

How to Conduct a Research Study in VINCI

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Infrastructure



Focus on using VINCI Resources

- VINCI is your one-stop shop for research IT resources
- This presentation will focus on studies that will be:
 - Conducting IRB Research
 - Using VINCI services
 - Requesting data steward access from National Data Systems (NDS)
 - Using VINCI available data
 - Using the VINCI Workspace

Your gateway is the VINCI Central web site
<http://vaww.vinci.med.va.gov/VinciCentral>



Basic Steps of a VINCI-based Study

1. Get VINCI Concierge assistance (Free!)
 - a) Feasibility Assessment (Is my study possible?)
 - b) Data Needs Assessment (What data do I need?)
2. Create your protocol and get an IRB letter
3. For Real SSN identifiers, get IRB approval
4. Request data with Data Access Request Tracker (DART) online program
5. VINCI data and project provisioning
6. Use the VINCI Workspace to do your analysis
7. Optional training

1a. Feasibility Assessment

- A Feasibility request is done prior to starting a protocol or study
- It is for determining if enough subjects exist to conduct the study you want
- To request a Feasibility determination, send the following to VINCI@va.gov:
 - Primary Investigator (PI) Name
 - PI phone number and email address
 - A detailed description of the project

1a. Feasibility Assessment

- Inclusion criteria: ICD-9 codes, CPT codes, labs (be very specific)
- Exclusion criteria: ICD-9 codes, CPT codes, labs (be very specific)
- Study population - National, VISN, or by station number(s)
- Study period - dates to be included
- Our VINCI Data Services Team will contact you to discuss your request and set expectations
- A feasibility request takes up to 3 weeks

1b. Get a Data Needs Assessment

- A Data Needs Assessment or DNA, is where VINCI helps you discover the data you need to conduct your study which saves you time and money
- It is not for Preparatory to Research where you explore the data yourself - see Preparatory to Research on VINCI Central for more information
- A DNA will deliver a list of variables mapped to VINCI data and a recommendation for your DART request

1b. Get a Data Needs Assessment

- To request a DNA, send an email to VINCI@va.gov with the following:
 - Your study protocol if you have one or similar objective study information
 - An extensive description of what kind of data you are looking for
- Our VINCI Data Services Team will contact you to discuss your request and set expectations
- A DNA typically takes up to two weeks

1c. Explore The Data Yourself

■ Meta Data Viewer

- Available from VINCI Central under Applications
- For Exploring CDW Dimension Table Data

■ Dim Data Viewer

- Available from VINCI Central under Applications
- For Exploring CDW Meta Data Table Data

■ Data Descriptions

- VHA Data Portal
- VA Information Resource Center (VIReC)
- Corporate Data Warehouse (CDW)

2. Create your Protocol and get IRB

- Create your study protocol
- Get HIPAA waiver or Patient Consent from your IRB
- Get your IRB approval letter - you will need one from each location where an investigator is involved
- Use "*VINCI Description for IRBs*" and "*VINCI Information Security Description*" in IRB application
- See VINCI Central website's "New to VINCI" page on IRB studies

3. For Real SSN Identifiers

- This form is for justifying use of Real SSN
 - Do you need Real SSN? Majority of data is available without
 - Get a DNA to determine necessary identifiers for linking data sets
 - Often needed for Chart Review studies
- You will need a Real SSN Access Request form signed by your IRB
- Information and form available on VHA Data Portal web site on the DART Request Process page vaww.vhadataportal.med.va.gov

4. Request data access with DART

- DART is the online application used by NDS and other data stewards to approve access to various data sources
- Collects study information and documentation via a 4-screen Wizard
- Wizard conveniently determines required documentation based on study information entries
- Distributes the request and documentation to data stewards who approve online
- Contact VINCI@va.gov for assistance

Poll Question #1

Select all that apply

- I am Interested in using VINCI for a new IRB research project.
- I am interested in moving an existing project to VINCI.
- I am interested in the potential for a VINCI project.
- I will contact VINCI@va.gov for more information.



