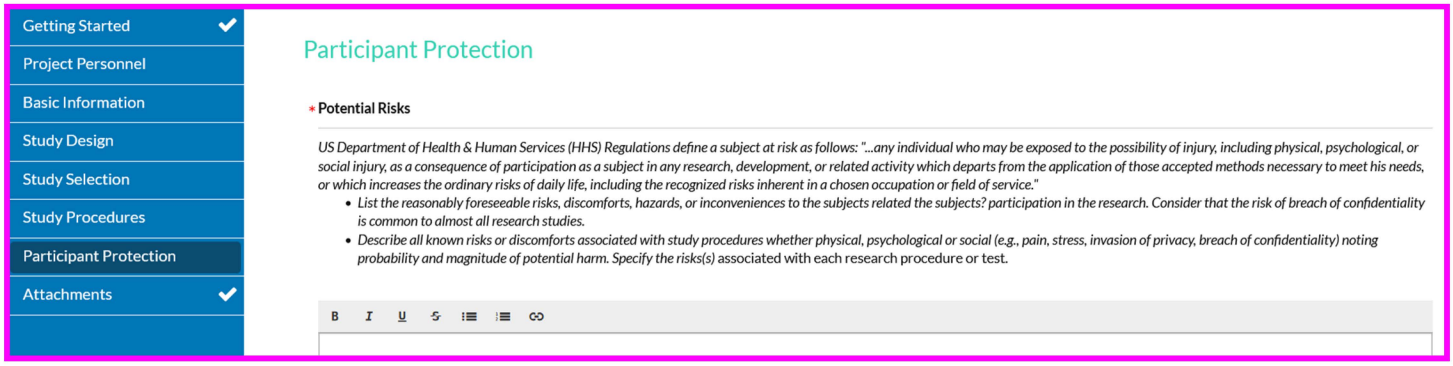
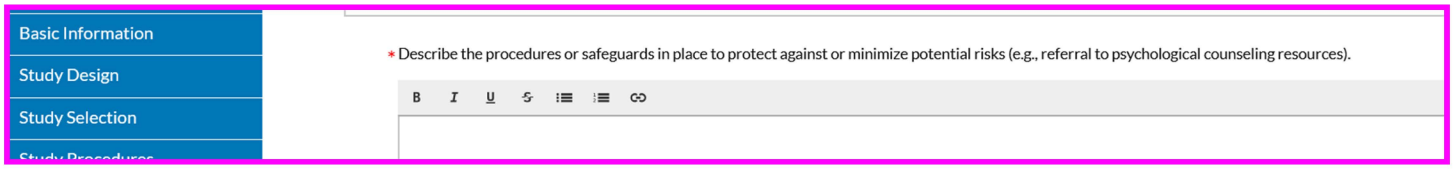
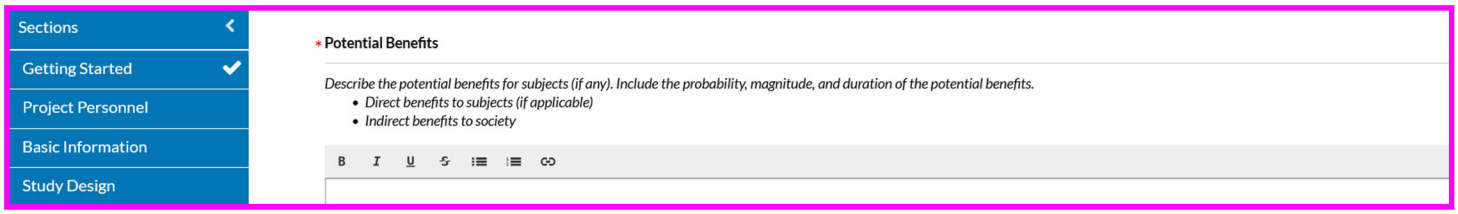
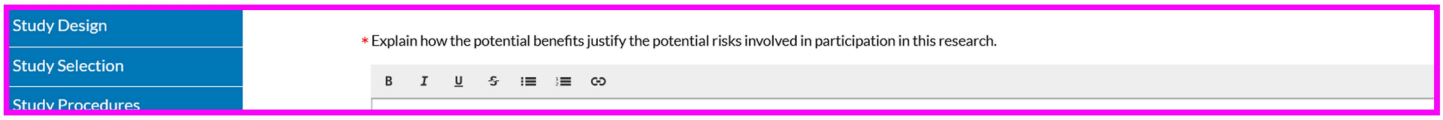
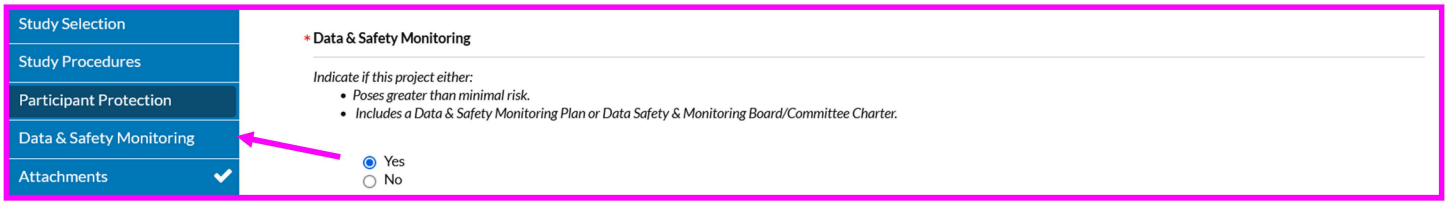
Participant Protections

