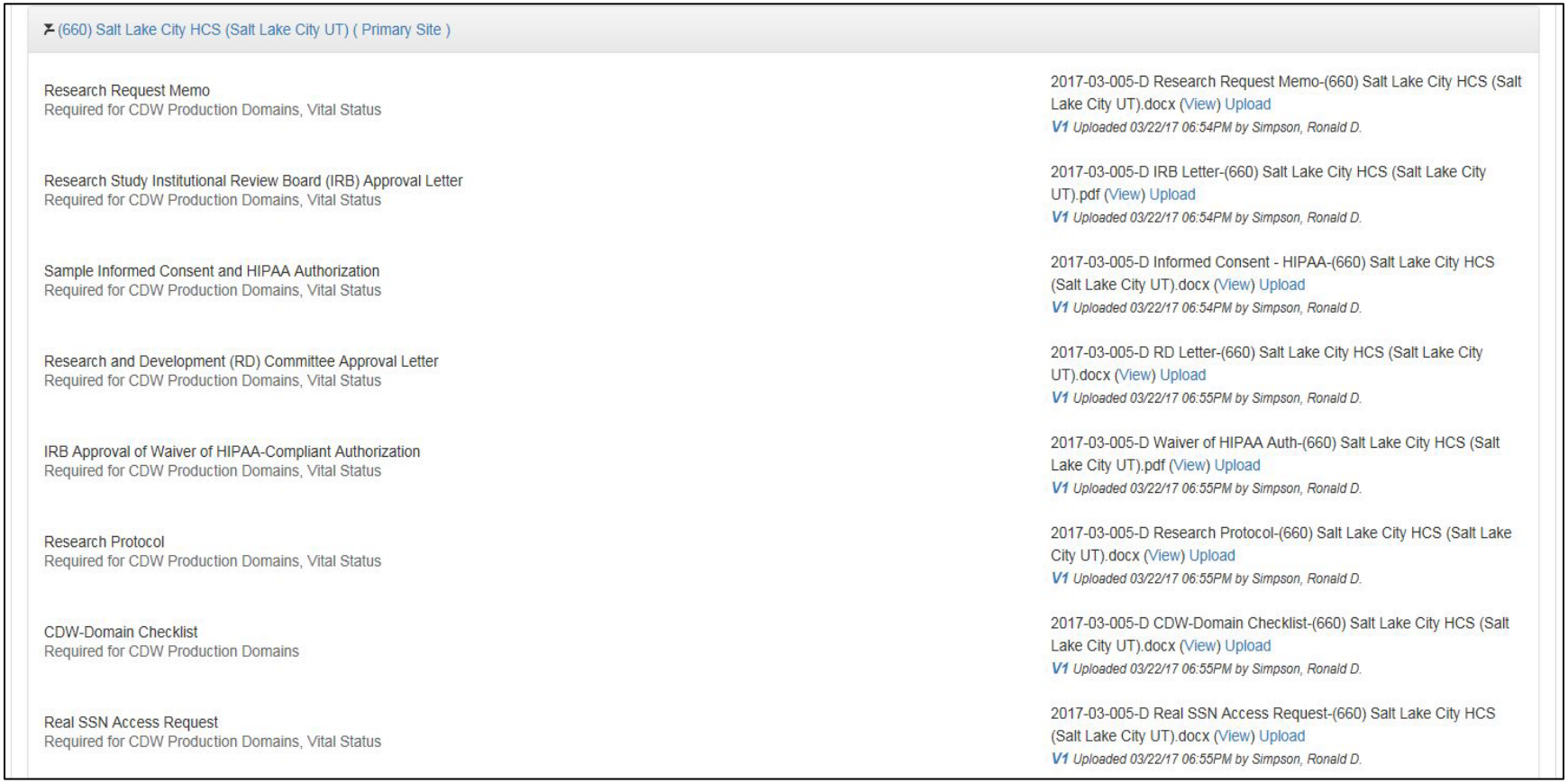
DART Demo - Documents



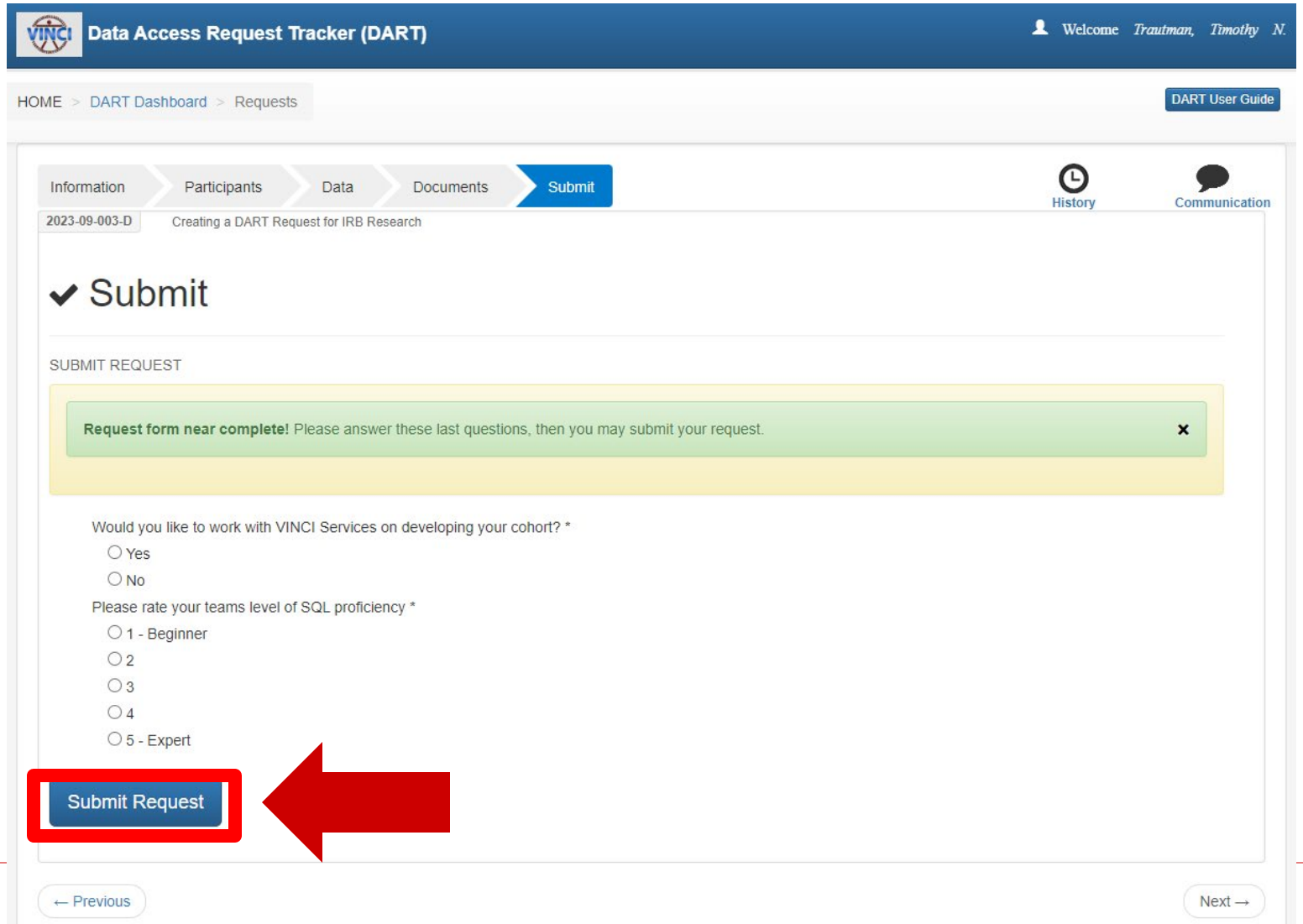
DART Demo - Documents



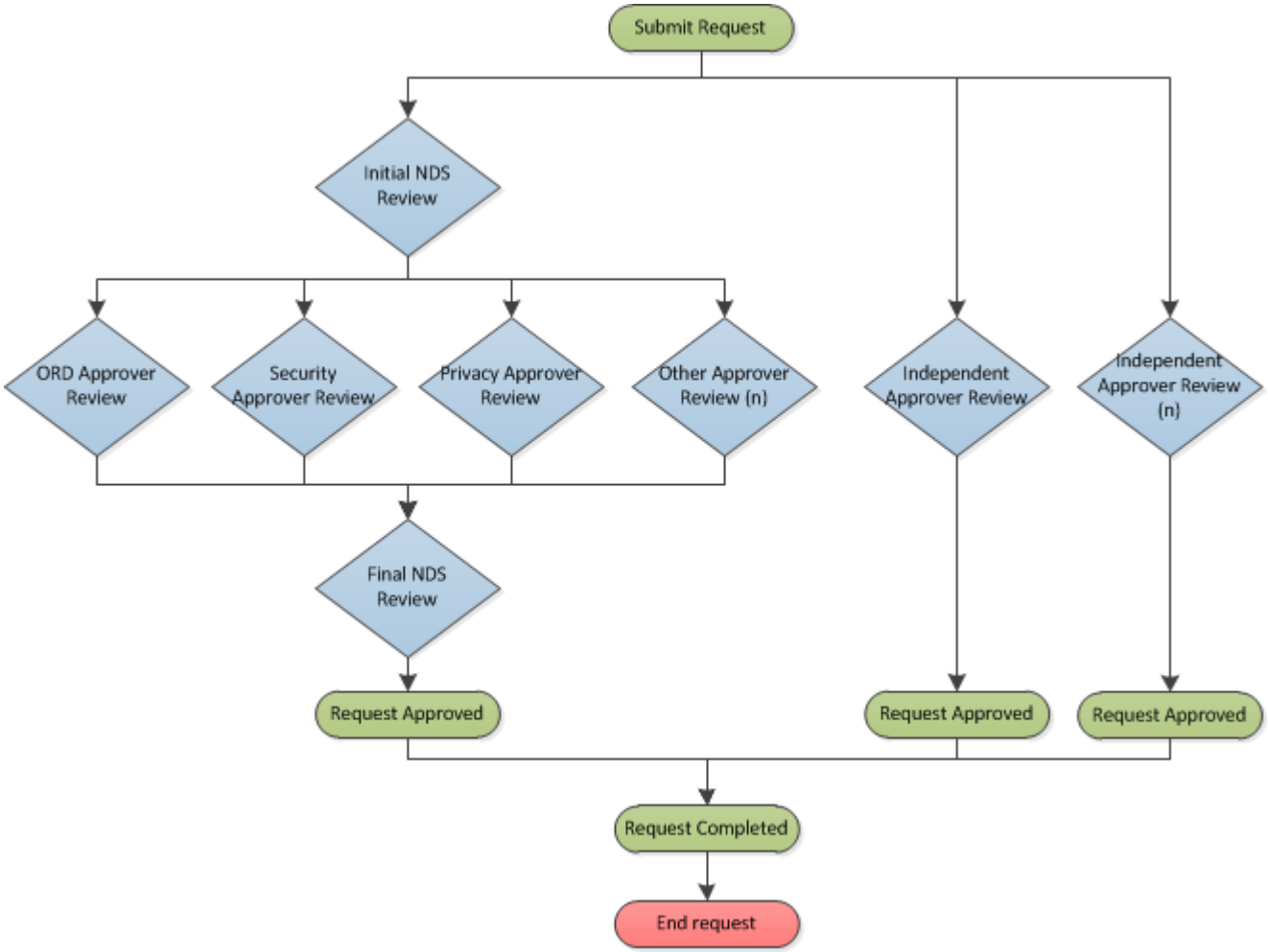
DART Demo - Documents



DART Demo - Submit



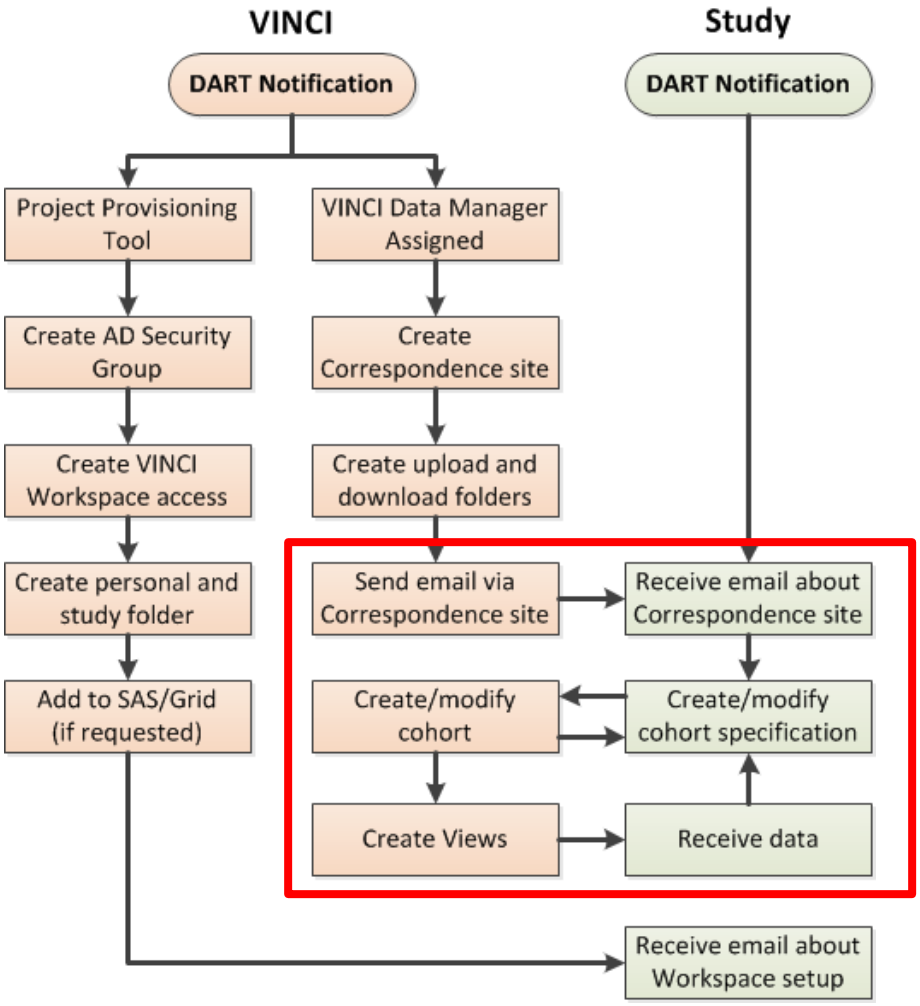
DART Processing - 7.5 days avg.



8. VINCI Provisioning

- VINCI is automatically notified of approvals by DART
- VINCI's Project Provisioning Tool automatically sets up AD Group, VINCI Workspace access, and creates a study file share folder
- VINCI Data Manager begins provisioning the study by creating study Correspondence SharePoint site and group directories within 1-business day
- ***Once Correspondence site is created, you will receive a welcome email from the Data Manager***
- All communications between study and the VINCI Data Manager run through Correspondence site

