

HIPAA and HIPAA Waiver

Medical University of South Carolina



What is HIPAA?

- The Health Insurance Portability and Accountability Act
 - Affects most researchers at MUSC
 - Designed to protect the use and disclosure of any identifiable health information
 - Protected Health Information (PHI)

What is PHI?

Any of the 18 identifiers + health information that is transmitted or maintained in any form that relates to the past, present, or future physical or mental health conditions of an individual.

- Names
- All geographic subdivision smaller than a state including street address, city, county, precinct, zip code, and or equivalent geocodes
- All elements of date (except year) for dates directly related to an individual (DOB, admission date, discharge date, date of death)
- Phone numbers
- Fax numbers
- Email address
- Social Security Numbers
- Medical Record number
- Health Plan Beneficiary number
- Account Numbers
- Certificate/license numbers
- Vehicle Identifiers and serial numbers
- Device Identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) addresses
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code





What is a Waiver of HIPAA Authorization?

- A HIPAA waiver for research is a special permission that allows researchers to use or access a person's private health information without getting their written consent. This is only allowed only under certain conditions such as:
 - When it's not feasible for subjects to sign an authorization form
 - Disclosure of PHI for research purposes is minimal risk to the subject
 - The research cannot practicably be done without access to the PHI

Justification for the waiver request

- Researchers must include information to justify the waiver request
 - The use of disclosure of PHI involves no more than minimal risk to the privacy of the individual
 - Provide a plan to protect identifiers
 - Provide a plan to destroy the identifiers
 - Statement that the information will not be disclosed
 - Justify why the research can't be done without the waiver
 - Provide written assurance that the PHI will not be re-used or disclosed except as required by law, for authorized oversight of the research, or for other research that has been reviewed and approved by the IRB with specific approval regarding access to the PHI.

Helpful Tips!

- Confirm that the PHI will remain confidential and that only the PI/study team will have access to the PHI.
- If coding will be used – describe the coding system and ensure that the linking document will be stored separately from the research data and on MUSC secure network storage.
- For a waiver of HIPAA to be approved, identifiers should be removed as soon as possible after the study is over. Your ID log may be deleted after analysis, research data needs to be stored for a minimum of 6 years.
- Describe how it would be impracticable to obtain authorization from each subject. (ex. Contacting a large number of patients and contact information recorded may be obsolete, data exists in medical records and was collected for clinical purposes and contacting patient to obtain authorization would increase loss of confidentiality, etc.)
- Thoroughly explain why you need the PHI to answer your research question.
- You should have the least number of identifiers needed to answer your research question. It is the identifiers + the health information that = PHI.
- Include all of the health information that will be abstracted for research purposes as well as the identifiers. (What is entered should match the elements that you have selected on the Access to PHI for Research smartform. ex. MRN, address, email, etc.)
- Explain why those PHI elements are needed.
- Describe the measures in place to protect privacy and confidentiality. (ex. Coding system, storage of data on the MUSC secure network storage, etc.).