

Conducting a Research Study Using VINCI

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Basic Steps of a VINCI Study

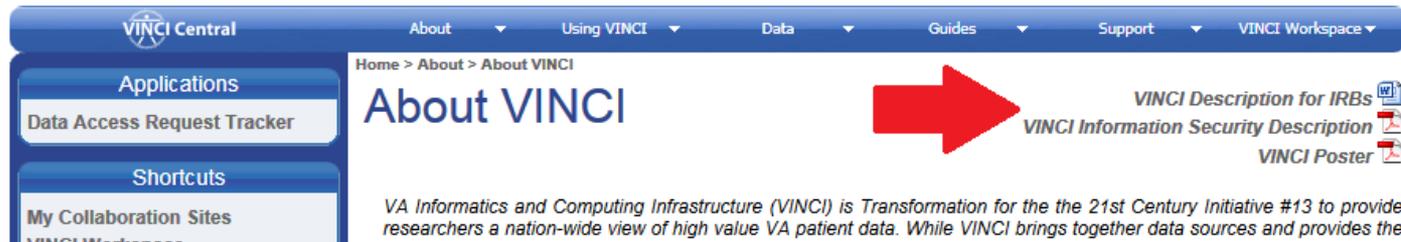
1. Create your protocol and get IRBs
2. For Real SSN - IRB signs Real SSN Access form
3. Get VINCI Concierge assistance
 - a) Data Needs Assessment
 - b) Project Needs Assessment
 - c) VA Form 9957
4. Initiate your DART request and submit
5. VINCI provisioning
6. Use the VINCI Workspace
7. Optional training

- *A VINCI Concierge can assist at any time by contacting VINCI@va.gov with your request*



1. Create your Protocol and get IRB

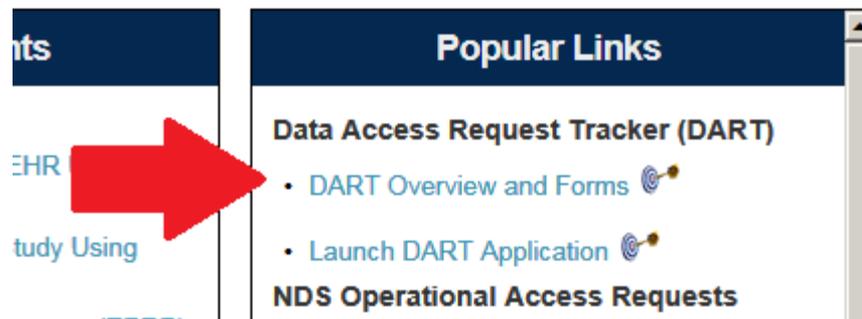
- Create your protocol
- Get HIPAA waiver or Patient Consent
- Get your IRB - you will need an IRB from each location where an investigator is involved
- Use VINCI Description for IRBs
- Use VINCI Information Security Description in IRB



The screenshot shows the VINCI Central website interface. The top navigation bar includes links for 'About', 'Using VINCI', 'Data', 'Guides', 'Support', and 'VINCI Workspace'. The main content area is titled 'About VINCI' and features a red arrow pointing to the 'VINCI Description for IRBs' link. Other links visible include 'VINCI Information Security Description' and 'VINCI Poster'. The footer contains a paragraph of text: 'VA Informatics and Computing Infrastructure (VINCI) is Transformation for the the 21st Century Initiative #13 to provide researchers a nation-wide view of high value VA patient data. While VINCI brings together data sources and provides the'.

2. 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 from Popular Links on home page at vaww.vhadataportal.med.va.gov



3a. Get a Data Needs Assessment

- A Data Needs Assessment helps studies determine what data to request and if it is available from VINCI/CDW
- Send VINCI@va.gov all information you have on the data points you are looking for - including protocol helps
- VINCI reviews and recommends data sources
- Takes 3-5 business days

3b. Get a Project Needs Assessment

- A Project Needs Assessment helps studies determine a step-by-step course of action, required and optional elements for establishing and conducting a study, documentation, timelines, resources available within and outside of VINCI, and useful contacts
- Initiate an assessment by sending request to VINCI@va.gov

