

“Complete Guide” to Obtaining EHR Data for Research, at Audie L. Murphy VAMC Preparatory to Research Process.

If you are preparing a research funding application or research proposal and wanting to determine if the type of data and patient counts are sufficient to make the research plausible/worthwhile, then Preparatory to Research (PTR) is what you need.

Processing time to expect: From the time you have a solid idea of the research question (such as specific inclusion and exclusion criteria) until the CDW data is made available to your data analyst, expect about 3 to 7 business days (this depends on how many forms are required by the DART process, your ability to avoid mistakes in filling out the forms, and how busy the DART review staff are). The amount of time your data analyst spends writing code to obtain the answer depends on how well thought out your question is and how complicated it is to translate it into SQL or SAS code, but you can expect about 0.5 to 3 business days. Altogether, expect a minimum of about a week and a maximum of 2 weeks under normal circumstances. [Note: for simple inclusion/exclusion criteria, the VINCI concierge can perform a count in about 1 week. The VINCI concierge can be contacted by email to establish a ticket for this at vinciservices@va.gov .]

Steps in the process:

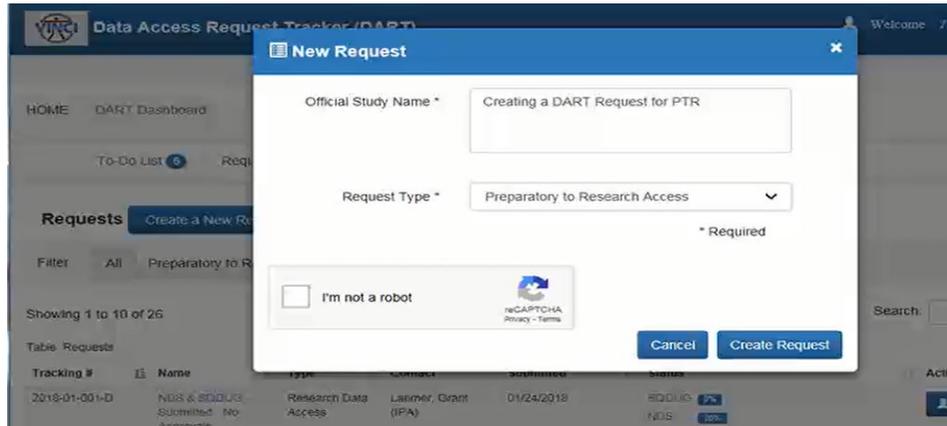
1. Fill out the local “Request for Data Query” form as completely as possible (see Appx 1). Plan to spend about a half-hour with the data analyst to discuss the details of the Inclusion and Exclusion criteria. To date, successful queries have included demographic information such as sex, age, or race; ICD-9 or ICD-10 diagnosis codes; CPT procedure codes; number of outpatient visits or inpatient stays; laboratory results; prescription fills using generic drug names; vital signs such as systolic and diastolic blood pressure or BMI; consults entered; and answers to mental health questions found in Health Factors.
2. Ask the Research Statistician to help you with filling out the DART request, if desired. Note that the goal for filling out the PTR DART request should be 0.5 to 1 hours of your time, including obtaining signatures. You will start the online application at:

