

VANDERBILT  UNIVERSITY
MEDICAL CENTER

Policy: Hybrid Entity Designation

Category	Information Mgmt.
Policy Number	
Approval Date	July 2019
Effective Date	July 2019
Supersedes	New

Applicable to VUMC Areas (and associated workforce members):

- Compliance Finance Hospitals and Clinics Human Resources
 Information Technology Research

Approval Committee(s)

- Compliance and Corporate Integrity Committee
 Information Privacy and Security Executive Committee

Content Expert(s)

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I. Purpose:

To facilitate compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and the implementing regulations of each, including but not limited to the 2013 Omnibus Final Rule, (collectively, HIPAA, HITECH and the regulations shall be referred to herein as “HIPAA”) by establishing guidelines for the proper use of the Hybrid Entity designation as defined by HIPAA.

Vanderbilt University Medical Center (VUMC) is a Covered Entity that is engaged in business activities that include both HIPAA-covered and non-covered functions. HIPAA allows entities that are engaged in both HIPAA-covered and non-covered functions to designate themselves as “Hybrid Entities,” with the result that HIPAA does not apply to the non-covered functions.

II. Policy:

VUMC is a Hybrid Entity, as defined by and designated in accordance with this policy.

The VUMC Covered Entity (VCE) is made of the VUMC Covered Components and includes but is not limited to the VUMC hospitals, clinics and practices, Vanderbilt Medical Group, and VUMC Administration, as well as Workforce Members, including those within the Vanderbilt School of Medicine and the

Vanderbilt School of Nursing, for Covered Functions that involve the use or disclosure of PHI. The VUMC Health Plan is also a Covered Entity and included in the VCE; however, it is treated as a separate covered entity with a separate Privacy Official and PHI is not shared between the VCE providers and VCE health plans unless it is allowed by HIPAA. (*See also*, Section IV.D, below). Whether a VUMC function or individual's activity on behalf of VUMC is included in the VCE is determined based not upon any particular department or unit, but instead upon the data being used and/or disclosed.

All components of the VCE are required to comply with VUMC's Information Management policies and HIPAA.

III. Definitions:

- A. **Business Associate:** A person or entity, other than a member of the workforce of the covered entity, who performs functions or activities on behalf of, or provides certain services to a covered entity, or for an organized health care arrangement in which the covered entity participates, that involves the creation, receipt, maintenance, or transmission of protected health information (PHI) of a Covered Entity. Business Associate includes a subcontractor who/that creates, receives, maintains, or transmits PHI on behalf of the Business Associate. Examples of Business Associates include, without limitation, service providers that perform claims processing or administrative services, accreditation, data analysis, billing, legal services, consulting, software maintenance or support that includes access to PHI, or accounting services. A covered entity can be a Business Associate of another covered entity.
- B. **Covered Components:** those components and individuals of a Covered Entity whose activities include functions that make the component or individual a Covered Entity or Business Associate.
- C. **Covered Entity:** (i) a health care provider who transmits any health information in electronic form in connection with a transaction between two parties to carry out financial or administrative activities related to health care; (ii) a health plan; or (iii) a health care clearinghouse.
- D. **Covered Functions:** those VUMC functions that involve the use or disclosure of PHI as a Covered Entity or Business Associate.
- E. **Hybrid Entity:** a single legal entity: (i) that is a Covered Entity; (ii) whose business activities include both HIPAA-covered and non-covered functions; and (iii) that designates the components covered by HIPAA in accordance with HIPAA.

