# Requesting Research Data Access Using DART

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*& DART Program Manager*


VA Informatics & Computing Infrastructure

# Request data access with DART

- DART is the Data Access Request Tracker online application used by Data Stewards (owners) 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
- **Also for Preparatory to Research requests**

# Poll #1

(choose all applicable)

- ❑ I want to request data for Research
- ❑ I want to request data for Preparatory to Research
- ❑ I want to learn more about using DART
- ❑ I'm just curious about DART

# Typical Required Documents

- Research Request Memo
- IRB Approval Letter
- Research and Development Committee Approval Letter
- Research Protocol
- HIPAA Informed Consent/Authorization or Waiver
- Real SSN Access Request Form (if needed)
- Any additional data source specific forms
- Forms can be found on the VHA Data Portal

http://vaww.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx

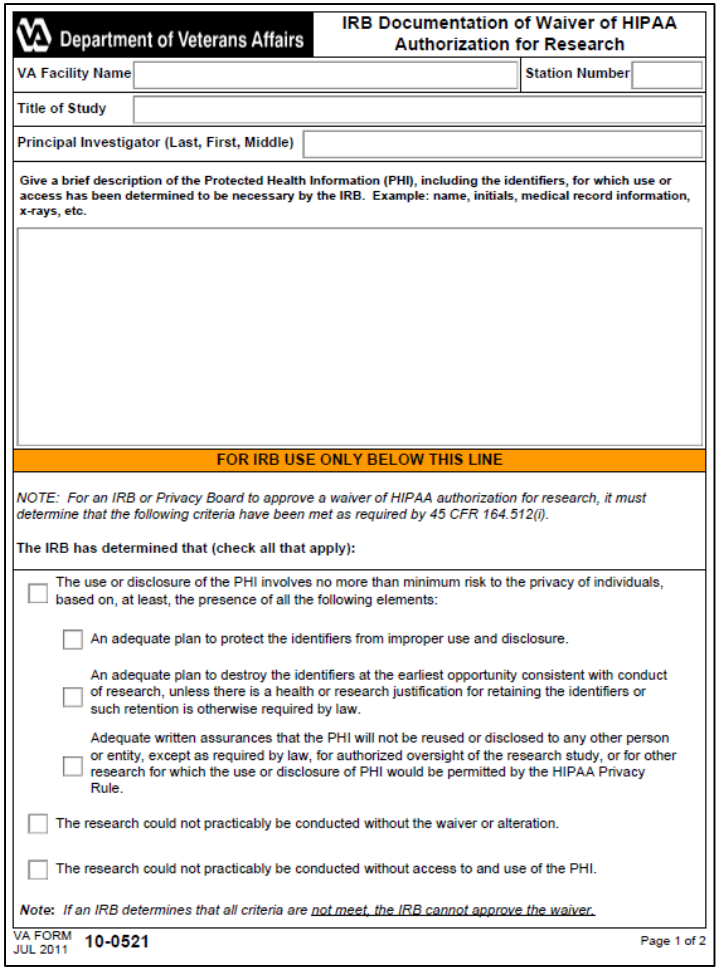
# Create your Protocol

- 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

# Institutional Review Board (IRB) Letter

- 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
- IRB Letters are not standardized across the VA
- If using VINCI for data storage, add to IRB:
  - *VINCI Description for IRBs*
  - *VINCI Information Security Description*

# 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):**

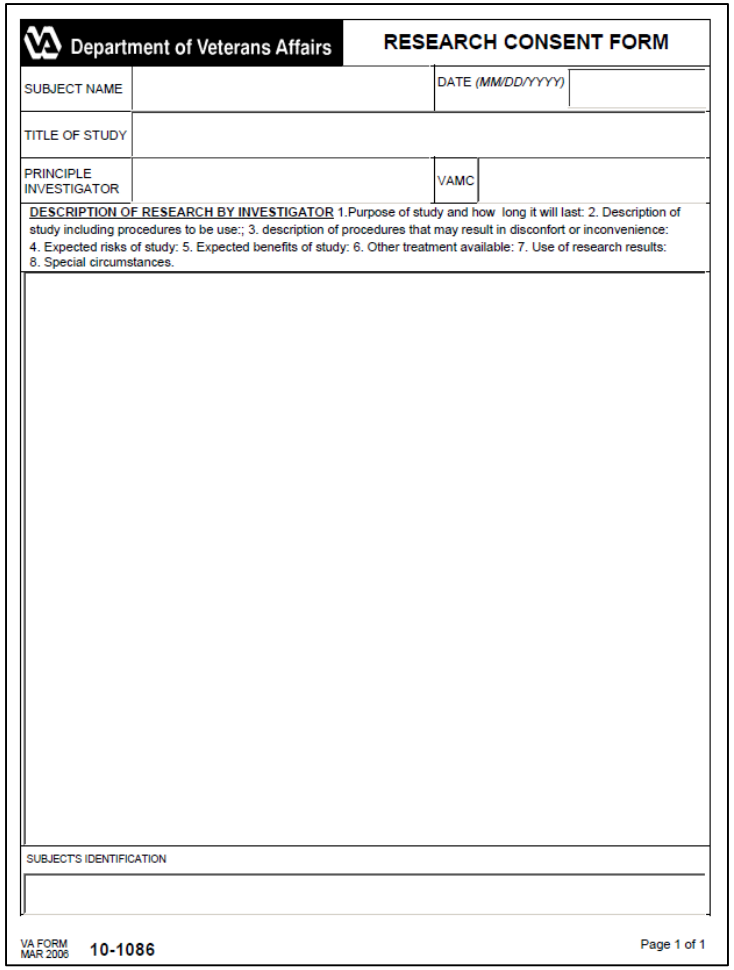
- ☐ The use or disclosure of the PHI involves no more than minimum risk to the privacy of individuals, based on, at least, the presence of all the following elements:
  - ☐ An adequate plan to protect the identifiers from improper use and disclosure.
  - ☐ An adequate plan to destroy the identifiers 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
- VA Form 10-0521 is available for use
  - VA Facility Name
  - Title of Study
  - PI Name
  - Brief description of PHI used

# Sample Informed Consent & HIPAA Authorization



Department of Veterans Affairs

**RESEARCH CONSENT FORM**

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

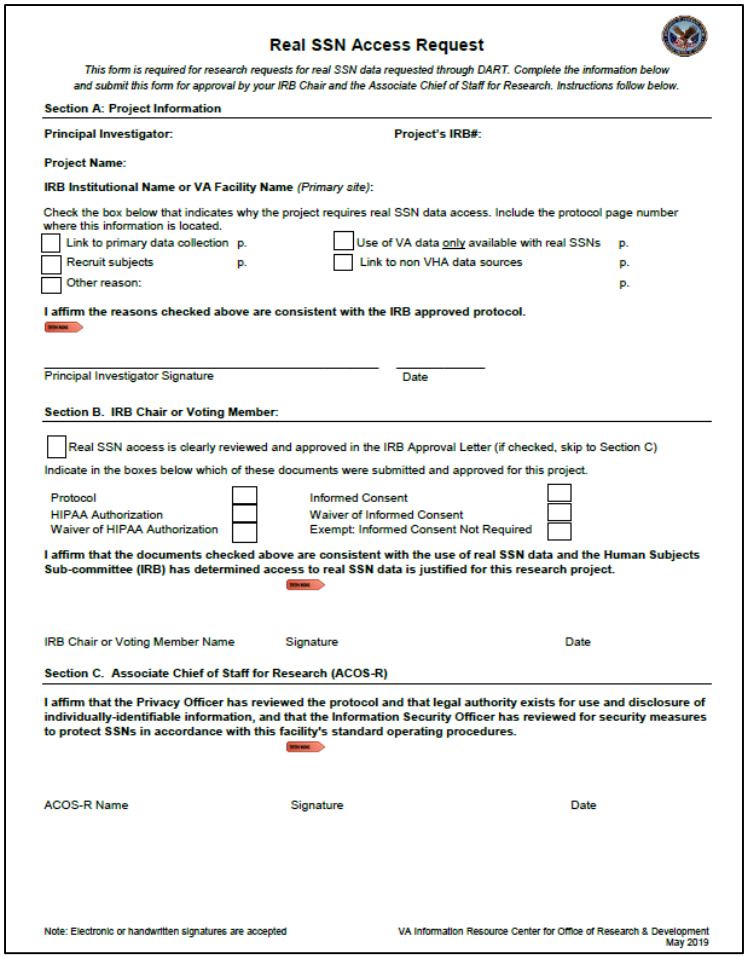
**DESCRIPTION OF RESEARCH BY INVESTIGATOR** 1.Purpose of study and how long it will last: 2. Description of study including procedures to be use:; 3. description of procedures that may result in disconfort or inconvenience: 4. Expected risks of study: 5. Expected benefits of study: 6. Other treatment 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
- VA Form 10-1086 is available for use
  - Subject Name (leave blank)
  - Title of Study
  - PI Name
  - Description of research by Investigator (8 sections)

# 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. ☐ Use of VA data only available with real SSNs p.
☐ Recruit subjects p. ☐ Link to non VHA data sources p.
☐ Other reason: 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 | ☐ | Informed Consent | ☐ |
| HIPAA Authorization | ☐ | Waiver of Informed Consent | ☐ |
| Waiver of HIPAA Authorization | ☐ | 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.**

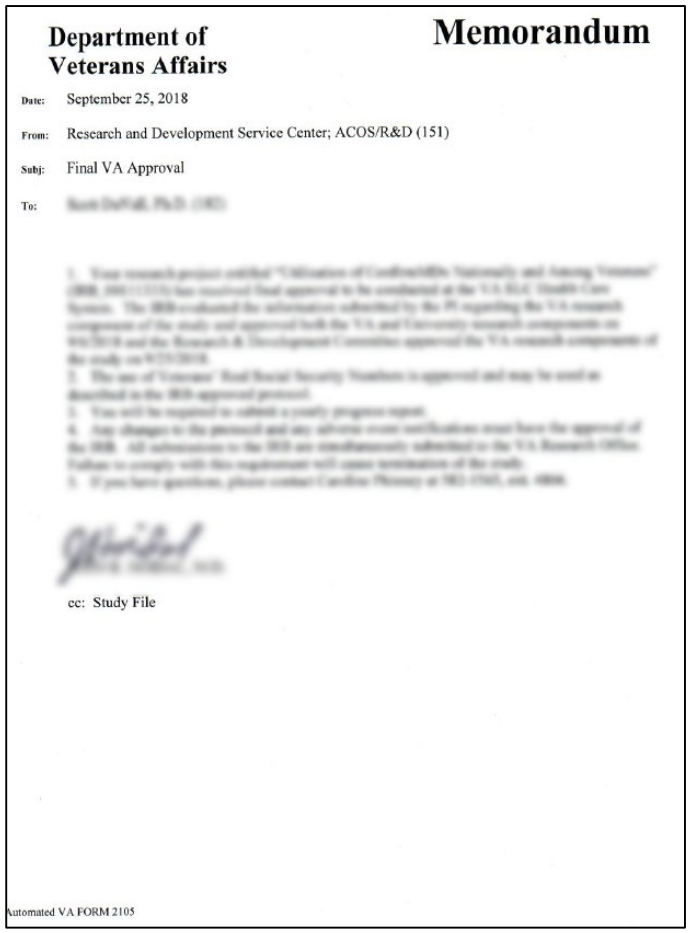
ACOS-R Name Signature Date

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 IRB
- More information is available on the VIReC Real SSN Data Request Process page.

