Requesting Research Data Access Using DART

Tim Trautman

Health Research Science Specialist & DART Program Manager





Request data access with DART

- DART is the <u>Data Access Request Tracker</u> online application used by Data Stewards (owners) 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
- Also for Preparatory to Research requests



Poll #1

(choose all applicable)

- I want to request data for Research
- I want to request data for Preparatory to Research
- I want to learn more about using DART
- I'm just curious about DART



Typical 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)
- Any additional data source specific forms
- Forms can be found on the VHA Data Portal

http://vaww.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx



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

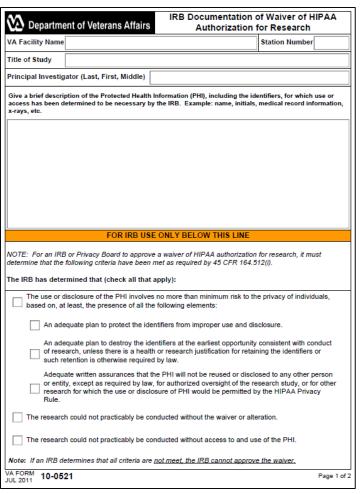


Institutional Review Board (IRB) Letter

- 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
- If using VINCI for data storage, add to IRB:
 - VINCI Description for IRBs
 - VINCI Information Security Description



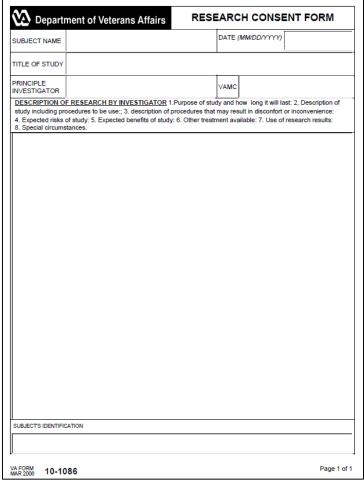
Waiver of HIPAA Authorization



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



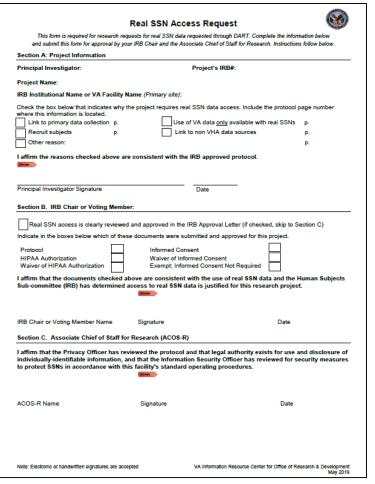
Sample Informed Consent & HIPAA Authorization



- 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)



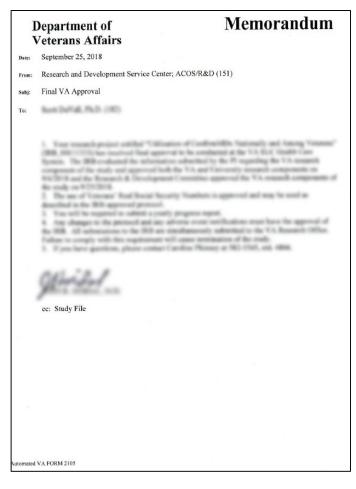
Real SSN Access



- 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</u> page.



