

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
	Date Effective	Date Modified
Title: JHSPH HIPAA Policy	1/27/2006	7/30/07

BACKGROUND

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provided the first national standards for protecting the privacy and security of health information and gave new rights to individuals with respect to their health information. The HIPAA Privacy Rule regulates how covered entities may use and disclose individually identifiable health information (called protected health information or PHI), in whatever form--on paper, electronic, or oral. Only individually identifiable health information that is created or received by a covered entity qualifies as PHI and is covered by HIPAA. HIPAA applies to covered entities and does not cover "researchers" per se. However, for JHSPH researchers to gain access to health information that is generated or stored at any HIPAA covered entity, investigators may have to provide the covered entity with written assurances regarding how the health information will be used and protected. These assurances are necessary in order for the covered entity to be allowed to release the health information to the investigator.

POLICIES AND PROCEDURES

The Johns Hopkins University is a single legal entity that performs both HIPAA covered and non-covered functions. A covered function is when a health plan, health care provider, or a health care clearinghouse transmits health information in an electronic form in connection with a HIPAA defined "standard transaction." (These transactions are generally transactions related to financial matters.) For entities like the University that contain both covered and non-covered functions, a "hybrid entity" determination can be made, specifying which parts are covered by HIPAA and which are not. JHU has elected to be a hybrid entity for HIPAA purposes. The health care provider components of the University, the School of Medicine and the School of Nursing, perform covered functions and are the designated covered entities within the University hybrid entity. Additionally, the Johns Hopkins Health System's affiliates (including JHH, BMC, JHCP, and Johns Hopkins HealthCare) are covered entities. (For a complete list of JHU/JHHS covered entities, please see the document entitled, "Johns Hopkins Covered Entities.") JHSPH is not a

health care provider component of JHU that transmits health information electronically as contemplated by HIPAA. Consequently, JHSPH does not perform covered functions and is not within the covered entity portion of JHU.

JHSPH Researcher HIPAA Considerations

If a study will use and disclose individually identifiable health information emanating from a covered entity or if the identifiable information will be manipulated in some way under a covered entity, then the study is likely to be impacted by HIPAA. If a study is impacted by HIPAA, the study design and required documentation will be affected by the Privacy Rule as well as this policy. For information on the application process, see the below section entitled, "Application Process."

- I. **JHSPH researchers may be affected by the Privacy Rule in various ways.**
 - A. **JHSPH researchers seeking to access PHI from a JHU/JHHS covered entity for a JHSPH protocol (i.e. a protocol on which the PI is a JHSPH researcher and which is being processed by the JHSPH IRB [hereafter sometimes referred to as "IRB"], if applicable).** (For a complete list of JHU/JHHS covered entities, please see the document entitled, "Johns Hopkins Covered Entities")
 1. Research Using de-identified information
 - a. If a JHSPH researcher desires to use de-identified information, the JHSPH researcher will be responsible for de-identifying (or obtaining the de-identification of) the PHI in accordance with HIPAA requirements.
 - b. The PI must complete a HIPAA application providing adequate assurance that the data is to be de-identified.
 - c. The JHSPH researcher must enter into a Business Associate Agreement with the Johns Hopkins HIPAA Office using a standard Johns Hopkins Business Associate Agreement (BAA) designed specifically for use with SPH researchers.
 - i. To obtain a BAA, JHSPH researchers must provide to the Johns Hopkins HIPAA Office their full name, their address, the name of their study, and an identification of the Johns Hopkins covered entity or entities that hold the records from which they intend to obtain the de-identified data.
 - d. If the data meets the HIPAA requirements of being de-identified, no waiver or Authorization is needed.
 - e. Health information, as described by the Privacy Rule, is not PHI once it is de-identified as defined by HIPAA.
 2. Research using a limited data set
 - a. If a JHPSH researcher desires to use a limited data set, the JHSPH researcher will be responsible for creating the limited data set in accordance with HIPAA requirements.
 - b. The JHSPH researcher must complete a HIPAA application representing that only a HIPAA compliant limited data set of PHI is to be obtained.

