How to Conduct a Research Study in VINCI

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What is VINCI?

The VA Informatics and Computing Infrastructure (VINCI) was created as a Health Services Research and Development (HSR&D) Resource Center to give VA researchers access to the data and the applications they need to select, transform, and analyze patient data in a central, secure environment inside the VA Intranet. VINCI supports HSR&D through four areas of focus: workspace; data; study and collaboration tools; and services.

VINCI Central web site

http://vaww.vinci.med.va.gov/VinciCentral



What does VINCI provide?

- Computing resources
 - Virtual computers
 - Fileshares
 - 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



Poll #1

What is your reason for attending today? (Select all that apply)

- I'm curious about VINCI
- I want to use VINCI
- I am using VINCI and want to know more
- I might move my research to VINCI
- I want to learn about how to do research



Focus on using VINCI Resources

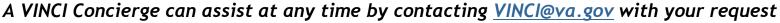
This presentation will focus on studies that will be:

- 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
 - HIPAA Waiver and/or Informed Consent
 - c. Real SSN Access (if needed)
- 4. Data Needs Assessment (optional)
- 5. R&D Committee approval
- 6. Create 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)





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 <u>VINCI@va.gov</u>:
 - Put "Feasibility Assessment" in email Subject line
 - Primary Investigator Name
 - Phone number and email address
 - Inclusion/exclusion criteria



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 3 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

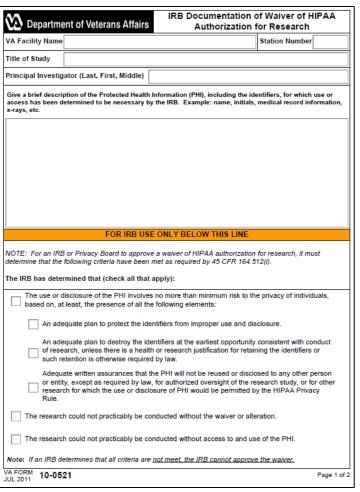


3a. Institutional Review Board (IRB) Letter

- 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
- Use <u>VINCI Description for IRBs</u>
- Use <u>VINCI Information Security</u> <u>Description</u> in IRB



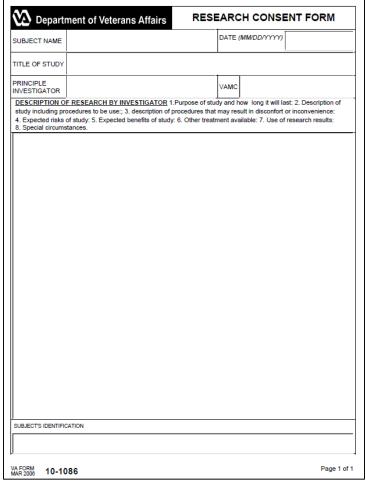
3b. Waiver of HIPAA Authorization



- HIPAA Waivers are not standardized across the VA
- <u>VA Form 10-0521</u> is available for use
 - VA Facility Name
 - Title of Study
 - PI Name
 - Brief description of PHI used



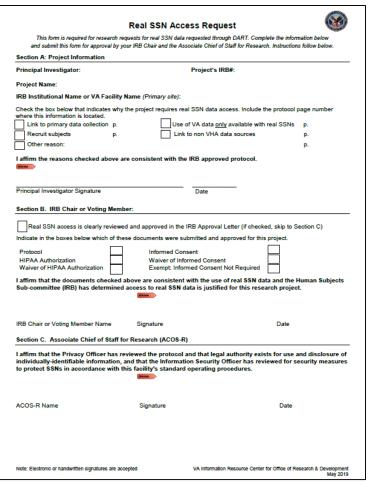
3b. Sample Informed Consent & HIPAA Authorization



- 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)



3c. Real SSN Access



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



4. Get a Data Needs Assessment

- 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 data and a CDW Checklist for your DART request



4. Get a Data Needs Assessment

- To request a DNA, send an email to <u>VINCI@va.gov</u> 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