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

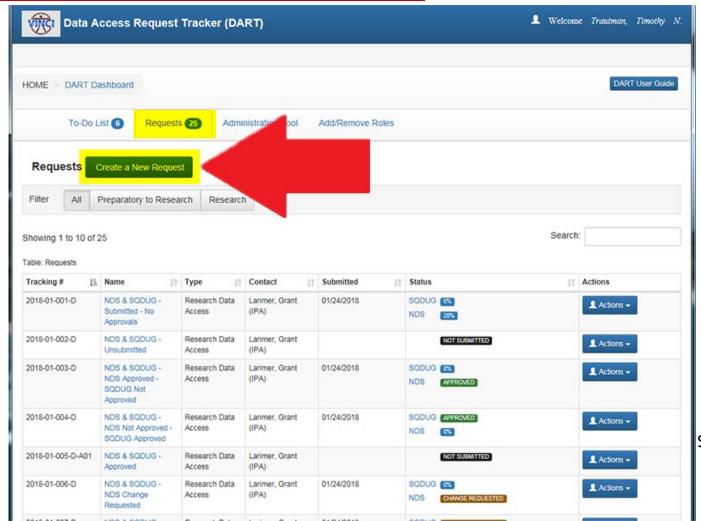


Research Request Memo

| Depa | artment of | | Men | norar | ndum | | | |
|---|----------------------------|-------------|----------------------|---------------|-----------|--|--|--|
| Veterans Affairs | | | | | | | | |
| Date: | | | | | | | | |
| From: | Principal Investigator | "Insert Nam | e of Principal Inves | stigator" | | | | |
| Subj: | Research Data Reques | t Memo for: | "Tracking Numbe | r - Name of F | 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? | | | | | | | | |
| A. 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. B. Provide a high level summary of how the requested data will be used in the research study. C. If Real SSN access is requested, please provide a justification. D. List the participants names and whether they are VA Employee, Contractor, or Without Compensation (WOC). | | | | | | | | |
| Estima | ated 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 P | RINCIPAL INVESTIGATOR | | | DATE SIGNED | BDH KM | | | |
| NAME AND | TITLE OF SUPERVISOR | | | DATE SIGNED | HP: KN | | | |
| Marc | ch 2019 | | | | | | | |

- 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

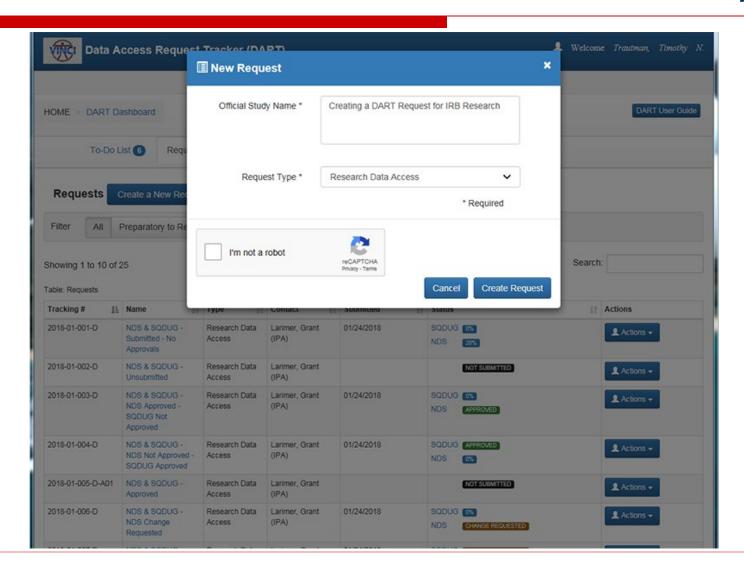




See a quick movie

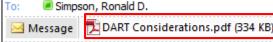








[WARNING: A/V UNSCANNABLE]DART 2017-03-005-D has been Initiated - Please Read Before Submitting This Request - Do Not Reply dart@va.gov Sent: Wed 3/22/2017 3:24 PM



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.

