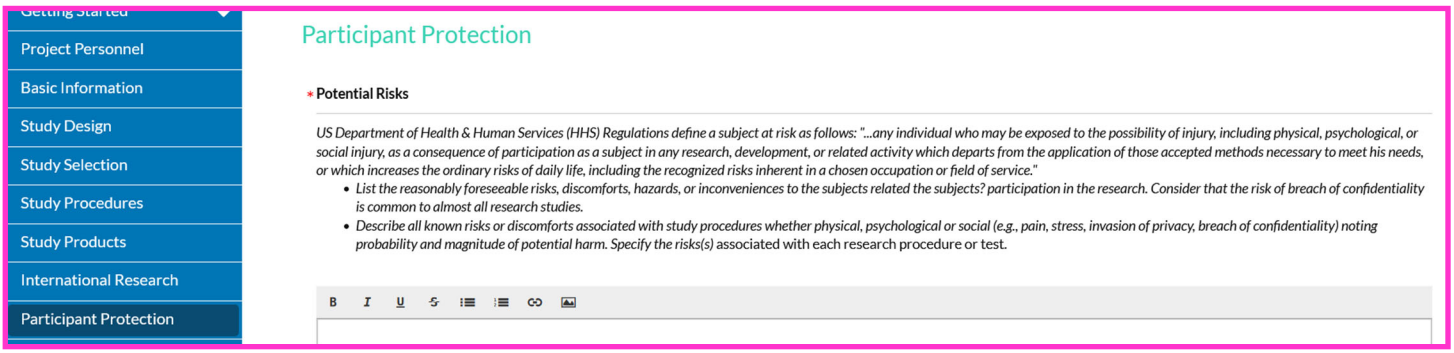
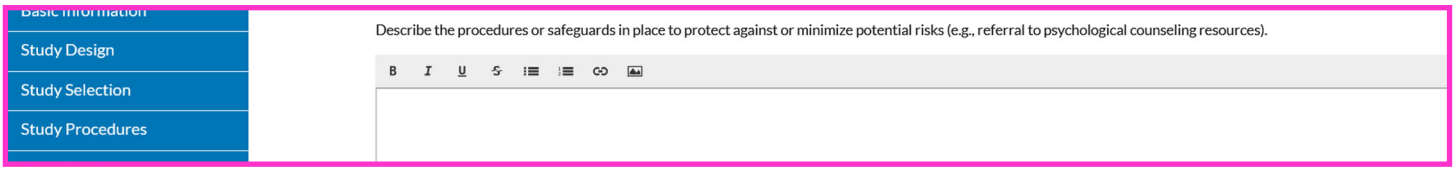
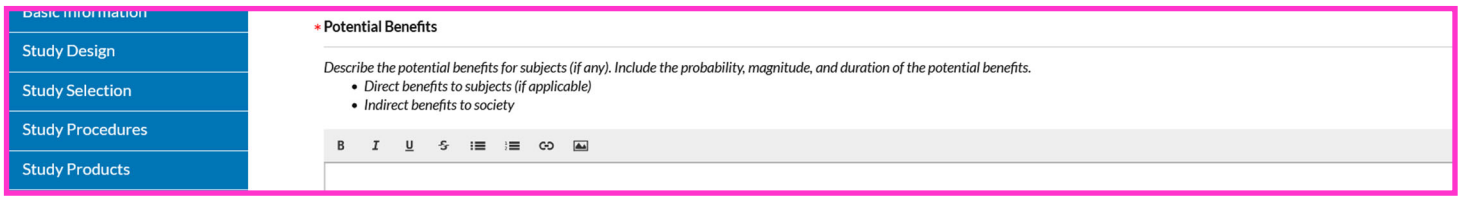
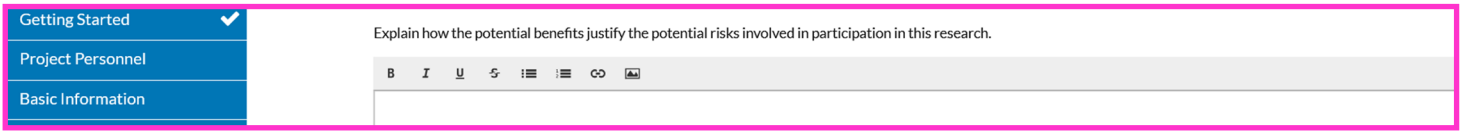
Participant Projections Section