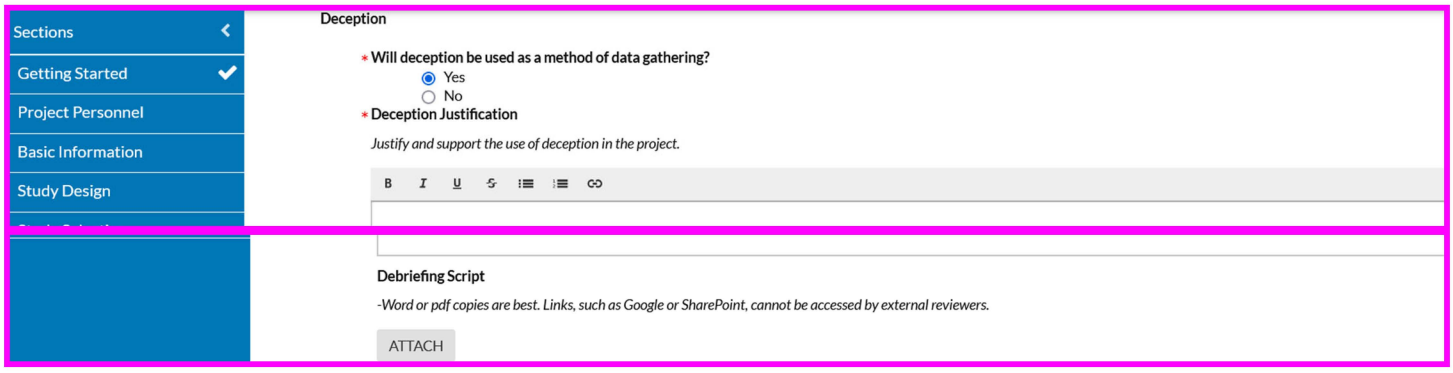


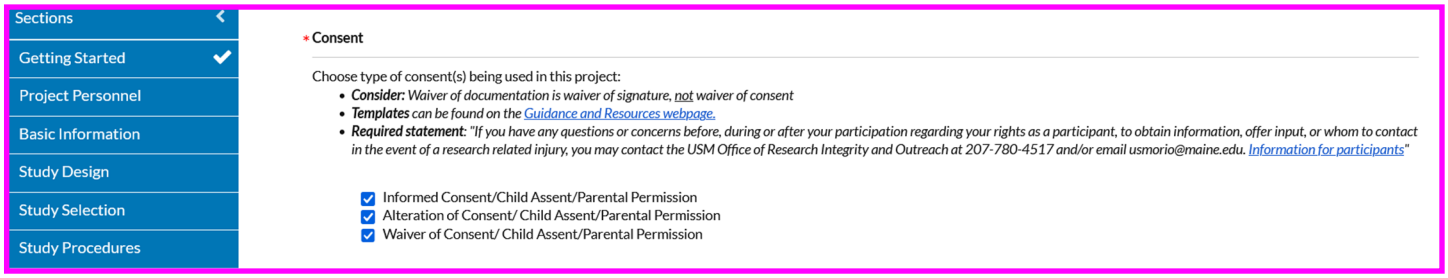








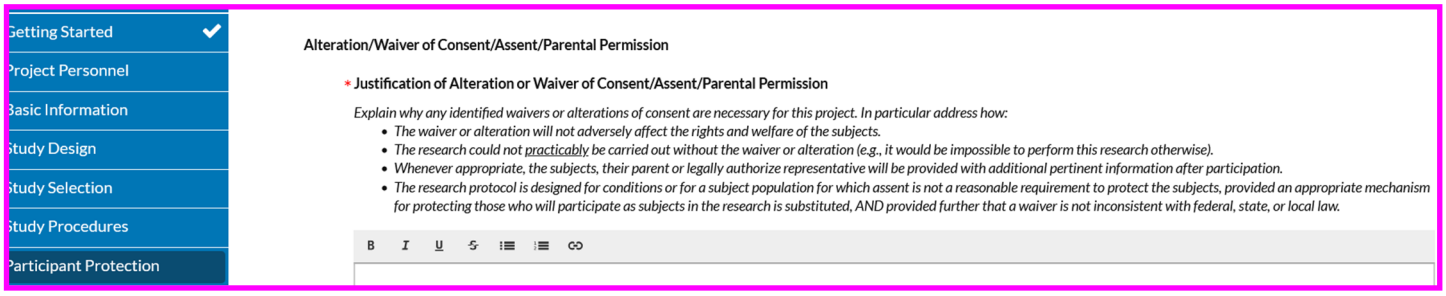


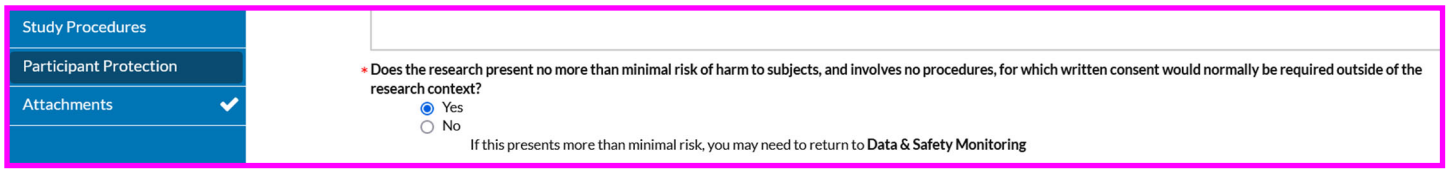


Guidance and Resources: https://usm.maine.edu/orio/irb-guidance-and-resources/

Required statement: *"If you have any questions or concerns before, during or after your participation regarding your rights as a participant, to obtain information, offer input, or whom to contact in the event of a research related injury, you may contact the USM Office of Research Integrity and Outreach at 207-780-4517 and/or email usmorio@maine.edu. Information for participants"*

https://usm.maine.edu/orio/irb-information-for-research-participants/





Informed Consent Process

All human subjects (or their legally authorized representatives) must give consent to participate in research.