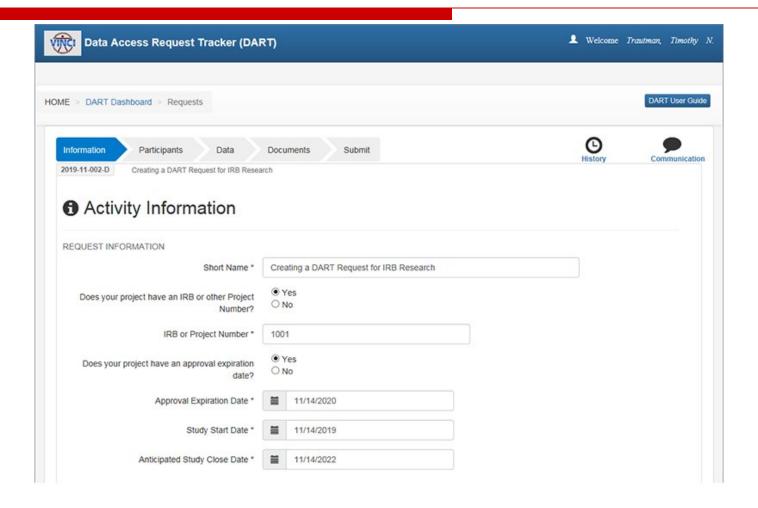
The attached document provides links to helpful resources, considerations to take into account when requesting data access, and what to expect. The DART User Guide provides complete details about how to use DART. If you need assistance with completing the DART request or have questions, please contact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

