

Institutional Review Board
Penn State College of Medicine
Penn State Milton S. Hershey Medical Center

HOW DOES HIPAA APPLY TO MY RESEARCH?

What is HIPAA? Federal regulations to improve the privacy of protected health information (PHI). These became effective April 14, 2003, and are in addition to other regulations that affect research.

How do HIPAA regulations affect my research studies and participants? HIPAA regulations affect all research participants enrolled after 4/13/03; participants enrolled prior to 4/14/03 are “grandfathered in”.

How do I know if this affects my research? *Ask yourself these questions:*

1. Does my research involve anything (e.g. data, specimens, treatment, etc.) related to humans (living or dead)? ‘Yes’ – Continue with these questions
‘No’ – There are no HIPAA issues to address.
2. Is it necessary for my research to use or disclose any of the 18 identifiers¹ listed by HIPAA?
‘Yes’ – Continue with these questions
‘No’ – Clarify in your IRB application that no identifiers are used in your research. There are no other HIPAA issues to address.
3. Is my research project only a chart review to prepare for a larger research protocol?
‘Yes’ – Skip to pg. 4, Review Preparatory to Research, & Research on Decedents Information.
‘No’ – Continue with these questions
4. Does my research involve only deceased persons?
‘Yes’ – Skip to pg. 4, Research on Decedents Information.
‘No’ – You need to use a HIPAA authorization tool for the use and disclosure of PHI.
You must either:
 - Include HIPAA authorization wording in the research consent form² OR
 - Request a waiver of authorization from the IRB. (See next question.)AND you must:
 - Ascertain that each participant has seen an HMC Privacy Notice³, and
 - Obtain signed confirmation of such from the participant.⁴

How do I know if I can request a Waiver of Authorization? *Ask yourself this question:*

1. Does the use and disclosure of PHI within my research involve a minimal privacy risk to the participants because all of the following are true?
 - there is adequate protection of the PHI, and
 - there is an adequate plan for destruction of the PHI, and
 - the research is not practicable without use and/or disclosure of the PHI, and
 - the research is not practicable without a waiver of authorization‘Yes’ – Request a waiver of authorization from the IRB⁵.
‘No’ – Obtain authorization from prospective participants by including the wording in the research Consent Form.²

¹ See next page for the list of items that HIPAA has declared to be identifiers.

² The IRB research consent form template includes the authorization wording (see the IRB web site, www.pennstatehershey.org/irb).

³ HMC patients will have viewed the HMC Privacy Notice. For other participants it is available on the IRB web site (above link).

⁴ The Acknowledgement of Receipt of Privacy Notice form is available on the IRB web site (above link).

⁵ Waiver of Authorization form on IRB Website (above link).

ADDITIONAL IMPORTANT HIPAA INFORMATION

I. MINIMUM NECESSARY INFORMATION

Any person on this campus who uses or discloses health information is required by the HIPAA regulations to use and/or disclose only the minimum necessary. Each research effort should be evaluated for compliance with this policy.

II. DE-IDENTIFICATION OF PROTECTED HEALTH INFORMATION

The following is a list of elements considered to be identifiers according to HIPAA regulations. If these 18 identifiers of the participant or of the relatives, employers, or household members of the participant are removed from the research, then the research is 'de-identified' and the HIPAA regulations do not apply. (Note: IRB review is still needed for your research.)

If you remove the following identifiers from your research, you may use the health information without having the participants sign an authorization form. (Also, see 'Limited Data Set' exception, next page.)

1. Names
2. All geographic 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.
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. 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 photographic images and any comparable images, and
18. Any other unique identifying number, characteristic, or code

III. ACCOUNTING OF DISCLOSURES

HIPAA provides that persons may request an accounting of the disclosures of their PHI made for research purposes without their authorization. Therefore, if PHI is used under a Waiver of Authorization, or as Review in Prep for research, or involves decedents, an accounting of the disclosures must be kept.⁶

This requirement does *not* apply to disclosures that are made using a Limited Data Set (see below) or disclosures made under a signed authorization.

IV. LIMITED DATA SET

An exception to the previous list is the use of a Limited Data Set, which allows the use of the following limited identifiable information:

1. Town
2. City
3. Zip code
4. Dates
5. All ages

To use a limited data set the recipient of the data must sign a Data Use Agreement⁷. (Note: The use of a Limited Data Set does *not* exempt the research from IRB review.)

With the use of a Limited Data Set the identifiers of the participant, relatives, employers, and household members that must be removed are:

1. Names
2. Postal address information, other than town or city, state and zip code
3. Telephone numbers
4. Fax number
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 finger and voice prints, and
16. Full face photographic images and any comparable images

⁶ Instructions for Tracking of Disclosures are available on the IRB website (www.hmc.psu.edu/hmc-irb).

⁷ A form for the Data Use Agreement is available online at www.pennstatehershey.org/irb.

V. REVIEW PREPARATORY TO RESEARCH

This HIPAA provision allows the use of PHI without participants' authorization when that use is only for *preparation* for a research protocol or to determine eligibility for a research protocol. A form, Request for Review Preparatory to Research, is available on the IRB web site to allow researchers to declare their compliance with the preparatory research provision of HIPAA and request IRB approval.

The following stipulations must be addressed on the Review Preparatory to Research form:

1. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research (e.g. determine eligibility).
2. No PHI is to be removed from the medical center by the researcher in the course of the review; and
3. The PHI for which use or access is sought is necessary for the research purposes.

VI. RESEARCH ON DECEDENT'S INFORMATION

This HIPAA provision allows the use of PHI without authorization when research is only on decedents' information. The form, Request for Research on Decedent's Information, is available on the IRB web site⁸ to allow researchers to declare their compliance with the research on decedents provision of HIPAA.

The following stipulations must be addressed on the Request for Research on Decedents Information form:

1. Representation that the use or disclosure sought is solely for research on the PHI of decedents;
2. Documentation, at the request of the IRB, of the death of such individuals; and
3. Representation that the PHI for which use or disclosure is sought is necessary for the research purposes.

⁸ IRB website: www.pennstatehershey.org/irb