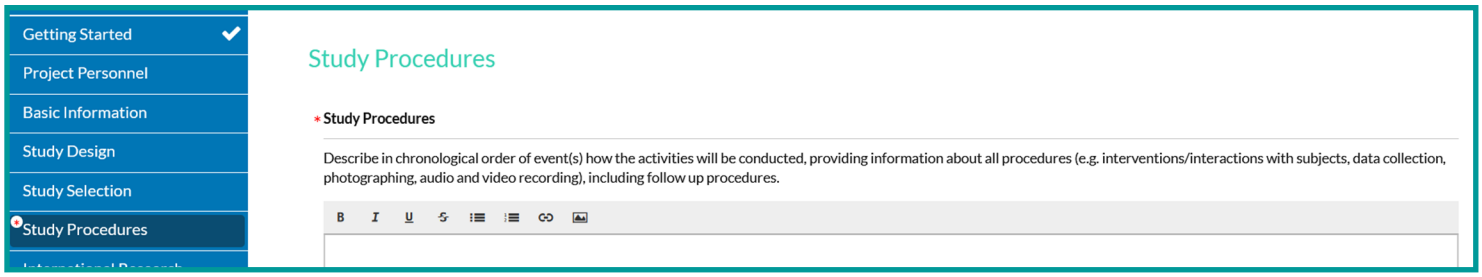
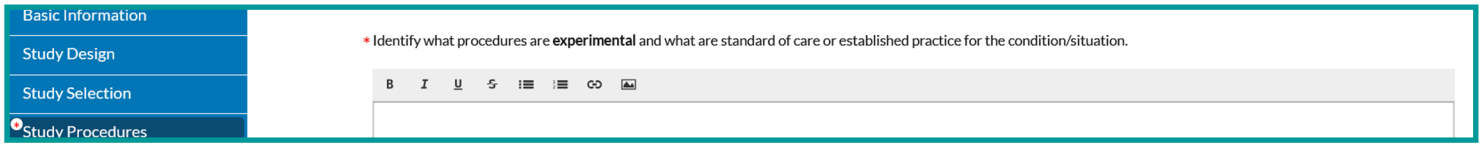
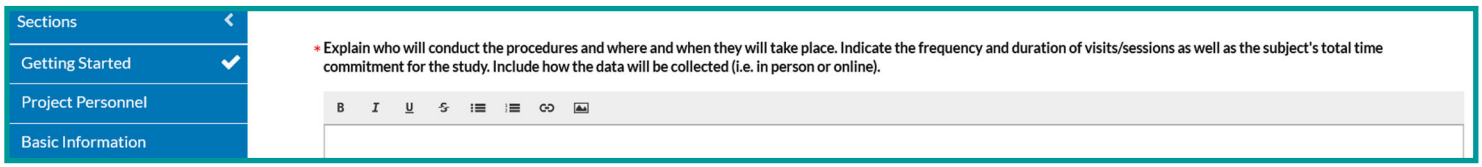
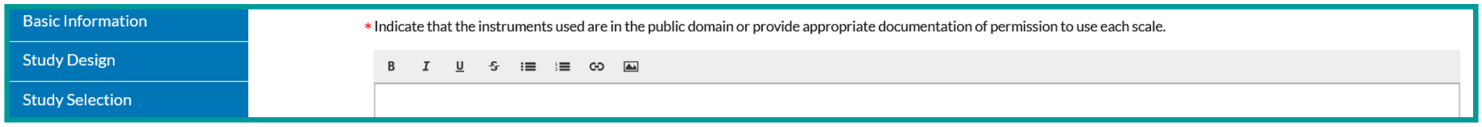
Study Procedures Section