# 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]

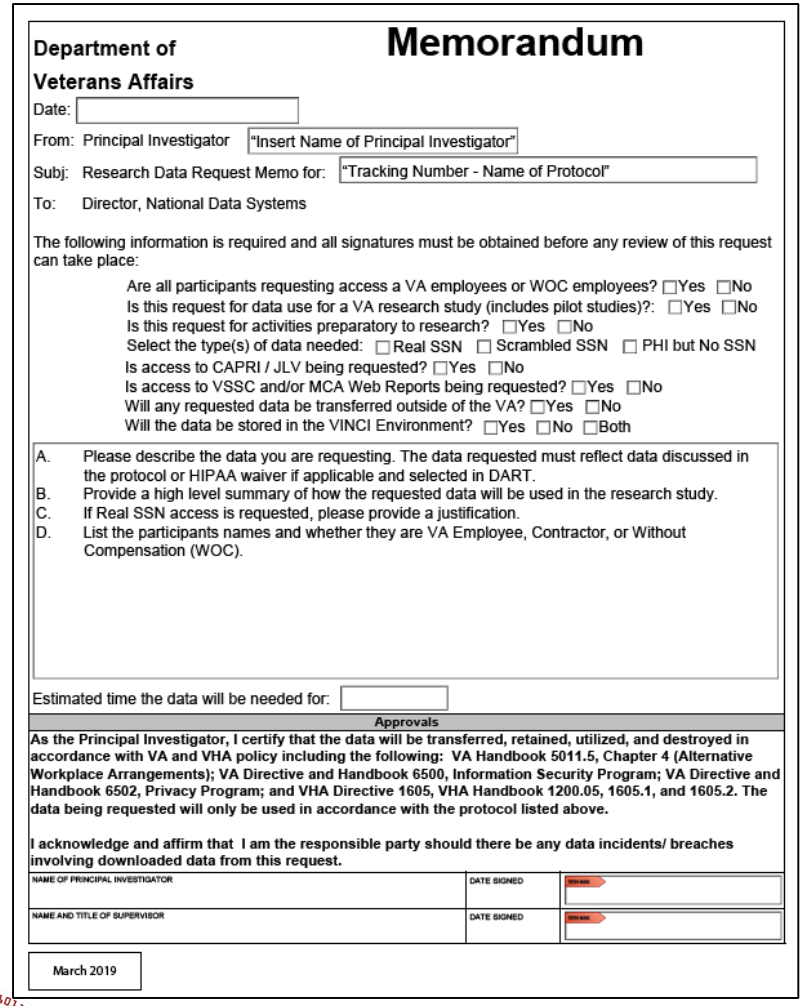
[redacted]

cc: Study File

Automated VA FORM 2105

- Each VA facility has a local Research and Development Committee
- All IRB Approved Research studies in DART must have and R&D approval letter for each location participating in the study

# 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.**

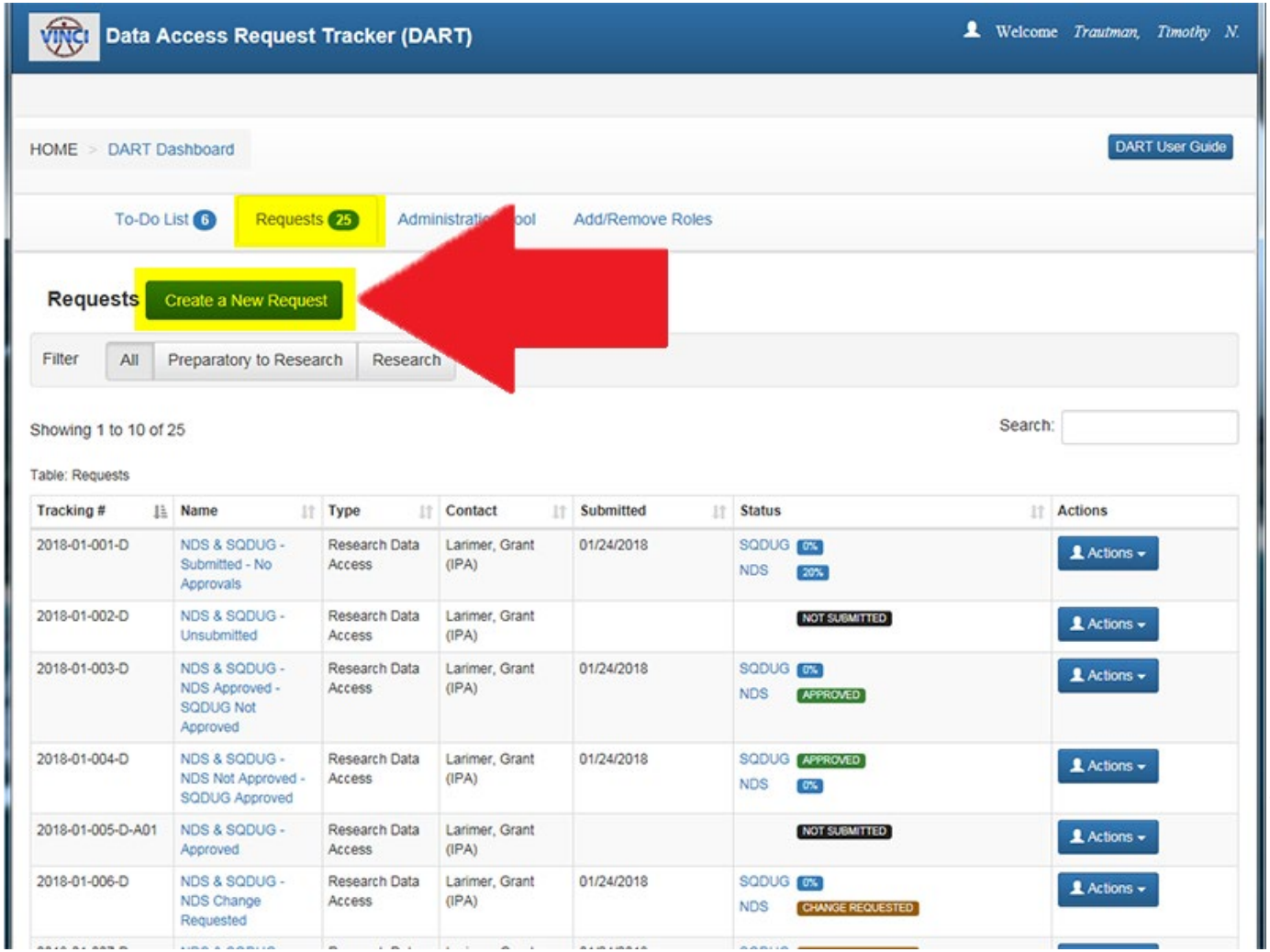
**I acknowledge and affirm that I am the responsible party should there be any data incidents/ breaches involving downloaded data from this request.**

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

March 2019

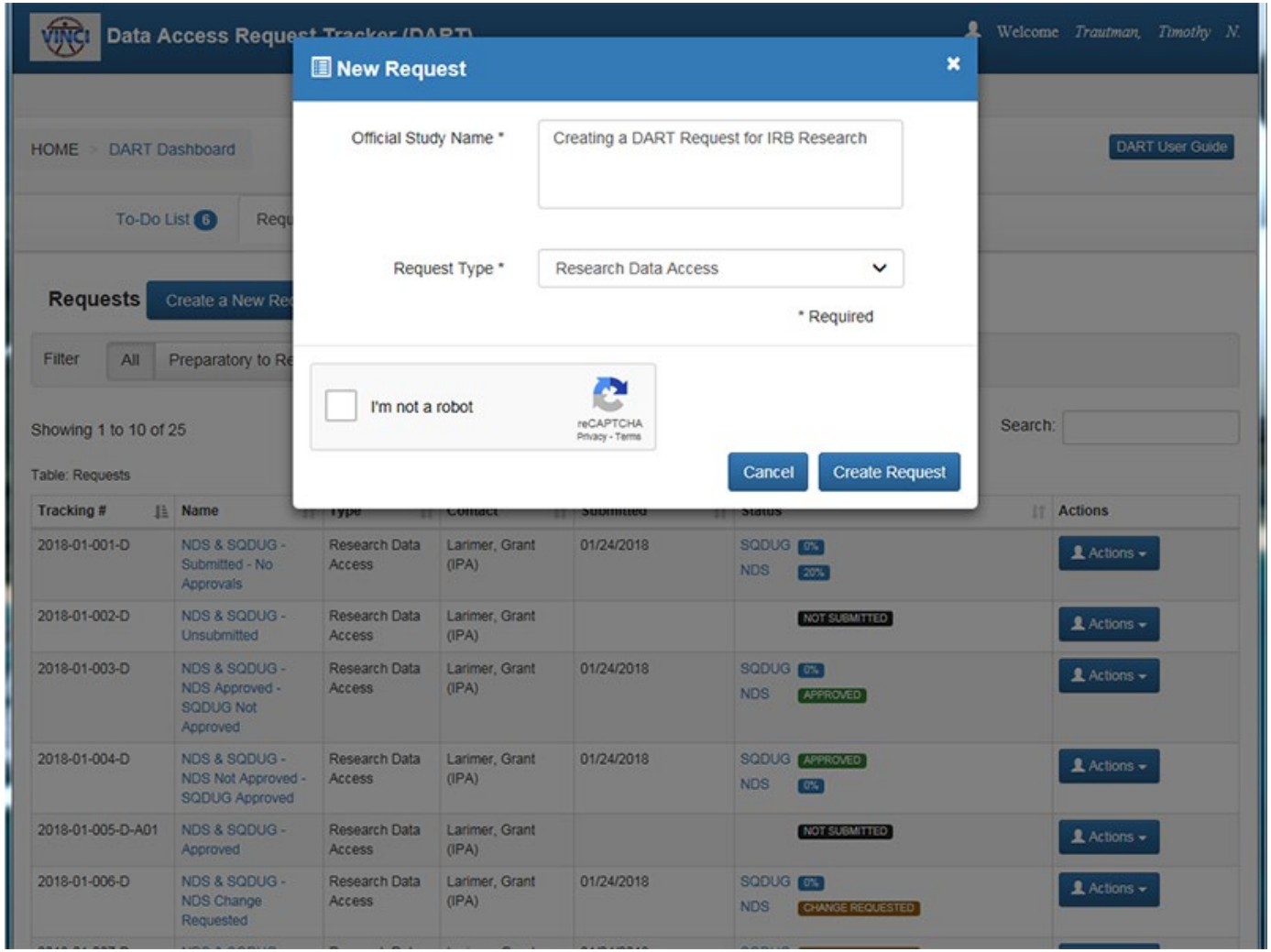
- Research Request Memo
- Instructions are in Appendix A of the DART User Guide
- Initiate your DART request to obtain your DART Tracking Number for the memo's Subject line