*** Type of Informed Consent**

Check all that apply to this project

- ☐ Informed Consent: All research subjects will be completely informed regarding aspects of the study. Signed form.
- ☐ Waiver of Documentation of Informed Consent
  -An IRB may waive the requirement for an investigator to obtain a signed consent form for some or all subjects.
  -Potential participants are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (signing of the consent form) has been waived by the IRB.
- ☐ Parental Permission
  Parents or legally authorized representatives of the research subjects will be completely informed regarding aspects of the study. Signed form.
- ☐ Waiver of Documentation of Parental Permission
  -An IRB may waive the requirement for an investigator to obtain a signed consent form Parents or legally authorized representatives.
  - Parents or legally authorized representatives are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (signing of the consent form) has been waived by the IRB.
- ☐ Child Informed Assent
  All child research subjects will be completely informed regarding aspects of the study. Assent is in addition to Parental Permission/Informed Consent. Assent should be written at the child's level of understanding.
  Consider: *Child Assent, in general, investigators must obtain the affirmative agreement of children. In the United States the legal age of adulthood is a matter of state and local law. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent form suitable for a 17 year old is not usually suitable for a 7 year old child).*
- ☐ Waiver of Documentation of Informed Assent
  -An IRB may waive the requirement for an investigator to obtain a signed assent form for some or all subjects.
  -Potential participants are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (signing of the consent form) has been waived by the IRB.

Type of Waiver or Alteration to the Informed Consent Process

* *Check all that apply for in part or in full to this project:*

- ☐ Alternation of Informed Consent
  An IRB may approve a consent procedure, which alters some of the elements of informed consent.
  -A list of all required elements is given below. Indicate which of these elements you would like to have altered. (In the case of a study involving deception or concealment, the IRB must waive the requirement to use all elements that are not truthfully presented in the initial consent document.)
- ☐ Waiver of Informed Consent
  An IRB may approve a consent procedure, which does not include all of the elements of informed consent.
- ☐ Alteration of Parental Permission
  An IRB may approve a consent procedure, which alters some of the elements of informed consent.
- ☐ Waiver of Parental Permission
  An IRB may waive the requirement to obtain documentation of parental permission (waiver of consent). Explain how this research study meets of the following criteria:
  -The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, AND provided further that a waiver is not inconsistent with federal, state, or local law.
- ☐ Alteration of Informed Assent
  An IRB may approve an assent procedure, which alters some of the elements of informed assent.
- ☐ Waiver of Informed Assent
  An IRB may waive the requirement to obtain documentation of informed assent (waiver of assent). Explain how this research study meets of the following criteria:
  -The research protocol is designed for conditions or for a subject population for which assent is not a reasonable requirement to protect the subjects, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, AND provided further that a waiver is not inconsistent with federal, state, or local law.

* **List of elements, check all that apply**

A list of all required elements is given below. Indicate which of these elements you would like to have altered. (In the case of a study involving deception or concealment, the IRB must alter the requirement to use all elements that are not truthfully presented in the initial consent document.)

- ☐ Study involves research
- ☐ Purposes of the research
- ☐ Duration of participation
- ☐ Procedures to be followed
- ☐ Identification of experimental procedures
- ☐ Foreseeable risks/discomforts
- ☐ Benefits to subjects or others
- ☐ Appropriate alternatives advantageous to subject. For most non-clinical trial studies the alternative is to not participate.
- ☐ Maintenance of confidentiality
- ☐ For more than minimal risk research, compensation/treatment available in case of injury
- ☐ Voluntariness of participation
- ☐ No penalty for refusal to participate
- ☐ May discontinue participation without penalty
- ☐ Contact for questions about research
- ☐ Contact for questions about participants? rights
- ☐ Contact for questions about research injury
- ☑ Other

Other reason, please explain

B I U S

Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Participant Protection
Attachments ✓

* **Consent Process**

* **Who will obtain subjects' consent? Check all that apply**

- ☐ Principal Investigator(s)
- ☐ Research Staff
- ☐ Other

Please explain

* **Describe the procedures for obtaining informed consent.**

Include what steps being taken to determine that a potential subjects are competent to participate in the decision-making process.