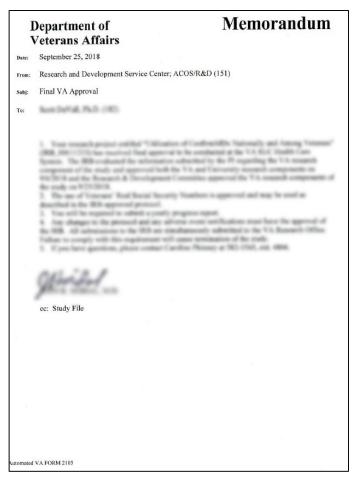


4. Explore the Data Yourself

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



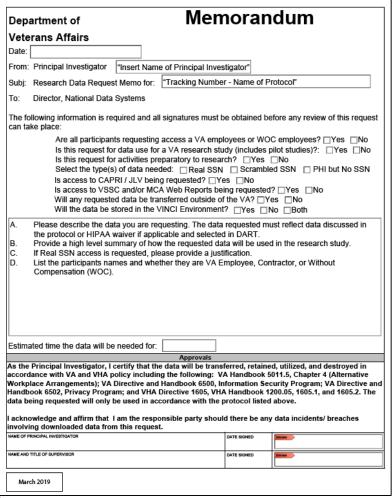
5. R&D Committee Approval



- 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



6. Create Research Request Memo



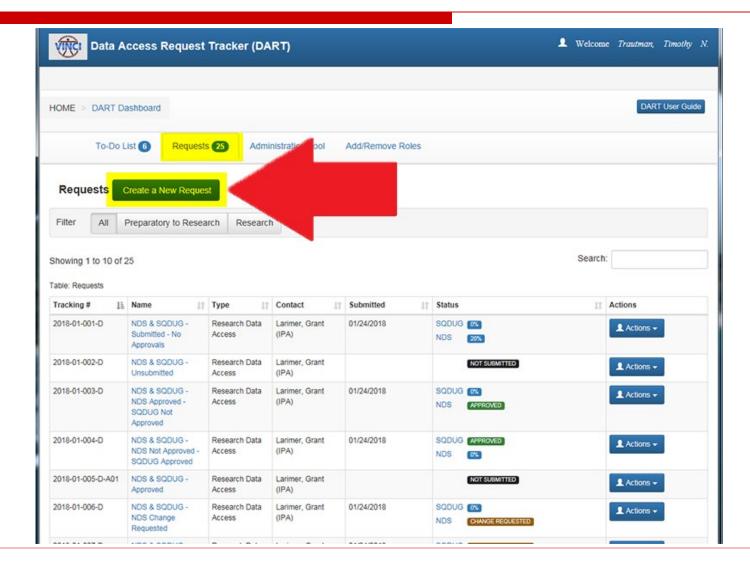
- Research Request Memo
- Instructions are in Appendix A of the DART User Guide
- Initiate your DART request to obtain your DART Tracking Number for the memo's Subject line



7. Request data access with DART

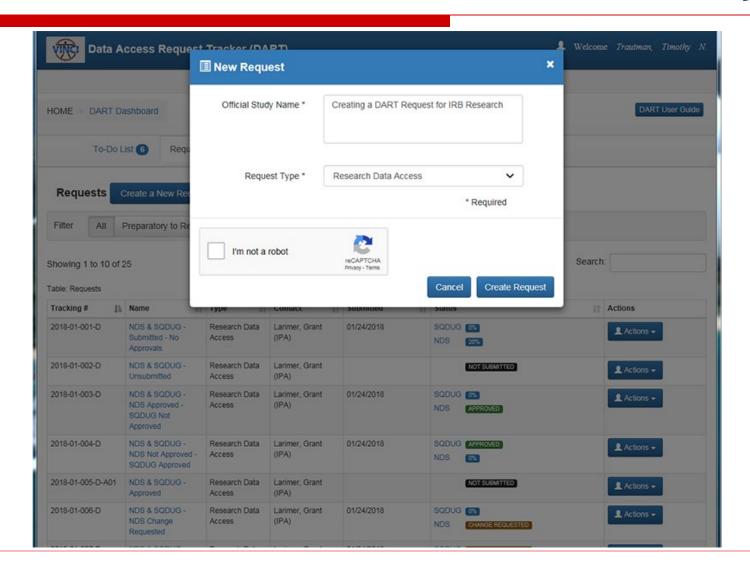
- DART is the <u>Data Access Request Tracker</u> online application used by National Data Systems (NDS) to approve access to various data sources including CDW/VINCI data
- Collects study information and documentation via a 4-screen "Wizard"
- Determines required documentation based on Wizard entries
- Distributes the request to approving authorities who approve online
- See <u>DART Research Request Process</u> page
- Contact <u>VINCI@va.gov</u> for assistance













[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

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.

