



Privacy and Security of Protected Health Information (PHI) During Research at WSU

Definition of HIPAA Covered Information

Health and Medical Information is Considered Protected Health Information (PHI) under HIPAA when:

- It is individually identifiable health information (e.g., information about the past, present, or future physical or mental health condition used in the provision of or payment for healthcare); and
- It is held or originates from a covered entity or its business associate. Please note that not all healthcare clinics, healthplans, or care providers are HIPAA covered entities. It is best practice to ask the entity you are working with if they are a covered entity under HIPAA; and
- It identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. Please note that a correctly de-identified set of data or a limited data set is not considered PHI.

Criterion Required for Waiver of HIPAA Authorization Pertaining to Protected Health Information (PHI)

A waiver of HIPAA authorization may be granted by an IRB or Privacy Board when these conditions are met.

1. The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals based upon the documentation of 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 conduct of research, unless there is a health or research justification for retention, or retention is required by law;
 - c. Adequate written assurances that the PHI 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 the subpart.
2. The research could not practically be conducted without the waiver or alteration.
3. The research could not practically be conducted without access to and use of the PHI.

Notification to Covered Entity of a Waiver or Alteration to HIPAA Authorization

Please note that for the Covered Entity to release the information, they must be provided a document entitled, "Notification to Covered Entity of Waiver of HIPAA Authorization" from the IRB or Privacy Board.

This document outlines the following requirements:



1. Identification of the IRB or Privacy Board and the date on which the alteration of waiver of authorization was approved;
2. A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization in whole or in part, satisfies the three criteria in the rule;
3. A brief description of the PHI for which use or access has been determined to be necessary by the IRB or Privacy Board;
4. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
5. The signature of the chair or other member, as designated by the chair, of the IRB or Privacy Board.

*Definition of De-identified and/or Limited Data Set Under HIPAA

De-identification under HIPAA means that the health information does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. Health information is de-identified only if: (A) the following identifiers of the individual or of relatives, employers, or household members of the individual are removed:

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 Census: the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and the three initial 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. e-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 URLs;
15. Internet Protocol (IP) address numbers;
16. biometric identifiers, including finger and voice prints;
17. full face photographic images and any comparable images;
18. any other unique identifying number, characteristic, or code.



Removing these identifiers will leave you with a limited data set to use in research.

Does My Research or Grant Proposal Need a Health Insurance Portability and Accountability Act (HIPAA) Authorization Form?

The flowchart below allows you to determine if your research study will require a HIPAA Authorization form.