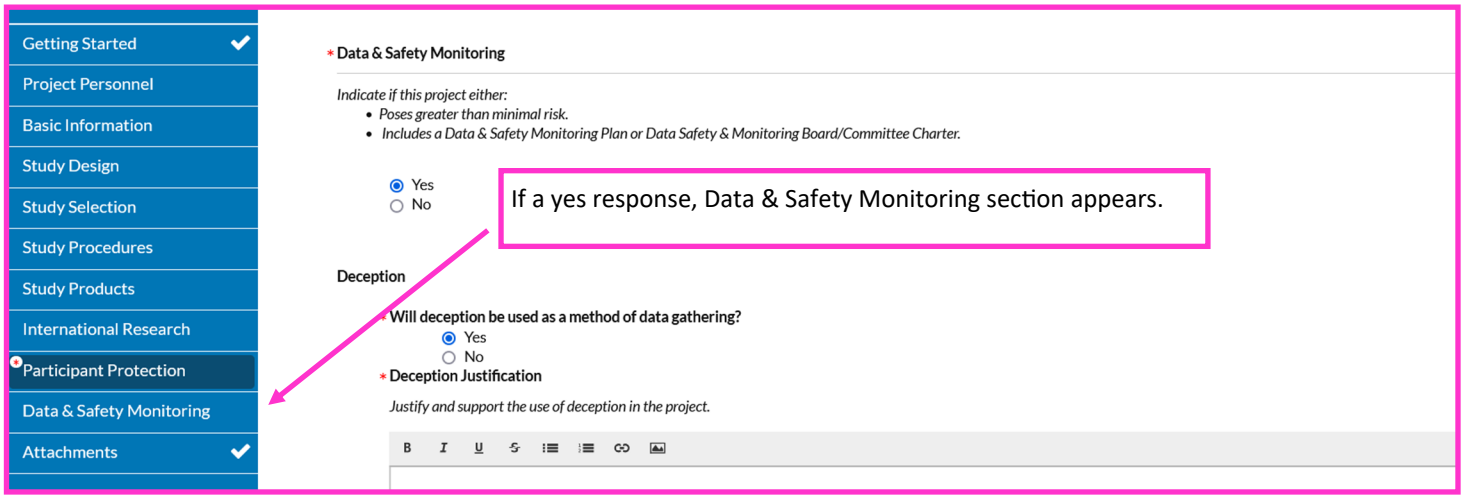
Depending on your responses, additional questions may appear.

