VINCI COMPLIANCE

Deborah Eddy, Audit Program Manager

VA Informatics & Computing Infrastructure

What will we cover today?

- Role of the VINCI Compliance Team
- Operations vs Research studies
- The HIPAA rule
    - What is a patient identifier
    - What are de-identified data
- What are aggregated data
- PII vs PHI
- The VINCI File Transfer Utility
- Common Pitfalls and Risky behavior
- Most important takeaways

Poll Question #1

What is your primary role in VA research (select one)?

- Principal Investigator
- Study Coordinator/admin support
- Statistician/Programmer
- Other Support
- I work on Operations studies only
- None of the above

Poll Question #2

What is your experience level with VINCI?

- I have no or minimal experience with the VINCI workspace.
- I’ve been a VINCI user for 1-3 years
- I’ve been a VINCI user for 4 or more years.

Compliance Team roles

Help VINCI customers stay in compliance with Federal and VA regulations regarding the storage and use of patient data.

Provide education and other support to the VINCI community.

Protect patient data by ensuring they are only removed from VINCI with permission of the data steward. VINCI downloads are reviewed for compliance.

Research vs Operations Projects Resources

VA HSR&D Cyberseminar 11/2/2020 “Requesting Access to VA Data”

by Linda Kok, VIReC (VA Information Resource Center) Senior Analyst for Data Access and Policy

https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=3882&Seriesid=22

VHA Data Portal

https://vaww.vhadataportal.med.va.gov/DataAccess/VINCIWorkspaceRequestProcess.aspx (includes link to Research vs Operations Decision Tool)

Compliance Considerations: Operations vs Research projects

Operations projects (e.g., Healthcare Quality Assessments, Operational Reporting, Program Evaluation, Forecasting and Financial Auditing projects)

- Researchers use the **NDS Healthcare Operations Request Process** Healthcare Operations Request Process (va.gov) to obtain access to identifiable patient data.
- An operations program manager may place restrictions on the removal of patient data from the VINCI workspace.

Research projects including Prep-to-Research studies (to aid in the preparation of a research protocol), IRB studies and IRB-exempt studies

- Researchers use the DART (Data Access Request Tracker) application to request access to identifiable patient data and specify data storage locations (VINCI, local VA server, outside entities).
- Once the DART application is approved, VINCI will create a project folder for the study and a Data Manager will provide views to the data.
- An email will be sent to the submitter's VA email address confirming approval and providing a link to the study correspondence site (the method of communicating with the Data Manager).

Research projects – special considerations

- Patient-level data may only be downloaded from VINCI with the express approval of the data steward. Data provisioned for Prep-to-Research studies may never be downloaded from VINCI.

- Always work with the VINCI Data Manager to access data for which you have been approved.

- A study team member may not use his/her operations access to view or pull data for a research project UNLESS all regulatory permissions have been approved. Data approved for one research project may not be reused for another research project UNLESS all regulatory permissions have been approved. Further guidance can be provided by the VINCI Compliance team and VIReC.

Research projects – downloading aggregate data and statistics

In general, statistical output and aggregate data for research projects may be downloaded from VINCI to a local VA server. HOWEVER…

- The Files created by executing Statistical programs might include patient-level data (e.g., original dataset, tables, min/max values) which may not be downloaded from VINCI without express permission of the data steward.

- Aggregated data must include counts for multiple patients. Counts provided on the patient level are not considered aggregated data.

- The National Data Systems Office has established numerical thresholds that must be met for data to be considered “Aggregated”:

Definition of Aggregate Data

The National Data Systems Office (NDS) has determined that data counts must meet the following thresholds in order to make reidentification of individuals extremely difficult:

- A count of patients where no HIPAA identifiers exist (e.g., a count of the number of patients seen in VA hospitals in 2003) may be as low as 3.
- A count of patients where HIPAA identifiers other than those related to location are included (e.g., a count of patients aged 90 and up seen in VA hospitals in 2003) may be as low as 11.
- A count of patients where HIPAA identifiers related to location are included (e.g., a count of patients aged 90 and up in Broward county) may not be lower than 21.

Patient Identifiers

- PII (Personally Identifying Information) is any information about an individual that can be used to determine an individual's identity. Examples: Name, SSN, Address, Date of Birth.

- PHI (Protected Health Information) refers to data about health status, provision of health care, or payment of health care that can be linked to a specific individual.

  Examples: Billing information, lab results, appointment information.