https://dart.vha.med.va.gov/vinci_dart_client/dart9/dashboard.html

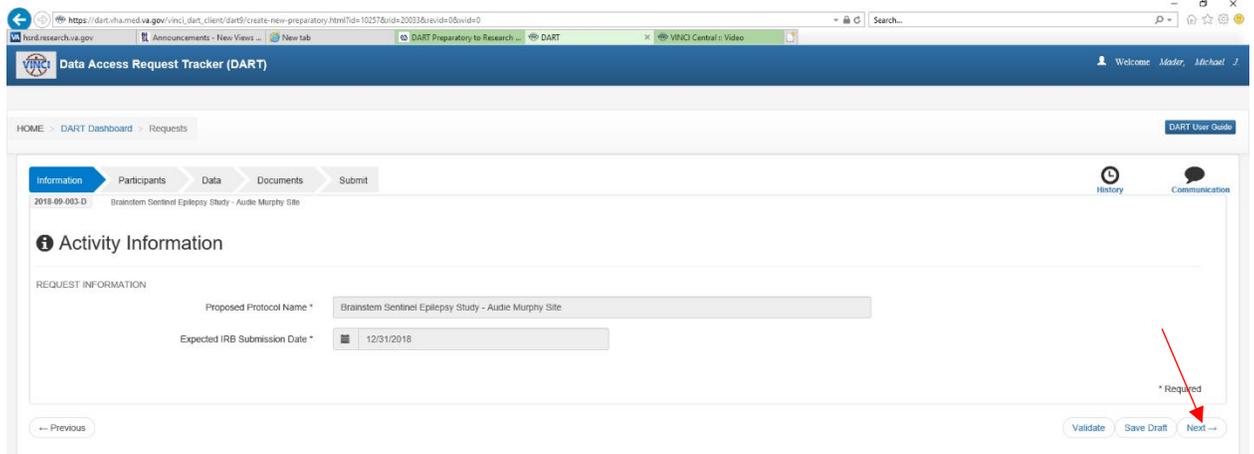
- a. Just below “HOME > DART Dashboard”, select the “Requests” button and then the “Create a New Request” button.

Tracking #	Name	Type	Contact	Submitted	Status	Actions
2015-03-017-D-A06	Sensmaking in VHA Health Care Systems: A Focus on Readmissions	Research Data Access	Pugh, Jacqueline A.	04/17/2018	NDS APPROVED	Actions +
2018-06-027-D	Impact of Finasteride on Bladder Cancer Outcomes	Research Data Access	Liss, Michael A.		NOT SUBMITTED	Actions +
2018-09-003-D	Brainstem Sentinel Epilepsy Study - Audie Murphy Site	Preparatory to Research Access	Nayak, Lipika	09/06/2018	NDS APPROVED	Actions +

- b. On the next screen, type a simple but unique name into the Official Study Name box and then select “Preparatory to Research Access” in the drop-down box for Request Type. Don’t be intimidated by the words “Official Study Name”; just pick a name for the study that is unique enough to be meaningful to you – don’t overthink it at this stage. Then check the “I’m not a robot” box and be persistent about following the instructions (such as identifying all photos with bicycles). Believe it or not, this may be the most frustrating part of the DART process. Finally, click on the “Create Request” button.



- c. Enter the Proposed Protocol Name (same name you provided on the previous page) and Expected IRB Submission Date. Choose an Expected IRB Submission Date of at least 30 days from today, but no more than 6 months. It will be the expiration date of your access to the data, unless you fill out an amendment (and you want to avoid doing amendments if possible because they take just as long to process as the original request). Click on “Next”.



- d. Enter the names of individuals who need to have data access. You can enter as many participants as you like but remember that the goal is to complete this in a short time, so limit the number of names that NDS must process once the request is submitted. The best practice is to limit the names to: the PI (who must be on the list), the research coordinator or assistant, and the data analyst. Yes, the PI for the study must be on the list, even if the PI will not look at the CDW data. Enter her/his name first. For each person to enter, start by clicking on the “Find People” tab. In the pop-up box, fill in the

person’s last name, followed by a comma and at least part of the first name and click “Find Now”. Pick the correct username of the participant in the Search Results table, which will bring you back to the Participants screen. Next, click on “Select a Location”. Find South Texas HCS by typing in “(671)” (include the parentheses) and then click on the location. Then, check boxes for what that person needs. The “Notifications” box will send an email for each step of the process. The “Data Access” box will allow the person to see files behind the VINCI firewall and work in the CDW database. The “CAPRI/JLV Access” box will allow the person to see all EHR data for individual patients at any VHA location, such as doctor notes. The best practice is to select “Notifications” for all participants, select “Data Access” only for the Data Analyst and anyone who might look at a list of patients behind the VINCI firewall, and *not* select the “CAPRI/JLV Access” box for anyone. (If someone needs to look at individual records, s/he probably already has access to CPRS for Audie Murphy patients, so CAPRI access would be redundant, and would extend the amount of time it takes NDS to process your request.) When you’ve finished filling in the correct information for the first participant, click on the “Add” box and do it again for the next participant.

