Data Access Request Tracker (DART): Amend a DART, Paperwork and Tips

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DART-Data Access Request Tracker

■ Follow me as we dive deeper into DART

- Amend a DART Demo
  - Also see [Amending a DART IRB Research Request](#) video on VINCI Central

- Discuss main forms needed for IRB Research Studies in DART
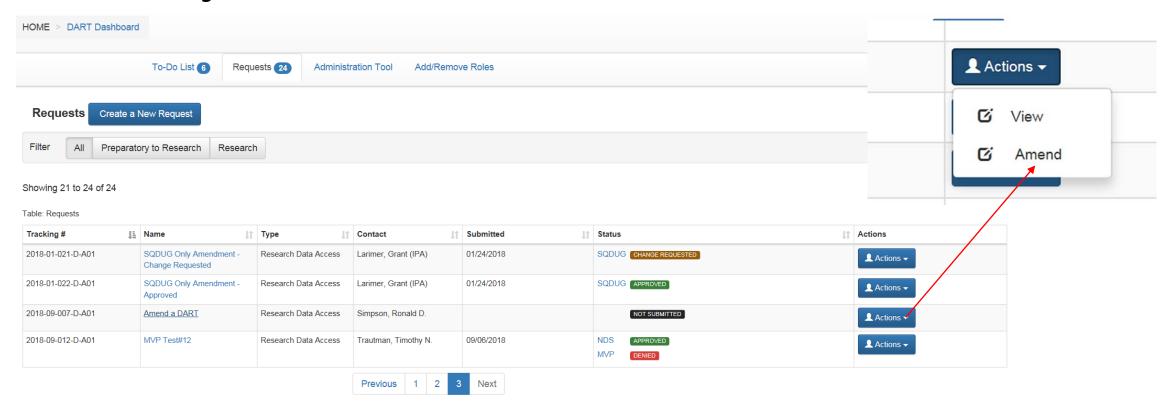
- Questions and Answers

Poll

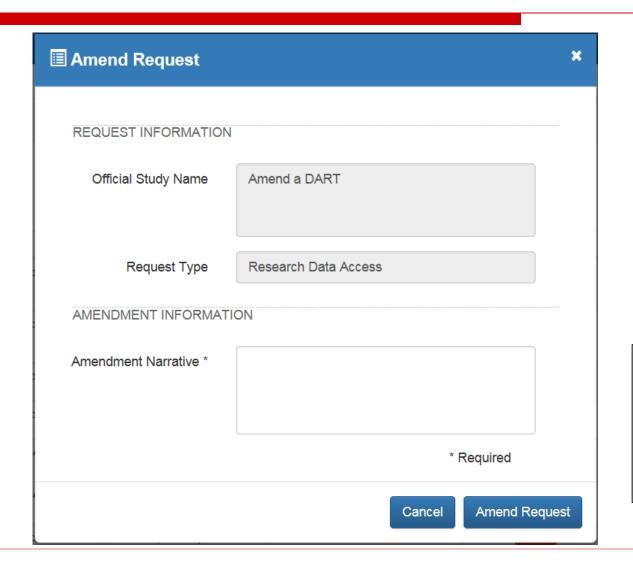- How familiar are you with amending a DART request?