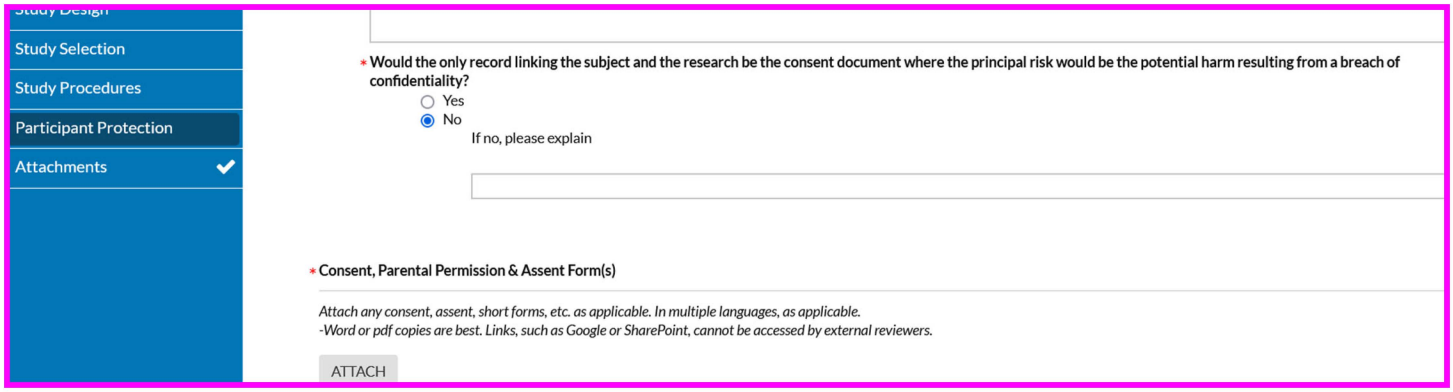
B I U S

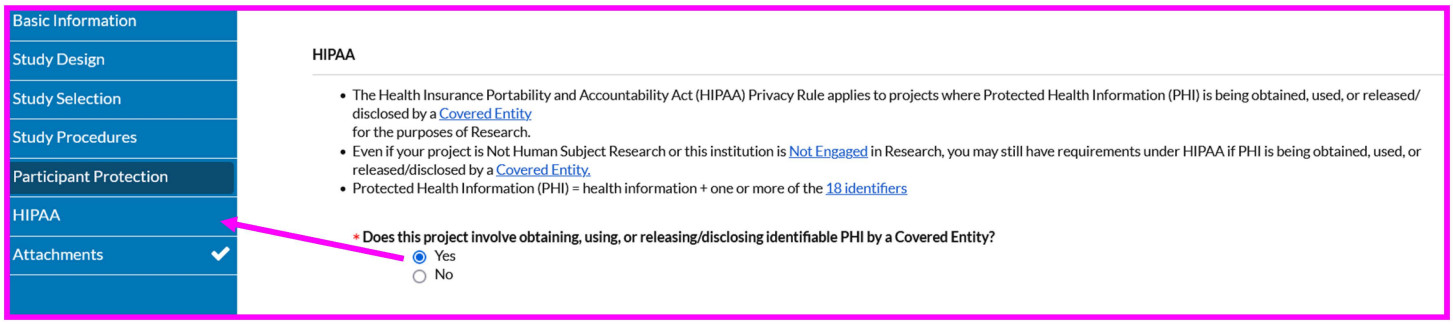
Getting Started ✓
Project Personnel
Basic Information
Study Design
Study Selection

* **Non-English Speaking Subjects**

If consent is being obtained from non-English speaking subjects, explain the translation process for all documents seen by subjects, including consent documents. Describe the consent process in these circumstances.
Note: Provide copies of translated and back-translated consent documents and provide the translator?s credentials.

B I U S


Study Design
Study Selection
Study Procedures
Participant Protection
Attachments
* Would the only record linking the subject and the research be the consent document where the principal risk would be the potential harm resulting from a breach of confidentiality?
Yes
No
If no, please explain
* Consent, Parental Permission & Assent Form(s)
Attach any consent, assent, short forms, etc. as applicable. In multiple languages, as applicable.
-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.
ATTACH


Basic Information
Study Design
Study Selection
Study Procedures
Participant Protection
HIPAA
Attachments
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