

VINCI COMPLIANCE

Deborah Eddy, Audit Program Manager



VA Informatics &
Computing
Infrastructure



What will we cover today?

- Meet the VINCI Compliance Team
- Operations vs Research projects
- 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
- Most important takeaways

VINCI Compliance Team

Jeffrey Scehnet, PhD, MSRegSci, CIPP/G



Deborah Eddy, B.S.
Audit Program Manager



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

<http://vaww.vhadataportal.med.va.gov/DataAccess/DataAccessOverview.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 ePAS tool to request access to identifiable patient data.
- The BaseCamp site is used to create a VINCI operations project folder.
- 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 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, a VINCI Data Manager will create a project folder and provide views to the data.

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 study's 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, including compliance with VHA Handbook 1200.12. Data repositories may be an option in some cases. 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 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 B of VHA Handbook 1605.1 address the de-identification of data. Data are considered to be sufficiently de-identified if either the Safe Harbor method or the Expert Determination method have been applied.
- 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

Uploading and Downloading files

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

Home About VINCI Skip to Content

VINCI Central

Welcome to the VA Informatics and Computing Infrastructure

Keyword Search

Deborah Eddy
VINCI Email: VINCI@VA.gov
Concierge Desk: 1-801-872-3324
Computer or General Help: Your IT
[VINCI Online Help](#)

- Launch Workspace
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Learn more about VINCI, VINCI Studies and the virtual environment.

My VINCI Dashboard
All your VINCI resources in one place!

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VINCIpedia

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User Guides

User Guides
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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 VAI](#)

Uploading file to VINCI:

VINCI File Transfer Tool

Upload

Download

Welcome, VHAMASTER\VHAISLEDDYD!

Before you get started

Important Note: 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 : Pick an upload destination

H:\Upload

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H:\Upload



Drop files here or click to upload

011001001001011001101110010011101010011110000100001101110110110

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VINCI Services
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Computing Cloud

Computing Cloud
Computers, software, and storage



Data Sources

Data Sources
Learn about our available data



Applications

- [See All Applications](#)
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I attest that transfer of any Pe
applicable VA/VHA policies a
Accountability ACT (HIPAA).
I will be subject to full penalty
criminal and civil penalties.

If your facility is not listed, ple

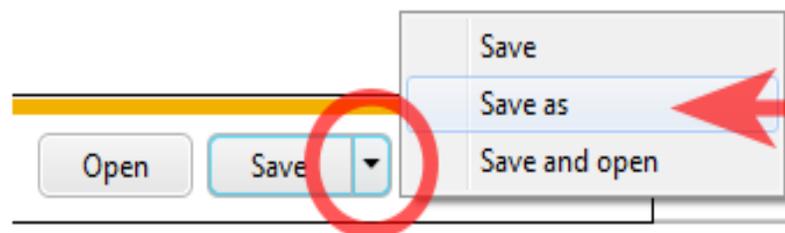
VINCI File Download



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

es is in accordance with all
ance Portability and
I am found to be in violation,
demotion, removal, and

CI@va.gov and we will add it.

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.

If your facility is not listed, please select the closest location that is listed or send your station number, city, and state to VINCI@va.gov and we will add it.

Choose a location

Select your location 

Select your location

- Select your location
- (642GD) Sewell, NJ
- (00CFM3) North Chicago, IL
- (00CFM3) Silver Spring, MD
- (00CFM3) Vallejo, CA
- (100) Auburn, NH

If your facility is not listed, please select the closest location that is listed or send your station number, city, and state to VINCI@va.gov and we will add it.

Choose a location

(514) Salt Lake, UT ▼ *

If you don't see one of your folders please try refreshing the page.

P:\Projects

O:\Projects

H:\Drive

SAS error.PNG

Do you want to open or save **SAS+ error.PNG** (6.44 KB) from www.vinci.med.va.gov?

Open

Save ▼

Save

Save as

Save and open

Avoid these Common pitfalls

- File transfer utility mistakes
- Storing patient data in VINCI Home Drive
- Aggregate data do not meet NDS threshold requirements
- Data aggregated by age do not meet HIPAA requirements
- Statistical output includes patient-level input 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 includes identifiers in comments
- Code looks for particular patient IDs
- Using operations access to view/pull data for a research study without regulatory permissions

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, including compliance with VHA Handbook 1200.12. 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 Handbook 1605.1 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

[\(<https://www.hhs.gov/hipaa>\)](https://www.hhs.gov/hipaa)

VHA Handbook 1605.1 Privacy
and Release of Information

[\(<https://www.va.gov/vhapublications>\)](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)

[\(<https://www.va.gov/vhapublications>\)](https://www.va.gov/vhapublications)

VINCI Workspace User Guide

DART User Guide

VINCI File Transfer Guide

[\(<https://vaww.vinci.med.va.gov/vincicentral/>\)](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