# DART Demo - IRB Research Study




See a quick movie

# DART Demo – IRB Research Study



# DART Demo – IRB Research Study

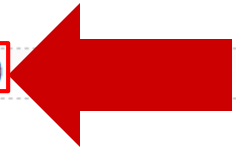
**[WARNING: A/V UNSCANNABLE]DART 2017-03-005-D has been Initiated - Please Read Before Submitting This Request - Do Not Reply**

dart@va.gov

Sent: Wed 3/22/2017 3:24 PM

To: Simpson, Ronald D.

Message | DART Considerations.pdf (334 KB)



**Greetings DART User,**

You are receiving this email because you initiated a new Research Data Access Request Tracker (DART) request:

- DART Tracking Number: 2017-03-005-D
- Study/Protocol Name: DART Cyberseminar

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.

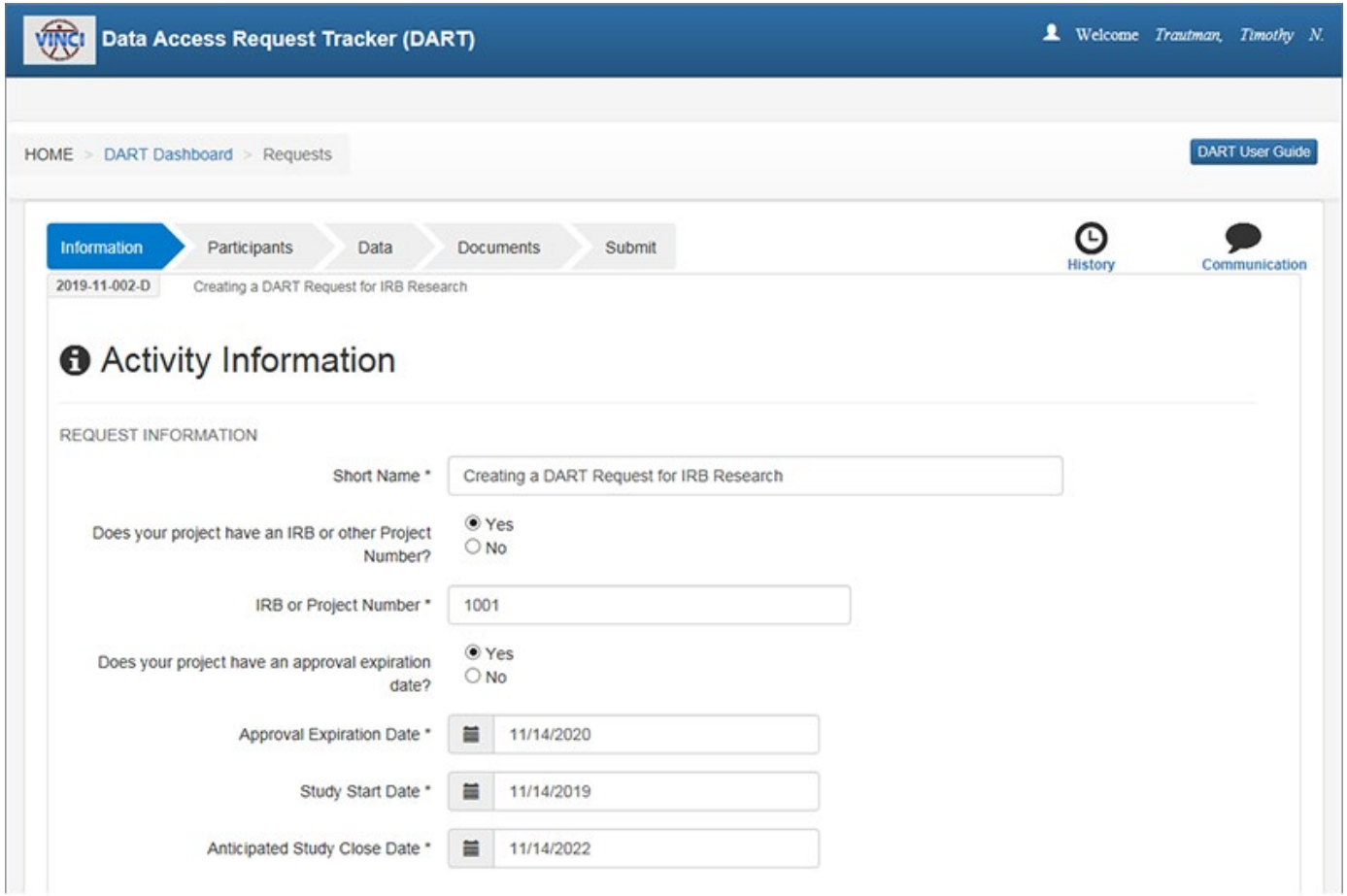
The attached document provides links to helpful resources, considerations to take into account when requesting data access, and what to expect. The DART User Guide provides complete details about how to use DART. If you need assistance with completing the DART request or have questions, please contact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

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

Sincerely,

***The DART Team***

# DART Demo- IRB Research Study



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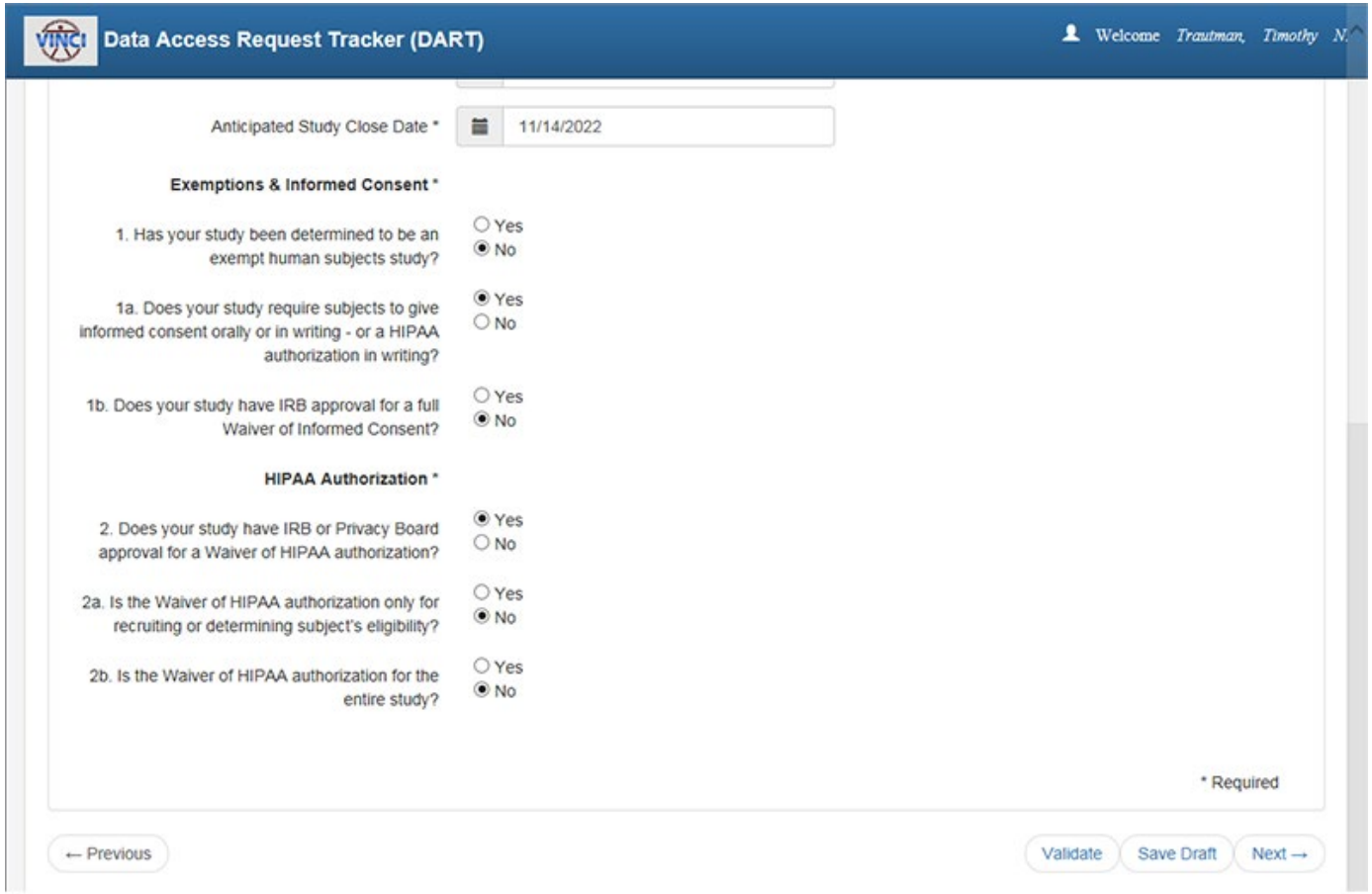

