Health Insurance Portability and Accountability Act (HIPAA)

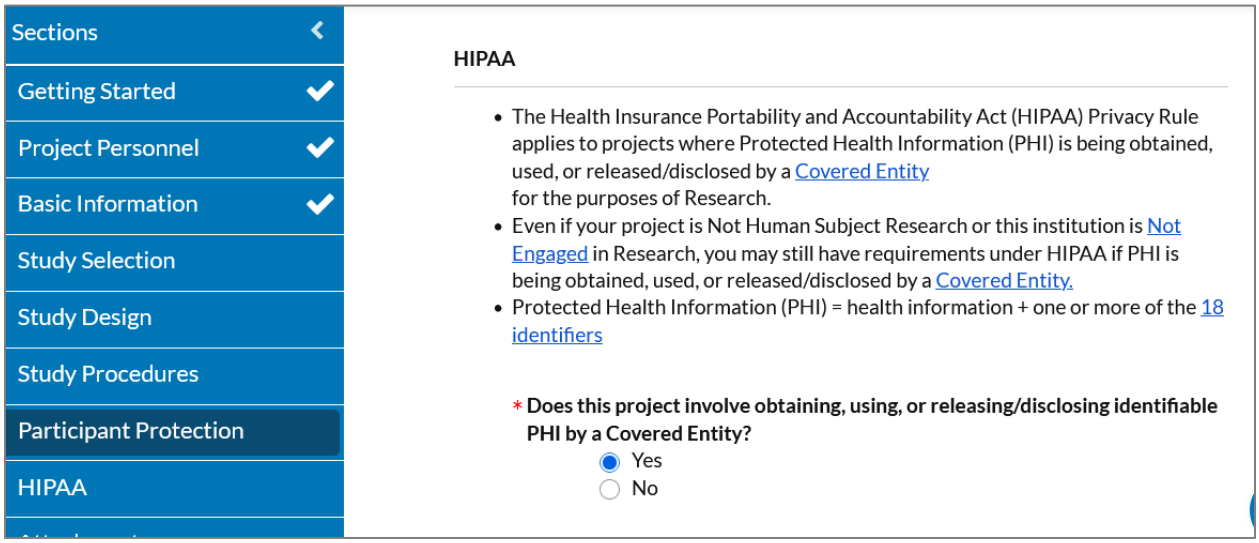
This section can be found at the end of the Determination for Human Subject Research form, as well as the end of the Participant Protection section of the Research Study form.

HIPAA

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule applies to projects where Protected Health Information (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

Does this project involve obtaining, using, or releasing/disclosing identifiable PHI by a Covered Entity?

Yes/No, if yes the option for the HIPAA section will appear in the left blue navigation bar.



HIPAA

- The HIPAA Privacy Rule applies to projects where Protected Health Information (PHI) is being obtained, used, or released/disclosed by a Covered Entity.
- Even if your project is Not Human Subject Research or this institution is Not Engaged in Research, you may still have requirements under HIPAA.
- Protected Health Information (PHI) means individually identifiable health information.