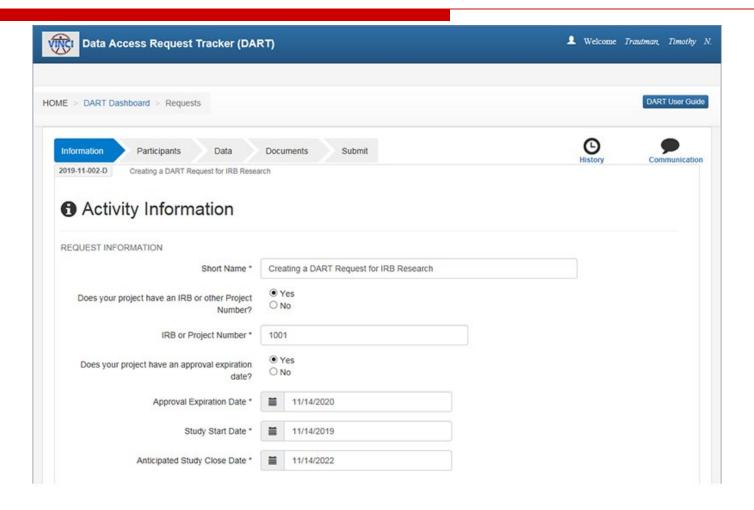
The attached document provides links to helpful resources, considerations to take into account when requesting data access, and what to expect. The DART User Guide provides complete details about how to use DART. If you need assistance with completing the DART request or have questions, please contact 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.