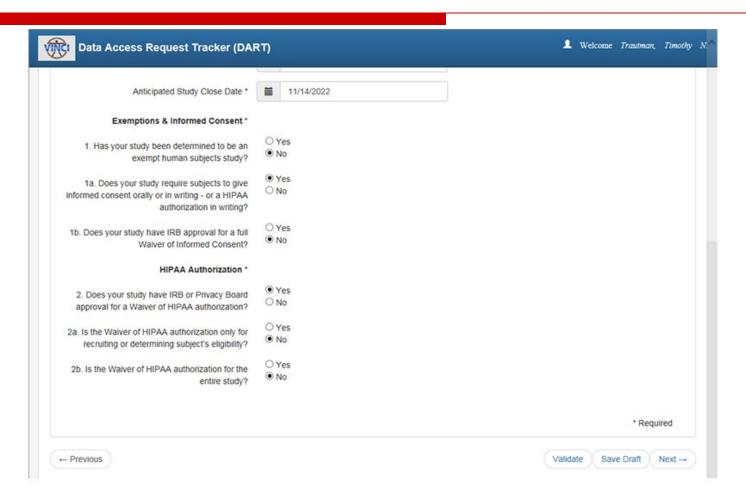
Sincerely,

The DART Team

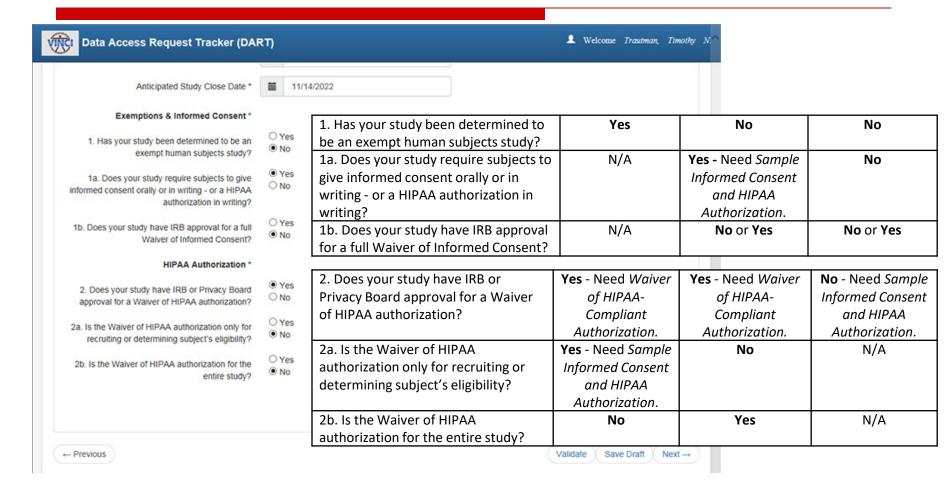




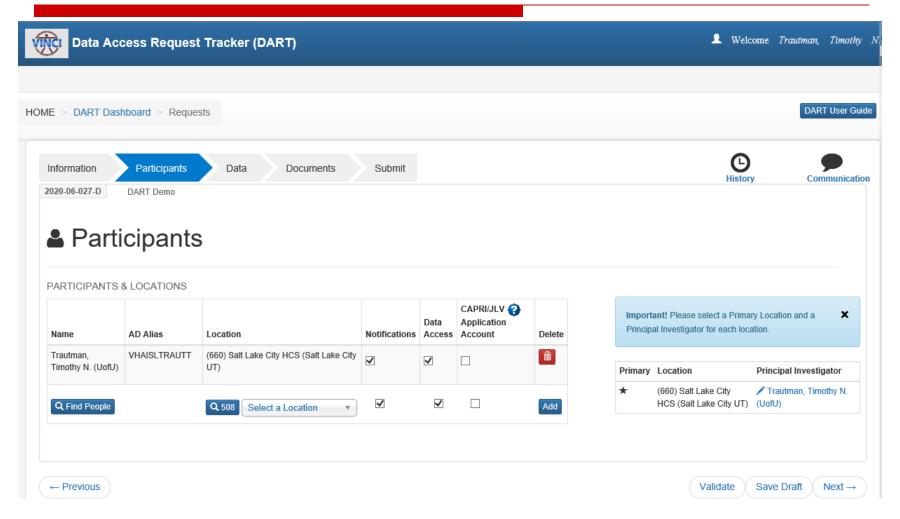




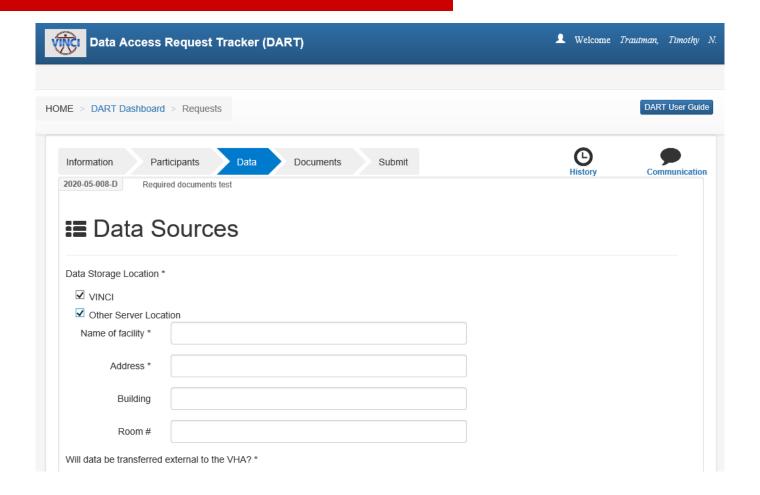














| Will data be transferred extern | nal to the VHA? * | | | | | | |
|---|---|--|--|--|--|--|--|
| consent and HIPAA author "finder" files are to be sent | rove a research request that would include disclosing the CDW data (identifiable or de-identified) outside of VHA without a signed research ization from the individual because of the risk of re-identification. The data may be used (internally or within VHA) for the approved protocol. If 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 are PI and the external agency must be submitted with the DART application. | | | | | | |
| ○ No • Yes (DUA is required) | | | | | | | |
| Name of Company/Agency* | | | | | | | |
| Street * | | | | | | | |
| City * | | | | | | | |
| State * | | | | | | | |
| Zip Code * | | | | | | | |
| Data Access Systems | | | | | | | |
| ☐ SAS Grid | | | | | | | |
| IDENTIFIERS (More about id | entifiers) | | | | | | |
| □ Real SSN | | | | | | | |
| □ Scrambled SSN | | | | | | | |
| ☐ Identifiable data but no real or scrambled SSNs | | | | | | | |