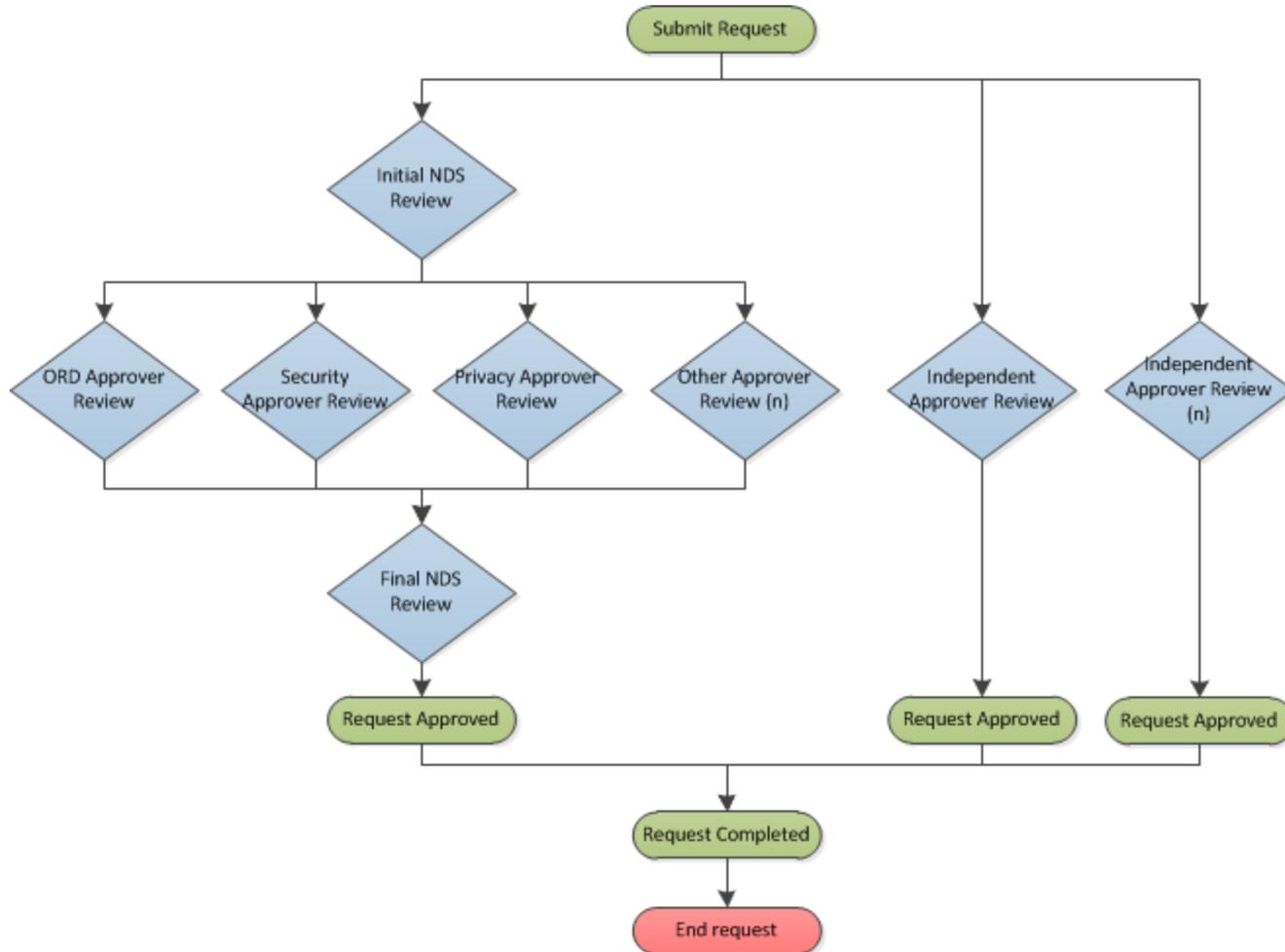
3c. VA Form 9957

- Most studies will need a VA Form 9957 from the Primary Investigator and sometimes all participants
- Most find the form difficult to fill-out so see DART User Guide Appendix B for instructions
- Send completed 9957 and DART Tracking Number to VINCI@va.gov for review prior to getting signatures
- Ensures the form is complete and correct