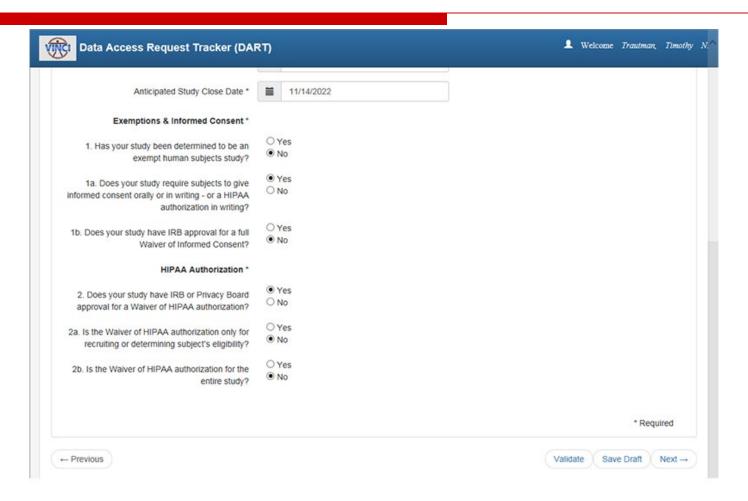
Sincerely,

The DART Team

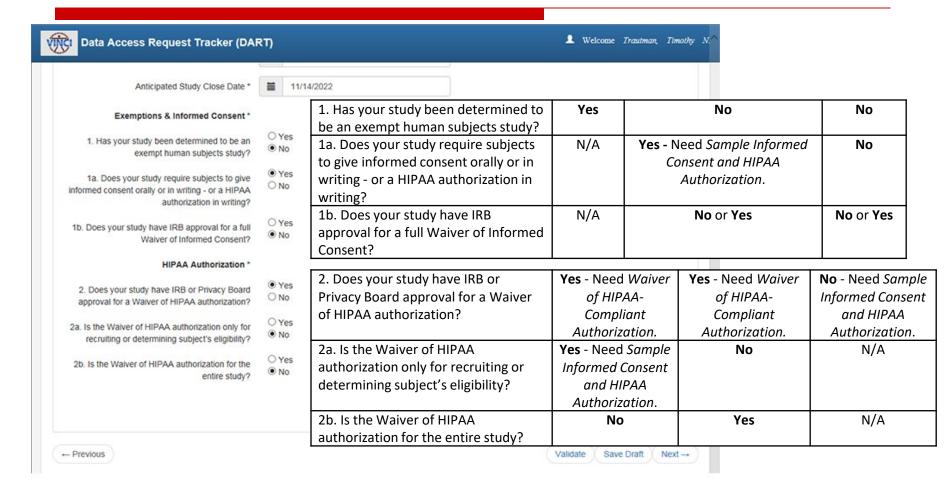




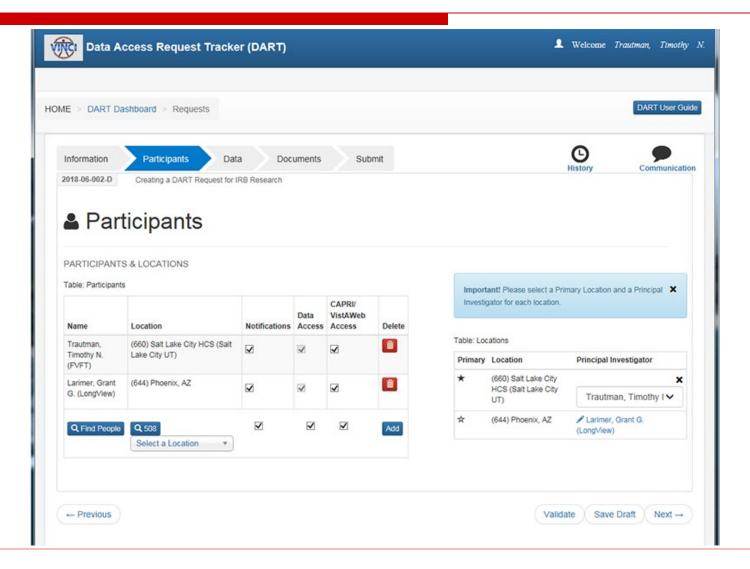




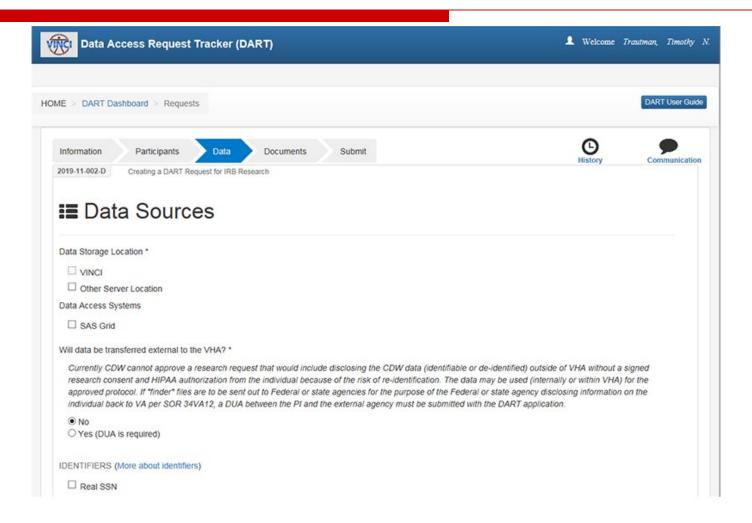




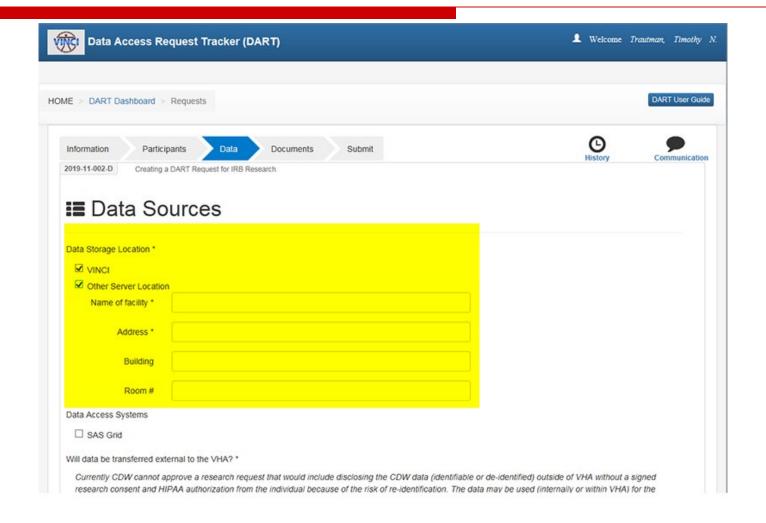




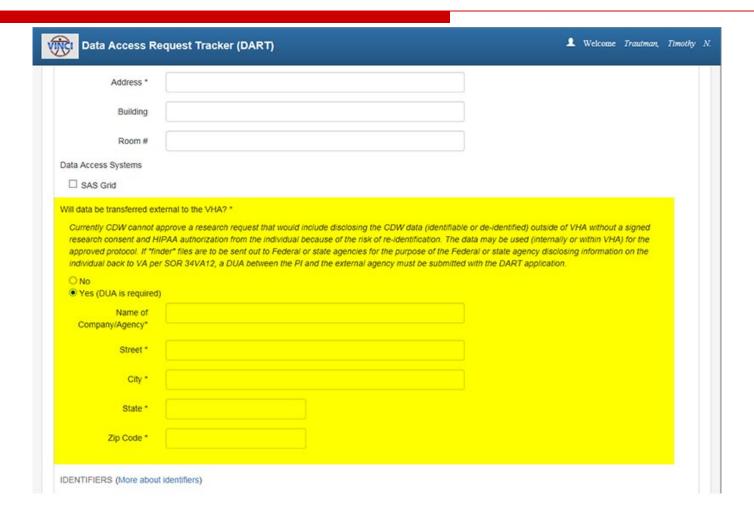




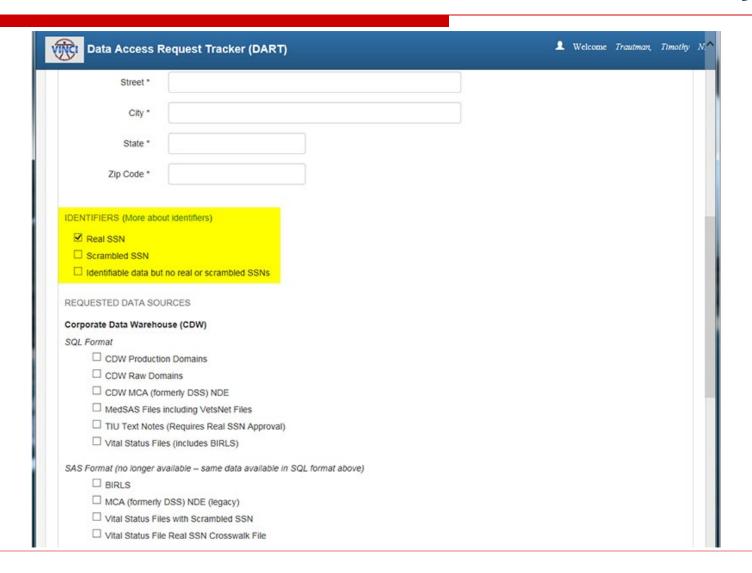




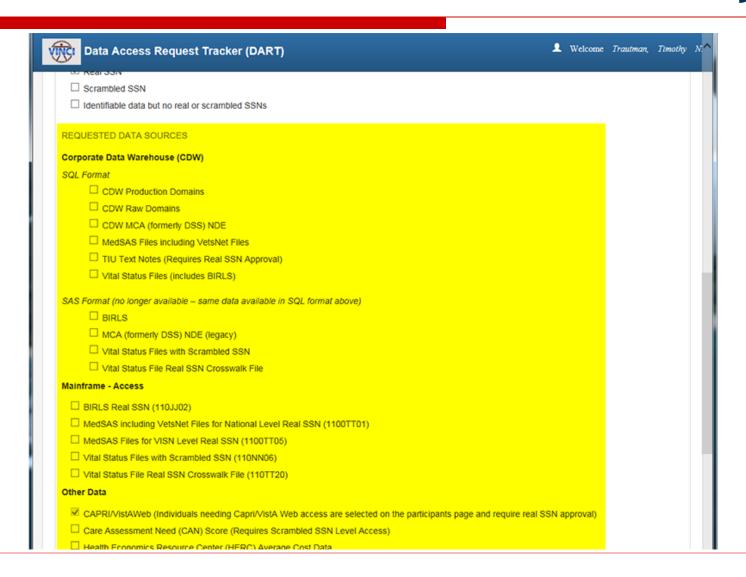




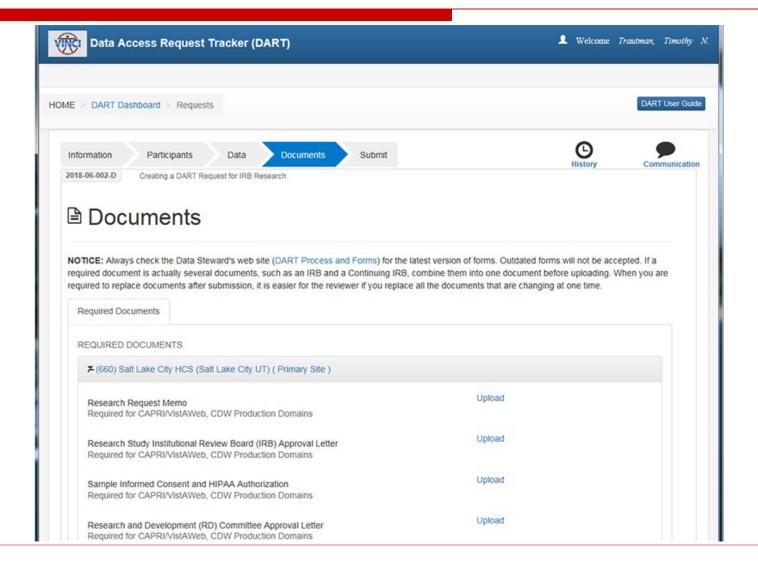














(640) Palo Alto HCS (Palo Alto CA)	
sesearch Study Institutional Review Board (IRB) Approval Letter equired for CDW Production Domains, Vital Status	Upload
tesearch and Development (RD) Committee Approval Letter tequired for CDW Production Domains, Vital Status	Upload
RB Approval of Waiver of HIPAA-Compliant Authorization equired for CDW Production Domains, Vital Status	Upload
Simpson, Ronald D. (Principal Investigator)	
iital Status Rules of Behavior equired for Vital Status	Upload
Scehnet, Jeffrey (Principal Investigator)	
ital Status Rules of Behavior required for Vital Status	Upload



