

Data Access Request Tracker (DART): Forms Follow Function

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VINCI Lead Concierge Specialist



VA Informatics &
Computing
Infrastructure

Forms Follow Function

- Follow me as we dive deeper into DART
 - Amend a DART Demo
 - Discuss main forms needed for IRB Research Studies in DART
 - Questions and Answers

Poll

- How familiar are you with amending a DART request?
 - I submit them often
 - I watched someone amend a DART request
 - I have never amended a DART request
 - I would like to learn what is needed to amend a DART request


Amend a DART

■ Start at your DART Dashboard

Tracking #	Name	Type	Contact	Submitted	Status	Actions
2017-06-018-D	Ron Test2 6/27/2017	Research Data Access	Simpson, Ronald D.	06/27/2017	SQDUG 0% NDS 66%	Actions ▾
2017-06-020-D-A01	6/28/2017 SQDUG only	Research Data Access	Simpson, Ronald D.	06/28/2017	NDS 0% SQDUG 0%	Actions ▾
2017-07-001-D	Amend a DART	Research Data Access	Simpson, Ronald D.	07/07/2017	NDS APPROVED	Actions ▾
2017-07-006-D	I am not a robot!	Research Data Access	Simpson, Ronald D.		NOT SUBMITTED	View Amend
2017-07-007-D	Test 2 RDS 7/26/2017	Preparatory to Research Access	Simpson, Ronald D.	07/26/2017	NDS 0%	

A close-up view of the 'Actions' dropdown menu from the table above. The menu is open, showing two options: 'View' and 'Amend', each with a document icon. A red arrow points from the right side of the slide towards the 'Amend' option.

Amend a DART

 Amend Request ✕

REQUEST INFORMATION

Official Study Name

Request Type


AMENDMENT INFORMATION

Amendment Narrative *

* Required

Cancel

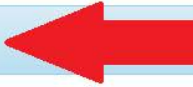
Amend a DART

 Data Access Request Tracker (DART) Welcome Simpson, Ronald D.

HOME > DART Dashboard > Requests DART User Guide

Information | Participants | Data | Documents | Submit History | Communication

2017-07-001-D-A01 Amend a DART

AMENDMENT NARRATIVE: Add participants Jay Tucker and Timothy Trautman 

Activity Information

REQUEST INFORMATION

Short Name *

IRB Number *

IRB Expiration *

Start Date *

End Date *



Amend a DART

2017-07-001-D-A01 Amend a DART

AMENDMENT NARRATIVE: Add participants Jay Tucker and Timothy Trautman

Participants

PARTICIPANTS & LOCATIONS

Table: Participants

Name	Location	Notifications	Data Access	CAPRI/ VistAWeb Access	Delete
Simpson, Ronald D.	(660) Salt Lake City HCS (Salt Lake City UT)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Tucker, Jay N.	(660) Salt Lake City HCS (Salt Lake City UT)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Trautman, Timothy N. (FVFT)	(660) Salt Lake City HCS (Salt Lake City UT)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	


Important! Please select a Primary Location and a Principal Investigator for each location. ✕

Table: Locations

Primary	Location	Principal Investigator
★	(660) Salt Lake City HCS (Salt Lake City UT)	Simpson, Ronald D.



Amend a DART

 Data Access Request Tracker (DART) Welcome Simpson, Ronald

HOME > DART Dashboard > Requests DART User Guide

Information > Participants > **Data** > Documents > Submit History Communication

2017-07-001-D-A01 Amend a DART

AMENDMENT NARRATIVE: Add participants Jay Tucker and Timothy Trautman

Data Sources

Data Storage Location *

- VINCI
- Local VA Server Location

Name of facility *

Address *

Building

Room #

Amend a DART



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

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)

Amend a DART



- 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)

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



Amend a DART

 Data Access Request Tracker (DART) Welcome Simpson, Ronald

2017-07-001-D-A01 Amend a DART

AMENDMENT NARRATIVE: Add participants Jay Tucker and Timothy Trautman

2017-07-001-D-A01 Research Request Memo-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload V2 - Uploaded 12/01/17 03:25PM by Simpson, Ronald D.

Documents

NOTICE: Always check the Data Steward's web site ([DART Process and Forms](#)) for the latest version of forms. Outdated forms will not be accepted. If a required document is actually several documents, such as an IRB and a Continuing IRB, combine them into one document before uploading. When you are required to replace documents after submission, it is easier for the reviewer if you replace all the documents that are changing at one time.