DART Demo - IRB Research Study

HOME > DART Dashboard DART User Guide

To-Do List **2** Requests **118**

Requests [Create a New Request](#)

Filter [All](#) [Preparatory to Research](#) [Research](#)

New Request

Official Study Name *

Request Type *

- Please select a Request Type
- Preparatory to Research
- Preparatory to Research Access
- Research
- Research Data Access

[Cancel](#) [Create Request](#)

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 3:21 PM

To: Simpson, Ronald D.

Message DART Considerations.pdf (334 KB)



Read Me!

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

Information Participants Data Documents Submit

History Communication

2017-03-005-D DART Cyberseminar

i Activity Information

REQUEST INFORMATION

Short Name *

IRB Number *

IRB Expiration *

Start Date *

End Date *

* Required

← Previous

Validate

Save Draft

Next →



DART Demo - IRB Research Study

Information **Participants** Data Documents Submit

History Communication

2017-03-005-D DART Cyberseminar

Participants

PARTICIPANTS & LOCATIONS

Table: Participants





Name	Location	Notifications	Data Access	CAPRI/ VistAWeb Access	Delete
Scehnet, Jeffrey	(640) Palo Alto HCS (Palo Alto CA)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Simpson, Ronald D.	(660) Salt Lake City HCS (Salt Lake City UT)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Table: Locations

Primary	Location	Principal Investigator
☆	(640) Palo Alto HCS (Palo Alto CA)	 Scehnet, Jeffrey
★	(660) Salt Lake City HCS (Salt Lake City UT)	 Simpson, Ronald D.

Find People 508 Add

Select a Location

← Previous

Validate

Save Draft

Next →



DART Demo - IRB Research Study

Information | Participants | **Data** | Documents | Submit

2017-03-005-D DART Cyberseminar

Data Sources

Data Storage Location *

- VINCI
- Local VA Server Location

Name of facility *	<input type="text" value="VA Salt Lake City"/>
Address *	<input type="text" value="500 Foothill Drive, Salt Lake City, UT 84113"/>
Building	<input type="text" value="2"/>
Room #	<input type="text" value="1A2c"/>



DART Demo - IRB Research Study

■ Data Storage Location

- IRB approves of study data storage location as defined in your IRB approval letter. You need IRB approval to move data storage locations to or from VINCI. Usually a DART Amendment.
- VINCI Study - Data is stored and analyzed in the secure VINCI Workspace. We secure your data and access.
- Download Study (AKA - Local study) - Data is stored and analyzed on local secure server authorized by your local Information Security Officer (ISO). You secure your data and access.

DART Demo - IRB Research Study

- Data Storage Location (continued)
 - Hybrid Study - Typically used to generate study subject mailing list in VINCI by analysis with results downloaded for mailers.
 - Moving data out of VINCI Workspace? Comply with your IRB, data steward, and DUA requirements. Don't move identifiable data without checking. If in doubt, ask your PI or study coordinator.
 - Aggregate, unidentifiable data is OK to download without permission.

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)

IDENTIFIERS ([More about identifiers](#))



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

DART Demo - IRB Research Study

- Data Use Agreement (DUA) is required anytime you want to share identifiable or non-identifiable data beyond the VA with outside concerns. Some data stewards require a DUA for internal sharing as well.
- DUA clearly defines data storage location and purpose for sharing.
- Identifiers are how to identify individual study subjects and link them across disparate data sources.
- See “More about identifiers” document

DART Demo - IRB Research Study

REQUESTED DATA SOURCES

Corporate Data Warehouse (CDW)

SQL Format

- CDW Production Domains
- CDW Raw Domains
- CDW MCA (formerly DSS) NDE
- MedSAS Files including VetsNet Files
- TIU Text Notes (Requires Real SSN Approval)
- Vital Status Files (includes BIRLS)

SAS Format (no longer available – same data available in SQL format above)

- BIRLS
- MCA (formerly DSS) NDE (legacy)
- Vital Status Files with Scrambled SSN
- Vital Status File Real SSN Crosswalk File