➤ (660) Salt Lake City HCS (Salt Lake City UT) (Primary Site)

Research Request Memo

Required for CDW Production Domains, Vital Status

Research Study Institutional Review Board (IRB) Approval Letter

Required for CDW Production Domains, Vital Status

Sample Informed Consent and HIPAA Authorization

Required for CDW Production Domains, Vital Status

Research and Development (RD) Committee Approval Letter Required for CDW Production Domains, Vital Status

IRB Approval of Waiver of HIPAA-Compliant Authorization Required for CDW Production Domains. Vital Status

Research Protocol

Required for CDW Production Domains, Vital Status

CDW-Domain Checklist

Required for CDW Production Domains

Real SSN Access Request

Required for CDW Production Domains, Vital Status

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2017-03-005-D IRB Letter-(660) Salt Lake City HCS (Salt Lake City UT),pdf (View) Upload

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2017-03-005-D Informed Consent - HIPAA-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload

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2017-03-005-D Waiver of HIPAA Auth-(660) Salt Lake City HCS (Salt Lake City UT).pdf (View) Upload

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2017-03-005-D CDW-Domain Checklist-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload

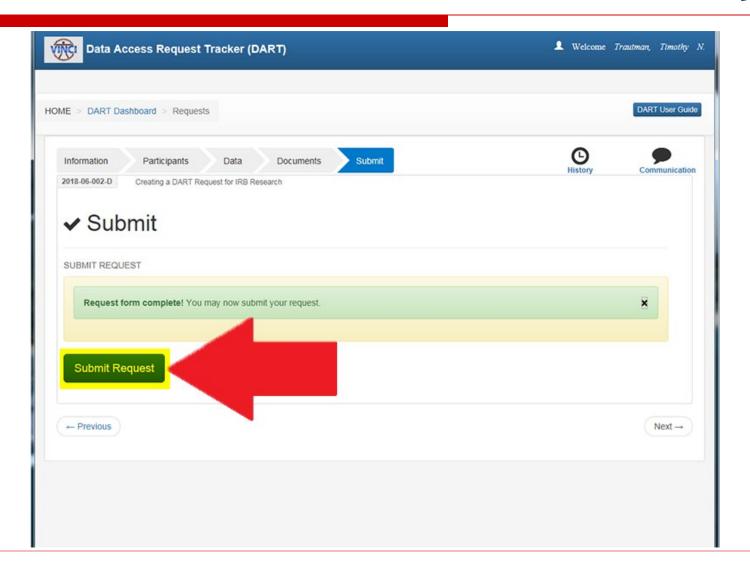
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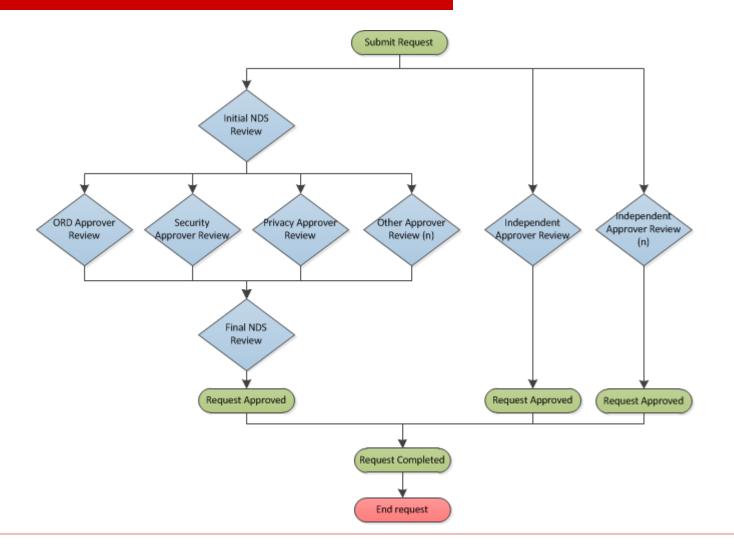
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DART Processing