De-Identified Data

- VINCI does not provide de-identified data.
- The HIPAA rule and Appendix A of VHA Directive 1605.01 (Privacy and Release of Information) address the de-identification of data. VHA Directive 1605.01 is the policy that combines the requirements of the Privacy Act and HIPAA Privacy Rule and the other VA statutes in one place so that disclosures can be made with the appropriate legal authority.
- Data are considered to be sufficiently de-identified if either the Safe Harbor method or the Expert Determination method have been applied.
- For either technique, VINCI will help you obtain the necessary approvals to release patient-level data. Aggregated data are only considered to be sufficiently de-identified if the counts meet thresholds set forth by the National Data Systems Office.

The HIPAA Rule

- The following identifiers of an individual, an individual's relatives, household members or employers may not be disclosed:
- 1. Names
- 2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
  - a. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
  - b. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

HIPAA identifiers, cont.

- 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
- 4. Telephone numbers
- 5. Fax numbers
- 6. Electronic mail addresses
- 7. Social security numbers

HIPAA identifiers, cont.

- 8. Medical record numbers
- 9. Health plan beneficiary numbers
- 10. Account numbers
- 11. Certificate and/or license numbers
- 12. Vehicle identifiers and serial numbers, including license plate numbers
- 13. Device identifiers and serial numbers
- 14. Web Universal Resource Locators (URLs)
- 15. Internet Protocol (IP) address numbers
- 16. Biometric identifiers, including finger and voice prints

HIPAA Identifiers, cont.

- 17. Full-face photographic images and any comparable images
- 18. Any other unique identifying number, characteristic, or code. Study-generated identifiers may be utilized but may not be based on the SSN or other identifiers listed here. NOTE: Scrambling of names and social security numbers is not considered a valid de-identification method.

VINCI File Transfer utility

Purposes:

To upload locally collected data for analysis

To download statistical output for publication or presentation

and, IF PERMITTED BY THE DATA STEWARD:

To download patient-level data for approved purposes, e.g., for recruitment or to use as a finder file.

Data Steward permissions

DART (Data Access Request Tracker)

- method for requesting access to data for a research study
- specifies who may access the data (P.I. must ensure this is kept current)
- documents where the data will be stored

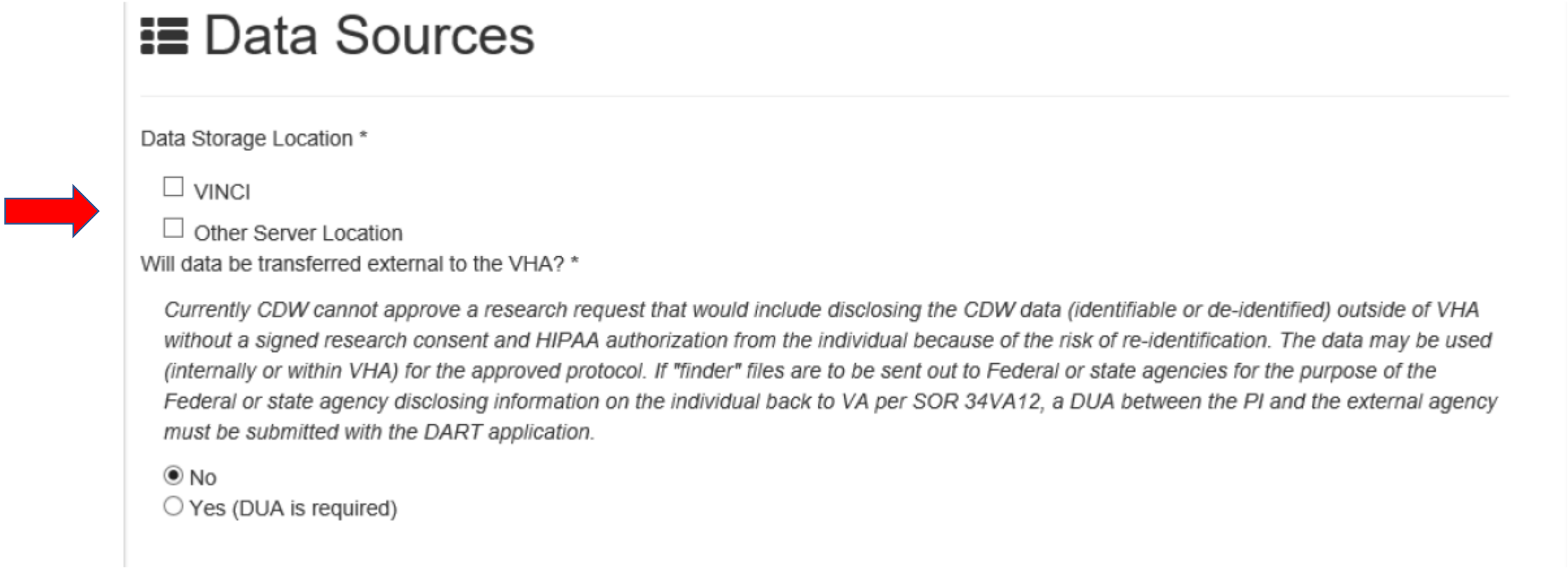
  VINCI
  Local VA server
  or both

  and whether they will be shared external to the VA

See DART User Guide *(https://vaww.vinci.med.va.gov/vincicentral/)*
for information and instructions