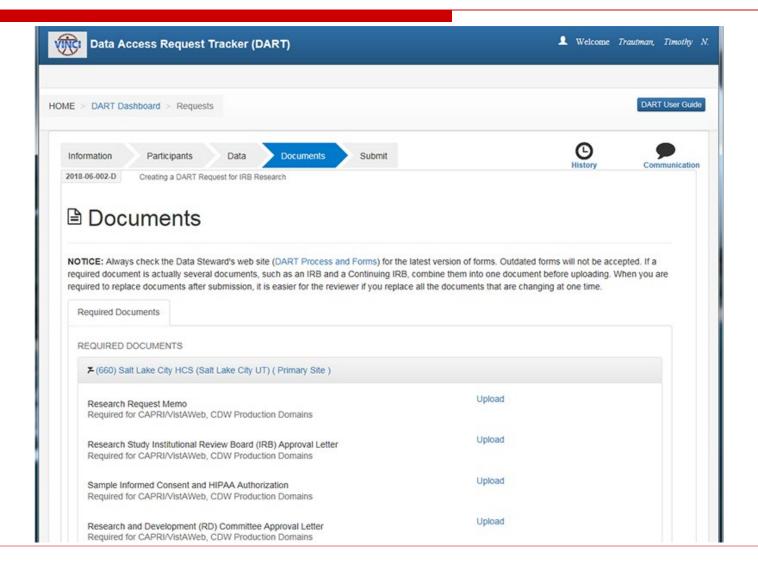


| REQUESTED DATA SOURCES | | | | |
|---|--|--|--|--|
| □ ADUSH Enrollment Files | | | | |
| ☐ Bereaved Family Survey | | | | |
| CAPRI & Joint Legacy Viewer (JLV) - Individuals needing system access are selected on the Participants page and require Real SSN approval | | | | |
| ☐ Care Assessment Need Score (CAN Score) - Scrambled SSN approval required | | | | |
| ☐ Clinical Assessment Reporting and Tracking (CART) CV | | | | |
| Corporate Data Warehouse (CDW) | | | | |
| ☐ Production Domains | | | | |
| ☐ Raw Domains | | | | |
| ☐ Text Integration Utility (TIU) Text Notes - Real SSN approval required | | | | |
| ☑ COVID-19: Shared Data Resource | | | | |
| □ DoD-VA Infrastructure for Clinical Intelligence (DAVINCI) | | | | |
| Geriatrics and Extended Care (GEC) | | | | |
| □ RAI/MDS | | | | |
| Health Economics Resource Center (HERC) Cost Data - Includes Average Cost Data, V21 and Nosos Risk Scores, and Discharge Data Sets with Subtotals | | | | |
| ☐ Homeless Veterans Registry (Disclaimer) | | | | |
| ☐ Lung Cancer Screening Demonstration Project (LCSDP) Cohort | | | | |
| Managerial Cost Accounting (MCA) | | | | |
| □ National Data Extracts (NDEs) | | | | |
| ☐ Web Reports - Real SSN approval required | | | | |
| ☐ Medical SAS Files & VETSNET File - CDW SQL tables | | | | |

