

**Vanderbilt University**  
**Statement on its Designation as a Hybrid Entity under HIPAA**

**I. INTRODUCTION**

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") is a consumer protection law intended to protect individually identifiable information relating to the physical or mental health of an individual, the provision of health care to the individual, or the payment for the provision of health care to the individual ("Protected Health Information" or "PHI"). HIPAA applies to "Covered Entities, which include health care providers, health plans and health care clearinghouses that conduct specified transactions electronically ("Covered Entities" or each a "Covered Entity"). Vanderbilt University is engaged in both Covered Entity activities and activities that are not Covered Entity functions. HIPAA allows entities that are engaged in both Covered Entity functions and other activities that are not Covered Entity functions to designate themselves as "Hybrid Entities," with the result that the HIPAA regulations do not apply to the non-covered functions.

**II. ASSESSMENT AND RE-ASSESSMENT OF HYBRID ENTITY STATUS**

In 2002, a task group comprised of representatives from Vanderbilt University administrative offices such as Information Technology, Office of the General Counsel, Medical Center Administration and the Privacy Office conducted an assessment to ascertain which Vanderbilt units engage in activities to which the HIPAA privacy standards apply. Based upon this assessment, Vanderbilt designated itself as a Hybrid Entity effective as of April 14, 2003.

Identifying those individuals and entities that are part of the Vanderbilt University Covered Entity ("VCE") is a difficult process complicated by the fact that Vanderbilt is engaged in multiple covered functions and non-covered functions with a mission that includes education, health care, and research. Workforce members often have multiple roles, both covered and non-covered. Therefore, determination of those entities and individuals who are included in the VCE is a dynamic and ongoing process. Based upon additional experience and learning since Vanderbilt's initial designation of Hybrid Entity status, Vanderbilt has determined the need to update its official designation of the functions and individuals included in its VCE to properly account for this ongoing dynamic.

Effective as of March 30, 2005, the VCE includes the Vanderbilt University Medical Center hospitals, clinics and practices, Vanderbilt Medical Group, Vanderbilt School of Medicine, Vanderbilt School of Nursing, Vanderbilt Health Plan, and Vanderbilt University Medical Center Administration, for covered functions that involve the use or disclosure of PHI. Whether a Vanderbilt function or individual's activity on behalf of Vanderbilt is included in the VCE is hereafter determined based not upon any particular department or unit, but instead upon the data being used and/or disclosed.

### III. DATA CATEGORIES

The following defined categories of data are critical to the determination of covered functions and activities:

- A. IIHI: Individually identifiable health information is information collected from an individual that is created or received by a health care provider, employer, plan or 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.
  
- B. PHI: Protected Health information is IIHI that is transmitted or maintained in any form or medium by a covered function within the VCE. This specifically excludes education records, which are protected by other privacy regulations, and employment records held by Vanderbilt in its role as an employer. This also excludes research health information (see definition below), which is protected by other regulatory requirements.
  
- C. RHI: Research Health Information is a term used by Vanderbilt to identify IIHI used for research purposes that is not PHI, and thus is NOT subject to the requirements of HIPAA. RHI is IIHI that is created in connection with research activity and is not created in connection with patient care activity. 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) 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. IIHI that is created as PHI and is needed for research purposes may be disclosed to a researcher (the same individual healthcare provider who is also a researcher may disclose PHI to herself in her research role) 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 becomes RHI, which is no longer subject to the requirements of 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.
  
- D. Key Determinants: The key determinants as to whether or not information is IIHI and not protected by the Privacy Rule 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 (treatment, payment, operations, other). Record

keeping practices are not the determinant. For example, the results of a fitness for duty exam are PHI when Vanderbilt as a provider and part of the VCE administers the test to a Vanderbilt employee. When the employee authorizes Vanderbilt, the health care provider, to turn over the information to Vanderbilt, 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 Vanderbilt health care provider to release the information to Vanderbilt, the employer.

#### **IV. CRITERIA FOR DETERMINING COVERED FUNCTIONS**

The following criteria are used to determine whether a function or individual workforce member is included in the VCE:

- A. Health care or health plan use or disclosure: When the use or disclosure of individually identifiable health information ("IIHI") is carried out in connection with a health care provider or health plan function by Vanderbilt 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;
- B. 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 Vanderbilt's health care provider and 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;
- C. Employer and education functions: When the use and disclosure of IIHI is carried out by Vanderbilt in its capacity as an employer or an educational institution, the information is not PHI and those Vanderbilt 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 Vanderbilt policy; and
- D. IRB functions: PHI may only be disclosed to a researcher for use in connection with an IRB-approved or exempt protocol and pursuant to a waiver or authorization. When a researcher requests access to PHI that has been created, received or maintained by the VCE, the Privacy Rule requires that the VCE receive specific assurances that the PHI will be protected once disclosed to the researcher for use as RHI, and Vanderbilt must account for certain disclosures as required by the HIPAA regulations. Vanderbilt's IRB will function as the Privacy Board as defined by HIPAA.

E. Examples of workforce members who may provide business, finance, legal or other services to covered functions: Workforce members of the following components of Vanderbilt may provide administrative functions on behalf of the VCE (use of PHI subject to the requirements of HIPAA) and on behalf of non-covered components of Vanderbilt (IIHI not subject to the requirements of HIPAA):

1. Finance;
2. Informatics;
3. Office of the General Counsel;
4. Office of Internal Audit;
5. Vanderbilt Environmental Health & Safety
6. Office of Risk Management;
7. News and Public Affairs;
8. Alumni Affairs;
9. Vanderbilt University Police Department;
10. Development Office;
11. Office of Compliance and Corporate Integrity;
12. Institutional Review Boards and individual Vanderbilt Researchers;
13. Information Technology and Office of Technology Transfer; and
14. Other Vanderbilt entities that perform covered functions for entities within the VCE as determined by the HIPAA Executive Committee.

## **V. TRANSFER OF PHI BETWEEN COVERED AND NON-COVERED COMPONENTS**

A. Patient authorization required: When workforce members who provide services to the VCE perform services on behalf of non-covered components of Vanderbilt, these non-covered functions are not part of the VCE. Workforce members must not disclose PHI to non-covered Vanderbilt 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 the Privacy Rule.

B. 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 entities unless it is allowed in the Privacy Rule.

## **VI. EXAMPLES OF INDIVIDUALS NOT INCLUDED IN THE VCE**

Examples of functions and individuals excluded from the VCE include, but are not limited to, the Student Recreation Center and the Psychological Counseling Center as well as the Vanderbilt Human Resource Services Department. Also, any research component of Vanderbilt that does not function as a health care provider and does not conduct business associate-like functions on behalf of a health care provider is not included in the VCE. For example, a research component that conducts purely records

research is not performing a covered or business associate-like function and thus, cannot be included in the VCE.

IIIHI collected and/or maintained by these components are not PHI and, therefore, are not subject to HIPAA.