

“Quick Start/Refresher Guide” for IRB Studies, Audie L. Murphy VAMC

IRB Research Process.

If your study has been approved by an Institutional Review Board (IRB) and the Audie Murphy R&D Committee, then the IRB Research process can grant you access to authorized EHR data.

Processing time to expect: About 2 to 5 weeks (from the time you have IRB and R&D approval letters and are ready to start the DART application, until a table of patients meeting the cohort definition is generated with a modest list of medical record variables).

Steps in the process:

1. Define your query. Fill out the local “Request for Data Query” form as completely as possible (see Appx 1) or meet with the analyst if the form doesn’t capture your needs. Either way, plan to spend up to an hour with the data analyst to discuss the details.
2. Gather together electronic copies of: the IRB Approval Letter, the R&D Committee Approval Letter, the approved protocol, the Sample Informed Consent form and HIPAA Authorization (if applicable), and the HIPAA waiver letter from the IRB (if applicable). The data analyst you’ve chosen to work with must be listed on the R&D Committee Approval letter.
3. Figure out who needs to look at/work with the data. Make sure they are listed on the R&D Committee Approval letter.
4. Start the online application at:
https://dart.vha.med.va.gov/vinci_dart_client/dart9/dashboard.html
 - a. Just below “HOME > DART Dashboard”, select the “Requests” button and then the “Create a New Request” button.
 - b. On the next screen, type the exact name of the approved protocol into the Official Study Name box (or as much of the name as will fit), and then select “Research Data Access” in the drop-down box for Request Type. Check the “I’m not a robot” box and be persistent about following the instructions. Click on the “Create Request” button.
 - c. Fill in a Short Name for the study: a nickname you create. IRB Number and Expiration come from your IRB Approval letter. Start Date and End Date come from the R&D Committee letter. Click on “Next”.
 - d. Enter the names of individuals who you’ve decided need data access. Enter the Principal Investigator at Audie Murphy first. If there are other sites, enter the PI at those sites next.
 - For each person you enter, click the “Find People” tab. Fill in the last name, first name. Click “Find Now”. Select the correct person.
 - Click on “Select a Location”. Use “(671)” to find STVHCS quickly, or the 3-digit station number of the site the person is from, enclosed in parentheses. If you don’t know the 3-digit number, search by system name or city.
 - Check appropriate boxes for what the person needs. The “Notifications” box sends an email for each step of the approval and provisioning process. The “Data Access” box allows one to see files behind the VINCI firewall and work in the CDW database. The “CAPRI/JLV Access” box allows one to see all EHR data for individual patients at any VHA location, such as doctor notes. Best practice: select “Notifications” for only the research coordinator and data analyst and maybe the PI; select “Data Access” for everyone; **do not** select the “CAPRI/JLV Access” box unless the project requires participants to look at notes’ pages in the EHR for patients at sites other than Audie Murphy.
 - Click “Add” button, then repeat for each participant.