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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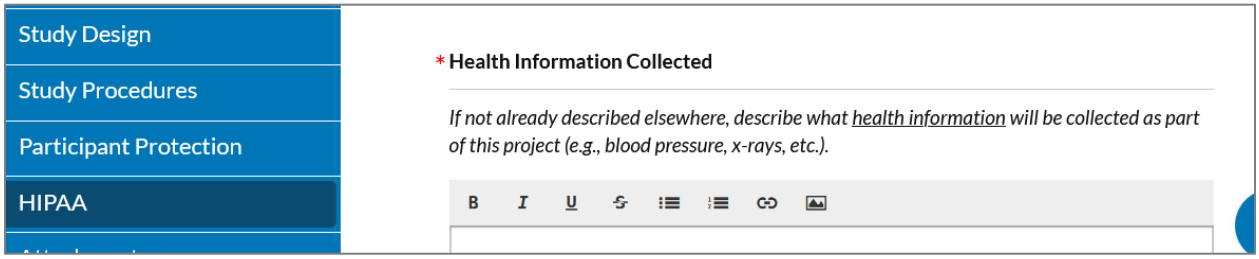
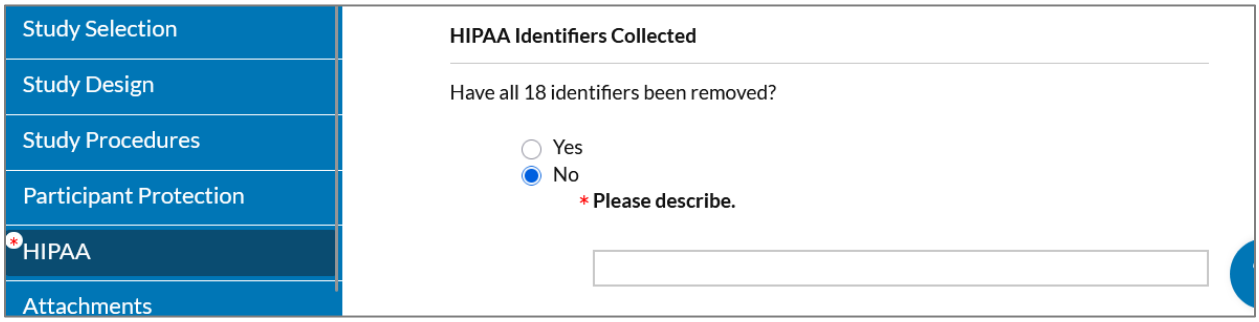


HIPAA Identifiers Collected

Have all 18 identifiers been removed?

Yes/No, If no Please describe.



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, if yes additional questions below

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: Text Box
- ☐ 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.

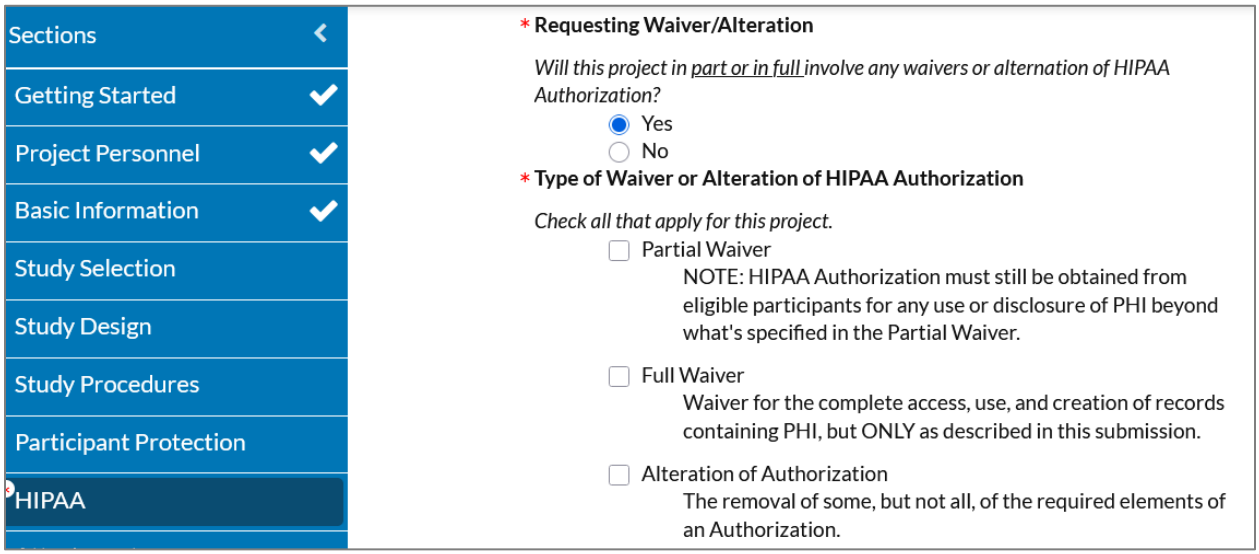
  Text Box

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).

