Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: X.A
Section: Conduct of Research
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: April 14, 2003
Revision Dates: March 19, 2004; May 28, 2004; November 16, 2005; July 1, 2015

Subject: Health Insurance Portability and Accountability Act (HRPAA) Policy

Definitions:
1. **Anonymous Data**: Information that was previously recorded or collected without any of the 18 identifiers as defined by HIPAA (See Appendix A), and no code is assigned which would allow data to be traced to an individual.

2. **Authorization**: A customized document, usually as a part of the informed consent document, that gives an Investigator permission to use specified protected health information (PHI) for a specific purpose, or to disclose PHI to a third party specified by the Investigator other than for treatment, payment or healthcare operations.

3. **Coded Information/Data**: For the purposes of this policy, identifying information that would enable the Investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

4. **Covered Entity**: A health plan, a health care clearinghouse, or a health care provider who transmits health information and is therefore subject to the HIPAA regulations. For the purpose of this policy, any individual creating or accessing Protected Health Information (PHI) for the delivery of healthcare at Vanderbilt University is within the covered entity. RHI (as defined below) is not considered part of the covered entity.

5. **Data Use Agreement**: An agreement between VUMC and the recipient of the PHI. This agreement establishes who is permitted to use or receive the limited data set; and provides that the limited data set recipient will:
   a. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
   b. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
   c. Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
   d. Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
   e. Not identify the information or contact the individuals.

6. **De-Identified Health Information**: Health information that has been stripped of all 18 identifiers as defined by HIPAA (See Appendix A), so that the information could not be traced back to an individual. De-identified data also pertains to health information that has been assigned and retains a code or other means of identification provided that:
   a. The code is not derived from or related to the information about the individual;
   b. The code could not be translated to identify the individual; and
   c. The covered entity (as described above) does not use or disclose the code for other purposes or disclose the mechanism for re-identification.

7. **Designated Record Set**: A group of records maintained by VUMC that includes medical and billing records about an individual for the purpose of treatment, payment, or provision of health care. Research records that are not contained in the participant’s medical record are not likely to be a part of the designated record set.
8. Disclosure of PHI: The release, transfer, or provision of access to, or divulging in any manner of information outside of the covered entity.

9. Individually Identifiable Health Information: Any information collected from an individual (including demographics) that is created or received by a health care provider, health plan, employer, and/or health care clearinghouse that relates to the past, present or future physical or mental health or condition of an individual, or 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 and/or to which there is reasonable basis to believe that the information can be used to identify the individual.

10. Limited Data Set: Protected health information that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual, with the exception of city, state, ZIP Code, elements of dates, and other numbers, characteristics, or codes not listed as direct identifiers.

11. Minimum Necessary Standard: The least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request of PHI.

12. Preparatory to Research: Any action taken in assessing the research question or hypothesis, such as accessing medical records, querying of databases for any type of individually identifiable health information, or any activity where PHI is accessed to prepare a research protocol.

13. Protected Health Information (PHI): Individually identifiable health information that is or has been collected or maintained by the covered entity in the course of providing healthcare that can be linked back to the individual participant.

14. Research Health Information (RHI): Individually identifiable health information that is or has been collected solely for the purposes of research.

15. Use of PHI: Querying, viewing, and/or extracting any protected health information for research purposes within the covered entity.

Policy:
It is the policy of the Human Research Protections Program (HRPP), in its role as the Privacy Board for Research for Vanderbilt University Medical Center (VUMC), that research data be used, stored and/or disclosed according to current HIPAA regulations.

I. This policy defines the circumstances under which Protected Health Information (PHI) may and may not be used internally or disclosed externally in connection with research activities. This Policy covers all PHI, which is or may be created, used or disclosed by, through or during research activities, and applies to all faculty and staff who conduct research, assist in the performance of research, or otherwise use or disclose PHI in connection with research activities at VUMC.

II. Research Use or Disclosure of PHI with Authorization.
A. An Investigator must obtain an authorization from all participants in research prior to the use or disclosure of PHI for any research related purpose not otherwise permitted or required under this policy.

B. A legally effective authorization must include the following:
   1. A specific and meaningful description of the information to be used or disclosed;
   2. The name or identification of the persons or class of persons authorized to make or receive disclosures of PHI and to use the PHI for research-related purposes;
   3. An expiration date or event, or a statement such as “end of research study” or “none” when appropriate (e.g., for a research database);
   4. A statement that the individual may revoke the authorization if requested in writing to the Principal Investigator. However, the Investigator may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual, pursuant to such authorization before it was revoked;
   5. A statement that an individual’s clinical treatment may not be conditioned upon whether the individual signs the research authorization;
6. A statement that information disclosed under the authorization could potentially be re-disclosed by the recipient and would no longer be protected under HIPAA; and
7. The individual’s signature (or that of his or her legally authorized representative) and date.

III. Waiver of Authorization.
A. In some circumstances, research authorizations otherwise required under this policy may be waived or altered by the IRB, provided the following criteria are satisfied and documented:
   1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on the presence of at least the following elements:
      (a) An adequate plan to protect the identifiers from improper use and disclosure;
      (b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such opportunity consistent with the conduct of the retention is otherwise required by law; and
      (c) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this Policy;
   2. The research could not practicably be conducted without the waiver or alteration; and
   3. The research could not practicably be conducted without access to and use of the PHI.
B. Disclosures of PHI made pursuant to a waiver are subject to the minimum necessary standard.
C. If a protocol is granted a "Waiver of Consent and/or Authorization" by the IRB, the PI must be prepared to provide the Vanderbilt Privacy Office the following information for any PHI disclosed:
   1. The date of the disclosure;
   2. The name, title, and contact number of the VUMC workforce member making the disclosure;
   3. The name of the entity or person who received the protected health information, and, if known, the address of such entity or person;
   4. A brief description of the protected health information disclosed; and
   5. A brief statement of the purpose of the disclosure that reasonably describes the basis for disclosure.
D. This mandate is pursuant to 45 CFR 164.528, which states that an individual has the right to request and receive an accounting from the covered entity of all possible disclosures of his/her protected health information that was permitted without the individual’s authorization.