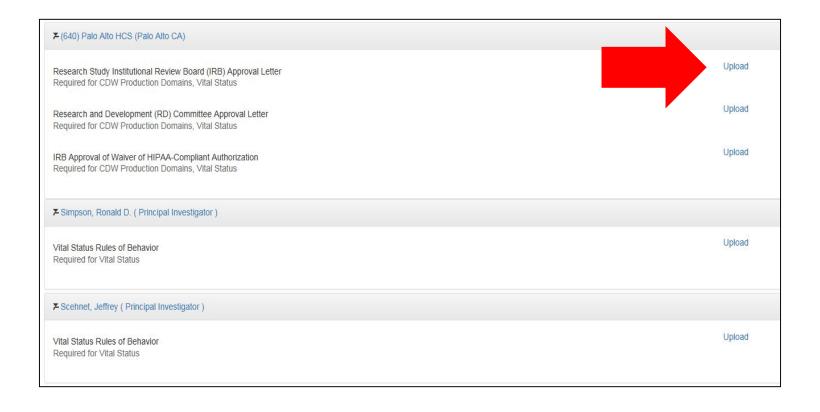


| ☐ Million Veteran Program (MVP) - Available only to MVP approved studies | |
|--|----------------------------|
| ☐ Million Veteran Program (MVP) plus Vital Status Files - Available only to MVP approved studies | |
| OMOP Common Data Model | |
| □ VA Corporate Data Warehouse | |
| □ DAVINCI DoD-VA | |
| ☐ Patient Aligned Care Team Implementation Index (PACT Pi2) | |
| ☐ PSSG Geocoded Enrollee Files | |
| ☐ SAS Fee (Disclaimer) | |
| ☐ Traumatic Brain Injury Screening and Evaluation Data | |
| VA Surgical Quality Improvement Program (VASQIP) - Real SSN or Scrambled SSN only | |
| ☐ Cardiac variables | |
| ☐ Non-cardiac variables | |
| VINCI Natural Language Processing (NLP) Output | |
| ☐ Ejection Fraction | |
| ☐ Vital Status File (VSF) - CDW SQL tables which includes BIRLS date of birth, date of death, and gender | |
| □ VSSC Self-Service Web-Based Products | |
| | |
| | * Required |
| ← Previous | Validate Save Draft Next → |











➤ (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

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.

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.

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.

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.

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.

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.

2017-03-005-D CDW-Domain Checklist-(660) Salt Lake City HCS (Salt

Lake City UT).docx (View) Upload

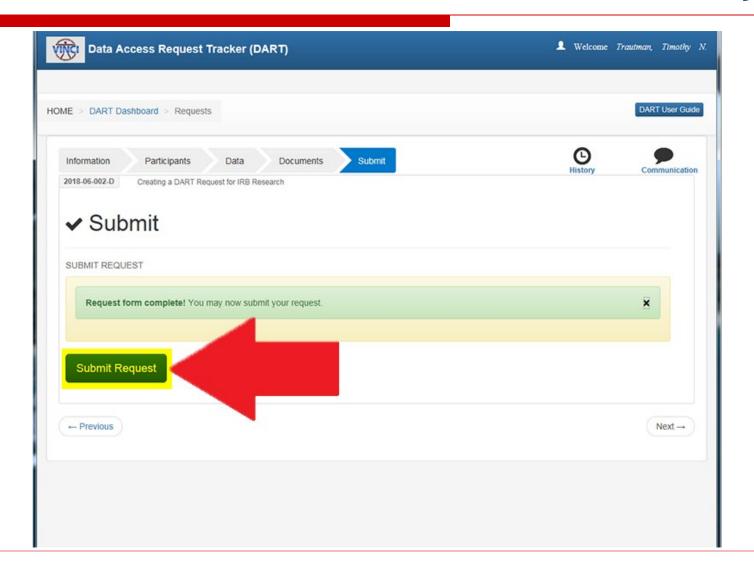
V1 Uploaded 03/22/17 06:55PM by Simpson, Ronald D.

2017-03-005-D Real SSN Access Request-(660) Salt Lake City HCS

(Salt Lake City UT).docx (View) Upload

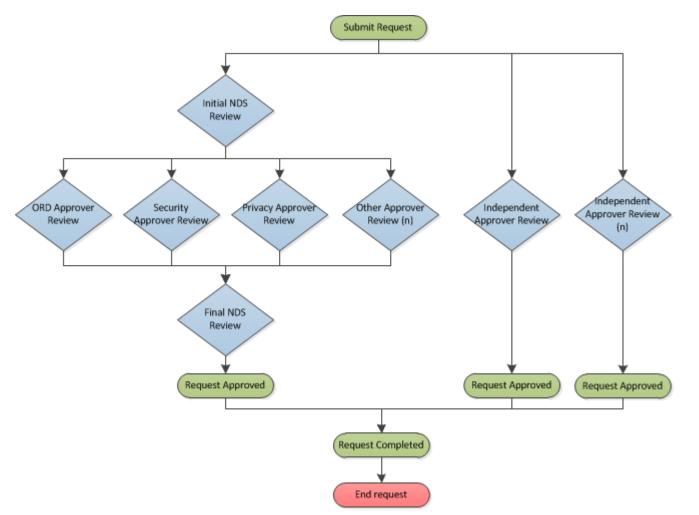
V1 Uploaded 03/22/17 06:55PM by Simpson, Ronald D.