8. Data Provisioning

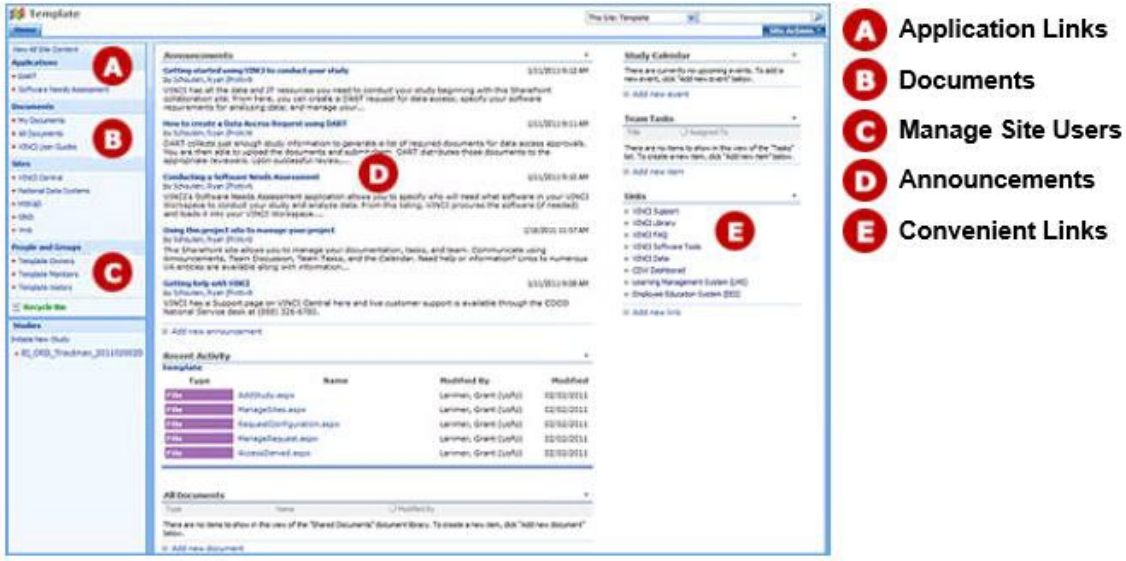


9. Use the VINCI Workspace

- VINCI firewall provides enhanced data security
- Can be accessed from outside the VA through VA VPN solutions
- Comes in two variations: Standard and Development Workspaces
- VINCI Workspaces (va.gov)
- VINCI Workspace User Guide
- VINCI Database User Guide
- VINCI File Transfer Guide

10. Project Collaboration Site

- Project Collaboration sites are custom SharePoint sites for your study to maintain documentation and manage your study
- Created through self-service VINCI Project Collaboration Site Registration application



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

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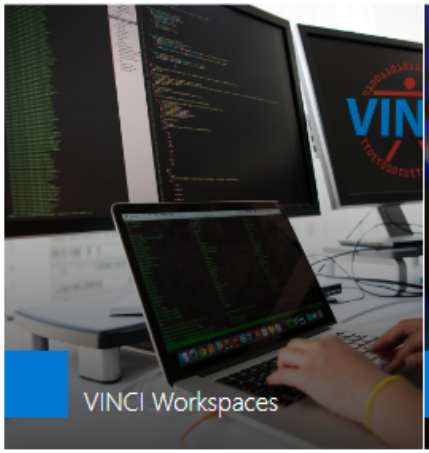

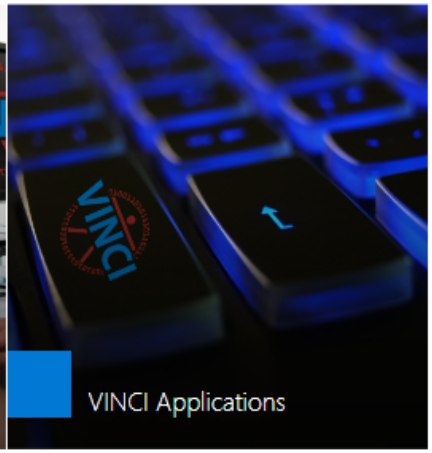

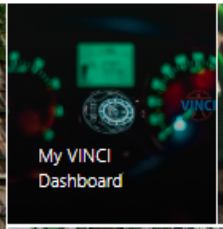

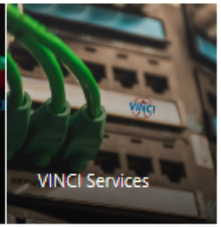

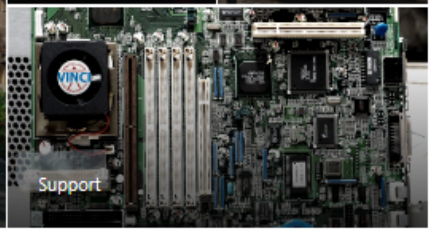

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- Full Standard Workspace (1 Monitor)
- Full Standard Workspace (Multi-monitor)
- Standard Workspace Applications
- Development Workspace (1 or 2 Monitor)

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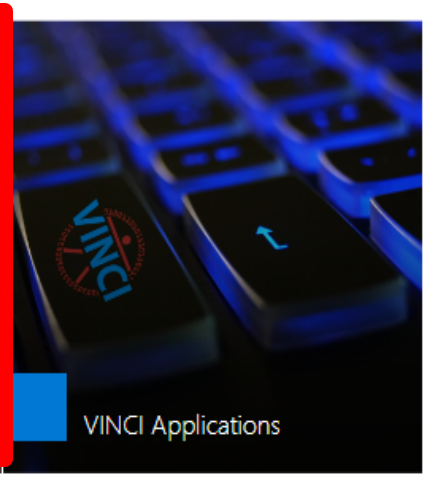