4. Initiate Your DART Request

- 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

DART Process



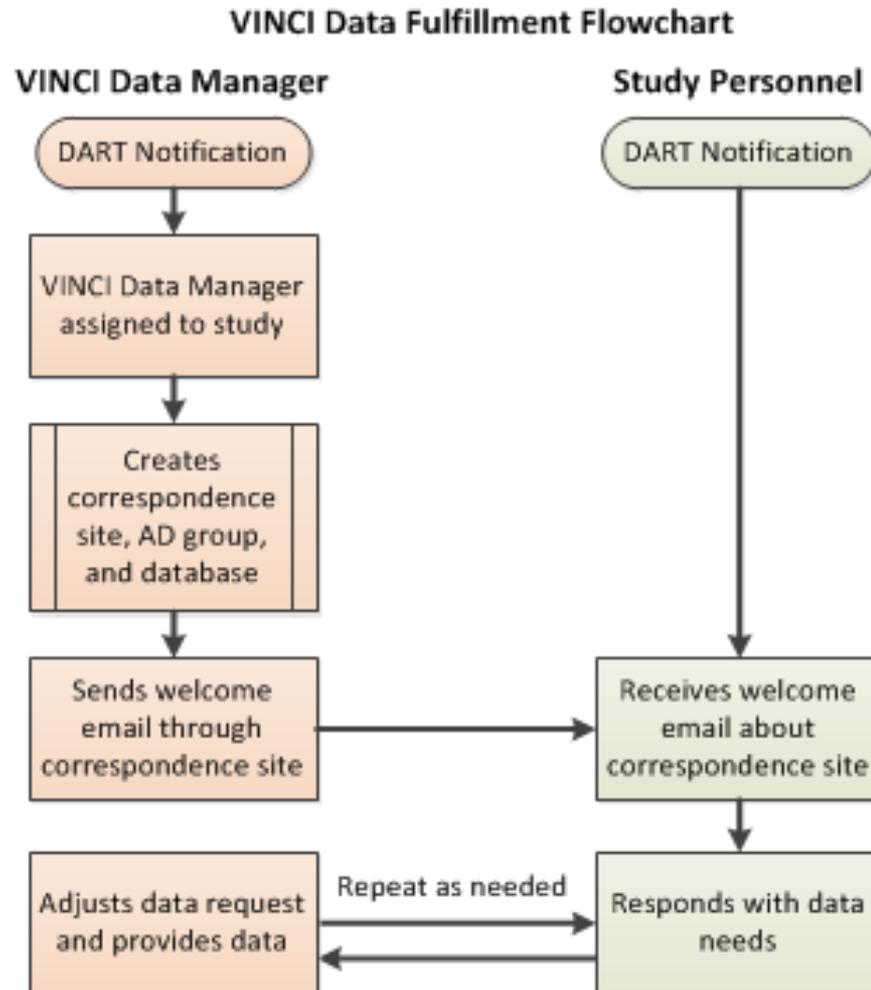
DART Paperwork

- Studies generally need the following:
 - Research Request Memo (DART User Guide Appendix A)
 - IRB Approval letter
 - HIPAA Consent/Authorization OR Waiver
 - Research & Development Committee letter
 - Research Protocol
 - Real SSN Access Request (For Real SSN identifiers - IRB)
 - VA Form 9957 (DART User Guide Appendix B)
- Forms can be found on the VHA Data Portal

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
- Both provisioning processes run concurrently

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



6. Use the VINCI Workspace

- Follow the guides! Found on VINCI Central
- VINCI Workspace User Guide
- VINCI Database User Guide
- VINCI File Transfer Guide



The screenshot displays the VINCI Central website interface. The top navigation bar includes links for About, Using VINCI, Data, Guides, Support, and VINCI Workspace. A left sidebar contains sections for Applications (Data Access Request Tracker) and Shortcuts (My Collaboration Sites, VINCI Workspace, VHA Data Portal, HSR&D, VReC, HSRData-L Listserv). The main content area is titled 'VINCI User Guides' and features three guide cards: 'VINCI Workspace User Guide', 'VINCI Database User Guide', and 'VINCI File Transfer Guide', each with a brief description of its content.

VINCI Central

About Using VINCI Data Guides Support VINCI Workspace

Home > Guides > VINCI User Guides

VINCI User Guides

VINCI guides provide information on using VINCI's resources.

- 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.
- 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, using CDW Project Specific databases, and the UMLS Metathesaurus database.
- VINCI File Transfer Guide**
This guide explains how to upload and download files to the secure VINCI Workspace.