The screenshot shows the DART interface for the 'Brainstem Sentinel Epilepsy Study - Audie Murphy Site'. The 'Participants' table lists two individuals: Michael J. Mader and Lipika Nayak, both at (671) South Texas HCS. The 'Locations' table shows (671) South Texas HCS as the primary location with Lipika Nayak as the Principal Investigator. Red arrows highlight the 'Find People' button, the 'Select a Location' dropdown, the 'Add' button, and the 'Primary' column in the Locations table.

Name	Location	Notifications	Data Access	CAPRI/ VistAWeb Access	Delete
Mader, Michael J.	(671) South Texas HCS (San Antonio TX)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Nayak, Lipika	(671) South Texas HCS (San Antonio TX)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Primary	Location	Principal Investigator
★	(671) South Texas HCS (San Antonio TX)	Nayak, Lipika

- e. When you’ve included everyone, make sure the PI is listed in the Locations Table on the right of the screen with a black star under Primary, and then click Next. Unless absolutely necessary, avoid including anyone from a second VHA station for a PTR data request, because you will need a PI for that location as well, and it just complicates matters for NDS.
- f. On the next screen, you select Data Sources. For the most typical data requests, you will click on only 3 or 4 boxes: “VINCI” for Data Storage Location; “Identifiable data but no real or scrambled SSNs” for Identifiers (but if the research coordinator will need to look up individual patients in CPRS, then you will need to check Real SSN instead); “CDW Production Domains” for Requested Data Sources; and “SAS Grid” for Data Access Systems (if the analyst will be using SAS rather than just SQL).

The screenshot displays the DART web interface for a request. The 'Data Sources' section is active, showing the following options:

- Data Storage Location:**
 - VINCI
- IDENTIFIERS (More about identifiers):**
 - Real SSN
 - Scrambled SSN
 - Identifiable data but no real or scrambled SSNs
- REQUESTED DATA SOURCES:**
 - Corporate Data Warehouse (CDW):**
 - 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)
- Mainframe - Access:**
 - 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:**
 - Bereaved Family Survey
 - 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
 - MCA (formerly DSS) Web Reports
 - Patient Aligned Care Team (PACT) Implementation Index (PI2)
 - VSSC Web Reports
- Data Access Systems:**
 - SAS Grid

At the bottom of the form, there are buttons for 'Previous', 'Validate', 'Save Draft', and 'Next'. A '* Required' note is visible in the bottom right corner.

- g. When you click on the Next button, you will arrive at the Documents screen. It will tell you which documents are required, and there is an upload button for each document. In almost all cases, you will only need to fill out and upload a “Preparatory to Research Request Memo”. (If you request Capri/VistAWeb Access, Vital Status Files, or Bereaved Family Survey data, you will have to fill out additional documents.) On this screen, in the section that says **NOTICE**, there is a hyperlink named “DART Process and Forms” which will bring you to an Overview page for the DART PTR Request Process. Click on the Documents & Forms tab on that page and then select the needed documents in the table on that page, usually just the first one. (Alternatively, the link for the Documents & Forms page is: <http://vaww.vhadataportal.med.va.gov/DataAccess/PreptoResearchRequestProcess.aspx#DocumentsAndForms>.) When you select the first document in the table, a fillable pdf will appear on your screen, like this:

- h. Fill in the form with the same information you already entered into the online application. The middle block asks for information on 6 items, and you are expected to add the information directly into that block. Make use of the description that is already there, and add in the requested information number by number. (See the examples below. The first example is for data requests that do not need Real SSN. The second is for requests that do need Real SSN). Item 4 is the most important one, because you need to give enough information about the tables within CDW that your analyst will use, without over-explaining. Ask the analyst to help with this. Finally, type in the signature blocks of the Principal Investigator and the Supervisor of the PI at the bottom of the form (usually on the second page). At this point, you can go no further in the DART application until you have signatures on the Memo, so click on the “Save Draft” button at the bottom of the DART application and close it out.