DART - Checking download permissions

Data Sources screen



DART - Checking download permissions Research Request Memo (Documents screen)

Department of Veterans Affairs

Memorandum

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

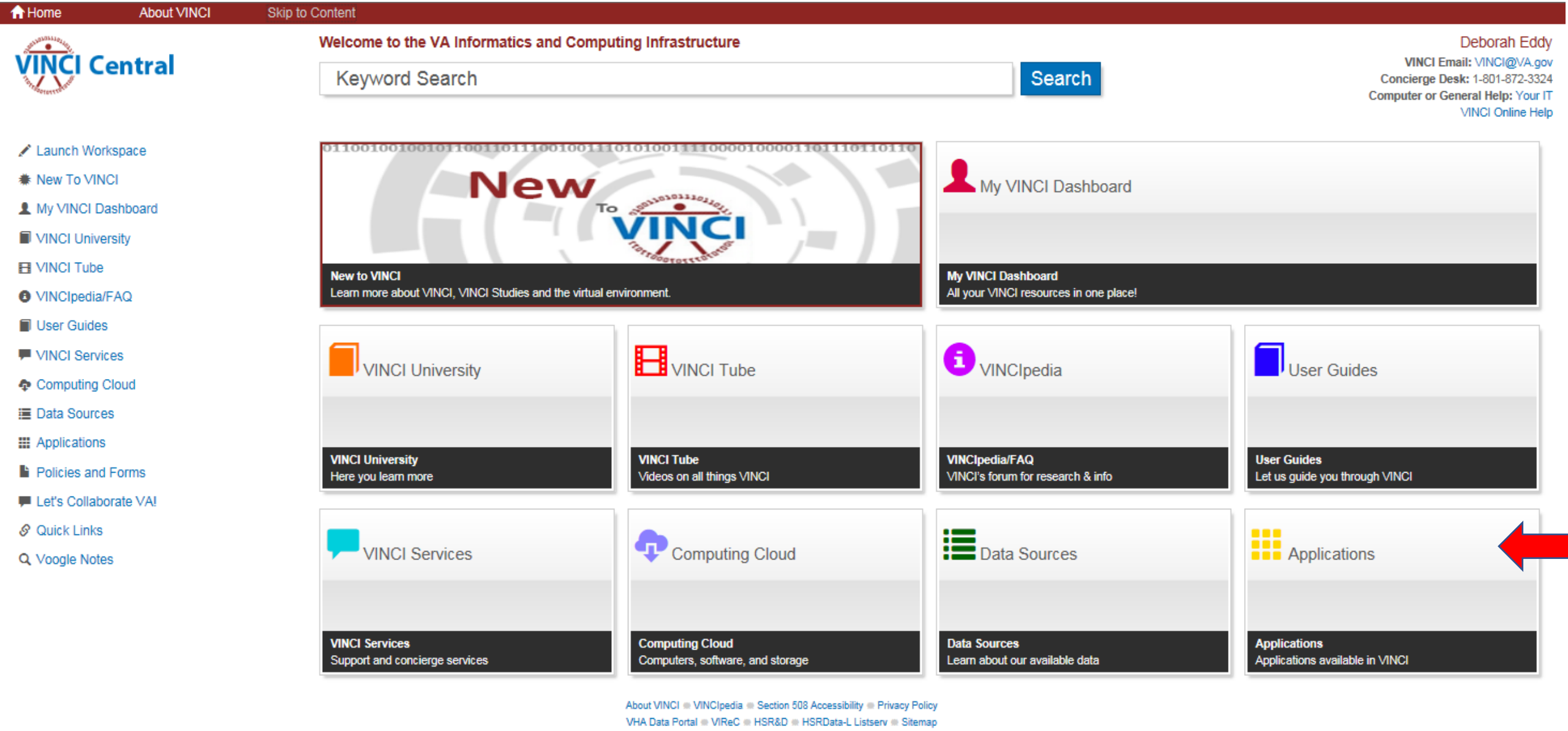
The following information is required and all signatures must be obtained before any review of this request can take place:

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 / JLV 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

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).