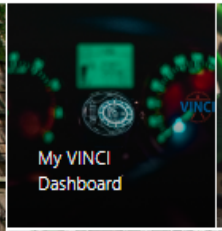

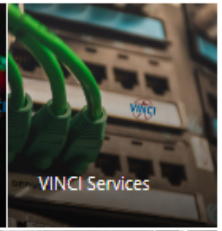

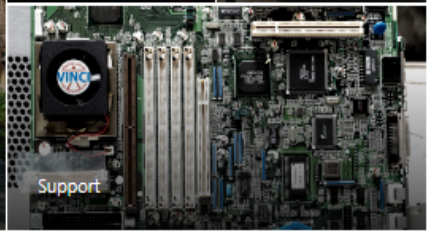

Launch VINCI Workspace

Full Standard Workspace (1 Monitor)
LAUNCH NOW
Standard Workspace
Applications
Development Workspace
(1 or 2 Monitor)
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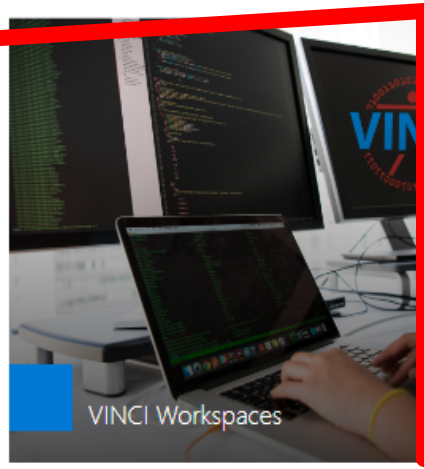

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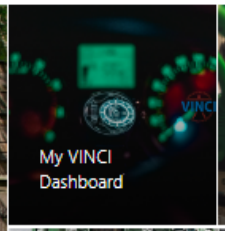