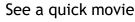






DART Processing - Avg. 14 Days









Poll #2

Do you know that DART can be used to request the COVID-19 Shared Data Resource for Research and Preparatory to Research?

- Yes
- No

COVID-19 Shared Data Resource SharePoint site



Tips and Tricks

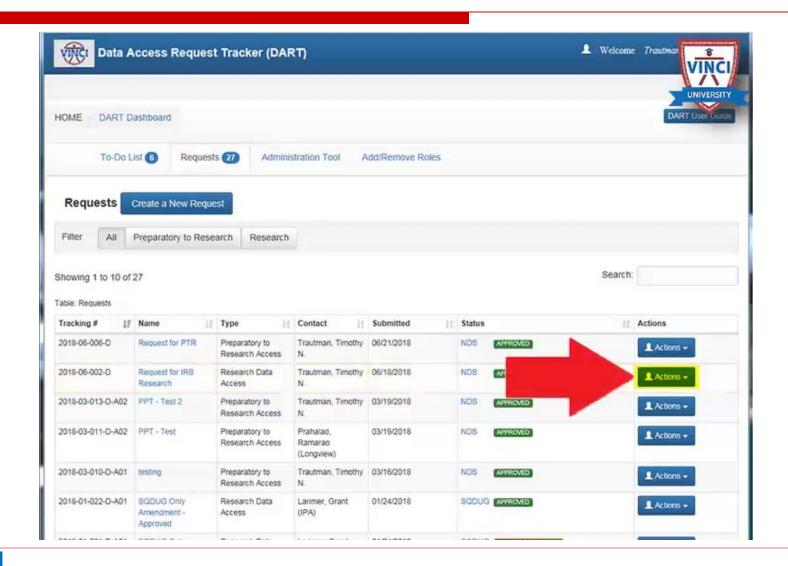
- When do I need to update the Research Request Memo?
 - When changing Participants, adding Data Sources, or adding a Data Storage Location.
 - Be VERY specific in the amendment narrative of exactly what is being changed.
- Are Digital Signatures required?
 - No, but are generally more convenient.
- What is a Change Request and how do I see it?
 - You will receive an email notice from DART.
 - Request appears in your To-Do list.



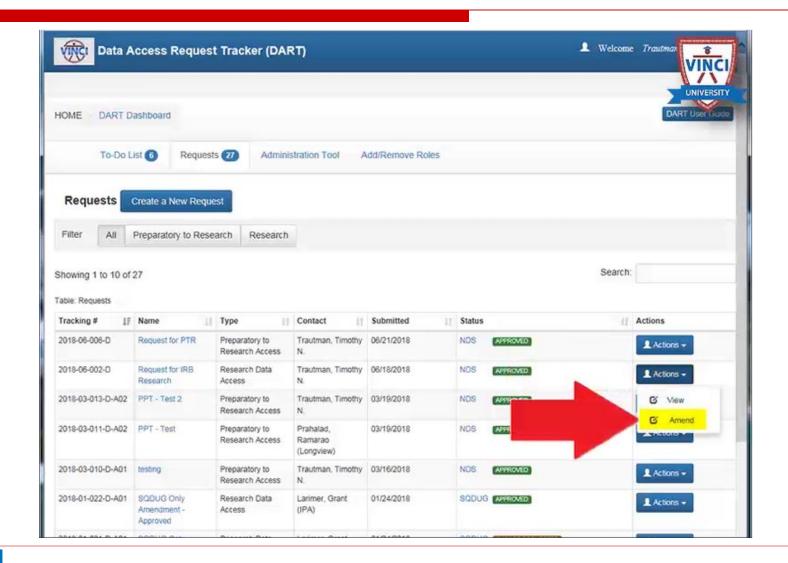
Tips and Tricks

- I changed my last name. How do I update it in DART?
 - In an amendment, have another Participant remove your old identity and add back your new identity.
- I moved stations. How do I update this in DART?
 - In an amendment, have another Participant remove your old identity and add back your new identity.
- How long do amendments take for approval?
 - Average of 6 days.
- Do not reply to emails from DART, reply to the reviewer in your DART request using Communications function.