- e. When you've included everyone, make sure the local PI is listed in the Locations Table on the right of the screen with a solid black star under Primary. If there are PIs from other systems, make sure they are in the Locations Table, with a hollow black star. Click Next.
 - f. Select Data Sources. Best practice is to discuss the choices with data analyst and PI if you are uncertain about what option to select. For Data Storage Location, select "VINCI" at a minimum. If your study needs patient level data on a local VA server (i.e., unaggregated data, even if there are no patient identifiers) also select the "Local VA Server" box. Enter information about the location of the local server, which the local ISO can provide.
 - g. If your study requires sharing unaggregated VHA data outside of the VA, select the "Yes (DUA is required)" button. You will need a data user agreement (DUA) with the agency before submitting the DART request, which requires support from the Audie Murphy R&D Service and the local ISO. Contact vinciservices@va.gov for more information on this step.
 - h. Select the type of patient identifier that will be used: "Real SSN" if you need patient names or SSNs or addresses; "Identifiable data but no real or scrambled SSNs" if you are working on a retrospective study that does not require you to know names or addresses; "Scrambled SSN" if you will be working with VA/CMS data.
 - i. Select the Requested Data Sources. "CDW Production Domains" is the most common choice, but there may be several others necessary. Discuss the choices with your data analyst.
 - j. For Data Access Systems section, select the "SAS Grid" box if the analyst will be using SAS rather than just SQL, which is likely for a complex set of inclusion/exclusion criteria.
 - k. Select the appropriate "Yes" or "No" buttons for questions about HIPAA Authorization and HIPAA Waiver, as agreed to by your IRB Approval letter. Click on "Next".
 - l. On the Documents screen, you will see a list of required documents, with an upload button for each. Some of the items will already exist, but others will need to be generated by you, most often the "Research Request Memo", the "CDW-Domain Checklist", and the "Real SSN Access Request". Find the forms on the Documents & Forms page: <http://vaww.vhadatportal.med.va.gov/DataAccess/PreptoResearchRequestProcess.aspx#DocumentsAndForms>. Click on the Documents & Forms tab on that page and select the needed documents in the table on that page.
 - m. The Research Request Memo is a fillable pdf. Fill it in with the same information you already entered into the online application. The middle block asks for information on 4 items, and you are expected to add the information directly into that block. For item A, give enough information about the tables within CDW that your analyst will use. Ask the analyst to help with this. Fill in the signature blocks of the Principal Investigator and the Supervisor of the PI at the bottom of the form.
 - n. The Real SSN Access Request Form requires signatures from the PI, from the chair of the IRB (or a voting member), and the Associate Chief of Staff for Research (ACOS-R). If the IRB Approval letter specifically and clearly states that Real SSN access is required and approved, then that box can be checked and no signature is needed from the IRB chair.
 - o. Download and fill in any other required forms that you don't already have.
 - p. Upload documents that already exist such as the IRB approval letter and IRB protocol. Click on the Upload button and follow the prompts on the pop-up screen. Repeat the process for all remaining documents you have available. Click on the "Save Draft" button at the bottom of the DART application and close it out for now.
5. Obtain signatures on the required DART documents. Log back into the DART application and go to the Documents screen. Upload the remaining documents. Click Next. On the Submit screen, if

everything was filled in and attached correctly, you will get a positive message and can click on the "Submit Request" button. If something is missing however, you will be prompted to fix it.

6. Monitor your emails. You may get 9 or more emails from: dart@va.gov, VINCI@va.gov, ppt@va.gov. You will need to take action only if an email from NDS asks for a Change to the application. The data analyst will take action when there is an email from the VINCI data manager.
7. When the data is provisioned, if the query is simple the data analyst can now use SQL Server Management Studio and get you an answer within 2 or 3 business days. For more complex queries, the data analyst will probably use SAS. Setting up space on the SAS server may take an additional business day or two. For a recruiting list, the coding may take two to eight business days.
8. When the coding is completed and data is available, the analyst will most likely put data in an Excel spreadsheet in the project folder behind the VINCI firewall. To get to the data behind the firewall:
 - a. Go to <https://vaww.vinci.med.va.gov/VinciCentral/Home/Index>
 - b. Left click once on the Launch Workspace hyperlink in the upper left of the screen.
 - c. Left click once on Full Standard Workspace (1 Monitor) icon on the pop-up box.
 - d. Left click once on Open on the white dialog box at the bottom of the screen.
 - e. Enter your 6-digit PIV code and wait about 30 seconds. This takes you to a remote site.
 - f. When the Security Warning screen comes up, click OK and wait about 30 seconds. This will result in a blue desktop screen with a few icons and a Start button on the bottom left that looks like an aqua-colored shell.
 - g. Left click once on the Start button, and left click once on Documents in the right column.
 - h. When the list of folders comes up, left click once on Projects (P:) in the left column, which will then give you a list on the right of all the folders available to you. One of the folders will be named ORD_Zzz_yyyymaaaD, where Zzz is the PI's last name and yyyymaaaD is the DART tracking number for your study. Left click twice on the appropriate folder and you will find the file(s) that the data analyst left for you.
9. You will receive an email from dart@va.gov on the data access expiration date. Data can no longer be pulled after the expiration date, unless you do an amendment to ask for an extension. You will also need to do an amendment if you need to grant data access to an additional participant.