

# Health Insurance Portability and Accountability Act (HIPAA)

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## HIPAA

- The HIPAA Privacy Rule applies to projects where PHI is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research.
- Even if your project is Not Human Subject Research or this institution is Not Engaged in Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a Covered Entity.
- Protected Health Information (PHI) = health information + one or more of the 18 identifiers.
  
- If the PI is granted a HIPAA waiver of authorization, the PI has access to the PHI in its entirety.
- OR
- The PI seeks a limited data set (demographics and dates) and signs a Data Use Agreement (DUA) that the explains how the PI will keep those limited identifiers confidential and secure.
- In most situations, the PI will not need to request a waiver of authorization under HIPAA if there is a DUA.

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### \* Health Information Collected

If not already described elsewhere, describe what health information will be collected as part of this project (e.g., blood pressure, x-rays, etc.).

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### HIPAA Identifiers Collected

Have all 18 identifiers been removed?

- Yes  
 No

\* Please describe.

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### Waiver and/or Alteration of HIPAA Authorization

#### \* Requesting Waiver/Alteration

Will this project in part or in full involve any waivers or alternation of HIPAA Authorization?

- Yes  
 No

#### \* Type of Waiver or Alteration of HIPAA Authorization

Check all that apply for this project.

- Partial Waiver

NOTE: HIPAA Authorization must still be obtained from eligible participants for any use or disclosure of PHI beyond what's specified in the Partial Waiver.

- \*  Waiver to disclose PHI from one covered entity to another for the purposes of contacting and recruiting individuals into the project.
- Waiver to collect PHI over the phone, fax, internet, or email from participants.
- Waiver to use PHI for research purposes for individuals who are unable to provide authorization and no Legally Authorized Representative (LAR) is available.
- Waiver for any other use and disclosure for ONLY part of the project.

\* Please describe:

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- Full Waiver  
Waiver for the complete access, use, and creation of records containing PHI, but ONLY as described in this submission.
- Alteration of Authorization  
The removal of some, but not all, of the required elements of an Authorization.

**\* Please describe:**

*Required Elements of Authorization:*

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

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**\* Justification of Waiver or Alteration**

For this project explain how:

- The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of
  - (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure;
  - (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and
  - (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, or (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- The project could NOT practicably be conducted without this waiver or alteration (e.g., would be impossible to carry out otherwise).
- The project could NOT practicably be conducted without access to and use of this PHI (e.g., would be impossible to carry out otherwise).

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**Does the study involve obtaining Protected Health Information (PHI) from a "covered entity" outside of University of Southern Maine (i.e. another organization or institution)?**

Yes  
 No

**Will this study involve the transfer from a covered entity as defined under HIPAA of protected health information (PHI) to you?**

Yes

**Protection of PHI**

If Yes, explain what arrangements have been made to comply with the HIPAA requirements of the entity from which the PHI will be obtained.

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


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**\* How and What PHI is Shared**

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Describe how PHI will be shared and with which entities. Be sure to address the following:

- What PHI will be shared.
- Who is receiving the data (e.g., Name of entity and if it is a Covered Entity).
- Under what authorization PHI is release (e.g., Limited Data Set under a Data Use Agreement, subject authorization, under a waiver of authorization, etc.).

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


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**Storage and Maintenance of Identifiers**

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If not already described elsewhere, describe the plan for the maintenance of the identifiers (collected under this waiver/ alteration) checked above after this project has ended. For example:

- Destroying data
- De-identifying data by removing all identifiers
- Maintaining identifiable or coded data for storage in a Research Repository for the conduct of Future Research

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**Will you be submitting a Data Use Agreement (DUA) or Business Associates Agreement (BAA)?**

Yes

If yes, has the Data Use Agreement or Business Associates Agreement been reviewed by system counsel. Please explain:

No

**Additional Documentation**

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Upload any additional documentation related to HIPAA Authorization, as applicable.  
-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

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