

How to Conduct a Research Study in VINCI

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VA Informatics &
Computing
Infrastructure



Focus on using VINCI Resources

- This presentation will focus on studies that will be:
 - Conducting IRB Research
 - Using VINCI services
 - Requesting data access from NDS
 - Using VINCI/CDW data
 - Using the VINCI Workspace

VINCI Central web site

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

Basic Steps of a VINCI Study

1. Get VINCI Concierge assistance (optional)
 - a) Feasibility Assessment
 - b) Data Needs Assessment
2. Create your protocol and get an IRB letter
3. *For Real SSN* - IRB signs Real SSN Access form
4. Request data access with DART
5. VINCI data and project provisioning
6. Use the VINCI Workspace
7. Optional training



1a. Feasibility Assessment

- A Feasibility request 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 determination, send the following to VINCI@va.gov:
 - Primary Investigator Name
 - Phone number and email address
 - A detailed description of the project

1a. Feasibility Assessment

- Inclusion criteria: ICD-9 codes, CPT codes, labs
- Exclusion criteria: ICD-9 codes, CPT codes, labs
- Study population - National or by station number(s)
- Study period - dates to be included
- Our VINCI Data 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 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 variables mapped to CDW data and a CDW Checklist 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 study information
 - An extensive description of what kind of data you are looking for
- Our VINCI Data team will contact you to discuss your request and set expectations
- A DNA typically takes up to two weeks

2. Create your Protocol and get IRB

- Create your protocol
- Get HIPAA waiver or Patient Consent
- Get your IRB - you will need an IRB from each location where an investigator is involved
- Use *VINCI Description for IRBs*
- Use *VINCI Information Security Description* in IRB
- See VINCI Central “IRB Research Study” page for these documents

3. For Real SSN

- You will need a Real SSN Access Request form signed by your IRB
- This form is for justifying use of Real SSN
- Information and form available on VHA Data Portal web site vaww.vhadataportal.med.va.gov on the Data Access Request Tracker (DART) Request Process page.

4. Request data access with DART

- DART is the Data Access Request Tracker 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
- Contact VINCI@va.gov for assistance

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 3:24 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

Information **Participants** Data Documents Submit

History  Communication 


2017-03-005-D DART Cyberseminar


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"/>	

Select a Location

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.

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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 *

VA Salt Lake City

Address *

500 Foothill Drive, Salt Lake City, UT 84113

Building

2

Room #

1A2c



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

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

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

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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

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

Research Request Memo
Required for CDW Production Domains, Vital Status

2017-03-005-D Research Request Memo-(660) Salt Lake City HCS (Salt Lake City UT).docx ([View](#)) [Upload](#)
V1 Uploaded 03/22/17 06:54PM by Simpson, Ronald D.

Research Study Institutional Review Board (IRB) Approval Letter
Required for CDW Production Domains, Vital Status

2017-03-005-D IRB Letter-(660) Salt Lake City HCS (Salt Lake City UT).pdf ([View](#)) [Upload](#)
V1 Uploaded 03/22/17 06:54PM by Simpson, Ronald D.

Sample Informed Consent and HIPAA Authorization
Required for CDW Production Domains, Vital Status

2017-03-005-D Informed Consent - HIPAA-(660) Salt Lake City HCS (Salt Lake City UT).docx ([View](#)) [Upload](#)
V1 Uploaded 03/22/17 06:54PM by Simpson, Ronald D.

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

2017-03-005-D RD Letter-(660) Salt Lake City HCS (Salt Lake City UT).docx ([View](#)) [Upload](#)
V1 Uploaded 03/22/17 06:55PM by Simpson, Ronald D.

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

2017-03-005-D Waiver of HIPAA Auth-(660) Salt Lake City HCS (Salt Lake City UT).pdf ([View](#)) [Upload](#)
V1 Uploaded 03/22/17 06:55PM by Simpson, Ronald D.

Research Protocol
Required for CDW Production Domains, Vital Status

2017-03-005-D Research Protocol-(660) Salt Lake City HCS (Salt Lake City UT).docx ([View](#)) [Upload](#)
V1 Uploaded 03/22/17 06:55PM by Simpson, Ronald D.