Uploading and Downloading files

Launch utility from VINCI Central: https://vaww.vinci.med.va.gov/vincicentral/



New to VINCI
Learn more about VINCI, VINCI Studies and the virtual environment.

My VINCI Dashboard

My VINCI Dashboard
All your VINCI resources in one place!

VINCI University

VINCI University
Here you learn more

VINCI Tube

VINCI Tube
Videos on all things VINCI

VINCIpedia

VINCIpedia/FAQ
VINCI's forum for research & info

User Guides

User Guides
Let us guide you through VINCI

VINCI Services

VINCI Services
Support and concierge services

Computing Cloud

Computing Cloud
Computers, software, and storage

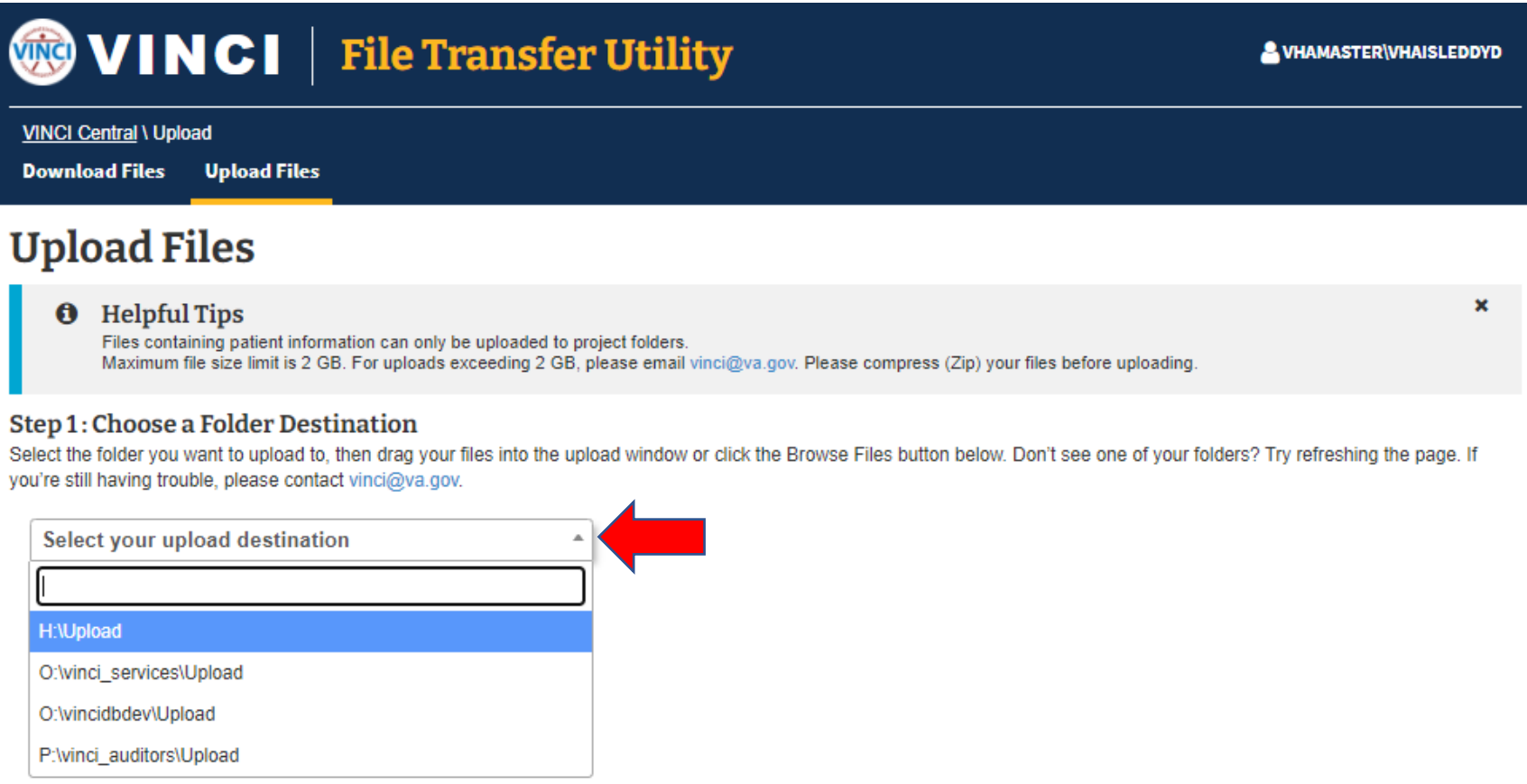
Data Sources

Data Sources
Learn about our available data

Applications

- See All Applications
- DART
- Upload Files
- Download Files
- Let's Collaborate VA!