- c. The JHPSH researcher must enter into a Business Associate Agreement with the Johns Hopkins HIPAA Office using a standard Johns Hopkins Business Associate Agreement (BAA) designed specifically for use with SPH researchers. The BAA allows the researcher to access the PHI to create the limited data set.
 - d. The JHSPH researcher also must enter into a Data Use Agreement with the Johns Hopkins HIPAA Office using a standard Johns Hopkins Data Use Agreement form designed specifically for use with SPH researchers. The Data Use Agreement limits the way that the information in the data set may be used and establishes how it will be protected.
 - e. Neither an Authorization nor a waiver of Authorization is needed for the disclosure of a limited data set.
 - f. Limited data sets contain individually identifiable health information. The limited data set may be used only for the purpose stated, and as provided, in the Data Use Agreement and for no other purpose.
3. Reviews of PHI preparatory to research
- a. For activities involved in preparing for research, such as records reviews to create a research question, the covered entities within the JHU hybrid entity or within JHHS may permit a JHSPH researcher to review PHI without a patient's or plan member's Authorization, an approval for a waiver of Authorization or a Data Use Agreement.
 - b. The researcher must complete a HIPAA application and represent that:
 - i. The use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
 - ii. The PHI will not be removed from the covered entity, or printed from an electronic record or saved in an electronic form, in the course of review, except that during a review preparatory to research where the researcher is accessing PHI at a Johns Hopkins covered entity, the researcher may:
 - 1. Leave the covered entity premises with only the minimal amount of PHI necessary to satisfy the tracking requirements under HIPAA (see I.A.3.d. and subsection 10 below), and
 - 2. The PHI taken from the covered entity premises for tracking purposes may be used only to complete the tracking database and for no other purpose.
 - iii. The PHI for which access is requested is necessary for the research.
 - c. The Office for Research will provide documentation to the JH HIPAA Office making these representations.

- d. The JHSPH researcher must make appropriate entries into the SPH tracking database, noting the disclosure of PHI.
 - e. JHSPH researchers with joint appointments must comply with the HIPAA policies for reviews preparatory to research for the entity whose IRB will review the research protocol. In most cases, the researcher will be allowed access to the PHI of his/her patients for these purposes without the need for written assurances.
4. Research that involves the PHI of decedents
- a. HIPAA covers the PHI of decedents. However, HIPAA does not require researchers to obtain the Authorization of the personal representative or next of kin, an approval for a waiver of Authorization, or a Data Use Agreement to have access to the PHI of deceased persons for research; other IRB action may be required.
 - b. The researcher must complete a HIPAA application and represent that:
 - i. the use or disclosure is sought solely for research on the PHI of decedents,
 - ii. the PHI sought is necessary for the research purposes, and
 - iii. be prepared to provide documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought by the researcher.
 - c. The Office for Research will provide documentation to the JH HIPAA Office making these representations.
 - d. The JHSPH researcher must make appropriate entries into the SPH tracking database, noting the disclosure of PHI.
5. Research that involves only records review (no patient contact) and that has obtained or is applying for a waiver of informed consent.
- a. The PI will need to seek a HIPAA waiver of Authorization for the whole study from the IRB by completing a JHSPH HIPAA application.
 - b. A complete waiver occurs when the IRB determines that no Authorization will be required for a covered entity to disclose PHI for the research project.
 - c. If the IRB grants a complete waiver, the Office for Research will supply this information to the JH HIPAA Office.
 - d. The JHSPH researcher must make appropriate entries into the SPH tracking database, noting the disclosure of PHI.
6. Research that requires recruitment in a JH covered entity
- a. The researcher's treatment relationship with a patient determines the recruitment practices allowable under HIPAA.
 - i. Some researchers have a "reason to know" individually identifiable health information by virtue of their treatment relationship with a patient. These individuals do not need

Authorizations or waivers to approach their patients about being in a study.

- ii. Non-treating researchers are required to obtain a waiver or an Authorization in order to recruit or get referrals.
- iii. Please see the guidance document on mechanisms for recruitment and referral for research permitted under HIPAA.

b. Research that requires access to patient records solely for recruitment purposes, and subsequently will not be accessing PHI.