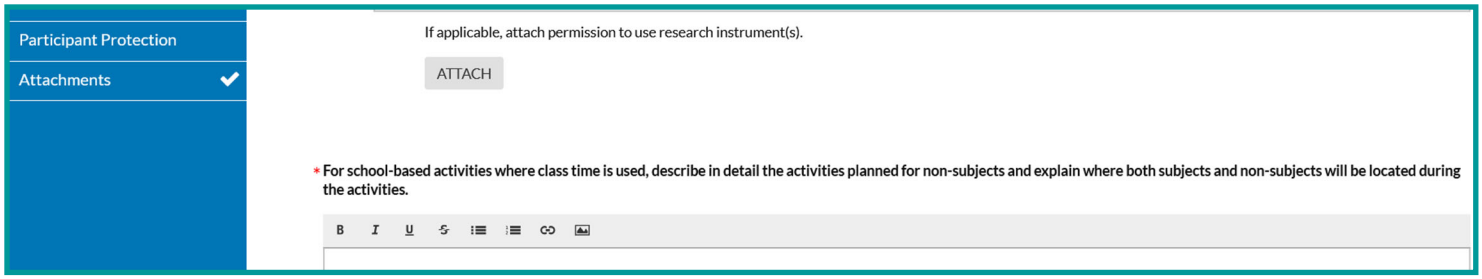
Depending on your responses, additional questions may appear.