Uploading file to VINCI:



VINCI | File Transfer Utility

VHAMASTER\VHAISLEDDYD

VINCI Central \ Upload

Download Files | Upload Files

Upload Files

Helpful Tips

Files containing patient information can only be uploaded to project folders.
Maximum file size limit is 2 GB. For uploads exceeding 2 GB, please email vinci@va.gov. Please compress (Zip) your files before uploading.

Step 1 : Choose a Folder Destination

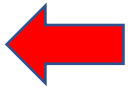
Select the folder you want to upload to, then drag your files into the upload window or click the Browse Files button below. Don't see one of your folders? Try refreshing the page. If you're still having trouble, please contact vinci@va.gov.

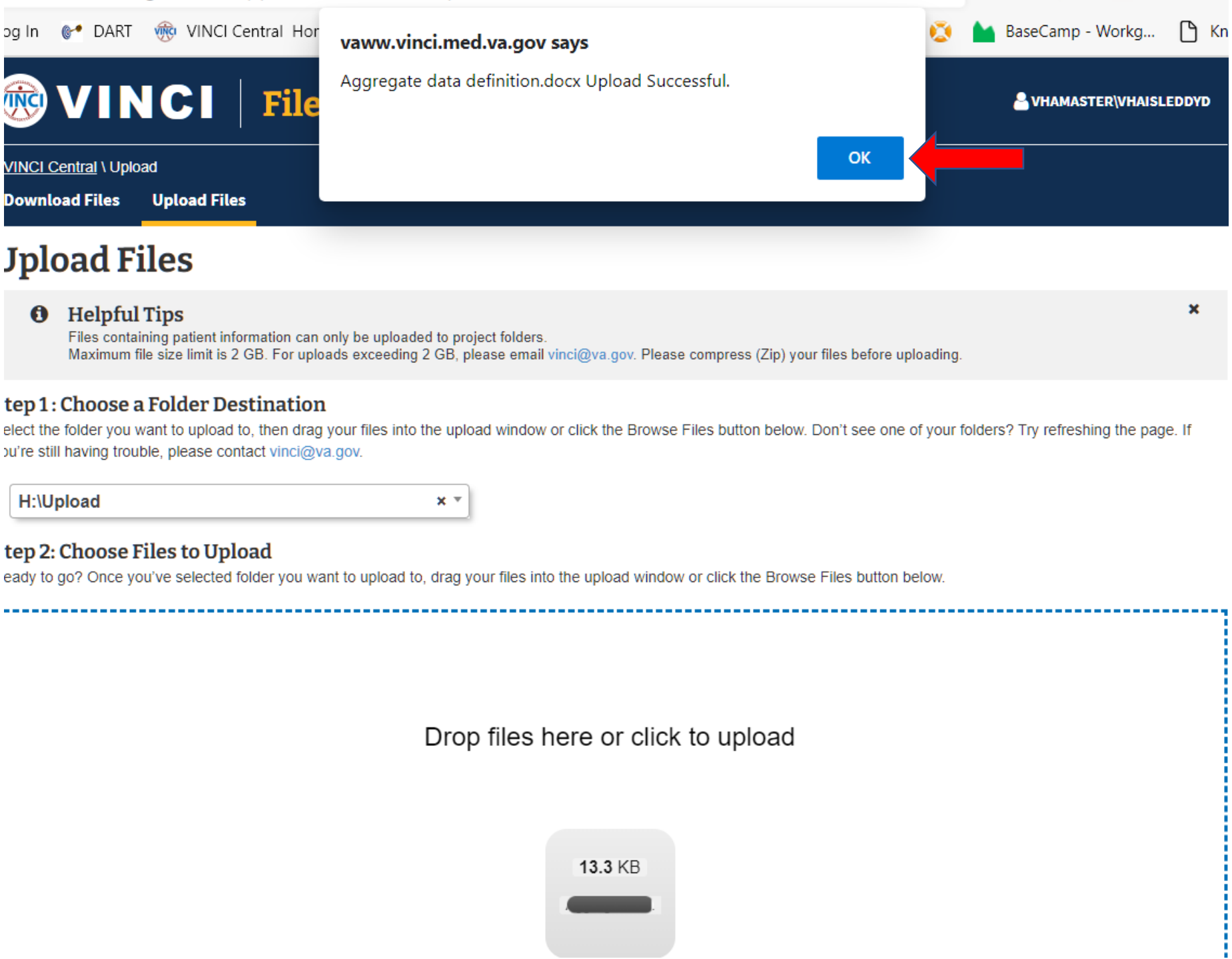
H:\Upload

Step 2: Choose Files to Upload

Ready to go? Once you've selected folder you want to upload to, drag your files into the upload window or click the Browse Files button below.