- i. The PI will need to seek a partial waiver of Authorization for recruitment by completing a JHSPH HIPAA application.
- ii. This includes research in which, following recruitment, the subjects will be surveyed, interviewed, or enrolled into an intervention that does not involve clinical activities and there will be no further accessing of PHI. Although the intervention may include obtaining private information that is protected by other privacy protections, the information obtained is not PHI.
- iii. If the IRB grants a partial waiver, the Office for Research will give the JH HIPAA Office HIPAA compliant documentation of the partial waiver.
- iv. The JHSPH researcher must make appropriate entries into the SPH tracking database, noting the disclosure of PHI.

c. Research that requires access to patient records for recruitment purposes but will subsequently consent the individuals for participation in research which will include further access to PHI.

- i. The PI must request a HIPAA partial waiver of Authorization for recruitment from the IRB by completing a HIPAA application.
- ii. If the IRB grants a partial waiver, the Office for Research will give the JH HIPAA Office HIPAA compliant documentation of the partial waiver.
- iii. The JHSPH researcher must make appropriate entries into the SPH tracking database, noting the disclosure of PHI.
- iv. At the time of the consent process, the PI must obtain the subject's Authorization for the disclosure of health information from the covered entity to the researcher using a HIPAA compliant Authorization form.

7. Research that will access PHI only post-consent process

- a. The PI must obtain the subject's authorization for the disclosure of PHI from the covered entity to the researcher using a HIPAA compliant Authorization form at the time of consent.
- b. An Authorization for the disclosure of health information allows a covered entity to release a patient's individually identifiable health information with the patient's signed permission.

- c. For JH covered entities, the JHSPH Authorization is available at www.jhsph.edu/hipaa.

8. International research

- a. Individually identifiable health information obtained for research purposes in a research setting outside the United States under an IRB approved protocol is not impacted by HIPAA if it is collected by and/or released to a JHSPH principal investigator *and* the data is held at JHSPH or another non-HIPAA covered entity.
- b. If information is sent from a research setting outside the United States to a Johns Hopkins covered entity, and if the information is identifiable (i.e. contains any of the 18 identifiers under HIPAA) or if the covered entity has access to a link between the information and the person from whom the information was obtained, the information may become subject to HIPAA.

9. Storing specimens at a Johns Hopkins covered entity

- a. If a JHSPH researcher stores specimens from a JHSPH protocol at a Johns Hopkins covered entity, those specimens will not become subject to HIPAA if all of the following exist:
 - i. The JHSPH researcher “owns” the specimens and has the total right to control the use of the specimens;
 - ii. The Johns Hopkins covered entity does not have control over the use of the specimens;
 - iii. The specimens are clearly identified as belonging to the JHSPH researcher;
 - iv. To the extent that the covered entity works with the samples, it works with de-identified information; and
 - v. If a link exists between the specimen and the individually identifiable information, the covered entity does not have access to that link.
- b. If the specimens stored at a Johns Hopkins covered entity are de-identified (i.e. the 18 identifiers under HIPAA are removed from the data), the specimens are not covered by HIPAA.

10. Accounting for disclosures

- a. A disclosure of PHI means communicating that information to a person or entity outside of the covered entity. This includes the communication of PHI from a health care provider component to a non-health care provider component of a hybrid entity (for example, from Johns Hopkins covered entities to JHSPH researchers).
- b. The Privacy Rule requires, upon receiving an individual’s request, that a covered entity give an “accounting” of certain disclosures by the covered entity, including those related to research, for a period of 6 years from the date of the disclosure. In order to be able to “account” for the disclosure, the disclosure must be “tracked” when made. Due to the close research relationship that JHSPH shares with the Hopkins “covered entity” health care components, it is

JHSPH policy to assist the JH covered entities in accounting for disclosures that occur as a result of a JHSPH study by “tracking” those disclosures. Therefore, JHSPH researchers are required to track information for the JH covered entity that discloses the PHI to them, by entering information into the designated SPH tracking database, when they obtain PHI through the following methods:

- i. Research where the IRB has fully or partially waived individual Authorization;
- ii. Research using the PHI of decedents; and
- iii. Reviews preparatory to research.