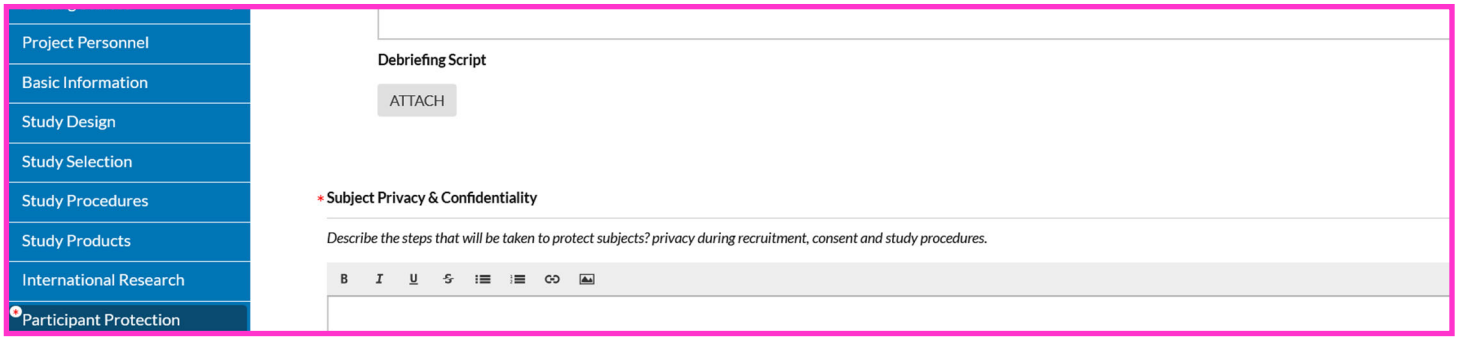


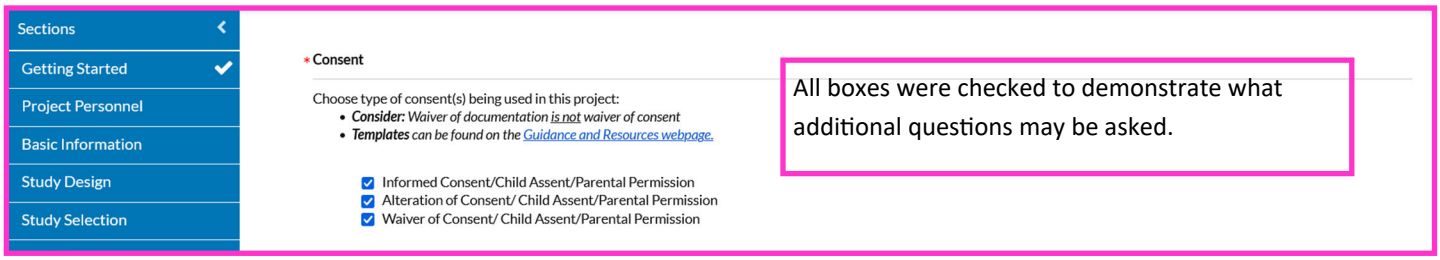


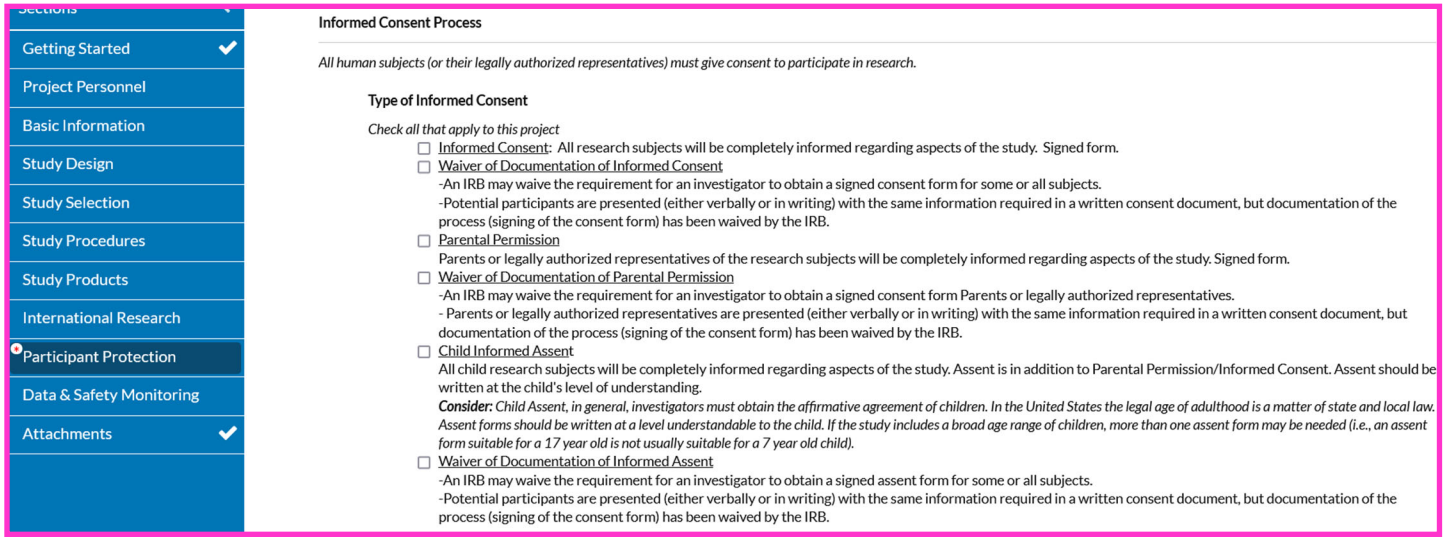


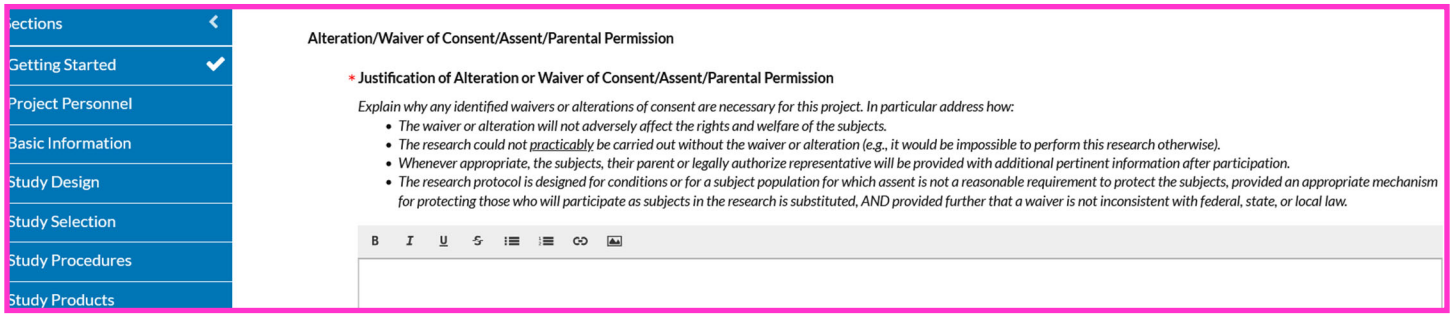


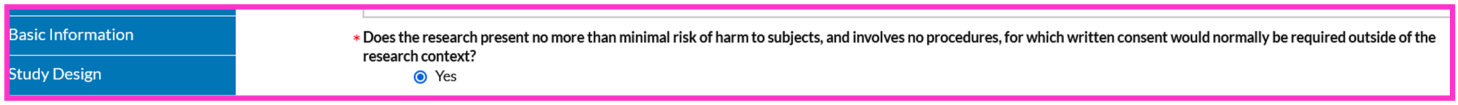


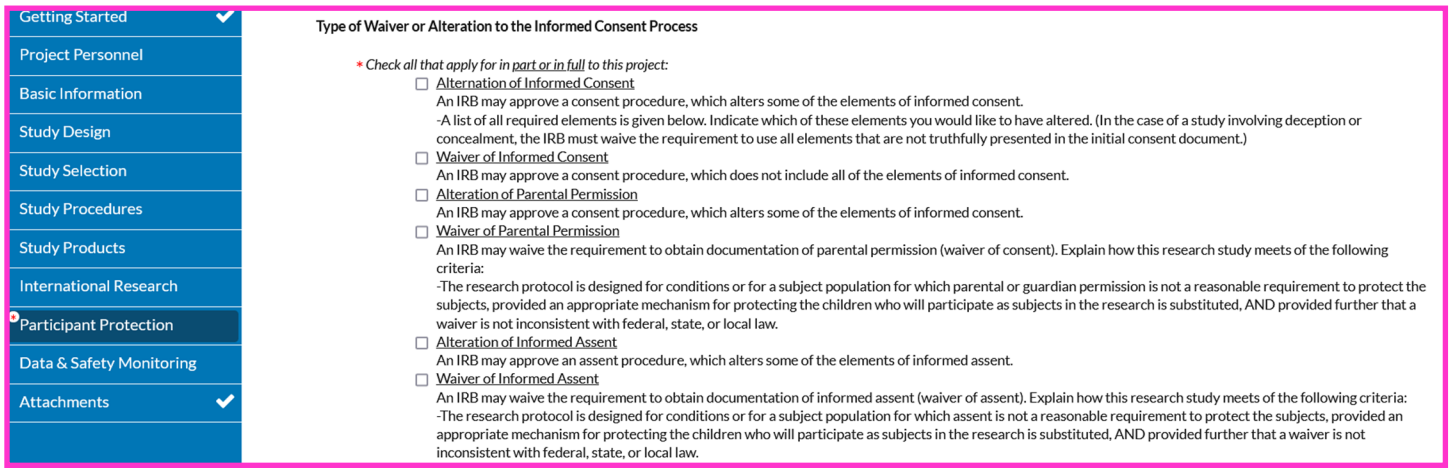


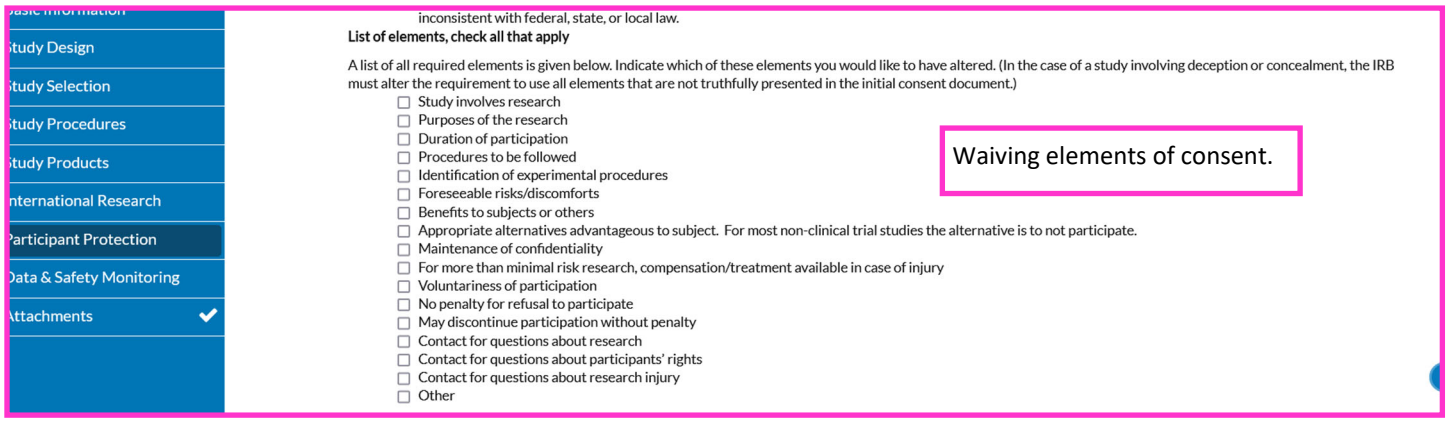

Sections
Getting Started
Project Personnel
Basic Information
Study Design
Study Selection
* Consent
