

## What is Covered by HIPAA at VCU?

The Privacy Rule was designed to protect private health information from incidental disclosures. The regulations specifically apply to health care providers, health plans, and health care clearinghouses that transmit health information electronically. The use of health information for research has been impacted by the Privacy Rule and HITECH by limiting the ways in which researchers may obtain or use health information that is Protected Health Information (PHI).

VCU and VCUHS are jointly covered by HIPAA regulations under what is termed the **VCU Affiliated Covered Entity (VCU ACE)**. All of the units included in the VCU ACE may have access to Protected Health Information through the conduct of standard business operations. The VCU ACE includes the following units:

- VCU Health System (VCUHS) and all satellite clinics
- School of Medicine
- School of Pharmacy
- School of Nursing
- School of Dentistry
- VCU Employee Health
- VCU Telecommunications
- VCU Audit & General Management
- VCU Police Services
- VCU Office of General Counsel
- VCU Office of Research

**Protected Health Information (PHI)** is individually identifiable health information that is obtained or used for treatment, payment or health care operations within the VCU Affiliated Covered Entity. Additionally, any identifiable health information obtained for purposes other than treatment, payment or healthcare operations (e.g., research) if held within a covered component of the VCU ACE is considered PHI. PHI must be maintained and used in compliance with the Privacy Rule (45 CFR 160). Health information is individually identifiable if it is associated with any one of a series of 18 identifiers:

1. Names
2. Geographic subdivisions smaller than state, except 3 initial zip code digits
3. All elements of dates (except year) and all ages over 89
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical Record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/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
17. Full face photographs and any comparable images
18. Any other unique identifying number, characteristic or code

Individuals who have involvement in conducting treatment, payment, or health care operations have access to PHI for business purposes. Having the ability to create or use PHI through standard operations does not allow for the use of PHI for research purposes without following one of the allowable pathways.

### **How does HIPAA affect research at VCU?**

Researchers who want to access, collect, or otherwise use PHI for research will need to follow a specific pathway for use as allowed by the Privacy Rule, regardless of the role played at VCU. Even health care providers cannot access or use PHI about their own patients for research unless following one of the pathways.

Access and use of PHI for research can be separated into two categories:

- 1) Use of Existing PHI
  - a. Regardless of the role a researcher plays (e.g., academic faculty, physician) or where the researcher works at VCU or VCUHS, the use of PHI for research purposes can only be done through specific pathways (identified below).
  - b. Researchers who are also health care providers are not permitted to use PHI from their own patient files without following one of the pathways.
- 2) Creation of new PHI
  - a. Individually identifiable health information created through research involving medical procedures within the VCU ACE that may involve billing to an insurance company (e.g., clinical trial) is PHI. In most cases, the research participant must sign a HIPAA authorization allowing the researcher to use the health information collected for research purposes.
  - b. Research related, individually identifiable health information that is not associated or derived from the provision of care or payment for care is PHI if the health information is held within a component of the VCU ACE. The health information must be protected according to the standards established by the Privacy Rule, meaning that any breach of confidentiality to unauthorized parties must be reported to the Privacy Office.
  - c. Specific examples of these concepts include:
    - i. Health information created through research that will be entered into the medical record is PHI.

- ii. Health information self-reported by a research subject to an investigator that is maintained in a research database within the School of Pharmacy is PHI.
- iii. Health information collected for non-treatment related reasons (i.e., purely for research) is PHI when it is held in a research database within the School of Medicine.
- iv. Health information collected for research purposes only when it is held within the School of Humanities and Sciences is not PHI.