11. Limitations on the use of medical information

- a. If a PI accesses PHI through a waiver, reviews preparatory to research, or through research on decedents, the research activity may be inconsistent with the wishes of patients or plan members.
- b. If a PI receives the records of an individual and later learns that the individual had a limitation on the use of their medical information, the PI must enter the name and other identifiers of these individuals into a special database maintained by the SPH and must note the nature of the limitations.
- c. In cases where a PI has obtained a waiver or partial waiver of the Authorization requirement, prior to contacting any individual to obtain a consent/authorization relating to research, the researcher must check the database to determine if the individual that the researcher wants to contact has limited his/her being contacted for research. If a limitation is noted, the researcher must abide by the limitation.
- d. If a PI is going to use individual data previously obtained from a JH covered entity pursuant to a waiver of the Authorization requirement or research on decedents, the PI must search the limitations database and abide by any applicable restrictions.

B. **JHSPH researchers with joint appointments at the School of Medicine or the School of Nursing.**

1. PHI obtained by an SPH researcher solely in his/her capacity of providing clinical care in a Johns Hopkins health care provider setting under his/her joint appointment at SOM/SON will remain PHI. The PHI may not be used or disclosed by the SPH researcher without complying with all applicable HIPAA limitations and requirements on covered entities.
2. When the SPH researcher is conducting research through the joint appointment for a JHSPH study (i.e. a study where the PI is a JHSPH researcher and where the study is approved by the JHSPH IRB, if applicable), and if the researcher obtains or has access to PHI when providing clinical care as part of an JHSPH study:
 - a. The clinical files/medical records remain PHI and are covered by HIPAA.
 - b. However, the separate research files are **not** covered by HIPAA and will be subject only to the Common Rule.

- c. The information obtained by the researcher in the separate research records will be considered disclosed and is no longer PHI.

C. A JHSPH researcher who obtains access to PHI due to being on a protocol on which a SOM or SON researcher is the PI.

1. In the case where a JHSPH researcher is on a protocol on which a SOM or SON researcher is the PI, the SPH researcher will be treated as an “outsider.”
2. The JHSPH researcher must be identified in the HIPAA compliant Authorization or request for waiver from the Authorization requirement.
3. Any PHI that the SPH researcher obtains from participating in the protocol may be used and disclosed by the SPH researcher only in accordance with the terms of the approved protocol.
4. The PHI may not be added to a database that is accessible by other researchers who are not part of the protocol unless permitted by the approved protocol or a subsequent protocol approved by the SOM IRB.

D. JHSPH researchers seeking to access PHI from a non-Hopkins covered entity.

1. A disclosure from a non-Hopkins covered entity is the same legally as a disclosure within a hybrid entity from a designated covered entity portion to a non-covered entity portion.
2. When working with a non-Hopkins covered entity, prior to completing a HIPAA application and/or HIPAA forms, the PI must consult with the entity (or entities) from which he/she is receiving data to determine their policies.
3. The covered entity may require that the PI use their forms or follow different guidelines than what JHSPH has implemented with Johns Hopkins covered entities. The JHSPH researcher should ask the covered entity’s privacy office/privacy officer if it has a form of Authorization for Use and Disclosure of Protected Health Information for Research purposes and if a JHSPH IRB waiver of Authorization and letter of IRB approval will suffice as record of IRB review. JH HIPAA forms may be used as default forms with the covered entity’s permission. Once the covered entity is contacted, the JHSPH researcher will know exactly what HIPAA forms will need to be completed to be compliant with that covered entity’s procedures.
4. The JHSPH IRB may approve waivers or alterations of Authorization and will provide HIPAA compliant documentation of the waiver or alteration to the covered entity.

E. JHSPH researchers maintaining research databases containing PHI.

1. With the exception of PHI obtained through a Data Use Agreement (i.e. a limited data set), or otherwise limited by specific contractual terms, the Privacy Rule does not continue to protect the PHI disclosed to the researcher as long as that data is maintained at JHSPH or any other non-covered entity.
2. Individually identifiable health information that is held by anyone other than a covered entity, including an independent researcher who is not in a covered entity, is not protected by the Privacy Rule and may be used or

disclosed without regard to the Privacy Rule. There may, however, be other Federal and State protections covering the information held by these entities that limit its use or disclosure, as well as, possibly, specific contractual limitations.

3. An Authorization for research uses and disclosures may be revoked, in writing, by the research subject at any time. The individual's revocation is effective, except to the extent that the covered entity has taken action in reliance upon the Authorization prior to revocation. Therefore, the covered entity is not required to retrieve the information that it disclosed under a valid Authorization before learning of the revocation. The Preamble to the Privacy Rule states that, for research uses and disclosures, the reliance exception would permit the continued use and disclosure of PHI already obtained with an Authorization to the extent necessary to protect the integrity of the research – for example to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.