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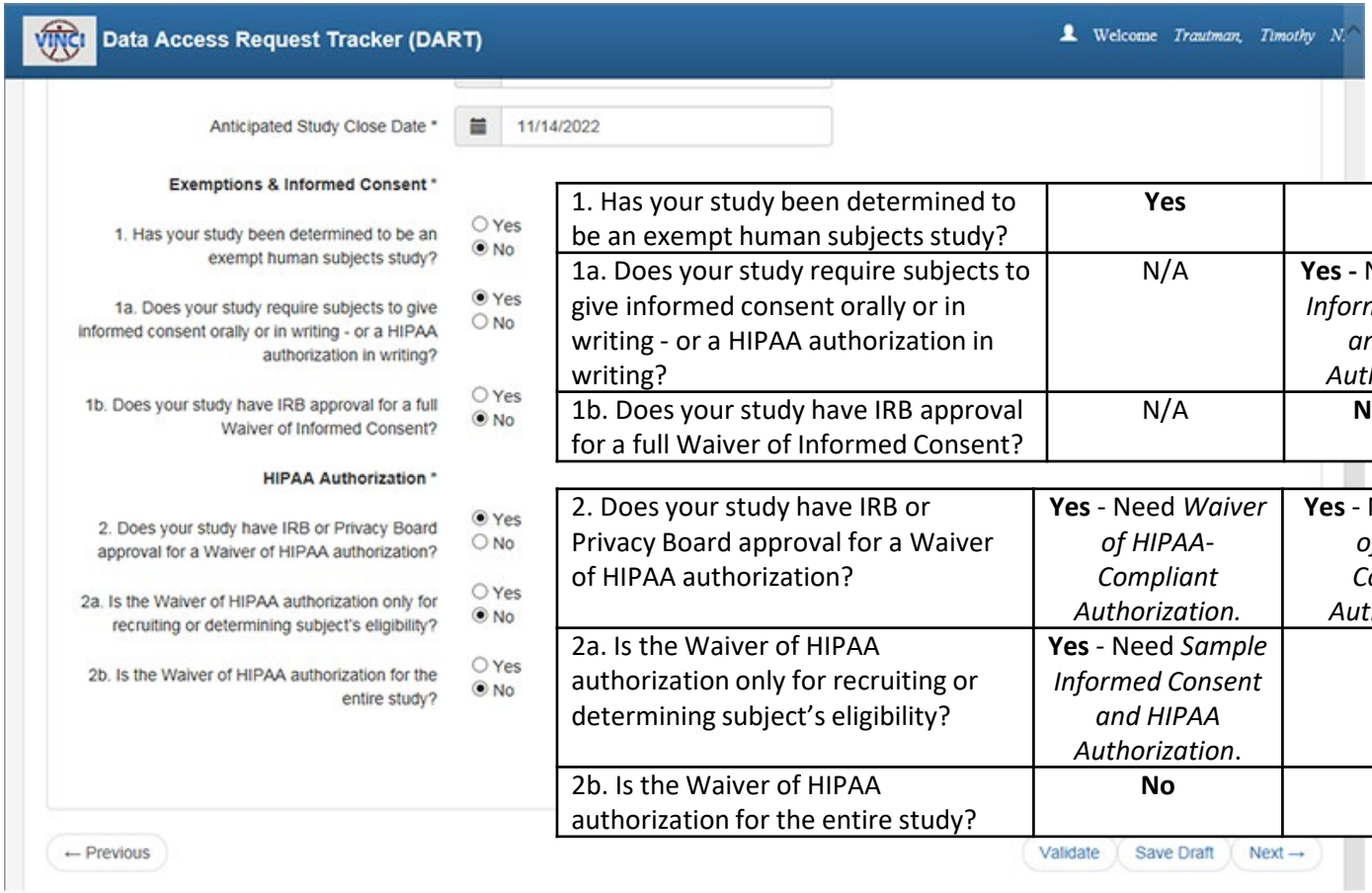
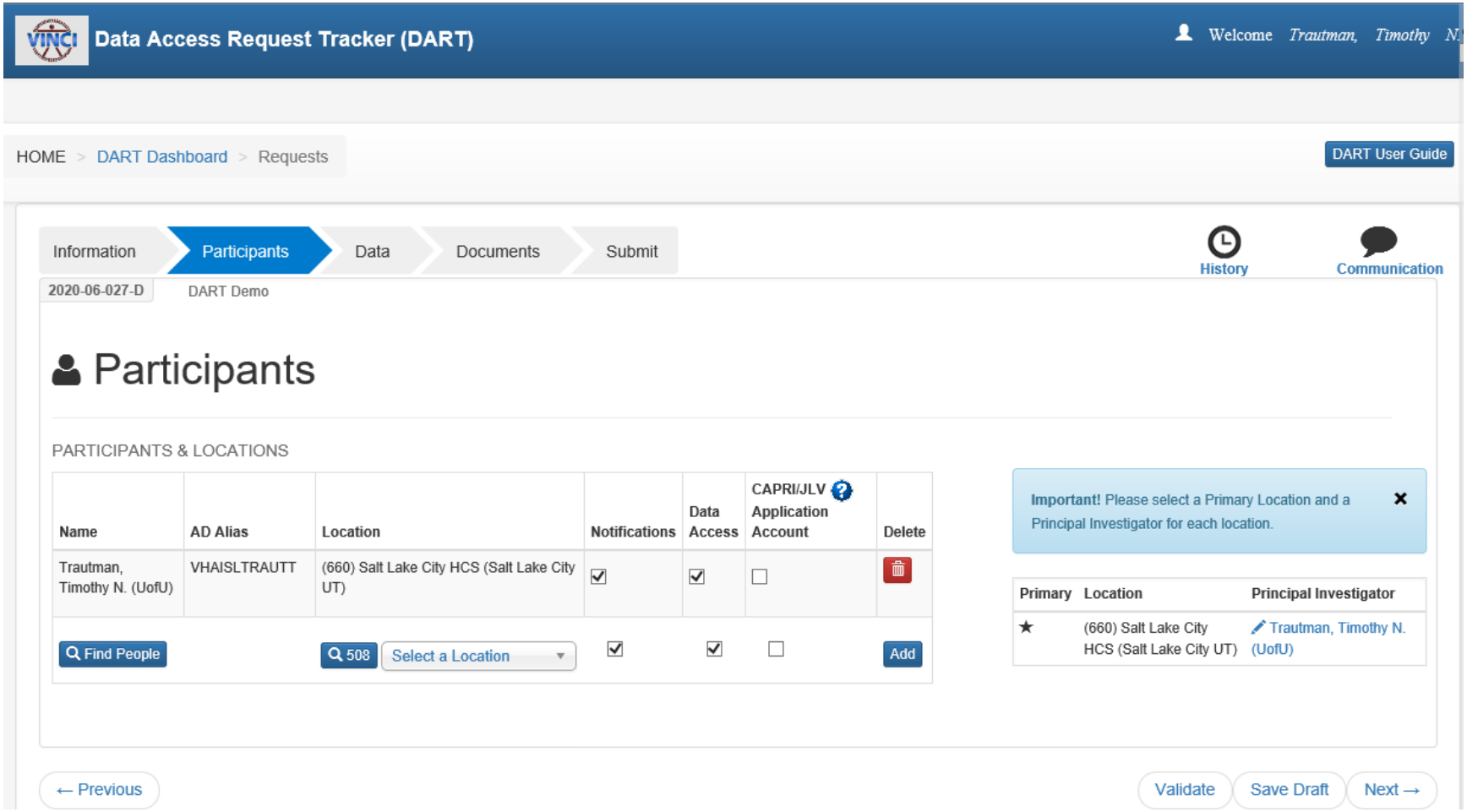