Drop files here or click to upload




og In
DART
VINCI Central Hor
BaseCamp - Workg...
Kn
vaww.vinci.med.va.gov says
Aggregate data definition.docx Upload Successful.
OK
VINCI
File
VHAMASTER\VHAISLEDDYD
VINCI Central \ Upload
Download Files
Upload Files
Jpload Files
Helpful Tips
Files containing patient information can only be uploaded to project folders.
Maximum file size limit is 2 GB. For uploads exceeding 2 GB, please email vinci@va.gov. Please compress (Zip) your files before uploading.
tep 1 : Choose a Folder Destination
elect the folder you want to upload to, then drag your files into the upload window or click the Browse Files button below. Don't see one of your folders? Try refreshing the page. If
ou're still having trouble, please contact vinci@va.gov.
H:\Upload
tep 2: Choose Files to Upload
eady to go? Once you've selected folder you want to upload to, drag your files into the upload window or click the Browse Files button below.
Drop files here or click to upload
13.3 KB

Prior to download…

- Make sure you know the exact name of the file you wish to download and its location on VINCI
- Ensure you are mapped to the local VA server destination
- If you intend to download multiple files, you may wish to first zip them up on VINCI, so they can all be downloaded at the same time

New to VINCI
Learn more about VINCI, VINCI Studies and the virtual environment.

My VINCI Dashboard

My VINCI Dashboard
All your VINCI resources in one place!

VINCI University

VINCI University
Here you learn more

VINCI Tube

VINCI Tube
Videos on all things VINCI

VINCIpedia

VINCIpedia/FAQ
VINCI's forum for research & info

User Guides

User Guides
Let us guide you through VINCI

VINCI Services

VINCI Services
Support and concierge services

Computing Cloud

Computing Cloud
Computers, software, and storage

Data Sources

Data Sources
Learn about our available data

Applications

- See All Applications
- DART
- Upload Files
- Download Files
- Let's Collaborate VA!

VINCI

VHAMASTER\VHAISLEDDYD

VINCI Central \ Download

Download Files | Upload Files

Download Files

Before You Proceed

I attest that transfer of any Persona
and directives, state and federal re
my files may be audited at any time
reprimand, suspension from work,

cordance with all applicable VA/VHA policies
(HIPAA). Furthermore, I acknowledge that
may include suspension of access privileges,

Choose Files to Download

Click on the files you want to download. Don'

contact vinci@va.gov.

H:\Drive

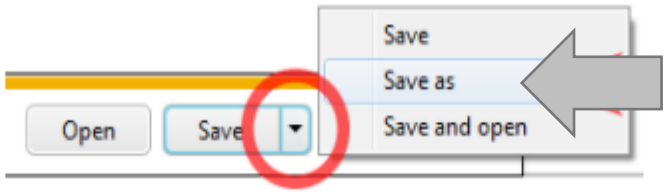
.spss

VINCI File Download

Watch out! Do NOT click "Save."

It will save to your "Downloads" folder, which may be a violation of your approved protocol and privacy and security policies.

Click on the little arrow at the right of the "Save" button and "Save as..." to the appropriate server location.



Close

VINCI | File Transfer Utility

VHAMASTER\VHAISLEDDYD

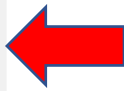
VINCI Central \ Download

Download Files **Upload Files**

Download Files

Before You Proceed

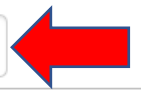
I attest that transfer of any Personally Identifiable Information (PII) or Protected Health Information (PHI) contained in the files is in accordance with all applicable VA/VHA policies and directives, state and federal regulations, and applicable statutes including the Health Insurance Portability and Accountability ACT (HIPAA). Furthermore, I acknowledge that my files may be audited at any time to ensure compliance. If I am found to be in violation, I will be subject to full penalty of law, which may include suspension of access privileges, reprimand, suspension from work, demotion, removal, and criminal and civil penalties.



Choose Files to Download

Click on the files you want to download. Don't see one of your files or folders? Try refreshing the page. If you're still having trouble, please contact vinci@va.gov.