Example 1: Real SSN is *not* needed.

Example 2: Real SSN is needed by coordinator because some exclusion criteria is not easy to detect by a data query but can be found efficiently within CPRS.

Department of	Memorandum
Veterans Affairs	
Date: <input type="text" value="Dec 18, 2018"/>	
From: Principal Investigator <input type="text" value="Ignacio De Cicco, MD, South Texas Veterans HCS"/>	
Subj: Preparatory to Research Data Request Memo	
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, either VA employees or WOC employees? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Select the type(s) of data needed: <input checked="" type="checkbox"/> Real SSN <input type="checkbox"/> Scrambled SSN <input type="checkbox"/> PHI but No SSN	
Is access to CAPRI / VistAWeb being requested? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Is access to VSSC and/or MCA Web Reports being requested? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Will OMOP data also be requested? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Will the data be stored in the VINCI Environment? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Brief description of how data will be used:	
1. Name of facility of the IRB: South Texas Veterans Health Care System (Audie L. Murphy VAMC)	
2. Proposed name: Prevalence of Infective Endocarditis in High Risk Patients	
3. Protocol will be submitted to the IRB by February 28, 2019.	
4. The data analyst will query the CDW data associated with hospitalizations and outpatient visits at Audie Murphy VAMC in the date range of 1 January 2013 to 31 December 2018, searching for patients that meet the inclusion criteria of Prosthetic Heart Valves with endocarditis, Infective endocarditis, Cyanotic heart defect, or Cardiac Transplant, using ICD-9 and ICD-10 codes as indicated by the dates of interest. If there are enough patients based on the inclusion criteria, then those patients will be assessed further for ability to meet study exclusion criteria, by the research coordinator doing a medical record search within VISTA within the STVHCS.	
5. Real SSN is requested to positively identify candidate study patients within the VISTA medical record search.	
6. Participants include:	
Ignacio De Cicco, MD, Staff Physician, VA Employee	
Joan Marie Hecht, RN, Research Coordinator, VA WOC	
Michael J Mader, MS, Statistician, VA Employee	
Affirmation: By signing below, I affirm that data access for this Preparatory to Research will either expire once this is submitted to the IRB, or no later than 6 months from the approval date.	
Approvals	

- i. Obtain the required signatures on the Memorandum. Electronic signatures are possible. If it was not electronically signed, scan it into pdf format. Save the signed memo in a convenient place on the local VA server, such as your Home Drive or the PI's research folder. Log back into the DART application and click on Next until you get to the Documents screen. Click on the Upload button and follow the prompts on the pop-up screen to Browse to the folder where your Memorandum is, highlight it, click Open, then Upload File. This will bring you back to the Documents screen. (If you have a Capri/VistAWeb or other document to upload, repeat this process). When all documents are uploaded, click Next.
- j. This brings you to 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, which will bring you back to the DART dashboard and you can relax a little, while NDS works on it. If something is missing however, you will be prompted to fix it.