- F. Individually Identifiable Health Information (IIHI): health information, including demographic information collected from an individual, created or received by a health care provider, health plan, employer, or health care clearinghouse and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and identifies the individual, or can reasonably be used to identify the individual.
- G. Protected Health Information (PHI): IIHI that is transmitted or maintained in any form or medium by a covered entity. PHI excludes IIHI in education records covered by the Family Educational Rights and Privacy Act (FERPA); in employment records held by a covered entity in its role as employer; and regarding a person who has been deceased for more than 50 years.
- H. Research Health Information (RHI): RHI is a term used by VUMC to identify IIHI used for research purposes that is not PHI. RHI is IIHI that is created in connection with research activity and is not created in connection with patient care activity. IIHI that is created as PHI and is needed for research purposes may be disclosed to a researcher pursuant to the IRB approval process, which includes proper patient authorization or IRB waiver of authorization. After the PHI is properly disclosed to the research setting, the IIHI transferred to the research setting become RHI.
- I. Workforce: Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.
- J. Workforce Member: Any individual performing work for or on behalf of VUMC and under the direct supervision or control of VUMC, whether or not the member is employed by VUMC; including, but not limited to:
 - 1. All staff, faculty, and house staff, including visiting house staff;
 - 2. Temporary or contract workers who will have direct access to Protected Health Information (PHI) in any form (verbal, written, or electronic);
 - 3. Students and trainees including, but not limited to:
 - a. Medical, nursing, and allied health professional students;

- b. Student internships/externship programs (medical and nursing);
- c. Student apprenticeships; and
- d. Visiting students.
4. Volunteers who will have direct access to PHI in any form (verbal, written, or electronic); and
5. Vendor representatives working on-site.

IV. Specific Information:

- A. Assessment and Re-Assessment of Hybrid Entity Status:
 1. In 2002, a task group comprised of representatives from Vanderbilt University (VU) administrative offices such as Information Technology, Office of the General Counsel, Medical Center Administration and the Privacy Office conducted an assessment to ascertain which VU components engaged in activities to which the HIPAA privacy standards applied. Based upon this assessment, VU designated itself as a Hybrid Entity effective as of April 14, 2003. The Hybrid Entity designation was updated in 2005 to better define Covered Functions based upon the data being used and/or disclosed.
 2. Effective April 29, 2016, VUMC transitioned from VU to a new 501c3 tax-exempt entity that continues its health care, education, and research missions as an academic medical center and VUMC re-designated itself as a Hybrid Entity.
 3. Identifying those individuals and departments that are part of the VCE is a difficult process complicated by the fact that VUMC is engaged in multiple Covered Functions and non-covered functions across its tripartite mission. Workforce Members include employees, volunteers, trainees, and other persons whose conduct, in the performance of work for VUMC, is under the direct control of VUMC whether or not they are paid by the VUMC. Workforce Members often have multiple roles, both covered and non-covered. Therefore, determination of those components and individuals who are included in the VCE is a dynamic and ongoing process.

B. Data Categories:

1. The data categories of IIHI, PHI and RHI are critical to the determination of Covered Functions and activities. IIHI is PHI when it is transmitted or maintained in any form or medium by a Covered Component within the VCE. This specifically excludes education records, which are protected by other privacy regulations, employment records held by VUMC in its role as an employer and RHI, which is protected by other regulatory requirements.
2. Key Determinants: The key determinants as to whether information is IIHI and not protected by HIPAA or PHI and protected are: 1) the function being performed by the provider or health plan; and 2) the purpose for which an entity or Workforce Member has received, created or maintained the medical information (e.g., treatment, payment, operations, other). Record keeping practices are not the sole determinant. For example:
 - a. The results of a fitness for duty exam are PHI when VUMC as a provider and part of the VCE administers the test to a VU or VUMC employee. When the employee authorizes VUMC, the health care provider, to turn over the information to VU or VUMC, the employer, it is a part of the employee's employment record and no longer PHI. It is important to note that in most circumstances (exceptions include workplace injury, illness or medical surveillance) the employee must provide a signed Authorization to the VUMC health care provider to release the information to VU or VUMC, the employer.
 - b. When a researcher is not also functioning as a health care provider and creates IIHI in connection with pure research activities (no patient care involved) and the IIHI is not maintained in the electronic medical record, the IIHI is not PHI and is not subject to the privacy and security rules of HIPAA. If a researcher is also a health care provider and IIHI is created in connection with the researcher's health care provider activities, then the IIHI is PHI subject to HIPAA. In certain cases, such as interventional clinical trials, it is expected there will be two copies of some IIHI: a copy kept in the patient's medical record which is PHI and

subject to HIPAA, and a copy of the same data kept in the research record which is RHI and not subject to HIPAA.