IV. Use and Disclosure of PHI without Authorization when it is Preparatory to Research. An Investigator may use or disclose PHI without IRB review for the development of a research protocol, provided that all of the following criteria are satisfied:
A. The use or disclosure of PHI is solely to prepare a research protocol, or to identify prospective research participants for purposes of seeking an authorization;
B. The Investigator shall not record or remove the PHI from VUMC; and
C. The PHI sought is necessary for the purposes of the research.
V. Use and Disclosure of Decedent's PHI without Authorization.

An Investigator may use and disclose a decedent's PHI for research purposes without IRB review provided that all of the following criteria are satisfied:

A. The use will be solely for research on the PHI of a decedent;
B. The PHI sought is necessary for the purposes of the research; and
C. The Investigator has documentation of the death of the individual about whom information is being sought.

VI. Use or Disclosure of “De-Identified” Health Information.

A. De-identified health information is exempt from HIPAA regulations and may be used or disclosed for research purposes without an authorization or IRB waiver of authorization.

B. Investigators must provide documentation to the IRB that the health information has been de-identified by one of the following two methods:

1. Statistical Method: The IRB may determine that health information is de-identified for purposes of this Policy, if an independent, qualified statistician:
   a. Determines that the risk of re-identification of the data, alone or in combination with other data, is very small; and
   b. Documents the methods and results by which the health information is de-identified, and the expert makes his or her determination of risk. Note: the expert may not be the Investigator or anyone directly involved in the research study.

2. Removal of All Identifiers: Identifiers concerning the individual and the individual’s employer, relatives and household members that must be removed include: names; geographic subdivisions smaller than a state; ZIP codes; dates directly related to an individual; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images; and any other number, characteristic or code that could be used to identify the individual.

C. The de-identified information (as described in the definition above) may be assigned a re-identification code that can be affixed to the research record that will permit the information to be re-identified if necessary, provided that, the key to such a code is not accessible to the Investigator requesting to use or disclose the de-identified health information and the code is not derived from any of the 18 identifiers listed in Appendix A of this policy (e.g., initials).

VII. Limited Data Set.

A. An Investigator may use or disclose a Limited Data Set for research purposes without an authorization or waiver of authorization.

B. A Limited Data Set must exclude all of the following direct identifiers of the individual or of the individual’s employer, relatives, or household members: names; postal address information other than town or city, state, and ZIP code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images; and any other number, characteristic or code that could be used to identify the individual.

C. A Limited Data Set may be used or disclosed only if there is a “Data Use Agreement” between the covered entity and the recipient of the limited data set. A sample “Data Use
Agreement" is on the HRPP Website at [http://www.mc.vanderbilt.edu/irb/](http://www.mc.vanderbilt.edu/irb/). The "Data Use Agreement" is submitted to the Office of Contracts Management for review and signature.

**D.** The Investigator must complete a request for exemption to include the "statements of affirmation" and "data use agreement."

1. By completing the exempt application for access to PHI, the Investigator is agreeing to the following:
   (a) The use of PHI will be solely to prepare the research protocol;
   (b) The Investigator will not remove the PHI from the covered entity; and
   (c) The PHI sought is necessary for the purposes of the research.

2. In signing the "data use agreement," the Investigator is agreeing to the following:
   (a) Not to use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
   (b) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
   (c) Report to the covered entity any use or disclosure of the information not provided for by this data use agreement of which the Investigator becomes aware;
   (d) Ensure that any agents, including a subcontractor, to whom the Investigator provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
   (e) Not to identify the information or contact the individuals.

**VIII.** Participant's Access to Research Information.

Individuals who participate in research have a right to access their own PHI that is maintained in a Designated Record Set. However, individuals participating in research protocols that include treatment may be denied access to their PHI obtained in connection with that research protocol, provided that:

A. The PHI was obtained in the course of the research;
B. The individual agreed to the denial of access in the research authorization;
C. The research remains in process; and
D. The individual's rights to access such PHI are re-instatement once the research study has ended and the research authorization has expired.

**IX.** Participant's Request to Revoke Research Authorization.

An individual may revoke his or her authorization, in writing to the Principal Investigator, at any time. However, the Investigator may continue to use and disclose, for research integrity and reporting purposes, any PHI collected about the individual pursuant to a valid authorization before it was revoked.

**References:**

45 CFR 160 and 164
VUMC Privacy Office: [www.mc.vanderbilt.edu/HIPAA](http://www.mc.vanderbilt.edu/HIPAA)

**List of 18 identifiers:**

- Names;
- All geographical 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: (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000;
- 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;
· Phone numbers;
· Fax numbers;
· Electronic mail addresses;
· Social Security numbers;
· Medical record numbers;
· Health plan beneficiary numbers;
· Account numbers;
· Certificate/license numbers;
· Vehicle identifiers and serial numbers, including license plate numbers;
· Device identifiers and serial numbers;
· Web Universal Resource Locators (URLs);
· Internet Protocol (IP) address numbers;
· Biometric identifiers, including finger and voice prints;
· Full face photographic images and any comparable images; and
· Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).