F. Any PHI received from a Johns Hopkins covered entity by a JHSPH researcher may not be used for any marketing or fundraising purposes.

II. The Application Process

- A. JHSPH investigators must complete a JHSPH HIPAA application prior to attempting to access PHI from a covered entity. If the study involves human subjects research and requires the use of individually identifiable health information emanating from a covered entity or if the identifiable information will be manipulated in some way under a covered entity, the HIPAA application must be completed. Manipulating identifiable information includes but is not limited to storage of information at a covered entity. If investigators are unsure as to whether their study is subject to HIPAA, they should contact the Research Regulations Specialist for consultation.

B. Required HIPAA documentation.

1. HIPAA Application for Disclosure of Identifiable Health Information

- a. This application should be completed whenever a study involves the use and disclosure of individually identifiable health information from a covered entity. This application helps researchers determine how they are impacted by the HIPAA Privacy Regulations. It guides investigators through the additional requirements that must be followed under HIPAA and directs investigators to the necessary forms.

2. Authorization Form

- a. Generally, the permission (authorization) of participants should be obtained when using or disclosing health information that emanates from a HIPAA covered entity. Unless the activity falls under one of the categories where Authorization is not required, the investigator must obtain an Authorization from all subjects to use and disclose their health information held by a covered entity.
- b. The JH HIPAA Authorization for the Disclosure of Health Information for Research is to be used for all IRB approved studies where PHI is being obtained from a JH covered entity pursuant to the participants'

agreement. The JH HIPAA Authorization Form has been written in simple language and contains the required HIPAA elements. The HIPAA required elements have been included as standard Authorization boilerplate for all studies that will use and disclose health information from a physician's office, a health care provider or a health plan. The HIPAA Authorization form should be separate from the consent form for research.

- c. While a combined consent form (a document that combines both the HIPAA Authorization and the informed consent form) is possible, this type of form is not encouraged or preferred at JHSPH. If an investigator is contemplating using a combined consent form, they should contact the Research Regulations Specialist. A combined consent form must be approved by the IRB.
- d. Investigators must comply with the covered entity's requirements when seeking protected health information. This may mean that the researcher is required to use the entity's Authorization form. The JH HIPAA Authorization forms may be used as a default form. If the sponsor or an outside entity requires an Authorization form, the Authorization must contain the following:
 1. The description of PHI to be used or disclosed;
 2. Persons or class of persons who may use or disclose PHI;
 3. Persons or class of persons to whom use or disclosure may be made;
 4. Purposes of the use or disclosure.
 5. The individual's signature (or that of his/her authorized representative as determined by the State law where the research will be conducted) and date.
 6. A statement that the individual may revoke the Authorization if done in writing to the covered entity holder of the PHI or to the Principal Investigator (provided that it is clear that the revocation is not effective until received by the covered entity holder of the PHI); however, the research may continue to use and disclose for research integrity and reporting purposes, any identifiable health information collected from the individual pursuant to such Authorization before it was revoked.
 7. A statement that an individual's clinical treatment or health plan participation may not be conditioned upon whether or not the individual signs the research Authorization. Participation in research may be conditioned on a signed Authorization, including treatment protocols.
 8. The possibility of re-disclosure.
 9. Expiration date (it may be the end of research study for most studies, or none for studies involving the creation of research databases.)
- e. A copy of the signed and dated Authorization should be given to the subject and a copy should be placed in the study records.

C. Tracking for Disclosures of PHI

1. Covered entities are required to account for all disclosures that they make of protected health information for the following research activities:

- a. Research where the IRB has fully or partially waived individual Authorization
 - b. Research using the PHI of decedents;
 - c. Reviews preparatory to research.
2. JHSPH researchers must enter information about the disclosure(s) into the SPH JH HIPAA Compliance System regarding the disclosure of PHI for all studies which fall into the aforementioned three categories and where the PHI is being obtained from a JH covered entity.

D. Data Use Agreement

1. A Data Use Agreement must be submitted with all JHSPH HIPAA applications requesting use of a limited data set.
2. All Data Use Agreements for limited data sets from Johns Hopkins covered entities must be the standard Johns Hopkins Data Use Agreement designed specifically for use with SPH researchers.
3. To enter into a Data Use Agreement to obtain a limited data set from a JH covered entity, contact the JH HIPAA Office at dbradfi4@jhmi.edu.