C. Criteria for Determining Covered Functions:

The following criteria are used to determine whether a function or individual Workforce Member is included as a Covered Component in the VCE:

1. Health care or health plan use or disclosure: When the use or disclosure of IIHI is carried out in connection with a health care provider or health plan function by VUMC Workforce Members, the individual's health information is defined as PHI, and HIPAA privacy and security regulations apply to those functions and to the Workforce Members who carry out those functions;
2. Functions that support health care or health plan: When the use or disclosure of IIHI is carried out by business, financial, legal or administrative functions on behalf of VUMC's health care provider or health plan activities, the individual's information is PHI and the HIPAA privacy and security regulations apply to those functions and to the Workforce Members who carry out those functions;
3. Functions in the role of a Business Associate: When the use and disclosure of IIHI is carried out in connection with a service agreement with another Covered Entity such that the VUMC Workforce Member is performing functions or activities on behalf of, or providing certain services to a Covered Entity, or for an organized health care arrangement in which the covered entity participates, that involves the creation, receipt, maintenance, or transmission of PHI of a Covered Entity, then that IIHI is PHI and the HIPAA privacy and security regulations apply to those functions and to the Workforce Members who carry out those functions. In such instances, the PHI should not be co-mingled with VUMC PHI nor should it be shared with other VUMC Workforce Members who are not acting in the Business Associate role;
4. Employer functions: When the use and disclosure of IIHI is carried out by VUMC in its capacity as an employer, the information is not PHI and those VUMC functions are not subject to the privacy or security regulations of HIPAA, but the confidentiality of the

individual's health information is protected by other state and federal law, as well as by VUMC policy; and

5. IRB functions: PHI may only be disclosed to a researcher for use in connection with an IRB-approved protocol pursuant to authorization or waiver of authorization or an exempted project. When a researcher requests access to PHI that has been created, received or maintained by the VCE, HIPAA requires that the VCE receive specific assurances that the PHI will be protected once disclosed to the researcher for use as RHI, and VUMC must account for certain disclosures as required by the HIPAA regulations. VUMC's IRB will function as the Privacy Board as defined by HIPAA.

D. Transfer of PHI Between Covered and Non-Covered Components:

1. Patient authorization required: When Workforce Members who provide services to the VCE perform services on behalf of non-covered components of VUMC or to VU, these non-covered functions are not part of the VCE. Workforce Members must not disclose PHI to non-covered VUMC components without the individual or patient's authorization, or waiver of authorization by the IRB in the case of disclosures for research purposes, as required by HIPAA.
2. Disclosure between Health Plan and Providers: Workforce Members who provide business and finance services to both VCE providers and VCE health plans cannot use or disclose PHI between those components unless it is allowed by, and in compliance with, HIPAA.
3. Disclosures between Covered Entity and Business Associate Components: Workforce Members who provide business and finance services to both the VCE and outside covered entities (or business associates) that are not part of the VUMC Affiliated Covered Entity pursuant to a service agreement cannot use or disclose PHI between the VCE and the outside entity unless it is allowed by, and in compliance with, HIPAA.
4. Service Level Agreements with VU: VU provides certain services to VUMC pursuant to various Service Level Agreements (SLAs). Business Associate Agreement(s) (BAAs) are also maintained where VU, other than as a Member of the VCE Workforce, is

performing functions or activities on behalf of, or providing services to, the VCE that involve the use or disclosure (including the creation, receipt, maintenance or transmission) of PHI. If no BAA is in place, Workforce Members must not disclose PHI to VU unless it is allowed by, and in compliance with, HIPAA.

V. Endorsement:

Information Privacy and Security Executive Committee May 2019

Compliance and Corporate Integrity Committee July 2019

VI. Approval:

Wright Pinson July 16, 2019
CEO of Vanderbilt Health System
Deputy CEO of Vanderbilt University Medical Center
Chair, Compliance and Corporate Integrity Committee

VII. References:

VUMC Policy Manual. (2019). Retrieved from <https://vanderbilt.policytech.com>.

Information Management Category:
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