7. Optional Training

- Need training to use VINCI's resources? Contact VINCI@va.gov
- Self-service training on VINCI Central
 - Video tutorials
 - VINCI Cyberseminars (like this one)
 - Other VINCI presentations



The screenshot displays the VINCI Central website interface. At the top, there is a navigation bar with the VINCI Central logo and several menu items: About, Using VINCI, Data, Guides, Support, and VINCI Workspace. Below the navigation bar, the page content is organized into sections. On the left, there is a sidebar with 'Applications' (Data Access Request Tracker) and 'Shortcuts' (My Collaboration Sites: VINCI Workspace, VHA Data Portal, HSR&D, ViReC, HSRData-L Listserv). The main content area features a breadcrumb trail 'Home > Support > Training' followed by the heading 'VINCI Concierge Customized Training'. Below this heading, there is a paragraph of text describing the concierge service, which includes guidance on VA Policy Handbooks, tutorials, and help documents from VINCI, ViREC, CDW, and the VHA Data Portal. A link is provided to 'See CDW/BISL Training on CDW site.' Below this, there is a section titled 'Self-Service Training' with a sub-heading 'VINCI Happy Hour (3rd Wednesday each month at 3PM ET)'. The text under this section states that the VA Informatics and Computing Infrastructure (VINCI) is holding its VINCI Happy Hour open forum every 3rd Wednesday of the month from 1:00PM to 3:00PM MT to field questions from users.

Time to Data

- After study creates protocol, gets IRB and other study documentation
- Get VINCI Concierge assistance
 - Data Needs Assessment: 3-5 business days
 - Project Needs Assessment: 3-5 business days
 - Can run concurrently
- DART approval for VINCI/CDW data only:
 - NDS takes up to 13 business days
 - Requestor fixes to their submission averages 9 business days

Time to Data

- VINCI provisioning following approval:
 - Study participant access and study folder setup in the workspace: up to 5 business days
 - VINCI data provisioning preparation: up to 5 business days
 - Runs concurrently
 - Study contacted within 5 business days to begin the data provisioning dialog - your timely responses to data manager inquiries speeds provisioning time
- **Overall time is approximately 2 months minimum to data**

VINCI Concierge

- Support for VINCI (Technical and other)
- Training and Education
- Help with data access and DART (Data Access Request Tracker)
- Data Needs Assessment
- Project Needs Assessment
- Study setup
- Feasibility (simple ICD-9 counts)
- **VINCI Happy Hour open Q&A forum every 3rd Wed. of the month from 3-4pm ET**

VINCI Services

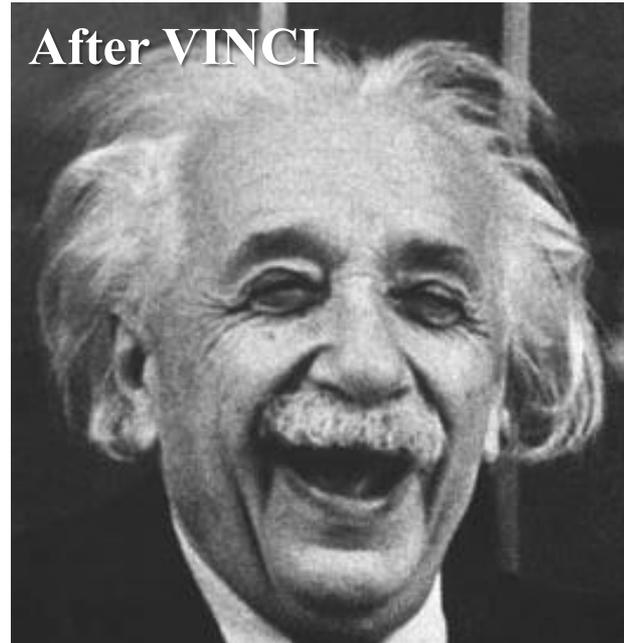
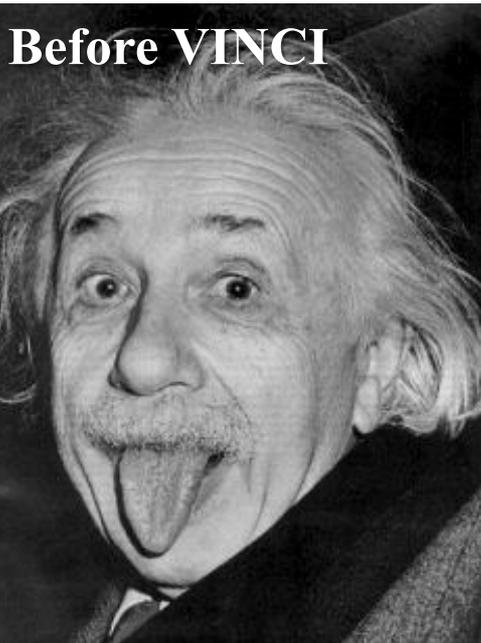
- *Fee-based services:*
- Clinical Trial Recruitment
- Annotation and Chart Review
- Natural Language Processing (NLP)
- Analytics and Data Services
- Application Development

Resources

- VINCI Central: <http://vaww.vinci.med.va.gov>
- VHA Data Portal
<http://vaww.vhadataportal.med.va.gov>
- VIREC <http://vaww.virec.research.va.gov>
- CDW <https://vaww.dwh.cdw.portal.va.gov>
- HSRData-L Listserv
<http://vaww.virec.research.va.gov/Support/HSRData-L.htm>

Questions?