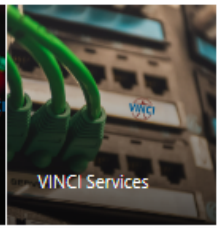

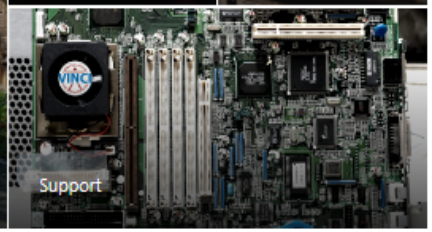

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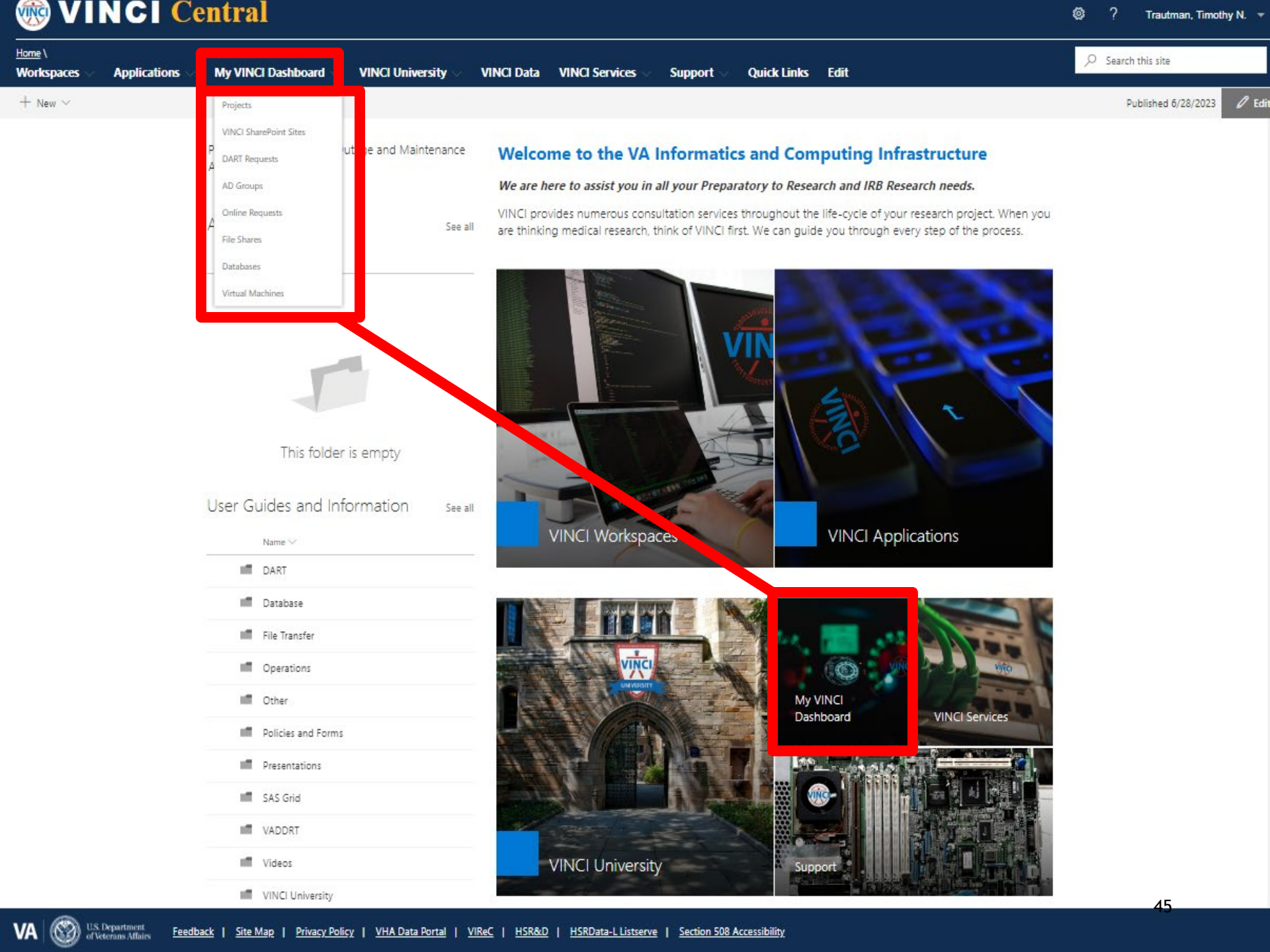
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My VINCI Dashboard

Projects

91
SharePoint Sites

DART Requests

217
Active Directory Groups

23
Online Requests

2
File Shares

1
Virtual Machines

4
Databases

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VINCI SharePoint Sites

Show 10 entries

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Project	Server Name	Type	Site Name	Actions
null	VINCI Central SharePoint	Collaboration Site	2-25-16 Test 1	
