



Data Use Agreements and Limited Data Sets: Applying the HIPAA Privacy Rule to Research

This guidance provides information about the Privacy Rule's requirements for de-identification of PHI, obtaining Authorization to use and disclose Protected Health Information (PHI), waiver or alteration of Authorization, Limited Data Sets, and Data Use Agreements. This guidance pertains only to the use and/or disclosure of PHI for research purposes.

The [HIPAA Privacy Rule](#) describes how covered entities can use or disclose Protected Health Information (PHI) for purposes of coordination and reimbursement of healthcare and research. The privacy rule only applies to covered entities.

What is a covered entity?

The Privacy Rule defines a covered entity as "(1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards" (HIPAA Privacy Rule and Its Impacts on Research 2007)

Protected Health Information can be de-identified by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members. You must not be able to re-identify individuals from data collected alone, or in combination with other information collected.

Wayne State University (WSU) is not a covered entity, however the WSU IRB serves as the privacy board for the use and disclosure of PHI for research purposes to all of our affiliates. The WSU IRB is responsible for reviewing and approving the use and disclosure of PHI for research purposes according to the Privacy Rule for the following organizations:

- Detroit Medical Center
- Barbara Ann Karmanos Cancer Institute,
- John D. Dingell Veterans Administration Medical Center,
- Wayne State University Practice Plan

The 18 Elements of Identifiable Data:

1.	Names	10.	Account numbers
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	11.	Certificate/license numbers
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 90 or older.	12.	Vehicle identifiers and serial numbers, including license plate numbers
4.	Telephone numbers	13.	Device identifiers and serial numbers
5.	Facsimile numbers	14.	Web universal resource locators (URL's)
6.	Electronic mail addresses	15.	Internet protocol (IP) address numbers
7.	Social security numbers	16.	Biometric identifiers, including fingerprints and voiceprints
8.	Medical record numbers	17.	Full-face photographic images and any comparable images
9.	Health plan beneficiary numbers	18.	Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
* Limited data set requires the removal of all elements with the exception of parts of #2 and all of #3			

(Department of Health and Human Services, 2003, p.10)

Authorization for Research Uses and Disclosures

Unless a waiver of authorization to use and disclose PHI for research purposes is permitted when specific conditions described in the Privacy Rule apply then researchers must obtain signed permission from the individual allowing a covered entity to use or disclose the individual's PHI for research purposes. This authorization must disclose all recipients of the individual's data in cases where the data will be shared outside of the covered entity from which the data originates from. The actual uses and disclosures made must be consistent with what is stated in the authorization that the individual signed.

"The signed Authorization must be retained by the covered entity for 6 years from the date of creation or the date it was last in effect, whichever is later." (Department of Health and Human Services, 2003, p.11)

Waiver or Alteration of Authorization to Use and Disclose PHI for Research Purposes:

The HIPAA Privacy Rule allows IRBs to approve a waiver or alteration of Authorization under certain conditions. In order to approve a waiver or alteration of Authorization, the research must meet the Privacy Rule's conditions for waiver or alteration of Authorization **and** the Common Rule's conditions for waiver or alteration of informed consent. (45 CFR 46.116) See our [Waiver and Alteration of Informed Consent guidance](#) for these requirements.

Privacy Rule Requirements for waiver or alteration of HIPAA Authorization:

The following criteria must be met in order for the IRB to approve a waiver or alteration of Authorization.

1. Use or disclosure involves no more than minimal risk to the privacy of individuals because of the presence of all of the following elements:
 - a. An adequate plan to protect health information identifiers from improper use or disclosure
 - b. An adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them, and
 - c. Adequate written assurances that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule.
2. Research could not be practicably be conducted without the waiver or alteration
3. Research could not practicably be conducted without access to and use of PHI.

(Department of Health and Human Services, 2003, p.11)

Limited Data Set and Data Use Agreement (DUA):

The Privacy Rule allows a covered entity to use and disclose PHI without obtaining authorization from the individual, or a waiver or alteration of Authorization if the data included is a limited data set. When researchers wish to use and disclose PHI without authorization or a waiver or alteration, a DUA is required.

Limited Data Set: Health information that that excludes 16 specific direct identifiers. The Privacy Rule's limited data set applies to information about the individual and information about the individual's relatives, employers, or household members. PHI used and/or disclosed in the study is limited to addresses greater than street (which includes city, state, zip code), elements of dates, and/or any other unique identifying numbers, characteristic, or codes (i.e. linked study identification numbers).

*All identifiers listed in the 18 elements of identifiable data with the exception of the geographic subdivisions smaller than a state described in element #2 and all of element #3 must be removed from health information in order to qualify for a limited data set.

Process for Executing a Limited Data Set Data Use Agreement:

The WSU IRB Administration Office reviews and executes DUAs **only** for limited data sets. Any DUAs that are for data not considered a limited data set are reviewed by WSU's Technology Commercialization Office. Contact the MTA assistant at mtainfo@wayne.edu if you are requesting a DUA and your data does not meet the requirements for a limited data set.

Each individual covered entity usually has their own DUA template. Generally, you would use the template provided by the covered entity sending the PHI. In most cases, the institution receiving the PHI will permit the use of the sending institution's DUA template. WSU's [DUA template](#) is located on the Forms and Submission Requirements page of our website.

When PHI for research purposes is being sent from one of the WSU IRB's affiliate covered entities:

Send the completed WSU IRB DUA template to the Director of the WSU Human Research Protection Program (HRPP): Monica Malian via e-mail attachment: monica.malian@wayne.edu. Additional guidance will be provided after the completed DUA template has been reviewed.

Process for when WSU or one of WSU IRB's affiliate covered entities is receiving PHI from an outside covered entity:

Send the completed outside covered entity DUA template to the director of the WSU Human Research Protection Program (HRPP): Monica Malian via e-mail attachment: monica.malian@wayne.edu. Additional guidance will be provided after the completed DUA template has been reviewed.

Amending the Study's IRB Approval:

DUA's are executed **after** the initial approval of the research protocol.

Once you have a fully executed DUA, you will submit an expedited amendment to the IRB. The amendment submission must include a copy of the fully executed DUA signed by both the covered entity sending data and the recipient of the data.

Resources:

Department of Health and Human Services. (2003). *Protecting Personal Health Information in Research: Understanding*

the HIPAA Privacy Rule (03-5388). Retrieved from National Institutes of Health website:

https://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf

HIPAA Privacy Rule and Its Impacts on Research. (2007, February 2). Retrieved from

https://privacyruleandresearch.nih.gov/pr_06.asp