H:\Drive



- .spss
- _rels
- AppData
- Application Data
- batch-etl
- cpt121217.txt(1)

VINCI File Transfer Utility

VHAMASTER\VHAISLEDDYD

VINCI Central \ Download

Download Files **Upload Files**

H:\Drive

- My Data Sources
- My SAS Files
- R
- SPSSInc
- SQL Server Management Studio
- Visual Studio 2010
- Visual Studio 2015
- .Rhistory
- Default.rdp
- desktop.ini
- err2019-04-10T17-51-42.log
- June GRs_All.pptx
- SAS error.PNG

Rectangular Snip

Bookmarks | VA Shortcuts | webTA Log In | DART | VINCI Central Home | SolarWinds | TMS | Timesheet – Univer... | TMS training

Downloads

What do you want to do with SAS+error.PNG?

Open | Save as

See more

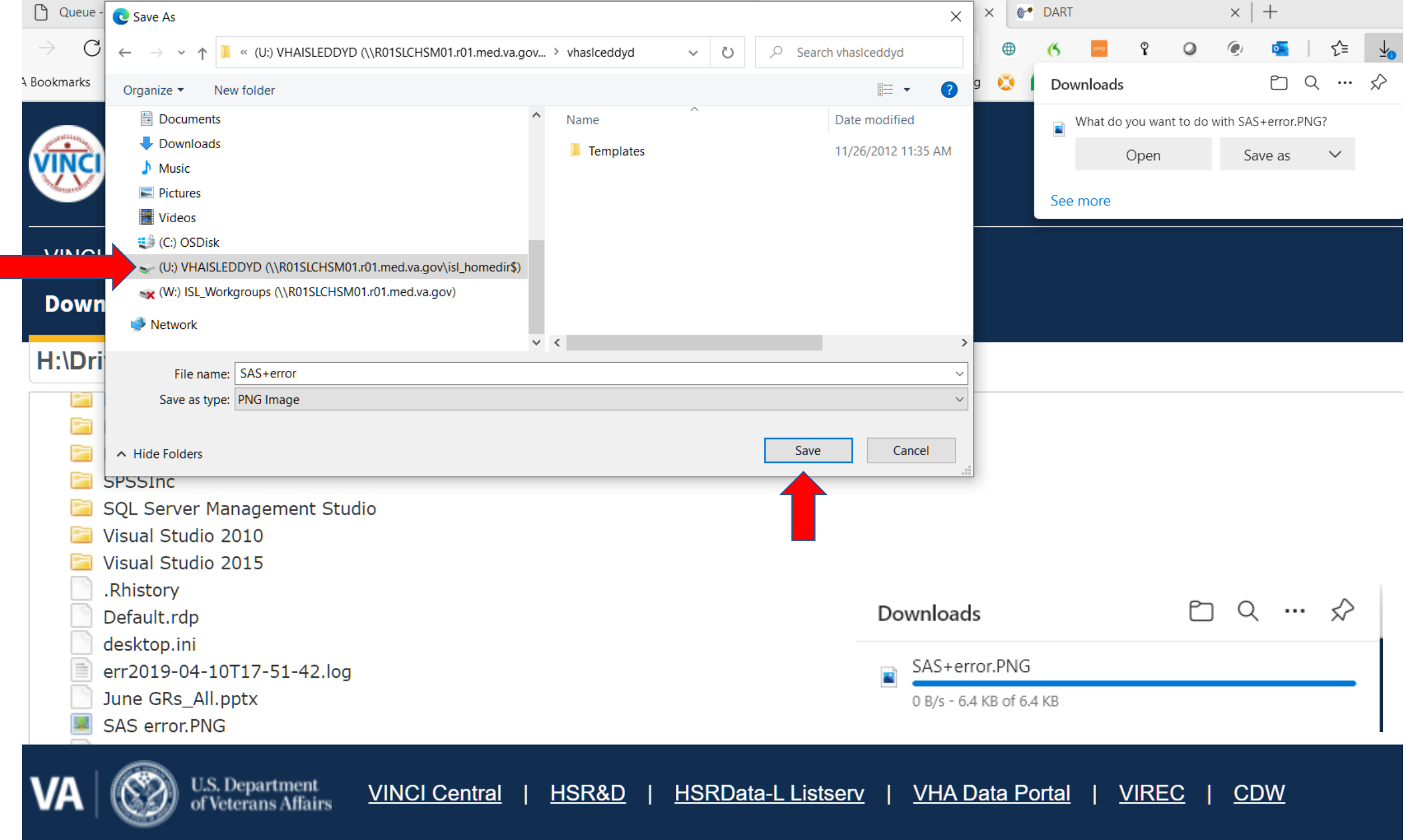
VINCI | File Transfer Utility

VINCI Central \ Download

Download Files **Upload Files**

H:\Drive

- My Data Sources
- My SAS Files
- R
- SPSSInc
- SQL Server Management Studio
- Visual Studio 2010
- Visual Studio 2015
- .Rhistory
- Default.rdp
- desktop.ini
- err2019-04-10T17-51-42.log
- June GRs_All.pptx
- SAS error.PNG