null	VINCI Central SharePoint	Collaboration Site	Compliance	
null		Collaboration Site	Data Management Team	
null	VINCI Central SharePoint	Collaboration Site	Data Managers	
null		Collaboration Site	Development Team	
null	VINCI Central SharePoint	Collaboration Site	DPT	
null	VINCI Central SharePoint	Collaboration Site	Education and Outreach Project	
null	VINCI Central SharePoint	Collaboration Site	Electronic Research Record Moderernization (ERR-M) Project	
null	VINCI Central SharePoint	Collaboration Site	Escalated Data Requests	
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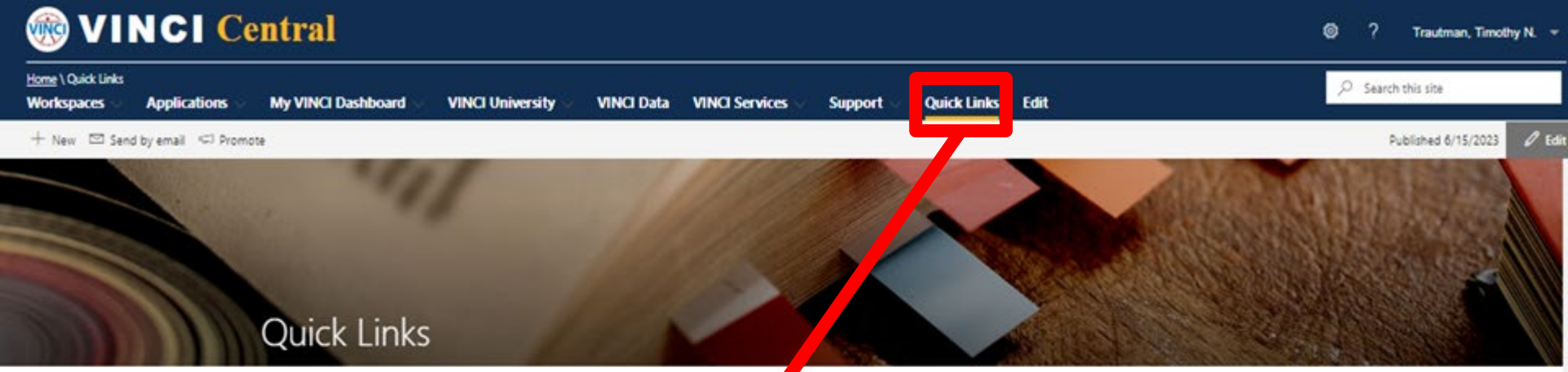