CDW-Domain Checklist
Required for CDW Production Domains

2017-03-005-D CDW-Domain Checklist-(660) Salt Lake City HCS (Salt Lake City UT).docx ([View](#)) [Upload](#)
V1 Uploaded 03/22/17 06:55PM by Simpson, Ronald D.

Real SSN Access Request
Required for CDW Production Domains, Vital Status

2017-03-005-D Real SSN Access Request-(660) Salt Lake City HCS (Salt Lake City UT).docx ([View](#)) [Upload](#)
V1 Uploaded 03/22/17 06:55PM by Simpson, Ronald D.



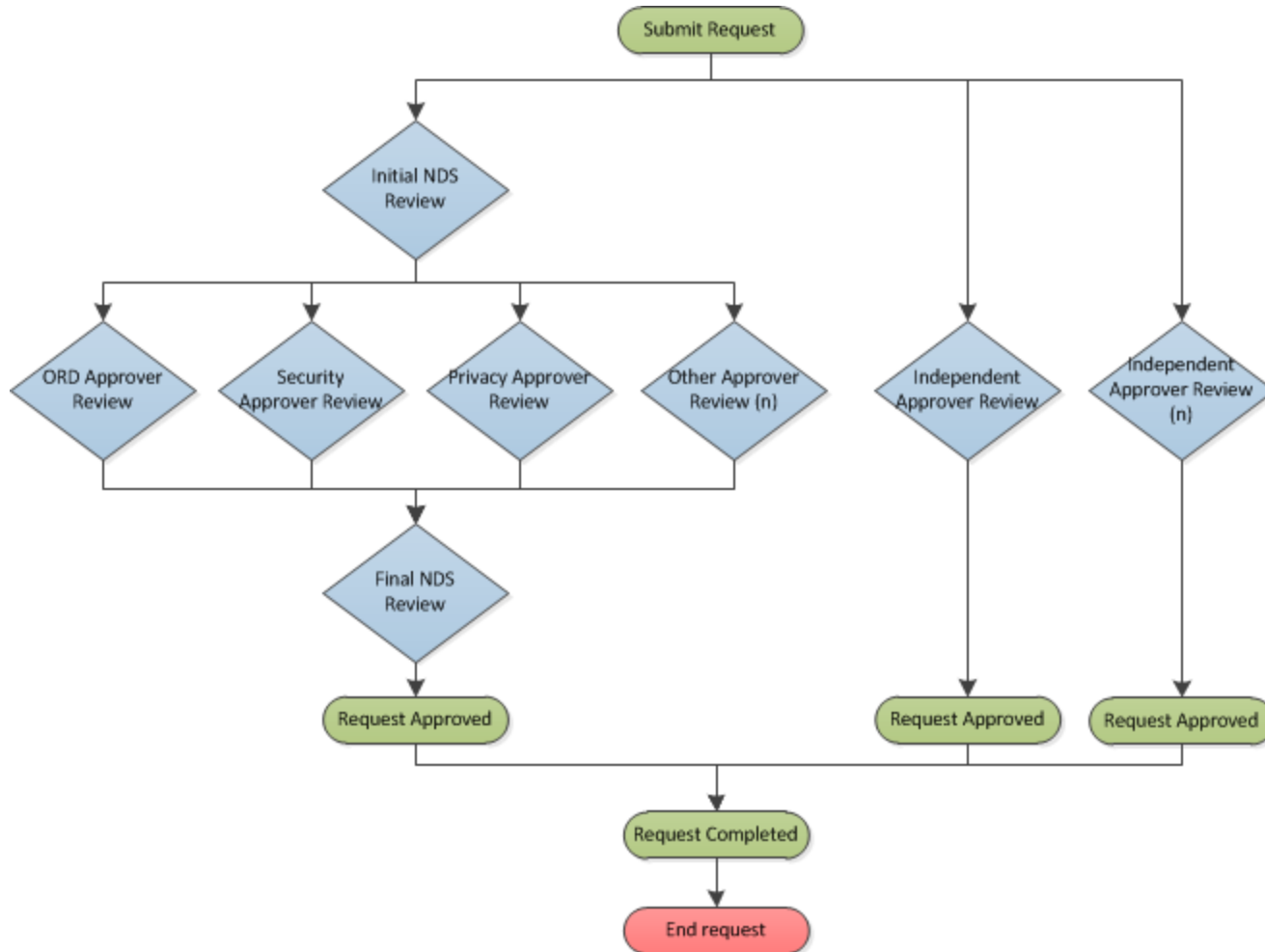
DART Demo - IRB Research Study

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DART Demo - IRB Research Study