Choose type of consent(s) being used in this project:
• Consider: Waiver of documentation is not waiver of consent
• Templates can be found on the Guidance and Resources webpage.
Informed Consent/Child Assent/Parental Permission
Alteration of Consent/ Child Assent/Parental Permission
Waiver of Consent/ Child Assent/Parental Permission
All boxes were checked to demonstrate what additional questions may be asked.

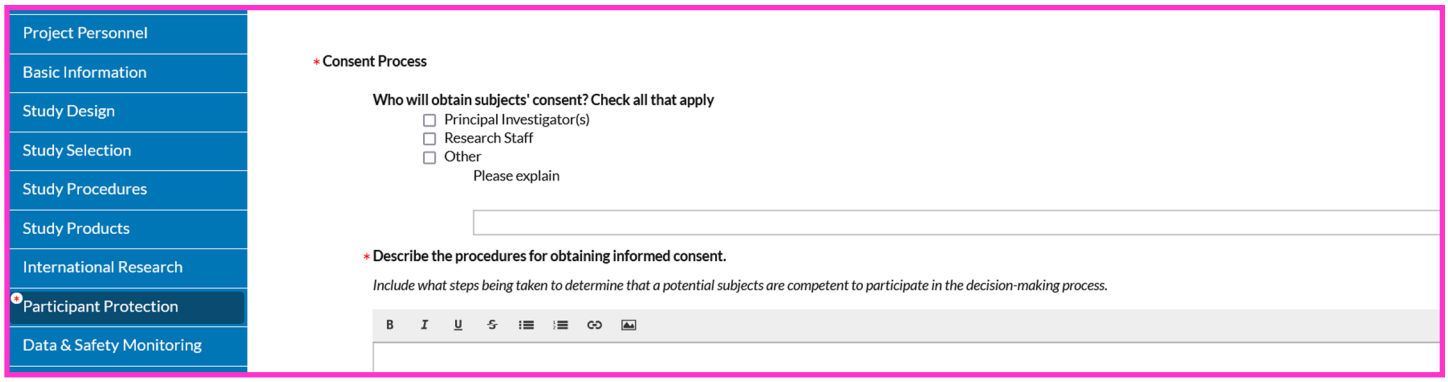

Getting Started
Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Study Products
International Research
Participant Protection
Data & Safety Monitoring
Attachments
Informed Consent Process
All human subjects (or their legally authorized representatives) must give consent 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.