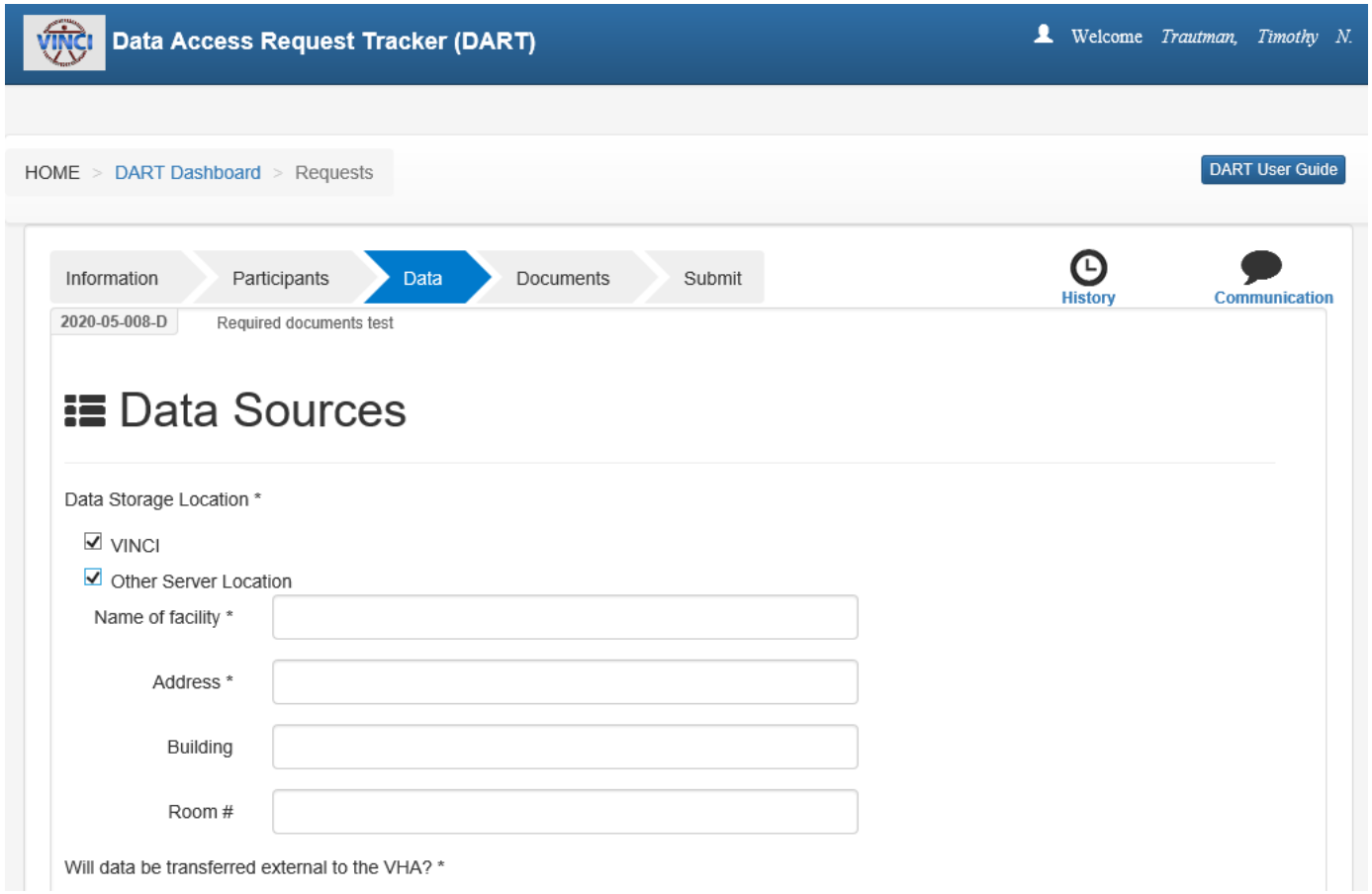

| | | | |
|---|---|---|---|
| 1. Has your study been determined to be an exempt human subjects study? | **Yes** | **No** | **No** |
| 1a. Does your study require subjects to give informed consent orally or in writing - or a HIPAA authorization in writing? | N/A | **Yes -** Need *Sample Informed Consent 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- IRB Research Study



# DART Demo - IRB Research Study



# DART Demo - IRB Research Study

Will data be transferred external to the VHA? *

*Currently CDW cannot approve a research request that would include disclosing the CDW data (identifiable or de-identified) outside of VHA without a signed research consent and HIPAA authorization from the individual because of the risk of re-identification. The data may be used (internally or within VHA) for the approved protocol. If "finder" files are to be sent out to Federal or state agencies for the purpose of the 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 - IRB Research Study

REQUESTED 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
- Corporate Data Warehouse (CDW)
  - ☐ Production Domains
  - ☐ Raw Domains
  - ☐ Text Integration Utility (TIU) Text Notes - Real SSN approval required
- ☑ COVID-19: Shared Data Resource
- ☐ DoD-VA Infrastructure for Clinical Intelligence (DAVINCI)
- Geriatrics and Extended Care (GEC)
  - ☐ 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)
- ☐ 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 - IRB Research Study

- ☐ Million Veteran Program (MVP) - Available only to MVP approved studies
- ☐ Million Veteran Program (MVP) plus Vital Status Files - Available only to MVP approved studies

OMOP Common Data Model

- ☐ VA Corporate Data Warehouse
- ☐ DAVINCI DoD-VA

- ☐ Patient Aligned Care Team Implementation Index (PACT Pi2)
- ☐ PSSG Geocoded Enrollee Files
- ☐ SAS Fee (Disclaimer)
- ☐ Traumatic Brain Injury Screening and Evaluation Data

VA Surgical Quality Improvement Program (VASQIP) - Real SSN or Scrambled SSN only

- ☐ Cardiac variables
- ☐ Non-cardiac variables

VINCI Natural Language Processing (NLP) Output

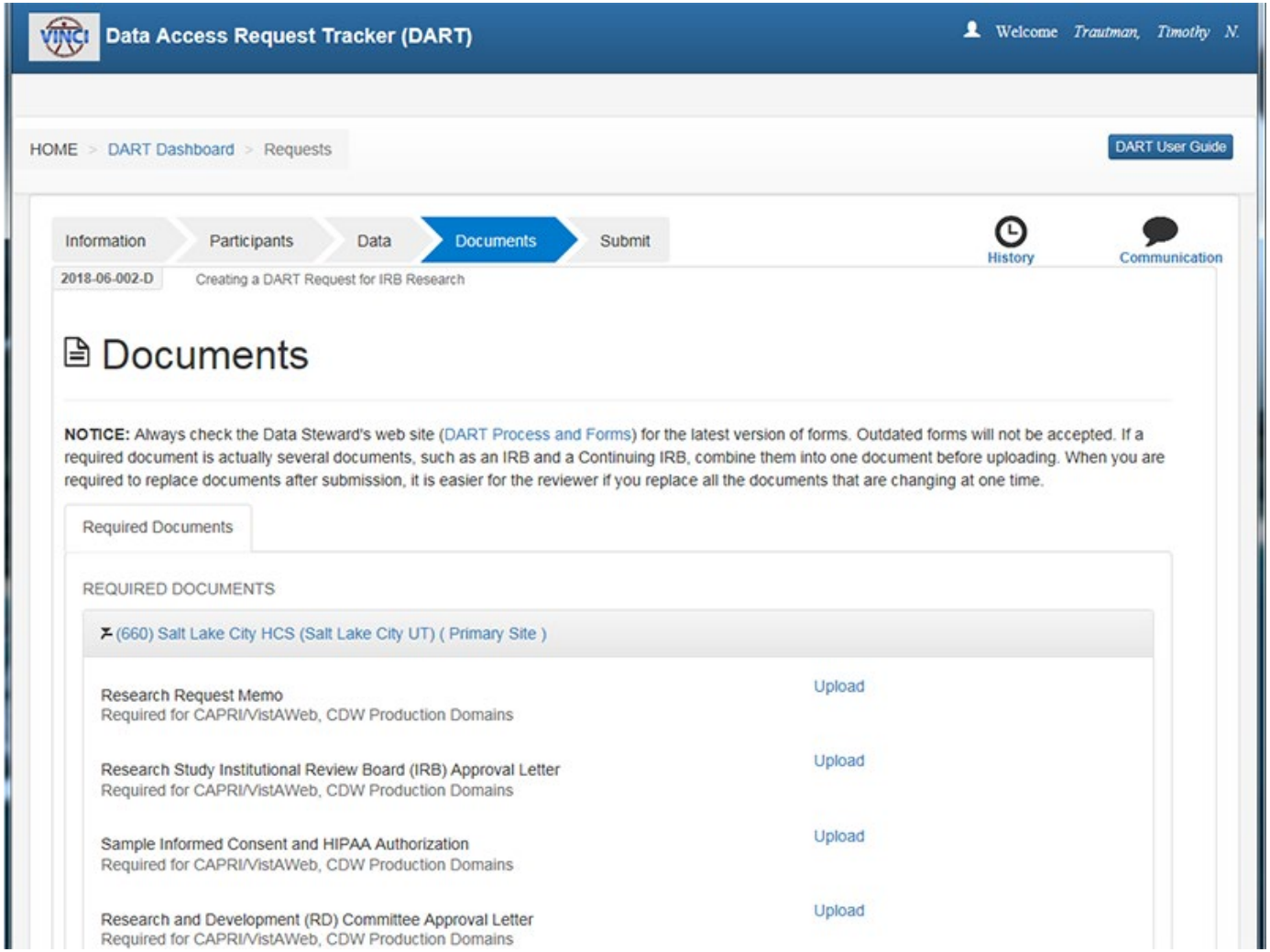
- ☐ Ejection Fraction

- ☐ Vital Status File (VSF) - CDW SQL tables which includes BIRLS date of birth, date of death, and gender
- ☐ VSSC Self-Service Web-Based Products

* Required

← Previous | Validate | Save Draft | Next →

# DART Demo – IRB Research Study



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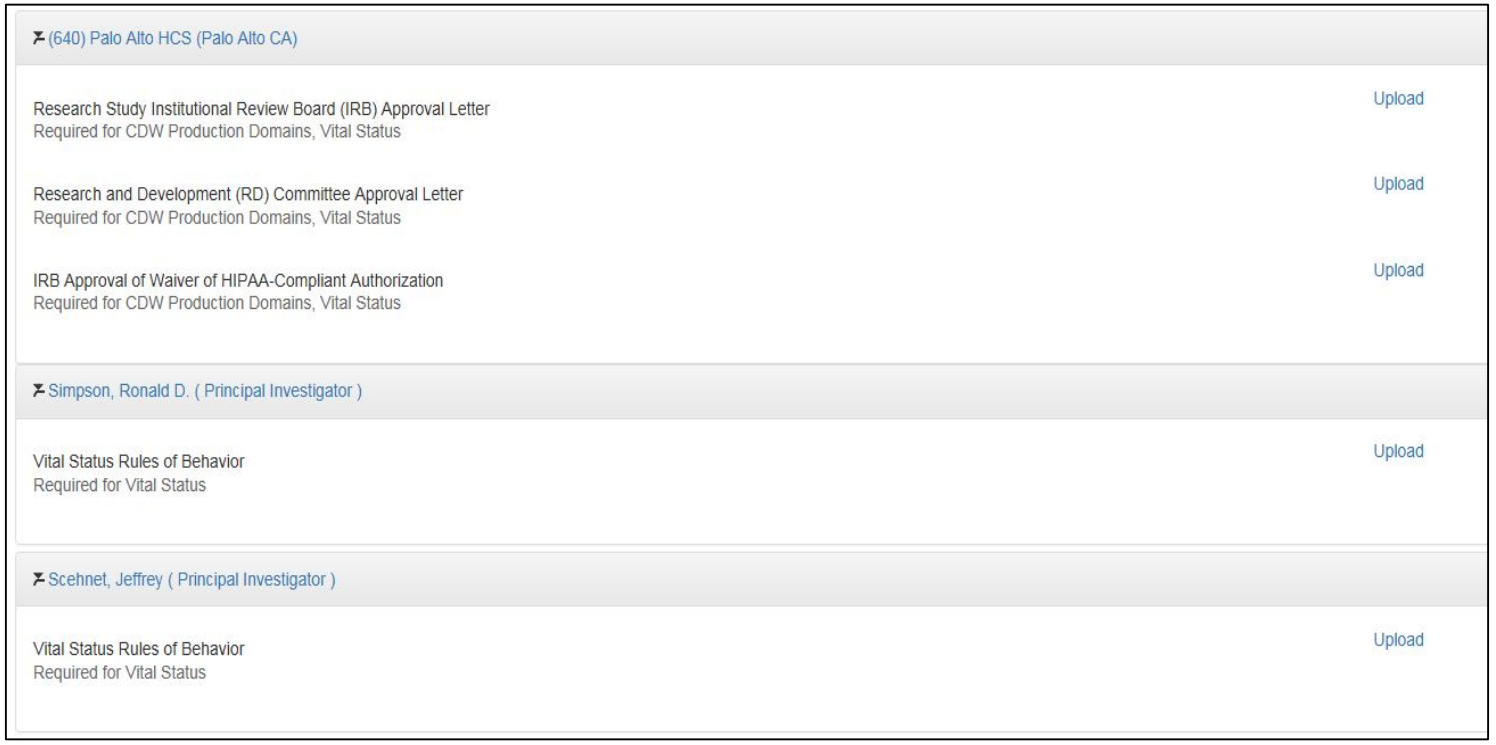