The screenshot displays a web interface for an IRB research study. At the top, a navigation bar contains five steps: 'Information', 'Participants', 'Data', 'Documents', and 'Submit'. The 'Submit' step is highlighted in blue. To the right of the navigation bar are two icons: a clock labeled 'History' and a speech bubble labeled 'Communication'. 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. Below the message box is a blue button labeled 'Submit Request'. At the bottom of the interface, there are two navigation buttons: '← Previous' on the left and 'Next →' on the right.

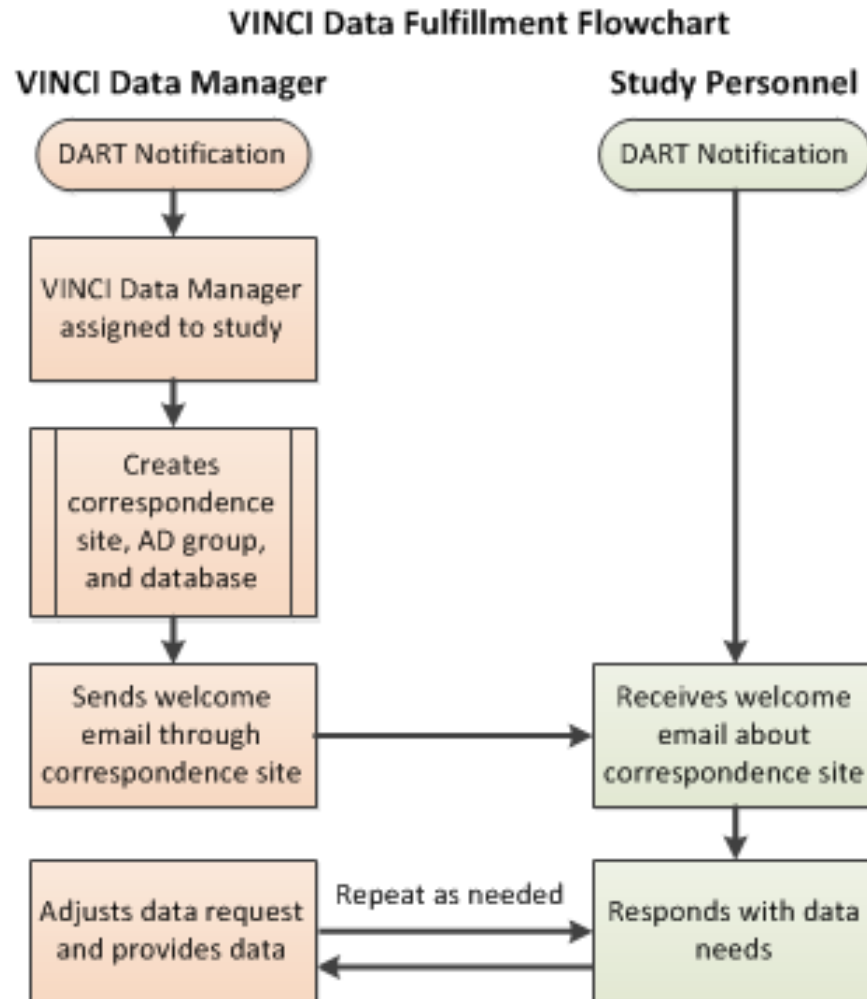
DART Processing



5. VINCI Provisioning

- VINCI is automatically notified of approvals by DART
- VINCI Help Desk begins provisioning VINCI Workspace for access and study data folder - takes up to 5-business days
- 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

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 - FAQs, DART Considerations, VINCI Data Topics, and links to policy handbooks

Questions?

VINCI@va.gov