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	2017-07-001-D-A01 Research Request Memo-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload V2 - Uploaded 12/01/17 03:25PM by Simpson, Ronald D.
Research Study Institutional Review Board (IRB) Approval Letter Required for CDW Production Domains, Vital Status	2017-07-001-D IRB Letter-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload V1 - Uploaded Jul 7 2017 4:00PM by Simpson, Ronald D.
Research and Development (RD) Committee Approval Letter Required for CDW Production Domains, Vital Status	2017-07-001-D RD Letter-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload V1 - Uploaded Jul 7 2017 4:00PM by Simpson, Ronald D.
IRB Approval of Waiver of HIPAA-Compliant Authorization Required for CDW Production Domains, Vital Status	2017-07-001-D Waiver of HIPAA Auth-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload V1 - Uploaded Jul 7 2017 4:00PM by Simpson, Ronald D.

Amend a DART



Research Protocol
Required for CDW Production Domains, Vital Status

2017-07-001-D Research Protocol-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload
V1 - Uploaded Jul 7 2017 4:00PM by Simpson, Ronald D.

CDW-Domain Checklist
Required for CDW Production Domains

2017-07-001-D CDW-Domain Checklist-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload
V1 - Uploaded Jul 7 2017 4:00PM by Simpson, Ronald D.

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

2017-07-001-D Real SSN Access Request-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload
V1 - Uploaded Jul 7 2017 4:00PM by Simpson, Ronald D.

➤ Simpson, Ronald D. (Primary Investigator)

Vital Status Rules of Behavior
Required for Vital Status

2017-07-001-D Vital Status ROB-Simpson, Ronald D..docx (View) Upload
V1 - Uploaded Jul 7 2017 4:00PM by Simpson, Ronald D.

➤ Trautman, Timothy N.

Vital Status Rules of Behavior
Required for Vital Status

2017-07-001-D-A01 Vital Status ROB-Trautman, Timothy N..pdf (View) Upload
V1 Uploaded 12/01/17 03:25PM by Simpson, Ronald D.

2017-07-001-D-A01 Vital Status ROB-Trautman, Timothy N..pdf (View) Upload
V1 Uploaded 12/01/17 03:25PM by Simpson, Ronald D.

➤ Tucker, Jay N.

Vital Status Rules of Behavior
Required for Vital Status

2017-07-001-D-A01 Vital Status ROB-Tucker, Jay N..pdf (View) Upload
V1 Uploaded 12/01/17 03:26PM by Simpson, Ronald D.



Amend a DART

The screenshot displays the DART web application interface. At the top, a blue header contains the VINCI logo and the text "Data Access Request Tracker (DART)". On the right side of the header, a user profile icon is followed by the text "Welcome Simpson, Ronald D".

Below the header, a breadcrumb trail reads "HOME > DART Dashboard > Requests". A "DART User Guide" button is located in the top right corner of this section.

The main content area features a navigation bar with five tabs: "Information", "Participants", "Data", "Documents", and "Submit". The "Submit" tab is currently selected and highlighted in blue. To the right of the navigation bar are two icons: a clock labeled "History" and a speech bubble labeled "Communication".

The main content area displays the following information:

- A header for the current request: "2017-07-001-D-A01 Amend a DART".
- A light blue box containing the text: "AMENDMENT NARRATIVE: Add participants Jay Tucker and Timothy Trautman".
- A large green checkmark followed by the text "Submit".
- A section titled "SUBMIT REQUEST" containing a yellow box with a green message: "Request form complete! You may now submit your request." and a close button (X).
- A blue button labeled "Submit Request".
- Navigation buttons at the bottom: "← Previous" and "Next →".

DART 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)
- CDW Domain Checklist
- Any additional data source specific forms
- Forms can be found on the VHA Data Portal:

<http://vaww.vhadatportal.med.va.gov/DataAccess/DARTRequestProcess.aspx>

Research Request Memo

**Department of
Veterans Affairs**

Memorandum

Date:

From: Principal Investigator

Subj: Research Data Request Memo for:

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 / VistAWeb being requested? Yes No
- Is AITC Main Frame access 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

Research Request Memo

Will the data be stored in the VINCI Environment? Yes No Both

Describe where the data will be stored within the VA network by providing the following information:

Facility/Company Name

Building Number Room Number

Street Address

City State Zip Code

Country

Please address the following five items in the body of the memo below:

1. Describe how the data will be transferred, (i.e. electronic, cd, etc.) between the Transferring Agency and Custodian and the methods that you will take to secure the transmission of the data.
2. Describe how the data will be securely retained with the Custodian's network.
3. Describe how and by whom the data will be accessed.
4. Describe how long the data will be retained after project completion and how the data will be destroyed.
5. Describe how you will maintain an auditing of the activity (users and location) of the data.