Text Box



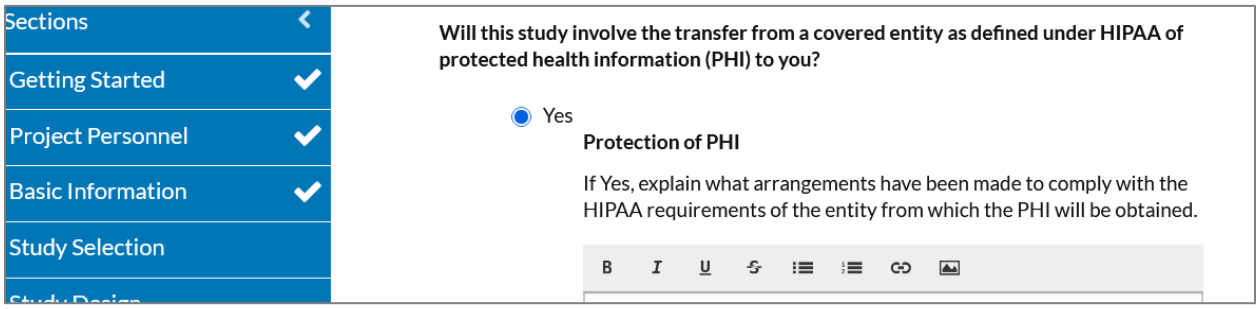
Does the study involve obtaining Protected Health Information (PHI) from a "covered entity" outside of University of Southern Maine (i.e. another organization or institution)?

Yes/No

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

Yes/No, if yes explain what arrangements have been made to comply with the HIPAA requirements of the entity from which the PHI will be obtained.

Text Box

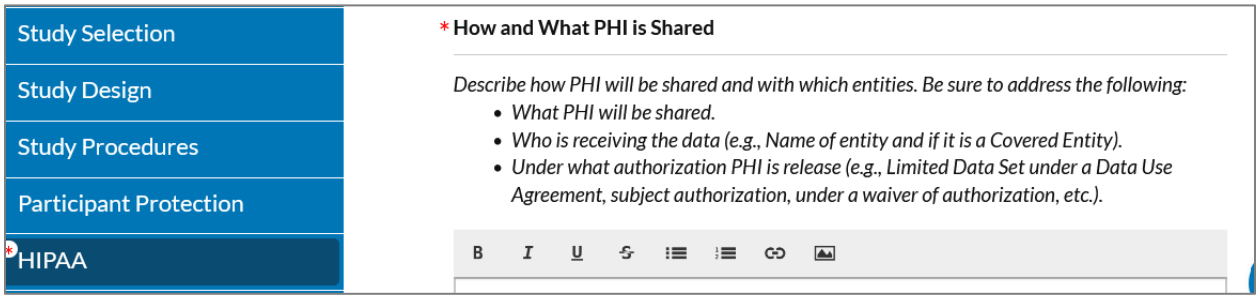


How and What PHI is Shared

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.).