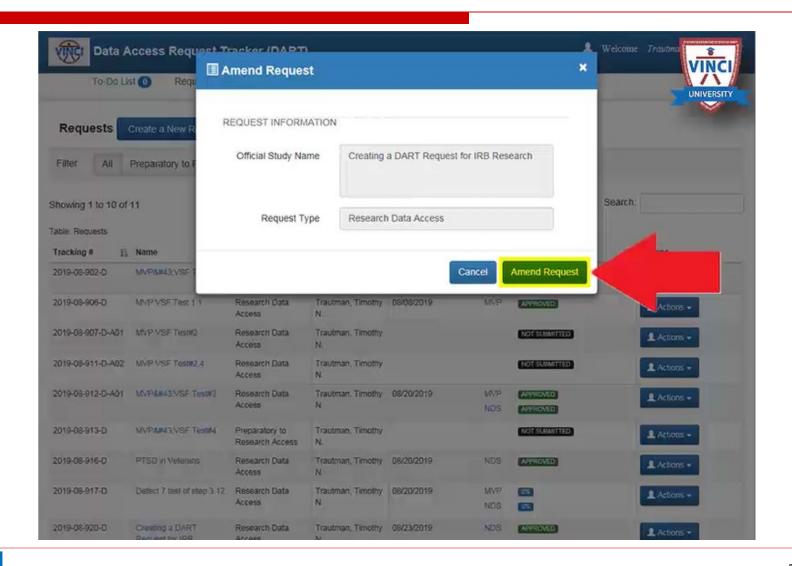




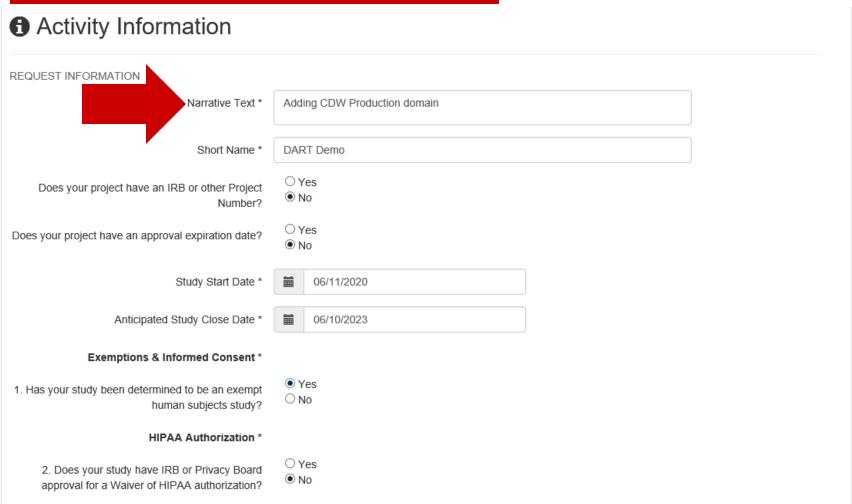














DART Resources

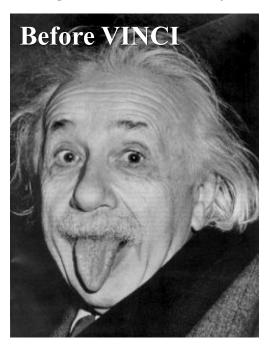
- DART videos on <u>VINCI Tube</u>
- DART Considerations in <u>VINCIpedia</u>
- DART pages in VHA Data Portal

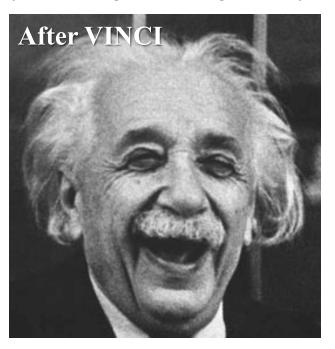


Questions?

VINCI@va.gov

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





Stay safe and healthy everybody!