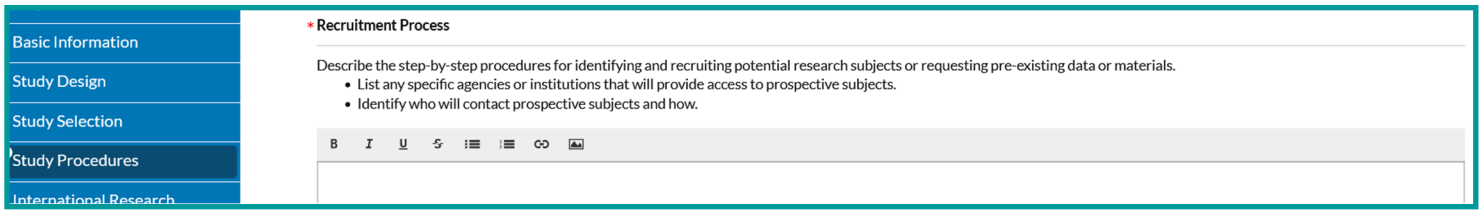


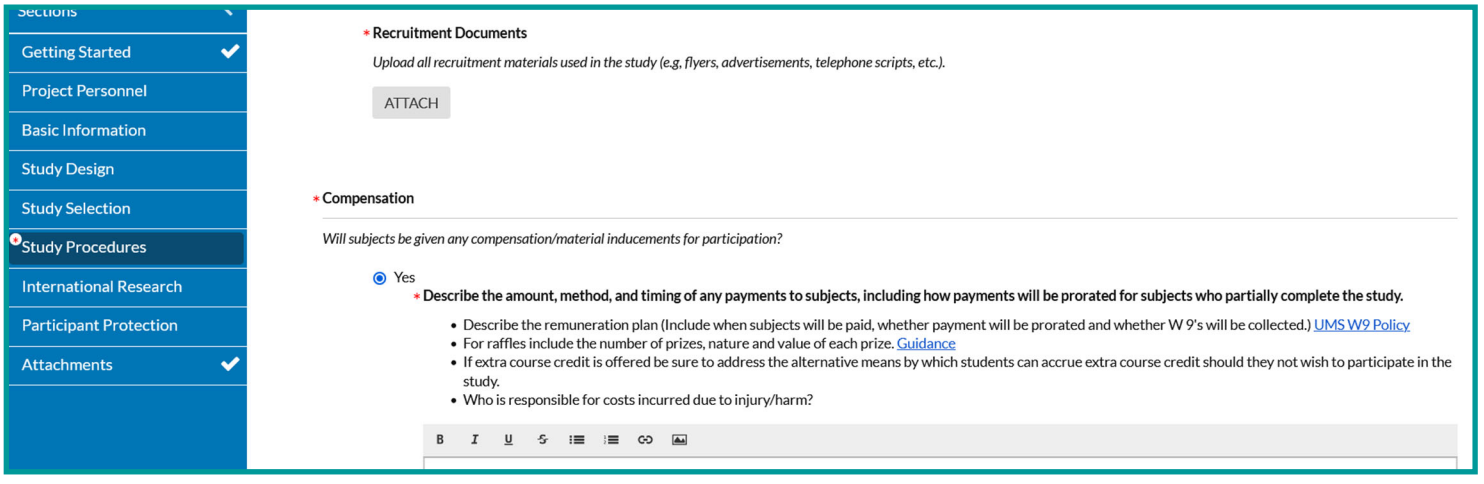


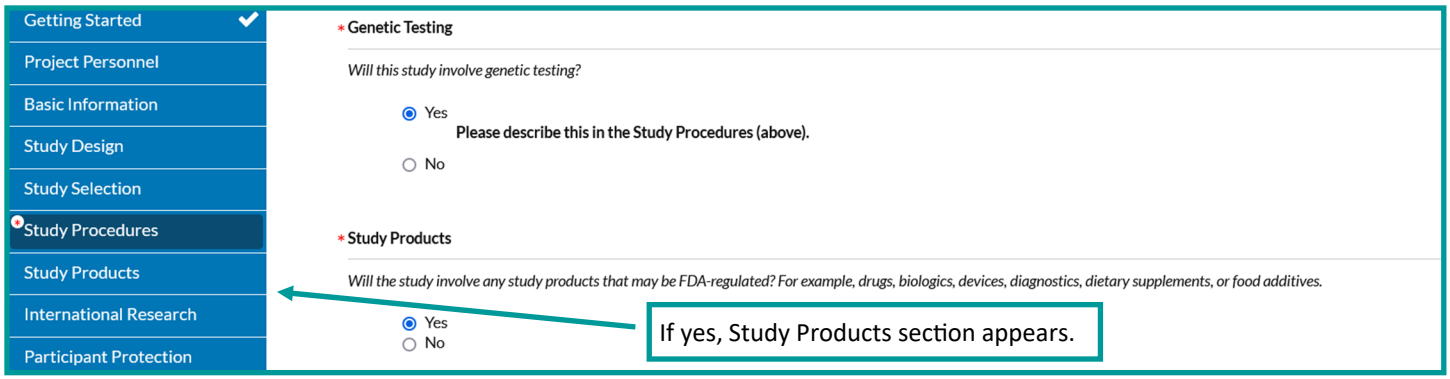


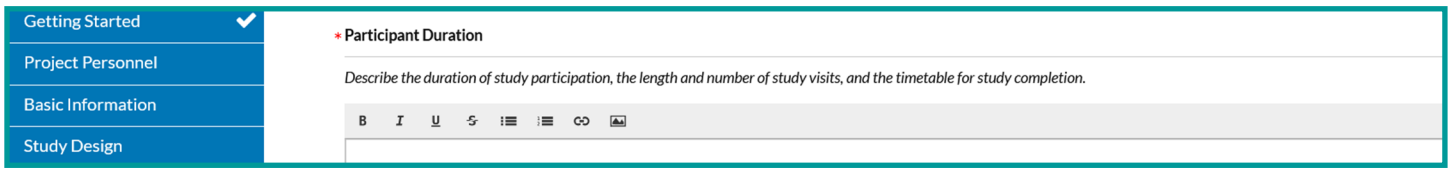


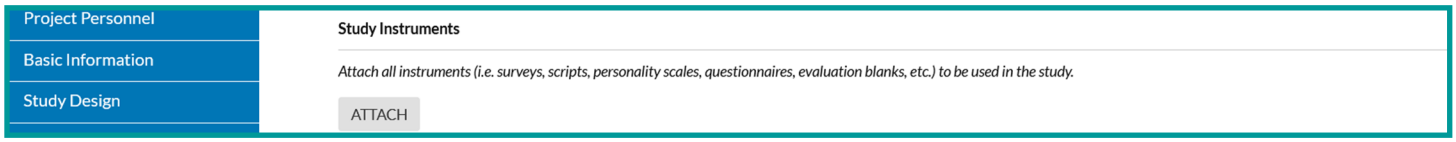




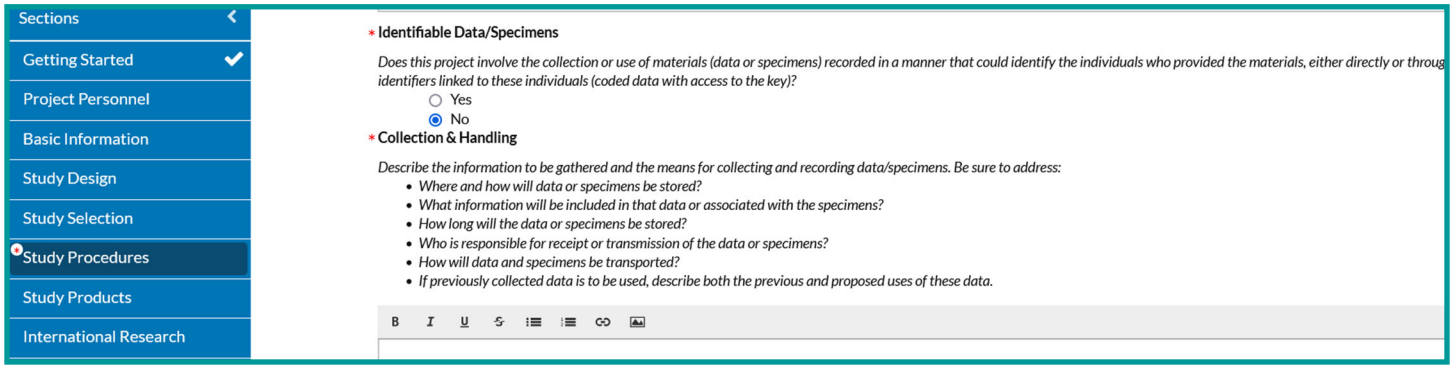


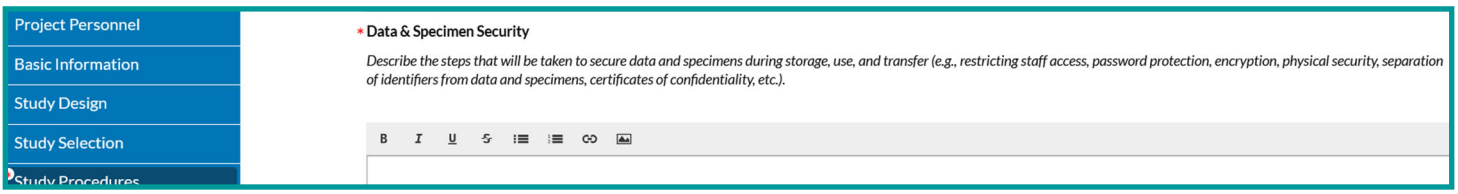

Getting Started
Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Study Products
International Research
Participant Protection
* Genetic Testing
Will this study involve genetic testing?
Yes
Please describe this in the Study Procedures (above).
No
* Study Products
Will the study involve any study products that may be FDA-regulated? For example, drugs, biologics, devices, diagnostics, dietary supplements, or food additives.
Yes
No
If yes, Study Products section appears.