Mainframe - Access

- BIRLS Real SSN (110JJ02)
- MedSAS including VetsNet Files for National Level Real SSN (1100TT01)
- MedSAS Files for VISN Level Real SSN (1100TT05)
- Vital Status Files with Scrambled SSN (110NN06)
- Vital Status File Real SSN Crosswalk File (110TT20)



DART Demo - IRB Research Study

Other Data

- CAPRI/VistAWeb (Individuals needing Capri/VistA Web access are selected on the participants page and require real SSN approval)
- Care Assessment Need (CAN) Score (Requires Scrambled SSN Level Access)
- Health Economics Resource Center (HERC) Average Cost Data
- Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data
- Homeless Registry
- Legacy Data Warehouses (i.e. VISN 21)
- MCA (formerly DSS) Web Reports
- OEF/OIF Roster File (**DUA required for internal data distribution/use**)
- Patient Aligned Care Team (PACT) Implementation Index (Pi2)
- Surgery Quality Data Users Group (SQDUG)
- VSSC Web Reports

Data Access Systems

- SAS Grid

Does your study require Informed Consent and HIPAA Authorization?

- Yes
- No

Does your study require a HIPAA Waiver?

- Yes
- No

DART Demo - IRB Research Study

- VINCI provisions a lot of the data but not all. Some are provisioned by other data stewards.
- Form 9957 is a prerequisite for Mainframe data access. See your local CUPS admin.
- Some data selections are no longer available and appear as greyed-out.
- When making your data selections, think about your data analysis resources. Does your team have the requisite skills?
- Again, see Data Description documents.

DART Demo - IRB Research Study

Required Documents

REQUIRED DOCUMENTS

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

Research Request Memo Required for CDW Production Domains, Vital Status	Upload
Research Study Institutional Review Board (IRB) Approval Letter Required for CDW Production Domains, Vital Status	Upload
Sample Informed Consent and HIPAA Authorization Required for CDW Production Domains, Vital Status	Upload
Research and Development (RD) Committee Approval Letter Required for CDW Production Domains, Vital Status	Upload
IRB Approval of Waiver of HIPAA-Compliant Authorization Required for CDW Production Domains, Vital Status	Upload
Research Protocol Required for CDW Production Domains, Vital Status	Upload
CDW-Domain Checklist Required for CDW Production Domains	Upload
Real SSN Access Request Required for CDW Production Domains, Vital Status	Upload



DART Demo - IRB Research Study

- The DART Wizard process is a business rules engine - your answers to the Wizard pages determine your required documents.
- Documents are both location based as well as individual based.
- DART automatically names documents according to their purpose and archives them thus preserving the data access authentication.
- Find blank forms on the VHA Data Portal.