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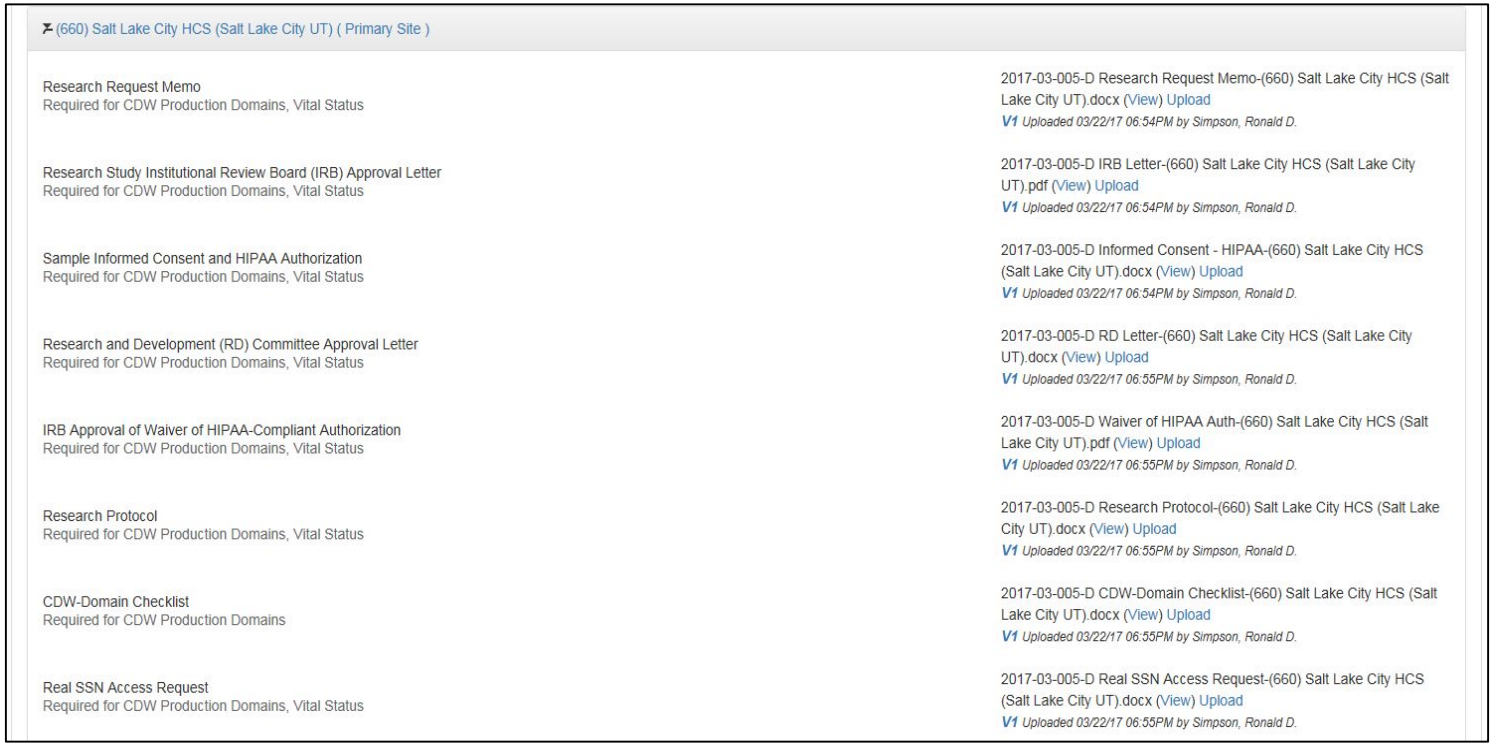
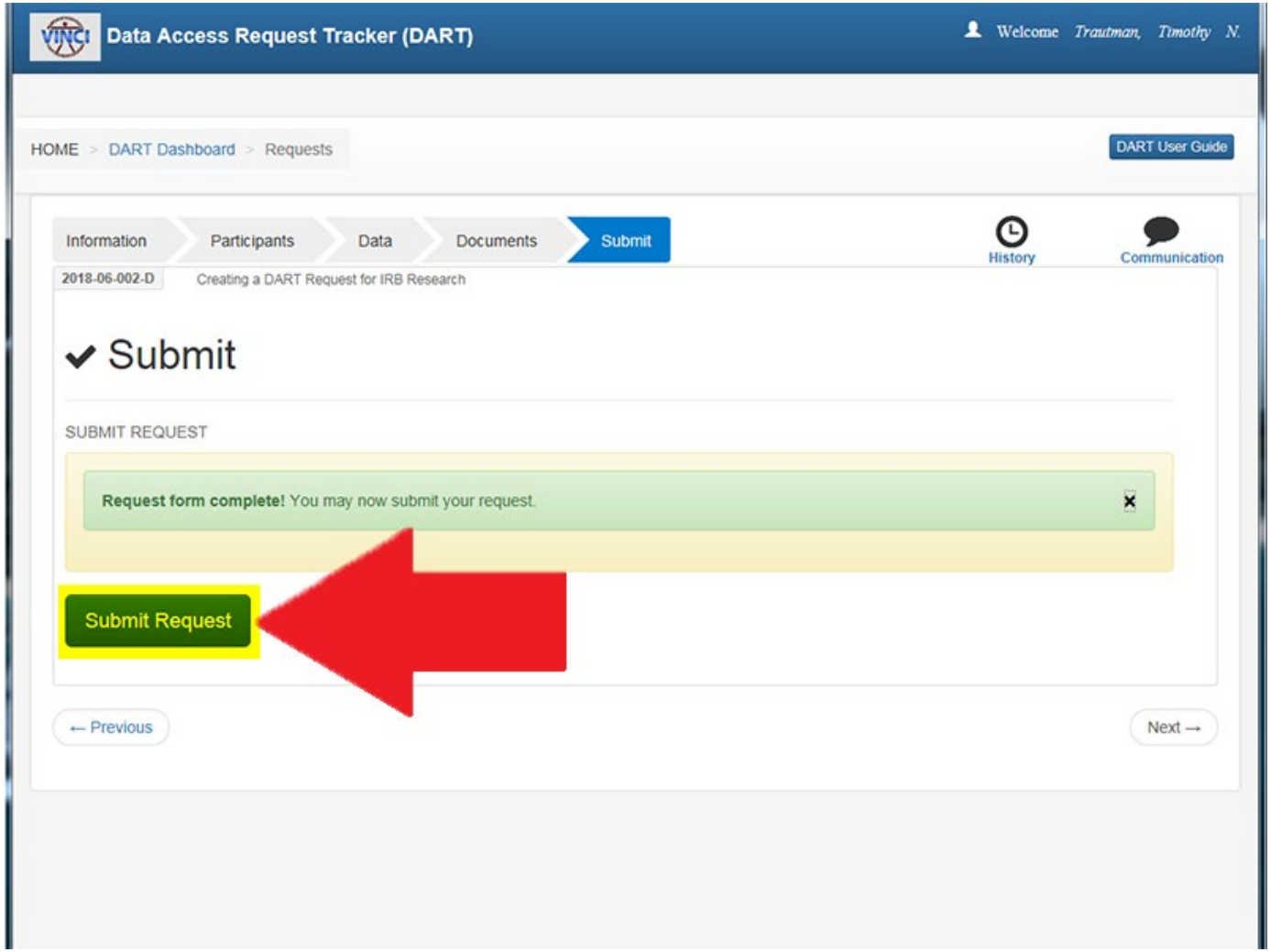
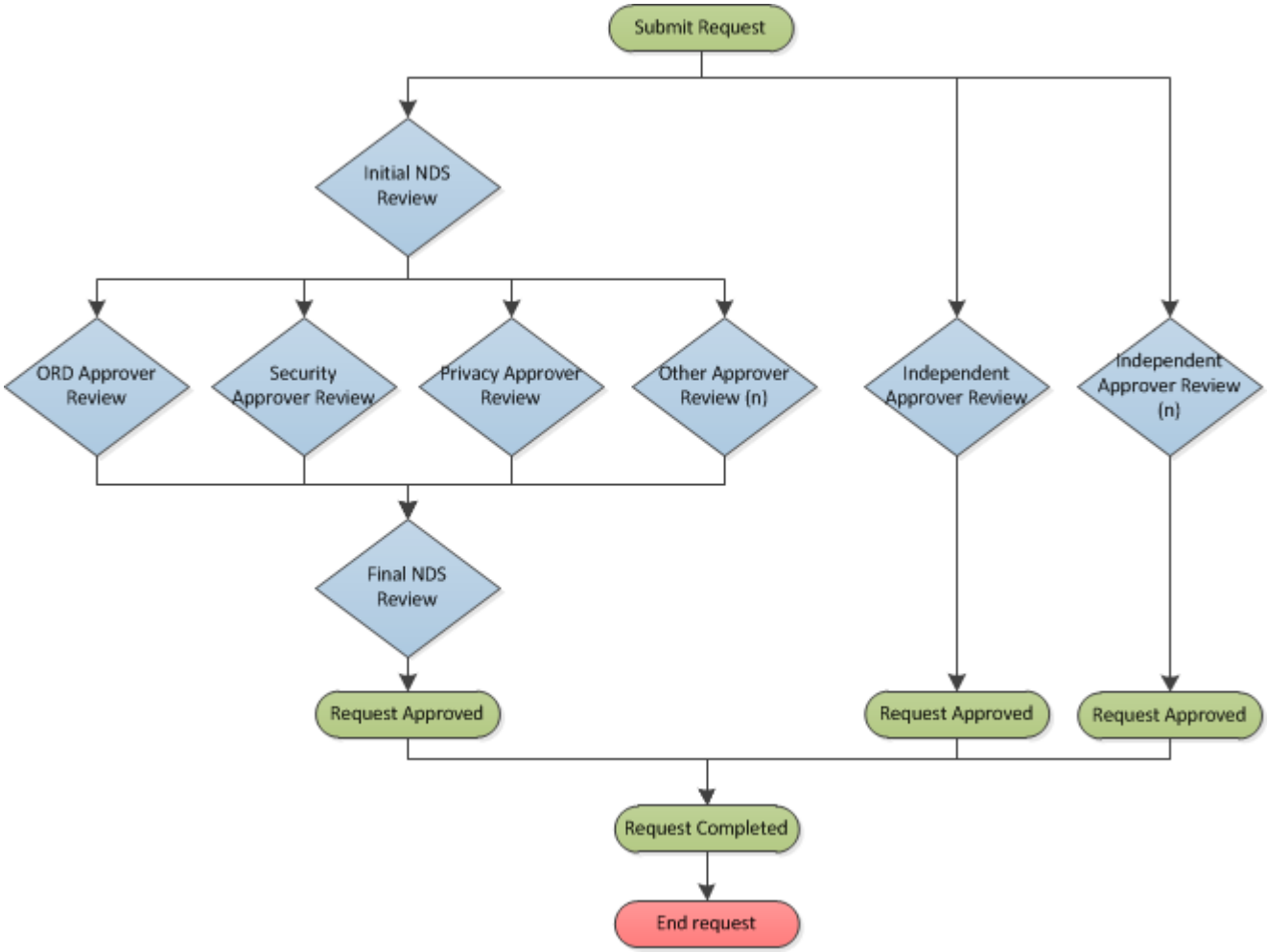