## Pathways for Accessing and Using PHI

De-Identified Data	Review Preparatory to Research (VCU PHI only)	Limited Data Set and Data Use Agreement	Research with Decedent PHI (VCU PHI only)	Signed HIPAA Authorization	Partial Waiver of Authorization	Waiver of Authorization
Affected Research Activities	Affected Research Activities	Affected Research Activities	Affected Research Activities	Affected Research Activities	Affected Research Activities	Affected Research Activities
<ul style="list-style-type: none"> <li>All research – related activities involving PHI where data is recorded without any of the 18 identifiers</li> </ul>	<ul style="list-style-type: none"> <li>Accessing PHI held by the VCU ACE to <b>determine feasibility</b> (# of possible research participants available)</li> <li>Only needed when determining feasibility requires researcher to review identifiable health information</li> </ul>	<ul style="list-style-type: none"> <li>Any PHI data where some specific identifiers are sufficient – see below</li> <li><b>The VCU data use agreement only applies to PHI collected from within the VCU ACE</b></li> <li>Other covered entities (e.g., private physicians) may require their own data use agreement</li> </ul>	<ul style="list-style-type: none"> <li>Any PHI data from within the VCU ACE pertaining to decedents</li> </ul>	<ul style="list-style-type: none"> <li>All research activities involving PHI where none of the other pathways apply</li> </ul>	<ol style="list-style-type: none"> <li>Accessing PHI to identify potential participants for <b>recruitment</b> with intent to obtain signed authorization upon enrollment</li> <li>Request to waive 1 or more required elements of Authorization, such as signature when documentation of Authorization is not practicable.</li> </ol>	<ul style="list-style-type: none"> <li>Research activities involving PHI where preceding pathways are not possible <b>AND</b> It is not practicable to obtain signed authorization</li> <li>Generally appropriate under the same circumstances as waiver of consent</li> </ul>
<b>How to Use PHI</b>	<b>How to Use PHI</b>	<b>How to Use PHI</b>	<b>How to Use PHI</b>	<b>How to Use PHI</b>		<b>How to Use PHI</b>
<ul style="list-style-type: none"> <li>Not subject to HIPAA if 1 of 2 options is followed.</li> <li>Option 1: <ul style="list-style-type: none"> <li>May not record any of the 18 HIPAA identifiers</li> <li>A unique code not derived from any of the 18 identifiers may be associated with</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Submit Review Preparatory to Research Form to ORSP. Form will be acknowledged.</li> <li>Other <b>KEY POINTS</b>: <ul style="list-style-type: none"> <li>NO PHI may be removed from the VCU ACE under a review preparatory to research</li> <li>Review Preparatory to</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Allowed identifiers: <ul style="list-style-type: none"> <li>Geographic information above the street level (e.g., city, state, zip code)</li> <li>Numbers including ages, dates, device ID numbers, serial numbers</li> <li>Other unique identifiers not on the list of 18</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Submit a Research on Decedents form to ORSP</li> <li>ORSP will review the form and acknowledge the use</li> <li>NO IRB review is required if the research only uses decedent data</li> <li>ORSP has the right to request documentation that all individuals are</li> </ul>	<ul style="list-style-type: none"> <li>Research authorizations require specific information and statements (see templates)</li> <li>Submit with IRB application: <ul style="list-style-type: none"> <li>Informed Consent document containing Authorization information and statements; OR</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Submit request to partially waive authorization with IRB application explaining whether the partial waiver is for recruitment or to waive elements of consent</li> <li>IRB will review and approve</li> </ul>	<ul style="list-style-type: none"> <li>Submit request for waiver of authorization with IRB application</li> <li>IRB will review and approve</li> <li>VCU IRB approval of a waiver may or may not be accepted by other covered providers outside of the VCU ACE</li> </ul>

<p>the data. The researcher may not have access to the key to the code.</p> <ul style="list-style-type: none"> <li>○ Select de-identified data as HIPAA pathway</li> <li>• Option 2: <ul style="list-style-type: none"> <li>○ Use statistical methods to render the information not individually identifiable</li> <li>○ Must have written certification from a qualified statistician that the risk of re-identification is "very small".</li> <li>○ Submit certification to ORSP</li> </ul> </li> <li>• IRB approval may be required for either option.</li> </ul>	<p>Research does not allow for recruitment activities</p>	<p>HIPAA identifiers</p> <ul style="list-style-type: none"> <li>• Submit a data use agreement to the ORSP</li> <li>• ORSP will sign and return a copy to the researcher</li> </ul>	<p>deceased</p>	<ul style="list-style-type: none"> <li>○ Separate authorization document in addition to Informed Consent</li> </ul>		
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