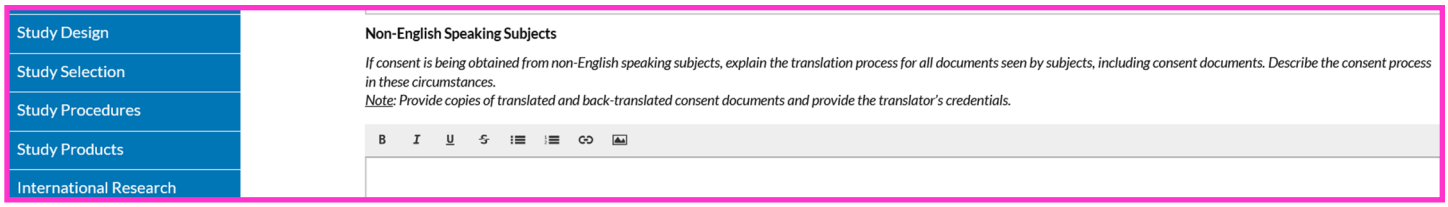

Getting Started
Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Study Products
Alteration/Waiver of Consent/Assent/Parental Permission
* Justification of Alteration or Waiver of Consent/Assent/Parental Permission
Explain why any identified waivers or alterations of consent are necessary for this project. In particular address how:
• The waiver or alteration will not adversely affect the rights and welfare of the subjects.
• The research could not practicably be carried out without the waiver or alteration (e.g., it would be impossible to perform this research otherwise).
• Whenever appropriate, the subjects, their parent or legally authorize representative will be provided with additional pertinent information after participation.
• 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 those 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.

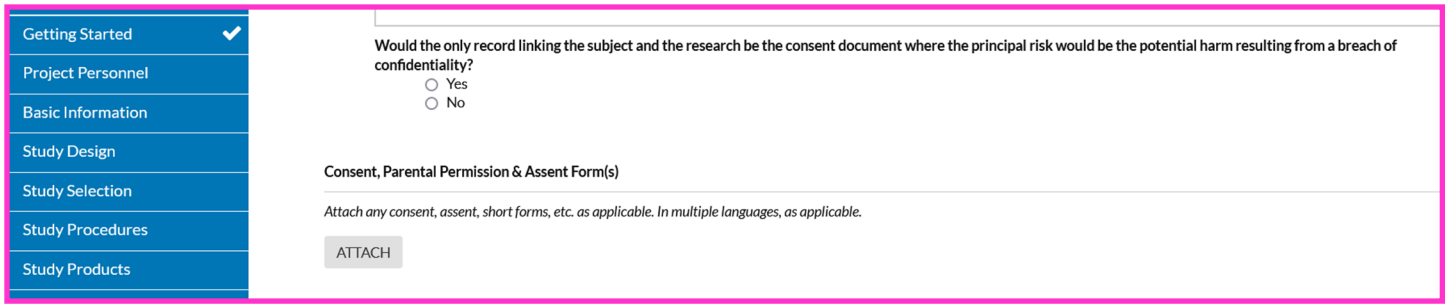

Basic Information
Study Design
* Does the research present no more than minimal risk of harm to subjects, and involves no procedures, for which written consent would normally be required outside of the research context?
Yes

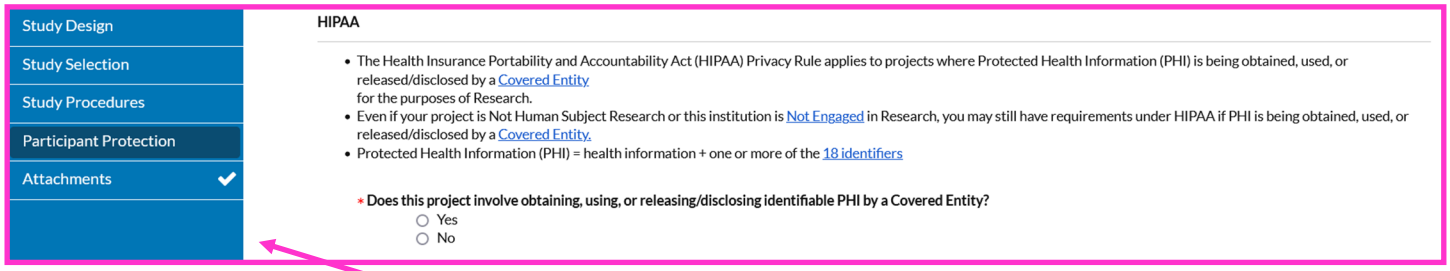

Getting Started
Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Study Products
International Research
Participant Protection
Data & Safety Monitoring
Attachments
Type of Waiver or Alteration to the Informed Consent Process
* Check all that apply for in part or in full 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.











If a yes response, HIPAA section appears

End of Participant Projections Section