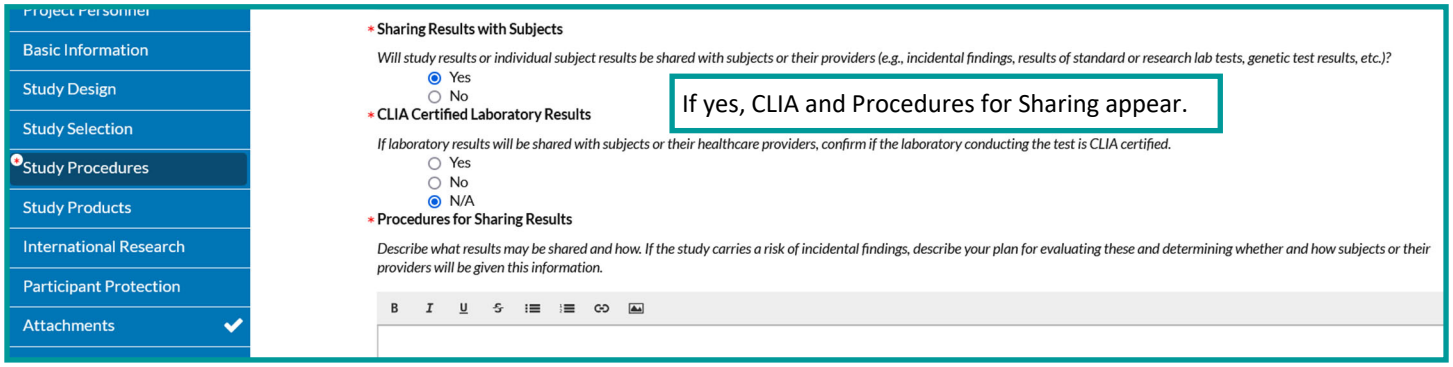

Getting Started
Project Personnel
Basic Information
Study Design
* Participant Duration
Describe the duration of study participation, the length and number of study visits, and the timetable for study completion.

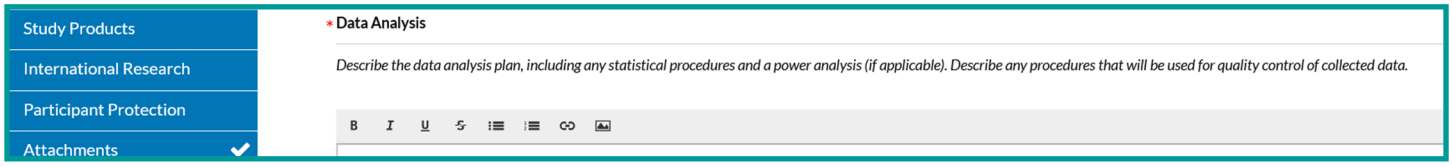

Project Personnel
Basic Information
Study Design
Study Instruments
Attach all instruments (i.e. surveys, scripts, personality scales, questionnaires, evaluation blanks, etc.) to be used in the study.
ATTACH


Study Products
International Research
Participant Protection
Data & Specimens
How will the results be shared, with whom, and in what form?


Sections
Getting Started
Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Study Products
International Research
* Identifiable Data/Specimens
Does this project involve the collection or use of materials (data or specimens) recorded in a manner that could identify the individuals who provided the materials, either directly or throug
identifiers linked to these individuals (coded data with access to the key)?
Yes
No
* Collection & Handling
Describe the information to be gathered and the means for collecting and recording data/specimens. Be sure to address:
Where and how will data or specimens be stored?
What information will be included in that data or associated with the specimens?
How long will the data or specimens be stored?
Who is responsible for receipt or transmission of the data or specimens?
How will data and specimens be transported?
If previously collected data is to be used, describe both the previous and proposed uses of these data.


Project Personnel
Basic Information
Study Design
Study Selection
* Data & Specimen Security
Describe the steps that will be taken to secure data and specimens during storage, use, and transfer (e.g., restricting staff access, password protection, encryption, physical security, separation
of identifiers from data and specimens, certificates of confidentiality, etc.).


Basic Information
Study Design
Study Selection
Study Procedures
Study Products
International Research
Participant Protection
Attachments
* Sharing Results with Subjects
Will study results or individual subject results be shared with subjects or their providers (e.g., incidental findings, results of standard or research lab tests, genetic test results, etc.)?
Yes
No
* CLIA Certified Laboratory Results
If yes, CLIA and Procedures for Sharing appear.
If laboratory results will be shared with subjects or their healthcare providers, confirm if the laboratory conducting the test is CLIA certified.
Yes
No
N/A
* Procedures for Sharing Results
Describe what results may be shared and how. If the study carries a risk of incidental findings, describe your plan for evaluating these and determining whether and how subjects or their
providers will be given this information.


Study Products
International Research
Participant Protection
Attachments
* Data Analysis
Describe the data analysis plan, including any statistical procedures and a power analysis (if applicable). Describe any procedures that will be used for quality control of collected data.