DART Demo - IRB Research Study

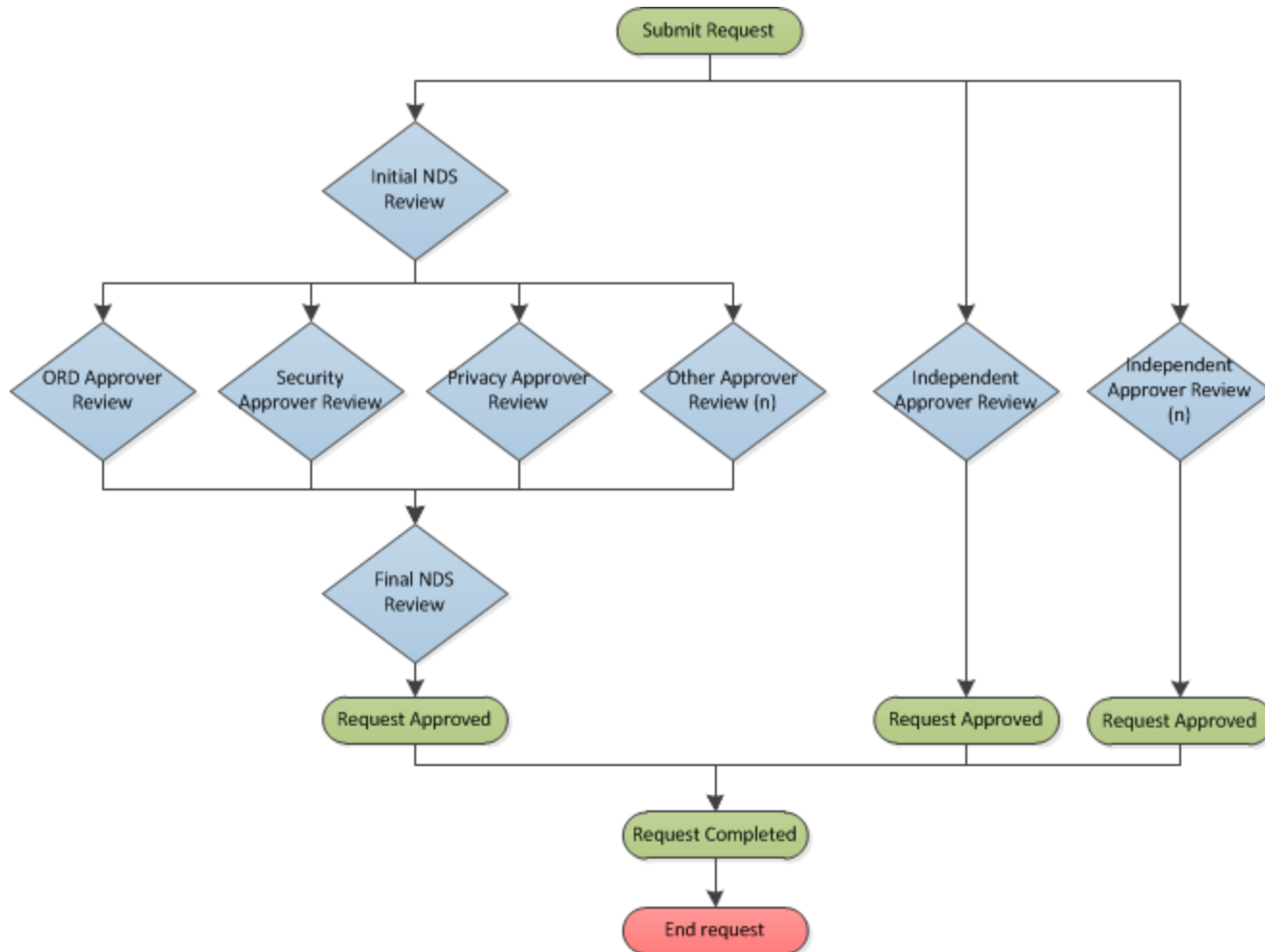
✖ (640) Palo Alto HCS (Palo Alto CA)	
Research Study Institutional Review Board (IRB) Approval Letter Required for CDW Production Domains, Vital Status	Upload
Research and Development (RD) Committee Approval Letter Required for CDW Production Domains, Vital Status	Upload
IRB Approval of Waiver of HIPAA-Compliant Authorization Required for CDW Production Domains, Vital Status	Upload
✖ Simpson, Ronald D. (Principal Investigator)	
Vital Status Rules of Behavior Required for Vital Status	Upload
✖ Scehnet, Jeffrey (Principal Investigator)	
Vital Status Rules of Behavior Required for Vital Status	Upload



DART Demo - IRB Research Study

The screenshot displays the 'Submit' step of the DART IRB Research Study process. At the top, a navigation bar includes tabs for 'Information', 'Participants', 'Data', 'Documents', and 'Submit' (which is highlighted in blue). To the right of the navigation bar are icons for 'History' (a clock) and 'Communication' (a speech bubble). Below the navigation bar, the study ID '2017-03-005-D' and the study name 'DART Cyberseminar' are visible. The main content area features a large checkmark icon followed by the word 'Submit'. Below this, the text 'SUBMIT REQUEST' is displayed. A prominent green message box with a yellow border contains the text: 'Request form complete! You may now submit your request.' To the right of this message is a small 'X' icon for closing the notification. A blue button labeled 'Submit Request' is positioned below the message box. At the bottom of the interface, there are two navigation buttons: '← Previous' on the left and 'Next →' on the right.