Research Request Memo

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.
Provide a high level summary of how the requested data will be used in the research study.
If Real SSN access is requested, please provide a justification.
List the participants names and whether they are VA Employee, Contractor, or Without Compensation

June 2017

(WOC).




Estimated time the data will be needed for:

Research Request Memo

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	
<input type="text"/>	<input type="text"/>	
NAME AND TITLE OF SUPERVISOR	DATE SIGNED	
<input type="text"/>	<input type="text"/>	
ISO Verification of Training and Account Status		
NAME OF INFORMATION SECURITY OFFICER	DATE SIGNED	
<input type="text"/>	<input type="text"/>	

IRB Approval Letter

- Can come from the CIRB or locally
- IRB letters are not standardized across the VA
- Key Items needed:
 - PI Name
 - Study Name
 - Approval Date
 - Expiration Date
 - Signed by the Chair of the IRB

Research and Development Committee Approval Letter

- 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 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

HIPAA Informed Consent/Authorization or Waiver

- HIPAA Waivers are not standardized across the VA
 - VA Facility Name
 - Station Number
 - Title of Study
 - PI Name
 - Brief description of PHI used for IRB
 - Must have Chair of IRB Signature
- Form 10-0521 is available for use

Real SSN Access Request Form

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.

Section A. Principal Investigator

Principal Investigator:

Project Name:

Check the boxes below that indicate why this project requires access to data with real SSNs. Include the page number where this information is located in the protocol.



- | | | | |
|--|-------------------------|--|-------------------------|
| <input type="checkbox"/> Link to primary data collection | p. <input type="text"/> | <input type="checkbox"/> Use of VA data available <u>only</u> with real SSNs | p. <input type="text"/> |
| <input type="checkbox"/> Recruit subjects | p. <input type="text"/> | <input type="checkbox"/> Link to non VHA data sources (specify) <input type="text"/> | p. <input type="text"/> |
| <input type="checkbox"/> Use VistAWeb, CAPRI, TIU Notes | p. <input type="text"/> | <input type="checkbox"/> Other reason (describe) <input type="text"/> | p. <input type="text"/> |

I affirm the reasons checked above are consistent with the protocol submitted for IRB approval.

Signature, Principal Investigator

Date

Real SSN Access Request Form

Section B. IRB Chair

Name of IRB Chair:

Project's IRB #:

IRB Committee Affiliation Name:

Check the boxes below to indicate which documents have been submitted and approved for this project. At least three boxes must be checked "yes" - Protocol, HIPAA Authorization and/or Waiver of HIPAA Authorization, and Informed Consent and/or Waiver of Informed Consent.

Protocol	<input type="checkbox"/>	Yes							
HIPAA Authorization	<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Waiver of HIPAA Authorization	<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A
Informed Consent	<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A	Waiver of Informed Consent	<input type="checkbox"/>	Yes	<input type="checkbox"/>	N/A

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.

Signature, IRB Chair

Date

Real SSN Access Request Form

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

Name of ACOS-R:

VA Facility Name:

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.

Signature, ACOS-R

Date

Note: Electronic or hand written signatures are accepted

VA Information Resource Center
February, 2015



CDW Domain Checklist

CDW DOMAIN CHECKLIST

Research Protocols typically request data from the CDW Patient Domain within the Patient and/or SPatient file. Please Select one or both of the following:

Patient

SPatient

CDW Production

- Allergy
- Appointment
- Consult
- CPRS Orders
- Dental
- Emergency Dept. Int. Software (EDIS)
- Health Factors
- Health Benefits Request
- Immunization
- Inpatient
- Lab Microbiology
- Lab Chem
- Mental Health Assessment
- Non-VA Meds
- Outpatient
- Patient Associated
- Patient Enrollment
- Patient Insurance
- Patient Record Flag
- PCMM (Primary Care Management Module)
- Pharmacy BCMA (Bar Code Medication Administration)
- Pharmacy Outpatient
- Pharmacy Patient
- Purchased Care (formerly fee)
- Recall Reminders