Save As
(U:) VHAISLEDDYD (\\R01SLCHSM01.r01.med.va.gov... › vhasIceddyd
Search vhasIceddyd
Organize
New folder
Documents
Downloads
Music
Pictures
Videos
(C:) OSDisk
(U:) VHAISLEDDYD (\\R01SLCHSM01.r01.med.va.gov\isl_homedir$)
(W:) ISL_Workgroups (\\R01SLCHSM01.r01.med.va.gov)
Network
Name
Date modified
Templates
11/26/2012 11:35 AM
File name: SAS+error
Save as type: PNG Image
Hide Folders
Save
Cancel
Downloads
What do you want to do with SAS+error.PNG?
Open
Save as
See more
SPSSInc
SQL Server Management Studio
Visual Studio 2010
Visual Studio 2015
.Rhistory
Default.rdp
desktop.ini
err2019-04-10T17-51-42.log
June GRs_All.pptx
SAS error.PNG
Downloads
SAS+error.PNG
0 B/s - 6.4 KB of 6.4 KB
VA
U.S. Department of Veterans Affairs
VINCI Central | HSR&D | HSRData-L Listserv | VHA Data Portal | VIREC | CDW

Avoid these Common pitfalls

- File transfer utility mistakes (accidental downloads, downloading to unapproved location)
- Storing patient data in VINCI Home Drive
- Aggregate data do not meet NDS threshold requirements
- Data aggregated by age do not meet HIPAA requirements
- PatientIDs such as PatientICN, ScrSSN downloaded without approval
- Dates such as Visit Dates, Dates of Admission/Discharge, dx dates downloaded without approval
- Screen shots with Patient Identifiers downloaded without approval
- Statistical output includes patient-level data or displays min/max values of identifiers
- Excel workbooks with multiple sheets not checked thoroughly
- Files created by another team member not checked prior to downloading
- Finder files or recruitment lists not approved through DART
- Code looks for particular patient IDs or includes identifiers in comments
- Using operations access to view/pull data for a research study without regulatory permissions

Risky Behavior

- Use of non-VA email for official business
  - Justified only if unavoidable
  - Convenience is not a justification
  - Can result in team missing important notifications
- Sharing patient data via VA email
  - Not considered a best practice even when encrypted
  - Requires permission of the study PI
- Sharing patient data via Teams
  - Not considered a best practice
  - Requires permission of the study PI
- The PI is responsible for the security of study data

TIPS for Staying in Compliance

- **REMEMBER** - data permissions are granted on a study by study basis. Operations data may not be used for a research study UNLESS all regulatory permissions have been approved. Data for one research study may not be shared with another study UNLESS all regulatory permissions have been approved. Further guidance can be provided by the VINCI Compliance team and VIReC.
- **READ** – if you are considering removing data from VINCI, stop and review the study's DART documentation. The DART application describes exactly where your data is to be stored. If you do not have access to DART, please consult with your P.I. or Study Coordinator. Also read the VINCI File Transfer Guide to avoid pitfalls.

More Tips!

- **REVIEW** – VHA Directive 1605.01 for a description of identifiable data and the HIPAA rule.

- **REMIND** – your team that they are each responsible for ensuring (1) only data permitted by the data steward may be downloaded from VINCI and (2) the data are downloaded to your local secure server.

- **REACH OUT** – contact the VINCI Compliance team if ever in doubt on whether study data may be downloaded from VINCI.

Resources

HIPAA RULE
(https://www.hhs.gov/hipaa)

VHA Directive 1605.01 Privacy and Release of Information *(https://www.va.gov/vhapublications)*

VHA Handbook 1200.12 Use of Data and Data Repositories in VHA Research (portions will be incorporated into Handbook 1080.01, Data Use Agreements) *(https://www.va.gov/vhapublications)*

VINCI Workspace User Guide
DART User Guide
VINCI File Transfer Guide
(https://vaww.vinci.med.va.gov/vincicentral/)

Your Principal Investigator,
Information Security Officer,
and Privacy Officer

and…please feel free to reach out to vinci@va.gov

Questions?

VINCI Support: VINCI@va.gov