DART Processing



Poll Question #2

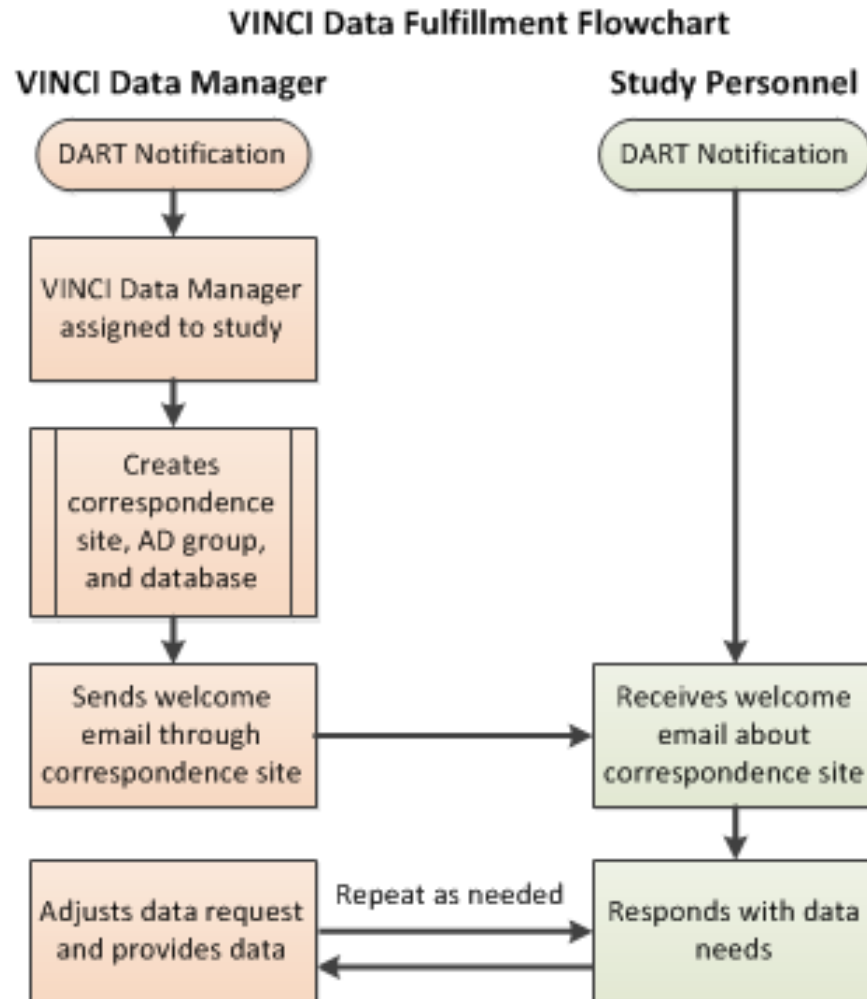
Select all that that are true

- DART is used to apply for IRB research data.
- I have already used DART.
- I will use DART in the future to apply for IRB research data access.
- I'm interested in operations research.
- I will contact VINCI@va.gov for more information.

5. VINCI Provisioning

- VINCI is automatically notified of approvals by DART including our automated Project Provisioning Tool.
- VINCI Data Manager begins data provisioning of the study with Data Provisioning Tool - allow up to 5-business days for initial contact.
- All communications between study and VINCI Data Manager run through SharePoint VINCI Data Correspondence site. Access through My VINCI Dashboard on VINCI Central.

5. Data Provisioning






6. 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)



6. Use the VINCI Workspace

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

Type	Guide Name	Description	Last 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
	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

7. Optional Training

- Need training to use VINCI's resources?
Contact VINCI@va.gov
- Self-service training on VINCI Central
 - VINCI Tube - video tutorials and cyberseminars
 - VINCI University - videos, user guides, cyberseminars, other resources
 - VINCIpedia - Frequently Asked Questions (FAQs), DART Considerations, VINCI Data Topics, and links to policy handbooks

Questions?

VINCI@va.gov

