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

<table>
<thead>
<tr>
<th>De-Identified Data</th>
<th>Review Preparatory to Research (VCU PHI only)</th>
<th>Limited Data Set and Data Use Agreement</th>
<th>Research with Decedent PHI (VCU PHI only)</th>
<th>Signed HIPAA Authorization</th>
<th>Partial Waiver of Authorization</th>
<th>Waiver of Authorization</th>
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<td><strong>Affected Research Activities</strong></td>
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<td>• All research-related activities involving PHI where data is recorded without any of the 18 identifiers</td>
<td>• Accessing PHI held by the VCU ACE to <strong>determine feasibility</strong> (# of possible research participants available)</td>
<td>• Any PHI data where some specific identifiers are sufficient – see below</td>
<td>• Any PHI data from within the VCU ACE pertaining to decedents</td>
<td>• All research activities involving PHI where none of the other pathways apply</td>
<td>1. Accessing PHI to identify potential participants for <strong>recruitment</strong> with intent to obtain signed authorization upon enrollment</td>
<td>• Research activities involving PHI where preceding pathways are not possible <strong>AND</strong> It is not practicable to obtain signed authorization</td>
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<td></td>
<td>• Only needed when determining feasibility requires researcher to review identifiable health information</td>
<td>• The VCU data use agreement only applies to PHI collected from within the VCU ACE</td>
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<td>2. Request to waive 1 or more required elements of Authorization, such as signature when documentation of Authorization is not practicable.</td>
<td>• Generally appropriate under the same circumstances as waiver of consent</td>
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<td>• Other covered entities (e.g., private physicians) may require their own data use agreement</td>
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**How to Use PHI**

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<td>• Not subject to HIPAA if 1 of 2 options is followed.</td>
<td>• Submit Review Preparatory to Research Form to ORSP. Form will be acknowledged.</td>
<td>• Allowed identifiers: o Geographic information above the street level (e.g., city, state, zip code)</td>
<td>• Submit a Research on Decedents form to ORSP</td>
<td>• Research authorizations require specific information and statements (see templates)</td>
<td>• Submit request to partially waive authorization with IRB application explaining whether the partial waiver is for recruitment or to waive elements of consent</td>
<td>• Submit request for waiver of authorization with IRB application</td>
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<td>• Option 1: o May not record any of the 18 HIPAA identifiers o A unique code not derived from any of the 18 identifiers may be associated with</td>
<td>• Other KEY POINTS: o NO PHI may be removed from the VCU ACE under a review preparatory to research o Review Preparatory to</td>
<td>o Numbers including ages, dates, device ID numbers, serial numbers</td>
<td>• ORSP will review the form and acknowledge the use</td>
<td>• Submit with IRB application: o Informed Consent document containing Authorization information and statements; OR</td>
<td>• IRB will review and approve</td>
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<td>o Other unique identifiers not on the list of 18</td>
<td>• NO IRB review is required if the research only uses decedent data</td>
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<td>• VCU IRB approval of a waiver may or may not be accepted by other covered providers outside of the VCU ACE</td>
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<td>• ORSP has the right to request documentation that all individuals are</td>
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<td>Research does not allow for recruitment activities</td>
<td>HIPAA identifiers</td>
<td>deceased</td>
<td>○ Separate authorization document in addition to Informed Consent</td>
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<td>○ Select de-identified data as HIPAA pathway</td>
<td>○ Submit a data use agreement to the ORSP</td>
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<td>○ Use statistical methods to render the information not individually identifiable</td>
<td>○ ORSP will sign and return a copy to the researcher</td>
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<td>○ Must have written certification from a qualified statistician that the risk of re-identification is &quot;very small&quot;.</td>
<td>○ Submit certification to ORSP</td>
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<td>○ IRB approval may be required for either option.</td>
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