3. Monitor your emails. Everyone with a checked Notifications box will receive emails. The sender address could be: dart@va.gov, VINCI@va.gov, ppt@va.gov, or Zzz_PTR_yyyymm-aaaD, where Zzz is the last name of the PI, yyyymm is the year and month of the request, and aaa is a 3-digit number that tracks the number of requests that month. If this is your first DART request, it's worthwhile to read all of the emails, but only the three with an asterisk below require action:
 - a. Your DART application was initiated. (This will include your DART Tracking Number, which will be yyyy-mm-aaa-D as just described above.)
 - b. * Change requested. ***[If you get this email, click on the hyperlink in the email to go to the DART dashboard, find your DART request, click on the button corresponding to the change request, take the action requested, and re-submit the DART application.]***
 - c. Initial NDS review is completed and has been sent to another office for their review.
 - d. Request was approved by one of the offices and is being sent to the next one.
 - e. NDS has approved the request.
 - f. Welcome, you may begin to use the VINCI Standard Workspace.
 - g. You've been subscribed to a Sharepoint site for your study. (This one will have the name of the VINCI data manager in it.)
 - h. * The VINCI data manager is waiting for your input. ***[When you get this one, the data analyst needs to go to the study's Sharepoint site and give a detailed description of the data needed. It should include a description of the limits of the cohort for the VINCI data manager to establish, such as "only living veterans 40 years old or older who have been inpatients at Audie Murphy VAMC, station 671, between 1 Oct 2015 and 30 Sep 2018 with primary diagnosis icd10code of yyy". The data description also needs to include the names of domains and tables needed, as well as a date range for the fact tables (for instance, you might need to look at outpatient records for up to 10 years prior to the cohort date range). The data description needs to be compatible with what was in the DART request.]***
 - i. * The VINCI data manager has a new message for you ***[This will either say the data has been provisioned (Hurray!), or that the data manager needs additional info to complete the request.]***

4. 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 one business day. For more complex queries, the data analyst will probably use SAS. If that's the case, the data analyst needs to email a request to VINCI SAS Admins to set up space on the SAS server (see example below). Setting up space on the SAS server usually takes up to one business day, and then the coding will take one to two business days.

How to request space on the SAS server: The email from the VINCI data manager telling you the data has been provisioned has a table like the one below. Use that info, plus the Domains you listed in your request, in an email to the VINCI SAS Admins.

Database Connection Information:	
Database	ORD_Pugh_PTR_201903014D
VINCI Database Server	vhacdWRB03.vha.med.va.gov
Extracted Data Schema (read only)	Src
Study Read/Write Schema	Dflt

Example email to VINCISASAdmins@va.gov :

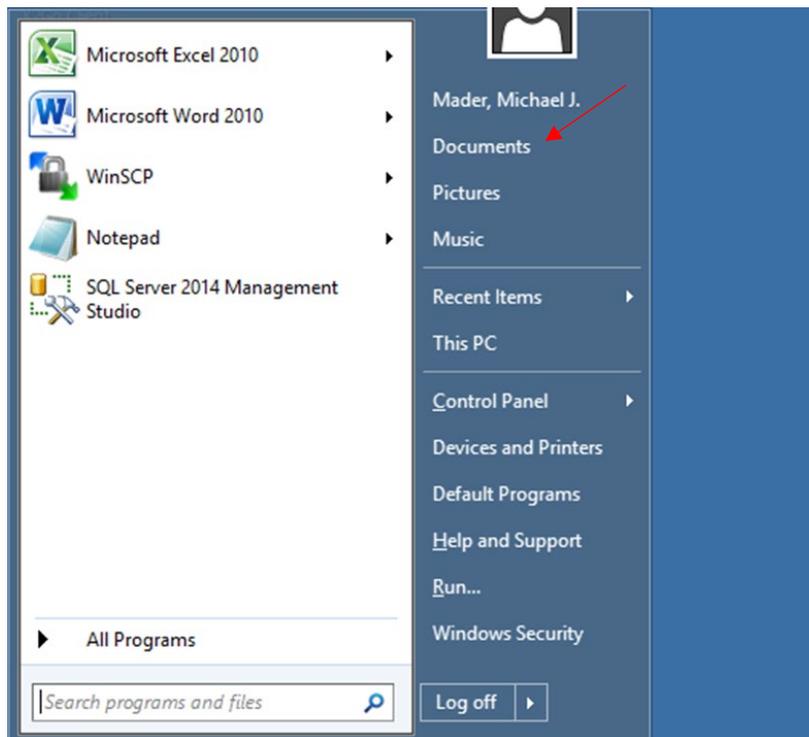
I have approval from NDS and VINCI for a prep-to-research study database. Can you please assign a DATASRC pointer?