  - I submit them often
  - I watched someone amend a DART request
  - I have never amended a DART request
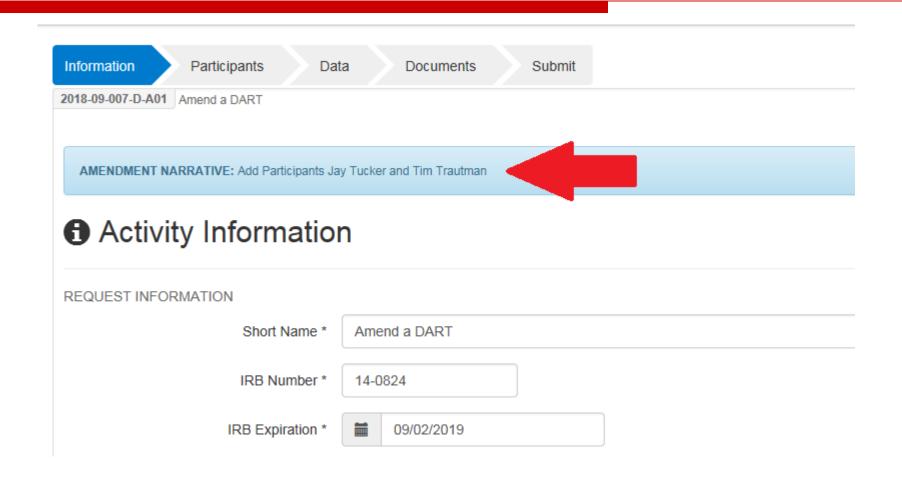 - I would like to learn what is needed to amend a DART request

Amend a DART

■ Start at your DART Dashboard

Amend a DART

Contact VINCI@va.gov to change an amendment narrative.

Amend a DART

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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

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)
- ☐ Veterans Affairs Surgical Quality Improvement Program (VASQIP)
- ☐ VSSC Web Reports
- ☐ Million Veteran Program (MVP) - Available only to MVP approved studies

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

2018-09-007-D-A01 | Amend a DART

AMENDMENT NARRATIVE: Add Participants Jay Tucker and Tim Trautman

📄 Documents

NOTICE: Always check the Data Steward's web site (DART Process and Forms) for the latest version of forms. Outdated (Salt Lake City UT).pdf (View) Upload
IRB, combine them into one document before uploading. When you are required to replace documents after submission,

2018-09-007-D-A01 Research Request Memo-(660) Salt Lake City HCS (Salt Lake City UT).pdf (View) Upload
V3 ⌄ *Uploaded Sep 5 2018 2:47PM by Simpson, Ronald D.*

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

2018-09-007-D-A01 Research Request Memo-(660) Salt Lake City HCS (Salt Lake City UT).pdf (View) Upload
V3 ⌄ *Uploaded Sep 5 2018 2:47PM by Simpson, Ronald D.*

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

2018-09-007-D IRB Letter-(660) Salt Lake City HCS (Salt Lake City UT).docx (View) Upload
V1 ⌄ *Uploaded Sep 5 2018 2:25PM by Simpson, Ronald D.*

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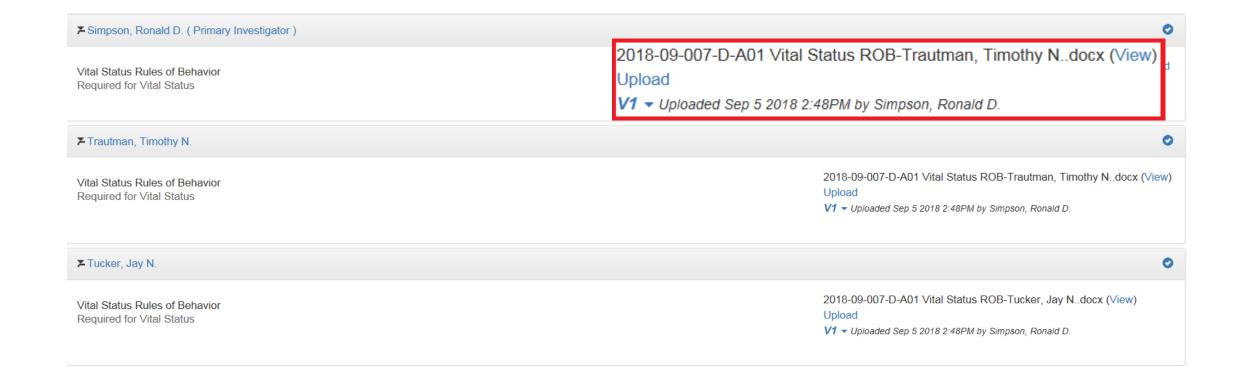Required for CDW Production Domains, Vital Status