VINCI@va.gov



VINCI Study Process for IRB Research

1. Create your protocol and get your local IRB. You will need an IRB from each location where an investigator is involved.
2. If you need Real SSN access, you will need to submit a Real SSN Access Request form to your IRB for signature. Please visit VIREC's information page on this at <http://vaww.virec.research.va.gov/Access/Real-SSN-Request-Process.htm>
3. *Optional if you intend to use VINCI Workspace for data storage and analysis* - As part of your IRB, you will want to state that you are using VINCI for data storage and analysis. See two boiler-plate descriptions for use in your documentation:
 - a. VINCI Description for IRBs - http://vaww.vinci.med.va.gov/vincicentral/documents/VINCI_Description_for_IRBs.docx
 - b. VINCI Information Security Description - http://vaww.vinci.med.va.gov/vincicentral/documents/VINCI_Information_Security_Description.pdf
4. *Optional* - Prior to submitting your IRB, you might want to have a VINCI Concierge work with you on a "Data Needs Assessment" to determine exactly what data you need to request. This may add a few days to your process though as we are very busy with other customers. If you wish this, just send as much data detail as possible to VINCI@va.gov and we will initiate the request for you. See these pages for information on data first:
 - a. VHA Data Portal - <http://vaww.vhadatportal.med.va.gov/DataSources/DataSourcesOverview.aspx>.
 - b. VINCI/CDW Data Descriptions - <http://vaww.vinci.med.va.gov/vincicentral/Data.html>
5. Initiate your Data Access Request Tracker (DART) request. One of the purposes of DART is to specify exactly what documentation is required based on a series of inputs such as who will be accessing the data and what data sources you are requesting. Once you upload the required documentation, submit your request. We recommend initiating a request immediately and inputting your study information so you will know what documents are required up front. *Please note that not all data sources are available through a DART request. The VHA Data Portal will indicate the process for each data source but all CDW/VINCI data is available through DART.* Here is DART information:
 - a. DART application online site where you initiate your request using your VA username (without VA domain) and VA password to login - https://vhacdwtest02.vha.med.va.gov:8443/vinci_dart_client/dart9/index.html
 - b. DART Overview and Forms - <http://vaww.vhadatportal.med.va.gov/DataAccess/DARTRequestProcess.aspx>
 - c. DART User Guide - http://vaww.vinci.med.va.gov/vincicentral/documents/DART_User_Guide.pdf
 - d. After you have drafted your 9957 form and prior to getting signatures on it, please send it and your DART Tracking Number to VINCI@va.gov for review so we may ensure it is properly filled-out and worded. See Appendix B in the DART User Guide on how to fill-out the 9957.
6. Once NDS has approved your request, VINCI will be automatically notified and a VINCI Data Manager will contact you within a few business days to work with you one-on-one to make the approved data available as soon as possible. If requested, VINCI will also set your study staff up for access to the VINCI Workspace within a week.
7. If you are using the workspace, login and conduct your analysis.
 - a. See the VINCI Workspace User Guide for information on accessing and using the Workspace - http://vaww.vinci.med.va.gov/vincicentral/documents/VINCI_Workspace_User_Guide.pdf
 - b. See the VINCI File Transfer Guide for information on uploading and downloading files from the Workspace. Please note that at this time you cannot remove any PHI/PII data from the VINCI Workspace without first obtaining NDS permission by way of a DART amendment - http://vaww.vinci.med.va.gov/vincicentral/documents/VINCI_File_Transfer_Guide.pdf
 - c. See the VINCI Database User Guide for information on interacting with databases from within VINCI - http://vaww.vinci.med.va.gov/vincicentral/documents/VINCI_Database_User_Guide.pdf

Resources:

- VINCI Central home page - <http://vaww.vinci.med.va.gov/vincicentral/default.aspx>
- VHA Data Portal - <http://vaww.vhadatportal.med.va.gov/Home.aspx>
- VIREC - <http://vaww.virec.research.va.gov/Index.htm>