# DART Demo - IRB Research Study



# DART Processing – Avg. 12 Days




See a quick movie

# Poll #2

Do you know that DART can be used to request the COVID-19 Shared Data Resource for Research and Preparatory to Research?

- Yes
- No

COVID-19 Shared Data Resource SharePoint site

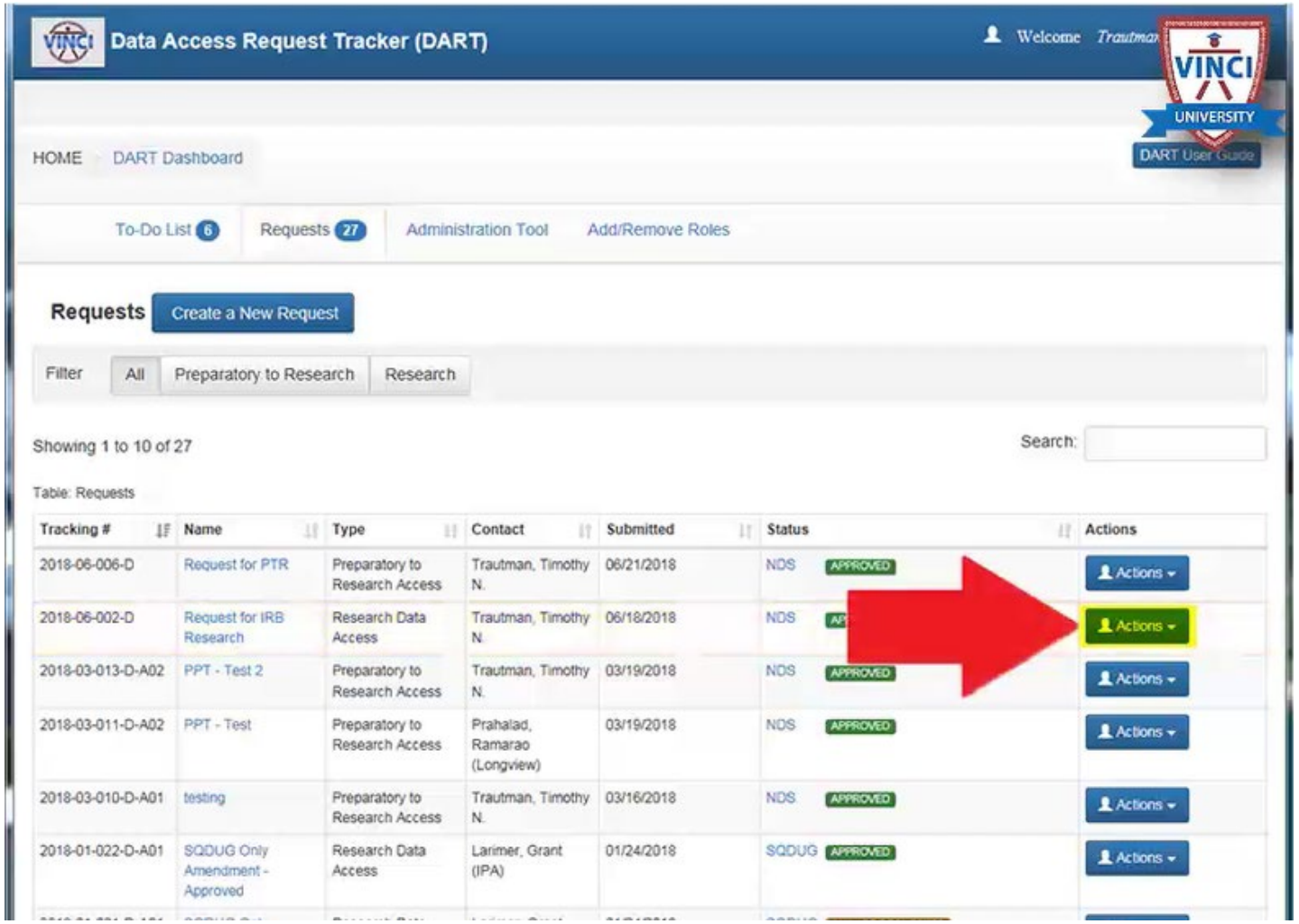
# Tips and Tricks

- When do I need to update the Research Request Memo?
  - When changing Participants, adding Data Sources, or adding a Data Storage Location.
  - Be VERY specific in the amendment narrative of exactly what is being changed.
- Are Digital Signatures required?
  - No, but are generally more convenient.
- What is a Change Request and how do I see it?
  - You will receive an email notice from DART.
  - Request appears in your To-Do list.

# Tips and Tricks

- I changed my last name. How do I update it in DART?
  - In an amendment, have another Participant remove your old identity and add back your new identity.
- I moved stations. How do I update this in DART?
  - In an amendment, remove your old identity and add back your new identity.
- How long do amendments take for approval?
  - Average of 7 days.

# DART Amendment



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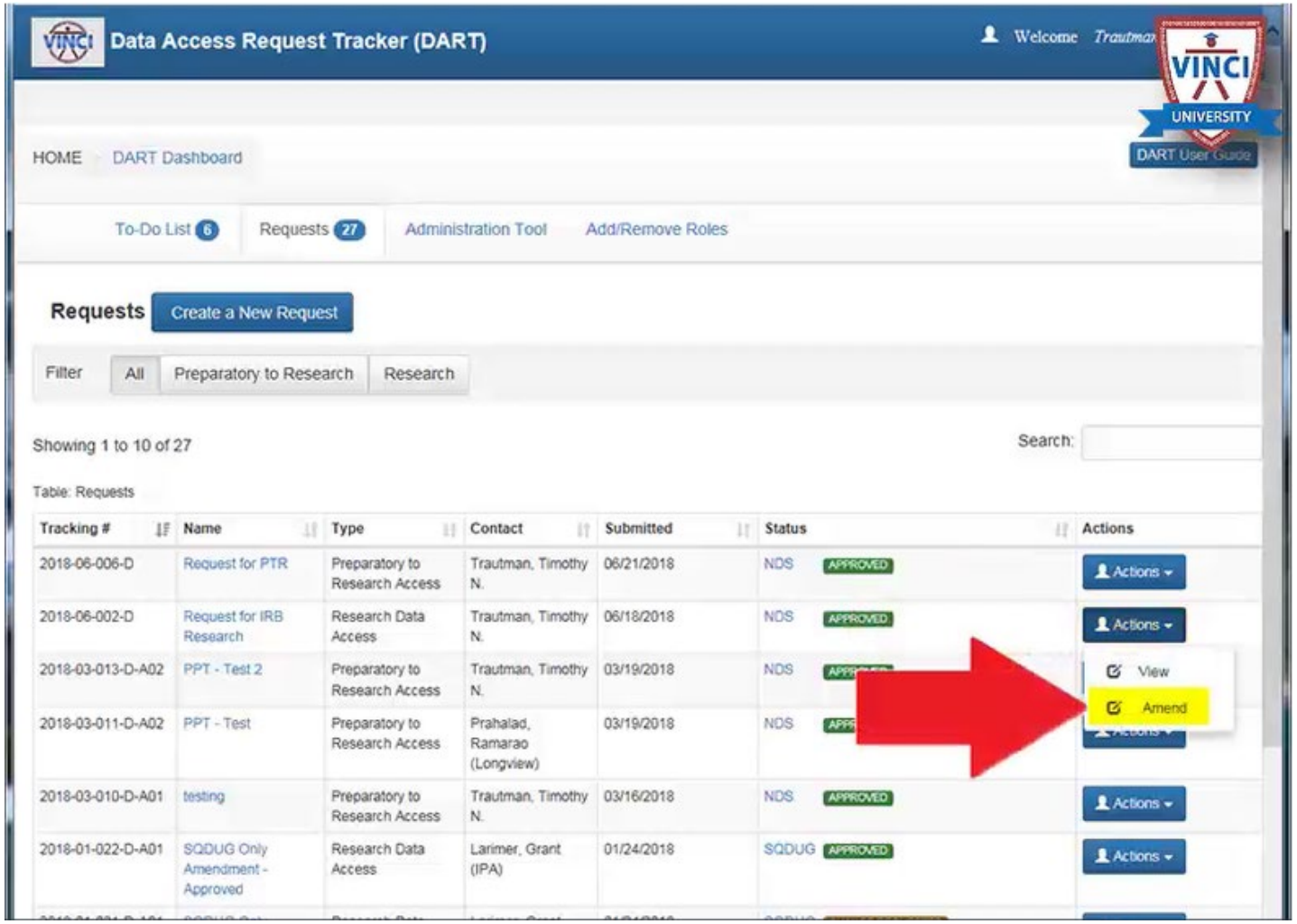