2018-09-007-D RD Letter-(660) Salt Lake City HCS (Salt Lake City UT).pdf (View) Upload
V1 ⌄ *Uploaded Sep 5 2018 2:25PM by Simpson, Ronald D.*

Amend a DART

Amend a DART

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.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx

Research Request Memo

Memorandum

Department of Veterans Affairs

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 / 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

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 (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	

February 2018

RRM instructions are in Appendix A of the DART User Guide.

IRB Approval Letter

- Can come from the CIRB, local VAMC or University Affiliate

- IRB letters are not standardized across the VA
  - IRB letters are needed from each site

- 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
- Use the most up to date Protocol

HIPAA Informed Consent/Authorization or Waiver

- HIPAA Waivers are not standardized across the VA
  - VA Facility Name
  - 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.

☐ Link to primary data collection   p. ▢   ☐ Use of VA data available _only_ with real SSNs   p. ▢
☐ Recruit subjects   p. ▢   ☐ Link to non VHA data sources (specify) ▢   p. ▢
☐ Use VistAWeb, CAPRI, TIU Notes p. ▢   ☐ Other reason (describe) ▢   p. ▢

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

_____   _____
Signature, Principal Investigator   Date

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   ☐ Yes
HIPAA Authorization   ☐ Yes   ☐ N/A   Waiver of HIPAA Authorization   ☐ Yes   ☐ N/A
Informed Consent   ☐ Yes   ☐ N/A   Waiver of Informed Consent   ☐ Yes   ☐ 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

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

VINCI

CDW Domain Checklist

CDW DOMAIN CHECKLIST

CDW Production
- Allergy
- Appointment
- Beneficiary Travel
- Consult
- CPRS Orders
- Dental
- Emergency Dept. Int. Software (EDIS)
- Health Factors
- Health Benefits Request
- Immunization
- Inpatient
- Integrated Billing
- Lab Microbiology
- Lab Chem
- Mental Health Assessment
- Non-VA Meds
- Outpatient
- Patient
- 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)
- Radiology
- Recall Reminders
- Reengineered Primary Care Management Module (RPCMM)
- SPatient
- Staff
- SStaff
- Surgery PRE, INTRA, and POST
- VistA Waitlist
- VistA Compensation & Pension
- Vital Signs
- Women's Health

CDW RAW*
- 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)
- Talent Management System (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.

Other Data
- Department of Defense and Department of Veterans Affairs Infrastructure for Clinical Intelligence (DAVINCI)
- Lung Cancer Screening Demonstration Cohort
- OMOP Common Data Model (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 6.1 June 26, 2018. 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:

☐ **CAPRI**
☐ **Joint Legacy Viewer (JLV)**

Level of Access

☐ **National**
☐ **Site Restricted List**

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.

It is the responsibility of BOTH the user and the supervisor to ensure training is completed every 365 days.

Approval

NAME OF INDIVIDUAL REQUESTING ACCESS	DATE SIGNED (MM/DD/YYYY)	
NAME AND TITLE OF PRINCIPAL INVESTIGATOR	DATE SIGNED (MM/DD/YYYY)	
NAME OF APPROVING AUTHORITY (ACOS-R or COS)	DATE SIGNED (MM/DD/YYYY)	

For CAPRI/JLV access, you will need Real SSN approval.

Tips and tricks

- **When do I need to update a new Research Request Memo?**
  - Be VERY specific in the amendment narrative of exactly what is being changed.
- **Are Digital Signatures required?**
- **What is a Change Request and how do I see it?**
- **I changed my last name. How do I update it in DART?**
- **I moved stations. How do I update this in DART?**
- **How long do amendments take for approval?**

VINCI

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

Before VINCI

After VINCI