CDW RAW*

- Beneficiary Travel
- Bill Claims (CBO)
- CAPRI Audit Trail table
- CliniComp
- Echocardiogram
- Equipment Inventory
- FBCS (Fee Basis Claim System)
- IFCAP (Integrated Funds Control, Accounting, and Procurement)
- Intravenous meds (IV)
- Oncology
- Prosthetics
- Pulmonary Function Test (PFT)
- Radiology
- TMS
- Unit Dose (Pharmacy)
- VACAA (Veterans Choice Program Eligibility)

**CDW Raw data is data that has been pulled directly from the VistA sites and the data has not been verified or had business rules applied. It may not be current and there is limited documentation for users. Requests for CDW Raw data require additional time for creating data extracts and it is more difficult for studies to use.*

CDW Domain Checklist

- Reengineered Primary Care Management Module (RPCMM)
- Staff
- SStaff
- Surgery PRE, INTRA, and POST(select SQDUG option in DART Data Source Page)
- VistA Waitlist
- VistA Compensation & Pension
- Vital Signs
- Women's Health

Other Data

- Lung Cancer Screening Demonstration Cohort
- OMOP Common Data Model v5 (CDW Production/Raw Source)
- PSSG Geocoded Files
- SAS Fee (Formerly HERC FEE)
- VINCI NLP Output

For additional information about the domains, please refer to the link below:

<http://vaww.virec.research.va.gov/CDW/Documentation.htm>

CDW Checklist V 5.0 June 7, 2017. This document revision supersedes any previous versions.

CAPRI/JLV Access Form

Department of Veterans Affairs		RESEARCH ACCESS TO VHA ELECTRONIC HEALTH RECORDS	
User Information			
1. Last Name, First Name, Middle Name, Suffix		2. VA E-Mail Address	
3. Job Title	4. Work Phone (Include Area Code)	5. Station (Facility) Number	
6. Full Social Security Number	7. Date of Birth (MM/DD/YYYY)	8. ISO Name	9. ISO E-Mail Address
10. Protocol Name		11. DART Tracking Number	
12. IRB Approval Date (MM/DD/YYYY)	13. IRB Expiration Date (MM/DD/YYYY)	14. Cooperative Studies Program Number (CSP#)	
Special User Access Requested for:			
<input type="checkbox"/> CAPRI <input type="checkbox"/> Joint Legacy Viewer (JLV)			
Level of Access			
<input type="checkbox"/> National <input type="checkbox"/> Site Restricted List			
<p>By signing below, I affirm that I will notify National Data Systems (NDS) of any change in my position or duties as related to this protocol. I also affirm that I will stay current on the required training to view Protected Health Information (PHI). I acknowledge that user access to this data will be restricted to what is approved for this protocol. Data will not be reused or shared with other research projects unless specifically authorized in the protocol and approved by the Institutional Review Board (IRB). Once the storage location of the data is approved, I will not move the data to other locations unless specifically authorized by National Data Systems.</p> <p>It is the responsibility of BOTH the user and the supervisor to ensure training is completed every 365 days.</p>			
Approval			
NAME OF INDIVIDUAL REQUESTING ACCESS	DATE SIGNED (MM/DD/YYYY)	SIGNATURE	
NAME AND TITLE OF PRINCIPAL INVESTIGATOR	DATE SIGNED (MM/DD/YYYY)	SIGNATURE	
NAME OF APPROVING AUTHORITY (ACOS-R or COS)	DATE SIGNED (MM/DD/YYYY)	SIGNATURE	



Tips and tricks

- When do I need to update a new Research Request Memo?
- Are Digital Signatures required?
- Who signed line items 22 and 23 on the CAPRI/JLV access form?
- If you are not sure on an item, contact us

Did You Know About Our Resources?

- Available only on VA Intranet
- VINCI Central -
<https://vaww.vinci.med.va.gov/vincicentral/>
- VHA Data Portal - DART -
<http://vaww.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx>
- CDW Metadata Documentation on Data Sources -
<https://vaww.cdw.va.gov/metadata/Metadata%20Documents/Forms/AllItems.aspx>
- CDW Documentation on Data Sources from VIREC -
<http://vaww.virec.research.va.gov/CDW/Documentation.htm>

Questions?

VINCI@va.gov