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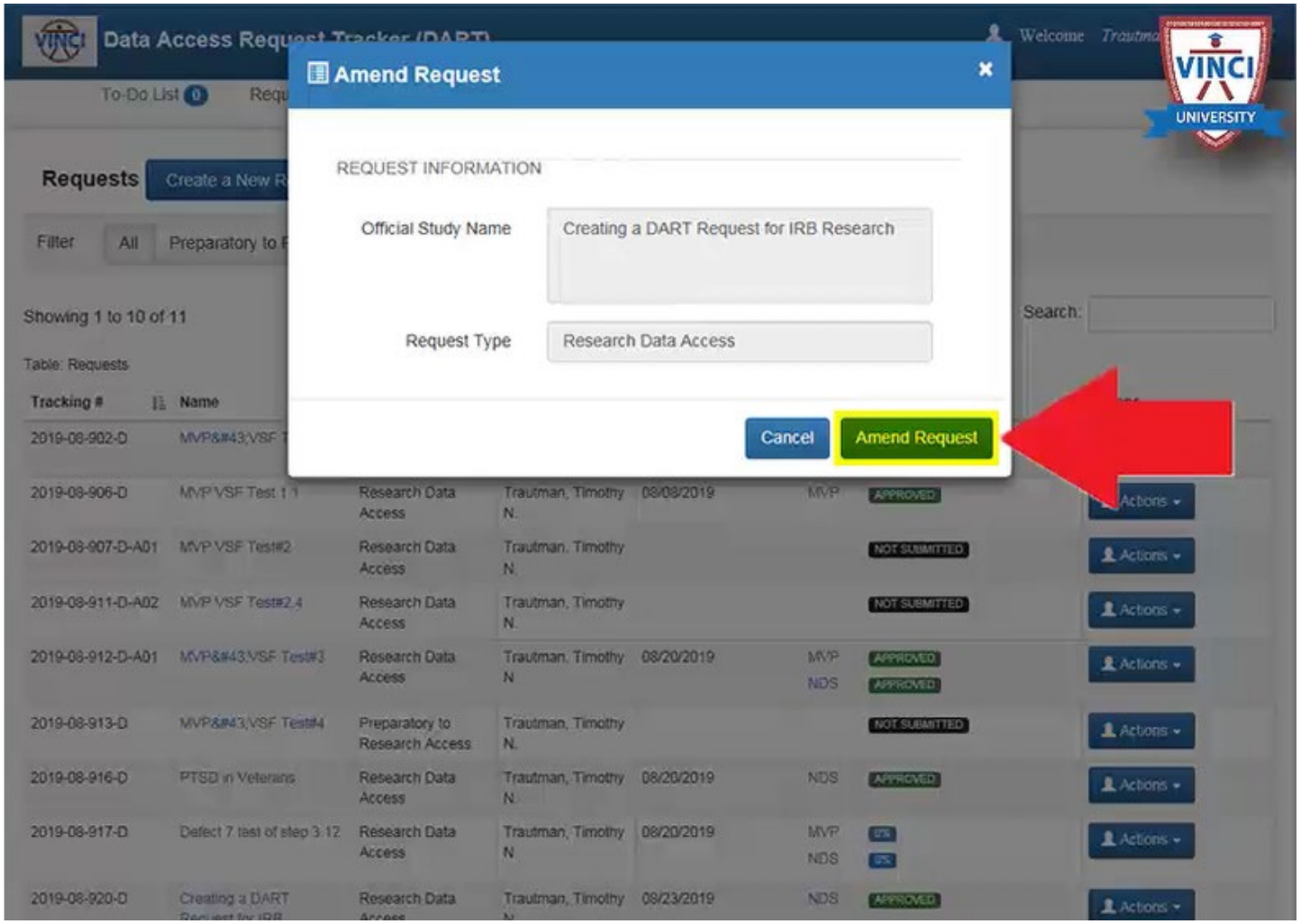
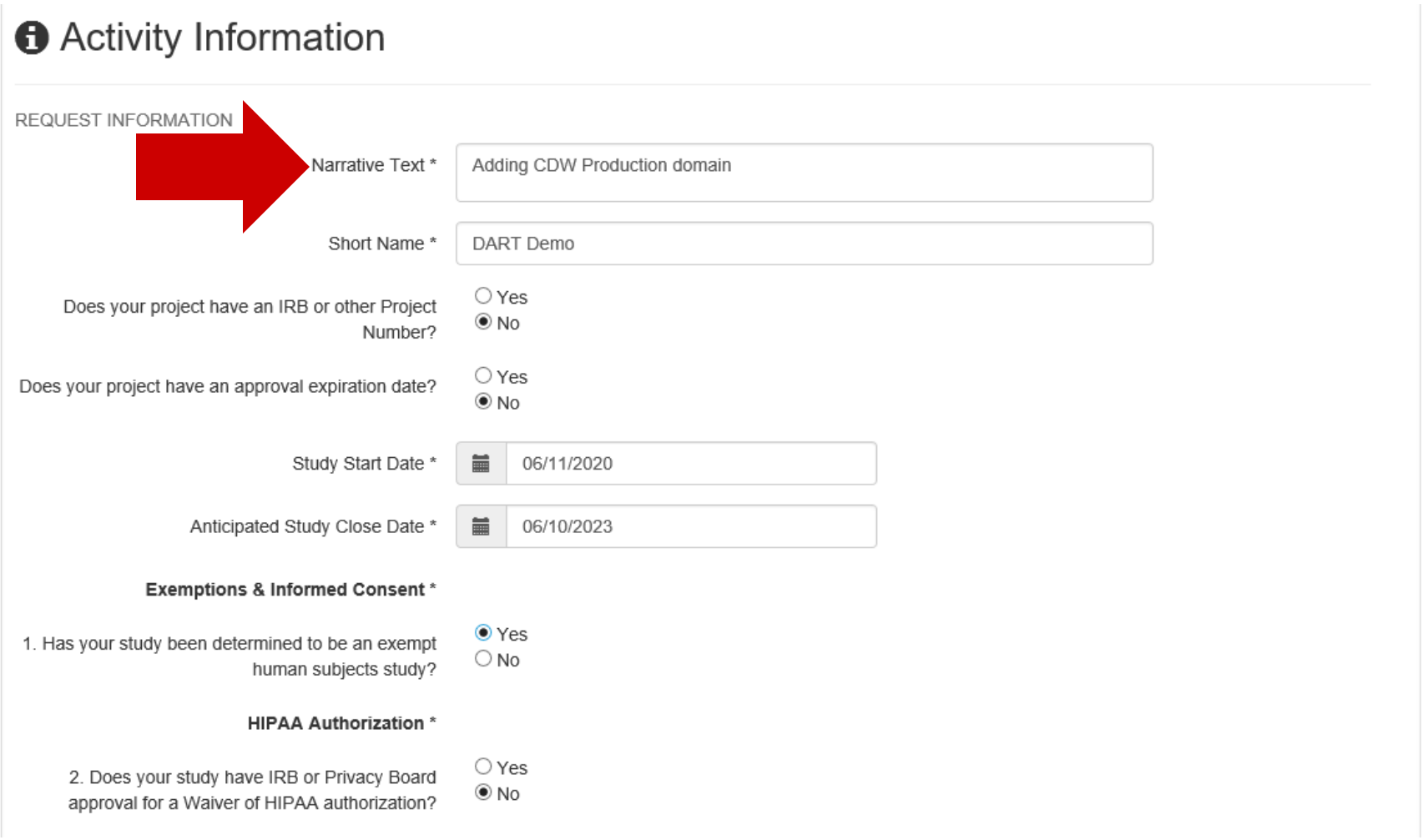


# DART Amendment



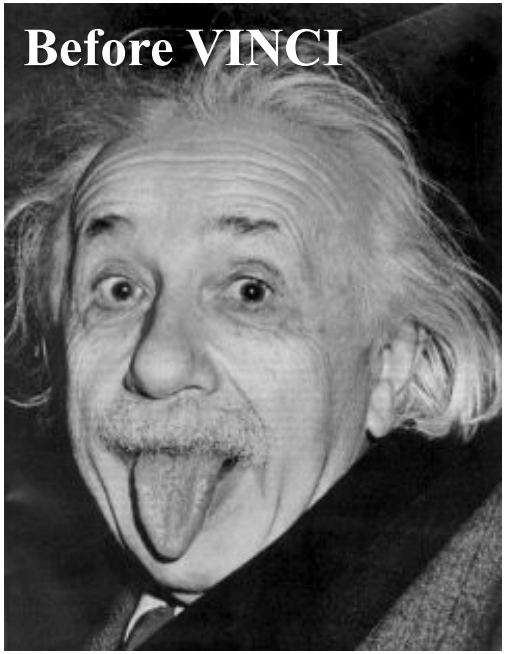
# DART Resources

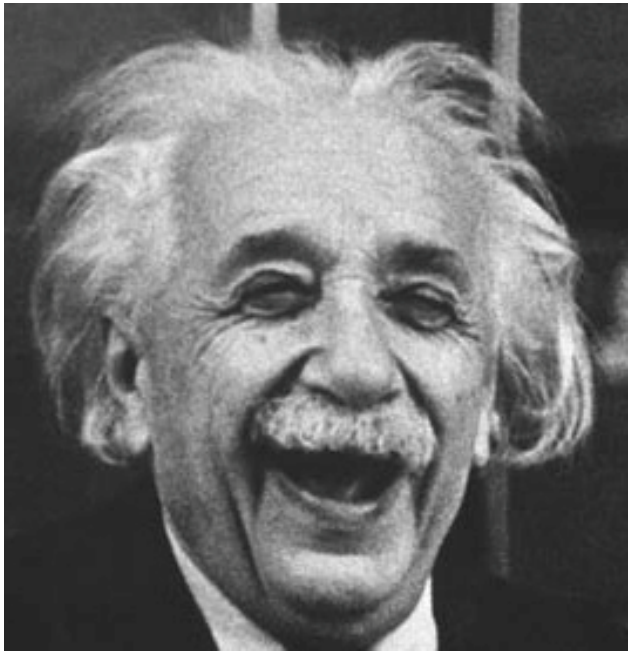
- DART videos on VINCI Tube
- DART Considerations in VINCIpedia
- DART pages in VHA Data Portal

# Questions?

## VINCI@va.gov

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



**Stay safe and healthy everybody!**