BaseCamp

CDW/BISL web site

Centralized Interactive Phenomics Resource (CIPHER)

COVID-19 Shared Data Resource SharePoint site

DART

Dim Data Viewer

Download Files from VINCI Workspace

EHR-Modernization

HERC Web Site

HSR&D web site

HSRData-L Listserv

Meta Data Viewer

ORD FIND Pro Tool

Request Management

SAS Grid Guides

Upload Files to VINCI Workspace

VHA Data Portal web site

VHA Support Service Center (VSSC)

VINCI Git Services Wiki

VINCI Linux Wiki

VINCI Operations

VIReC web site

Questions?

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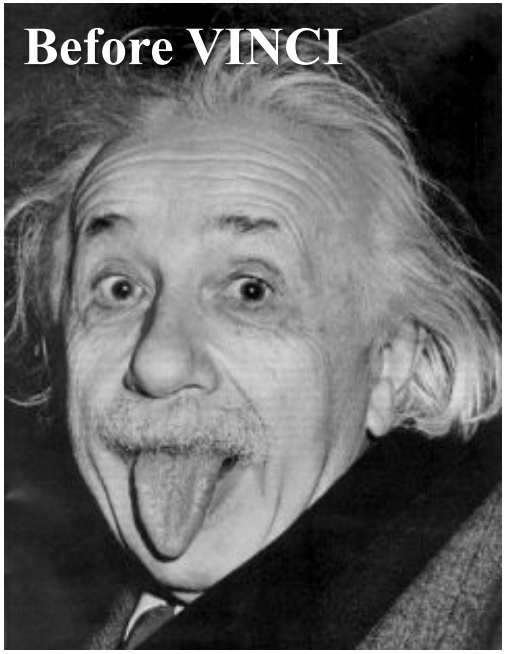

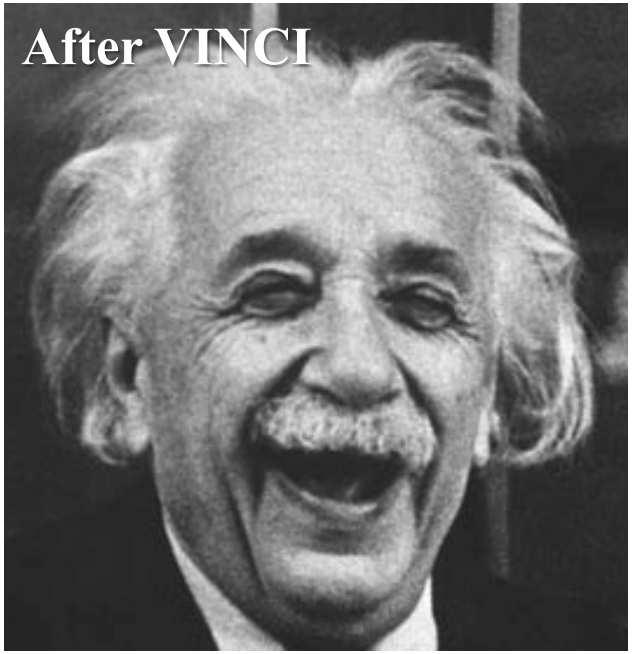

A VINCI Concierge can assist at any time by contacting VINCI@va.gov with your request