E. Business Associate Agreement

1. A Business Associate Agreement (BAA) must be submitted for all applications to create limited data sets or de-identified information. This allows a JHSPH researcher to have access to the full health record in order to create a limited data set or de-identify information.
2. A BAA may be obtained from the JH HIPAA Office. A researcher must provide his/her full name, their address, the name of the study, the study number, and the identification of the Johns Hopkins covered entity or entities that holds the records from which he or she intends to obtain the de-identified data or limited data set.
3. To enter into a BAA, contact the JH HIPAA Office at dbradfi4@jhmi.edu.

F. Completing the Forms

1. The HIPAA application is located electronically within the IRB PHIRST application and should be completed at the same time that the PHIRST application is completed. Relevant HIPAA documents, including Authorization forms (if applicable), should be uploaded to the PHIRST application. The PHIRST application can be accessed at phirst.jhsph.edu. The Johns Hopkins Authorization for Disclosure of Health Information Form for use with Johns Hopkins covered entities is available at www.jhsph.edu/hipaa.
2. A paper copy of the HIPAA application should only be completed for amendments to previously approved research studies. A paper copy of the HIPAA application for previously approved studies should be submitted to the IRB along with an amendment form. The IRB will forward paper copies of the HIPAA application to the Research Regulations Specialist for administrative review. The HIPAA Application for Disclosure of Identifiable Health Information can be found at www.jhsph.edu/hipaa.

III. Review Process

- A. The Research Regulations Specialist in the Office conducts the administrative review of HIPAA applications and applicable HIPAA forms. The IRB must review

all requests for waivers to or alterations of Authorization, otherwise the HIPAA application will be subject to administrative review.

- B. Any questions regarding your HIPAA application or requests for more information will come from the Research Regulations Specialist. All HIPAA forms must have an IRB stamp of receipt before being used in a study.
- C. IRB approval letters will indicate to investigators that their HIPAA review is complete.

IV. **Who to Contact About Questions**

- A. Questions should be directed to the Research Regulations Specialist in the Office for Research at mjoshi@jhsp.hopkins.edu or 410-502-0433. For general HIPAA questions, you may also contact the main Johns Hopkins HIPAA Office, hipaa@jhmi.edu, or 410-735-6509 or visit their website <http://www.insidehopkinsmedicine.org/hipaa/>. Questions about your IRB application should be directed to the IRB Staff Office, 410-955-3193.

V.

DEFINITIONS

Authorization- The written permission of an individual allowing a covered entity to use or disclose his/her specified PHI for a particular purpose.

Business Associate- A person or entity who performs or assists in performing a function or activity on behalf of a covered entity involving the use or disclosure of individually identifiable health information.

Covered Entity- A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard.

Covered Function- The functions of a covered entity which make the entity a health care provider, health plan, or health care clearinghouse under HIPAA.

De-identified information- For data to be de-identified, the following identifiers must be removed from the data:

1. Names;
2. All Geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census;
 - (a) The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people; (b) the initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000;
3. 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;
4. Telephone numbers;
5. Facsimile 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 fingerprints and voiceprints;
17. Full-face photographic images and any comparable images;
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

Disclosure- The release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.

Hybrid Entity- A single legal entity that is a covered entity whose business activities include both covered and non-covered functions, and that designates health care components in accordance with the HIPAA Privacy Rule.

Individually Identifiable Health Information- Information that is a subset of health information, including demographic information collected from an individual, and:

1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
 2. 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
- (a) that identifies the individual; or
- (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Limited Data Set- A HIPAA compliant limited data set may include city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. The following identifiers must be removed from the health information:

1. Names;
2. Postal address information, other than town or city, state, and ZIP Code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;

11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web universal resource locators (URLs);
14. Internet protocol (IP) address numbers;
15. Biometric identifiers, including fingerprints and voiceprints;
16. Full-face photographic images and any comparable images.

Protected Health Information- PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes educational records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

RESOURCES & REFERENCES

45 C.F.R. 164, Subpart E.

Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, available at http://privacyruleandresearch.nih.gov/pr_02.asp.