Server IP address: vhadwRB03.vha.med.va.gov

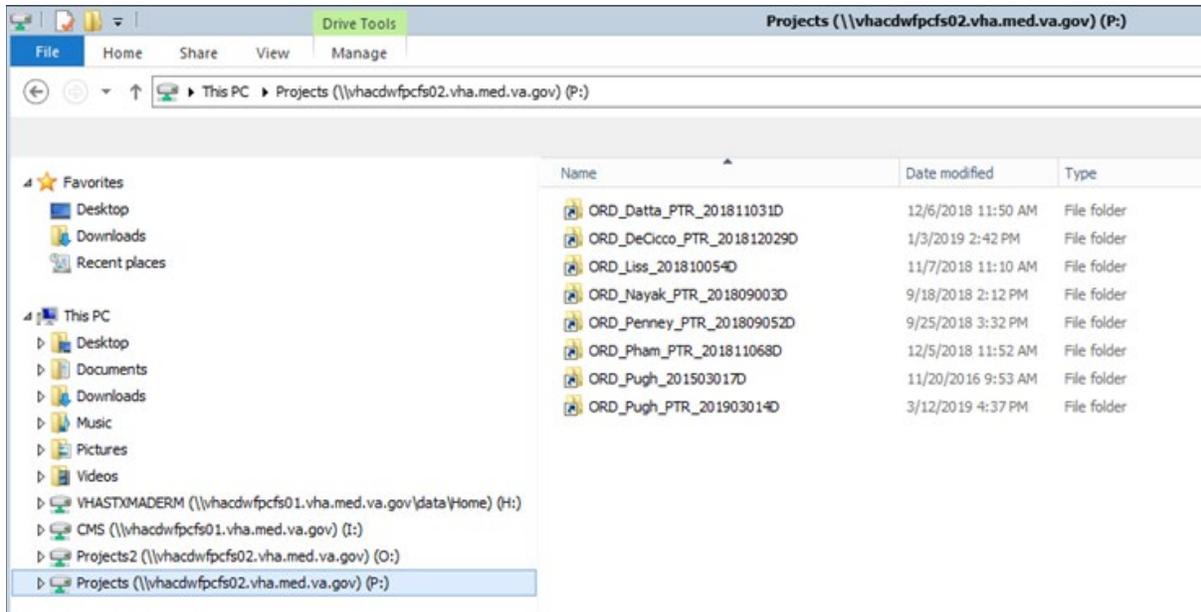
Database created by VINCI: ORD_Pugh_PTR_201903014D

Schemas to query: Src, Dflt, Dim, Outpat, Inpat, Patient, HF

5. When the coding is completed and data is pulled, the analyst will provide counts by email if that is all that is required, or will 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 that appears 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_PTR_yyyymmaaD, where Zzz is the PI's last name and yyyymmaaD 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.

- i. There is a blue dialog box centered at the top of the remote screen, with a name in it, something like: VHACDWDWHRDBKR.VHA.MED.VA.GOV. If you need to take a break from the remote screen and get back to your local screen, left click once on the "minus sign" to the right of the name. When you want to go back to the remote screen, left click once on the icon of a blue screen you will find at the bottom of your local screen. When you are finished using the remote site, left click once on the "letter x" to the right of the name on the blue dialog box at the top of the remote screen and confirm that you want to disconnect. 
6. If you intend to go forward with the research, obtain an IRB approval letter and VA R&D Committee approval letter and then do an IRB DART request (see Section D).
7. You will receive an email from dart@va.gov on the PTR data access expiration date. Data can no longer be pulled after the expiration date, unless you do an amendment to ask for an extension.

Where to get more detailed information on a DART PTR request:

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

This website includes Quick Links to the DART User Guide and a few short videos (< 5 minutes) on how to fill out the online application and what happens next. I highly recommend watching the video on "Creating a DART PTR Request" if there was anything unclear about the instructions above, and "DART Approval Process for PTR" if you are curious about what happens behind the scenes or why it takes so long.