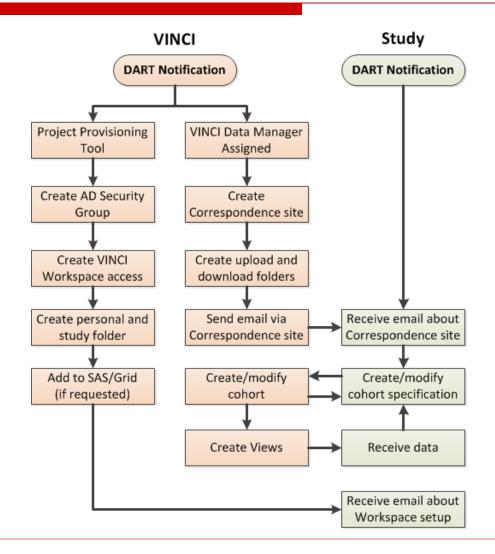


8. VINCI Provisioning

- 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 fileshare folder
- VINCI Data Manager begins provisioning the study by creating study Correspondence SharePoint site, group directories, and database - takes up to 5-business days
- All communications between study and VINCI Data Manager run through Correspondence site



8. Data Provisioning







9. Use the VINCI Workspace

- VINCI firewall provides enhanced data security
- Access to computing power, software tools, databases, SAS/Grid, file and data storage
- Can be accessed from outside the VA through VA VPN solutions of Rescue and CAG
- The VINCI Workspace and shared Project Folders allow for national collaboration in a research group
- Comes in two variations:
 - Standard Workspace
 - Development Workspace (for software development)







9. Use the VINCI Workspace

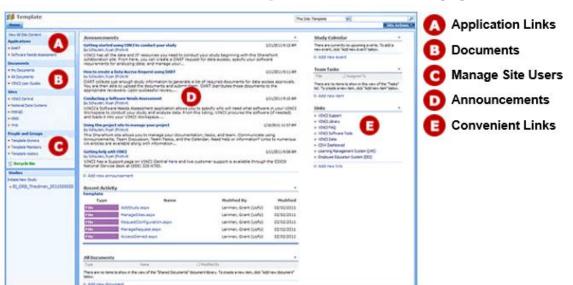
- Follow the guides! Found on <u>VINCI Central's User</u>
 <u>Guides</u> page
- VINCI Workspace User Guide
- VINCI Database User Guide
- VINCI File Transfer Guide

Туре	Guide Name	Description	Updated
(VINCI Database User Guide	This guide provides users with step-by-step instructions on how to access and query their study's SQL database in the VINCI Workspace, getting started with using SAS, and using CDW Project Specific databases.	2017-02-01
(VINCI File Transfer Guide	This guide explains how to upload and download files to the secure VINCI Workspace.	2017-02-01
(i)	VINCI Workspace User Guide	This guide is intended to provide users with pre- requisites and instructions on accessing the VINCI Workspace for the first time as well as instructions on using the VINCI Workspace.	2017-03-27



10. Project Collaboration Site

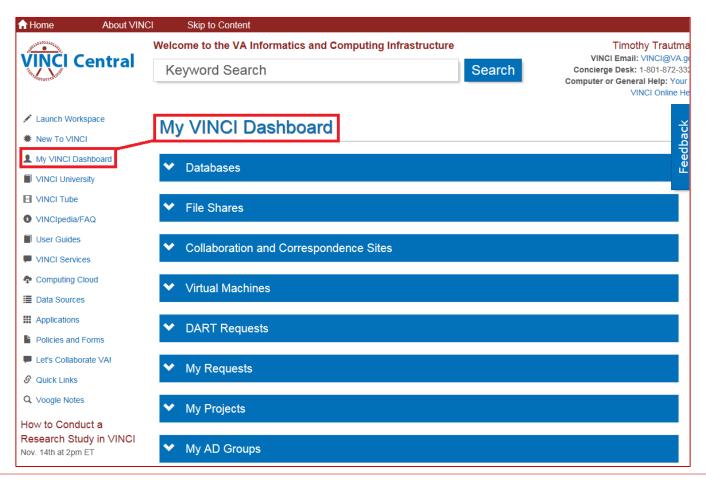
- Project Collaboration sites are custom
 SharePoint sites for your study to maintain documentation and manage your study
- Created through self-service <u>VINCI Project</u>
 <u>Collaboration Site Registration</u> application