Text Box



Storage and Maintenance of Identifiers

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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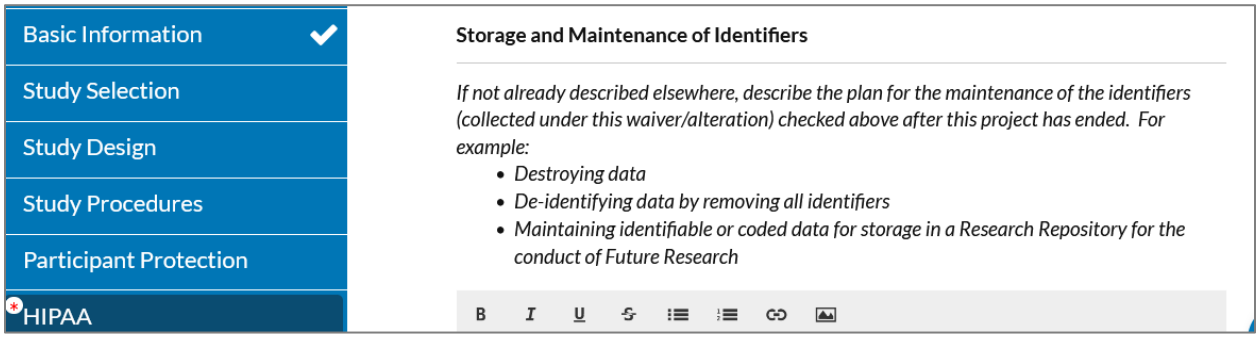

Will you be submitting a Data Use Agreement (DUA) or Business Associates Agreement (BAA)?

Yes/No, if yes, has the Data Use Agreement or Business Associates Agreement been reviewed by system counsel. Please explain:

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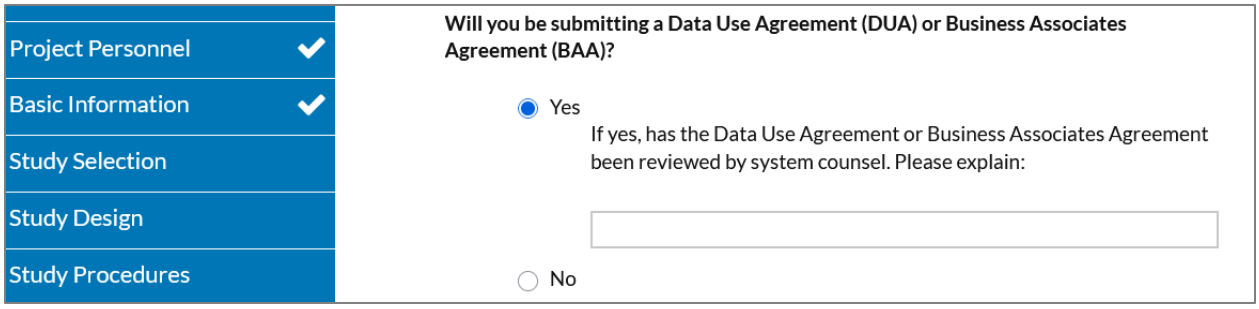
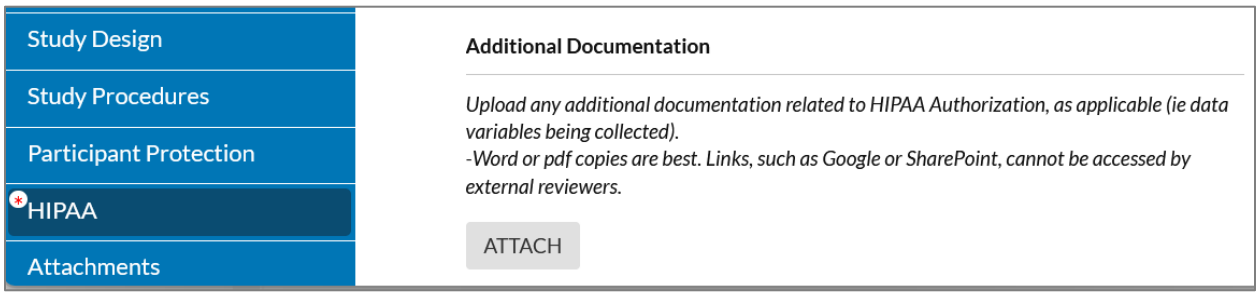


Additional Documentation

Upload any additional documentation related to HIPAA Authorization, as applicable (ie data variables being collected).

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

ATTACH button



After clicking on the **ATTACH button** a pop-up for Documents will state "Click the plus button to upload files…" After clicking on the plus sign search for the document you wish to attach, click on it and click the green APPLY button on the pop-up.