VINCI Central - My VINCI Dashboard

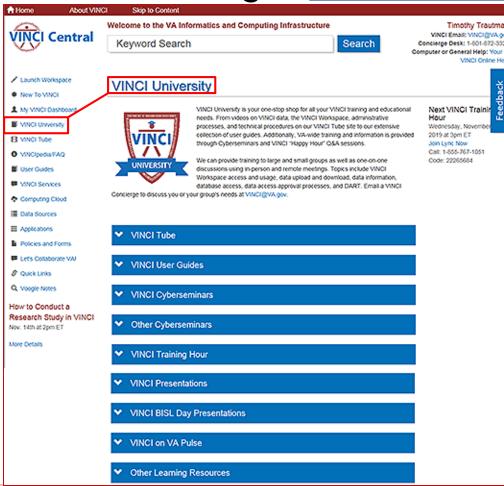
Access your VINCI Resources from My VINCI Dashboard





VINCI Central - VINCI University

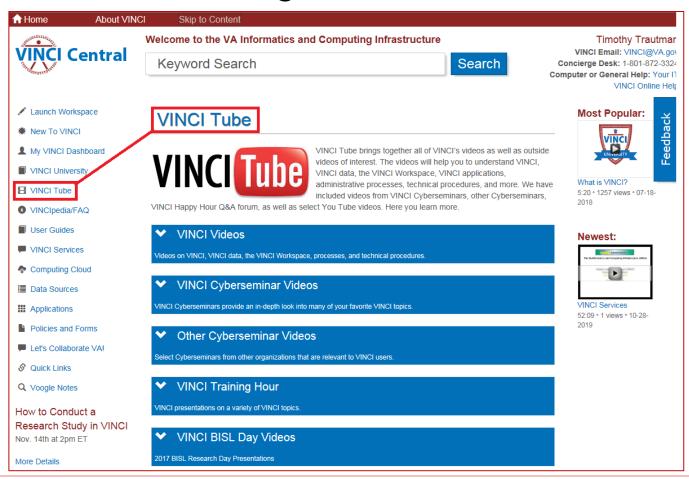
Access all training in VINCI University





VINCI Central - VINCI Tube

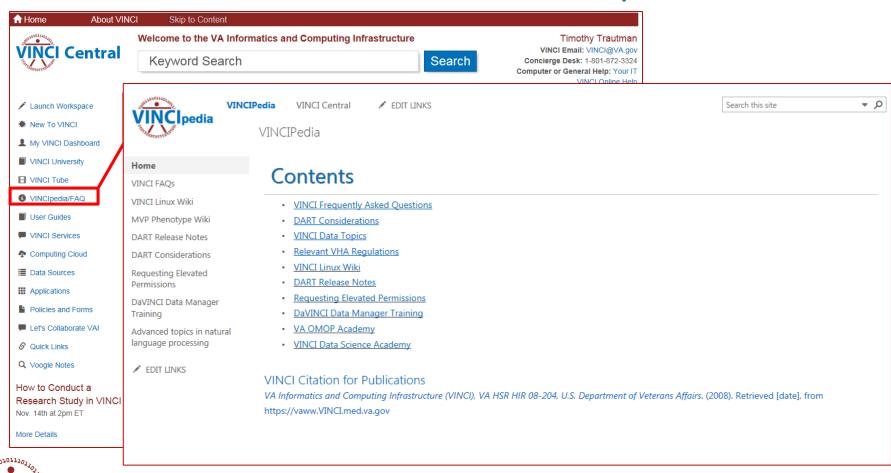
Access training videos on **VINCI Tube**





VINCI Central - VINCIpedia

Find FAQs and more in VINCIpedia



Poll #2

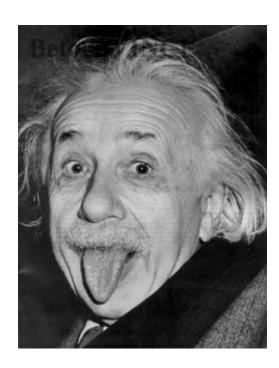
Now that you know how to conduct research in VINCI, how interested are you in doing so?

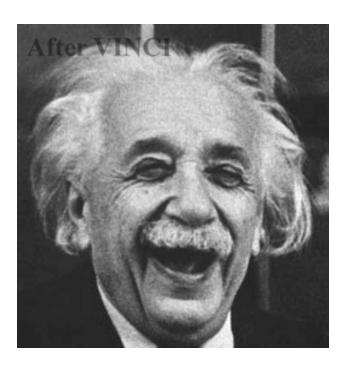
- o Definitely!
- Very interested
- Somewhat interested
- Not interested
- I already use VINCI



Questions?

VINCI@va.gov





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

