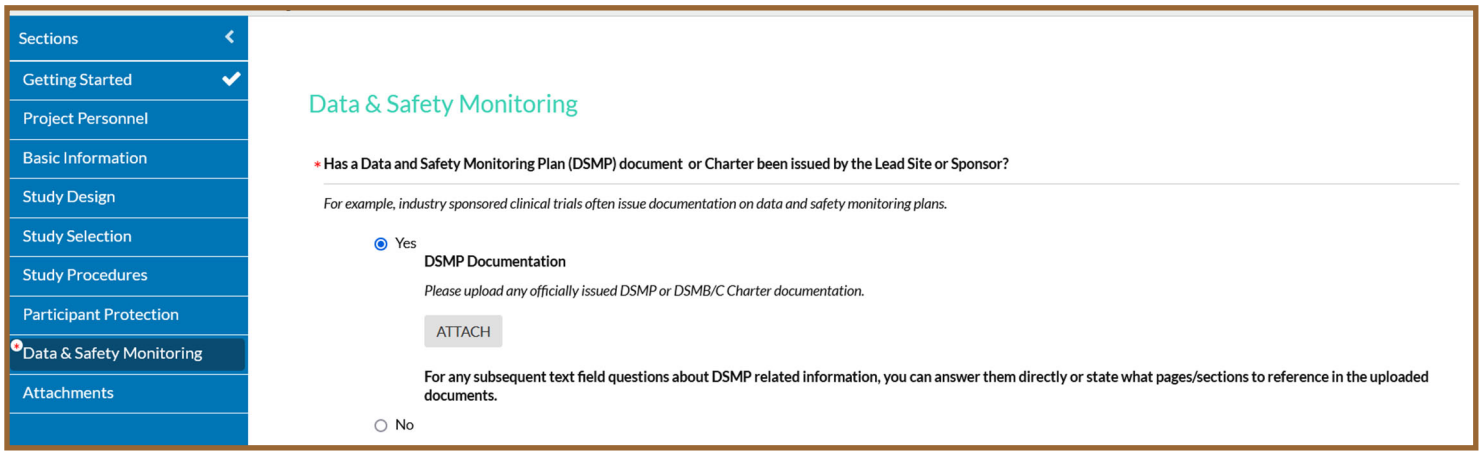
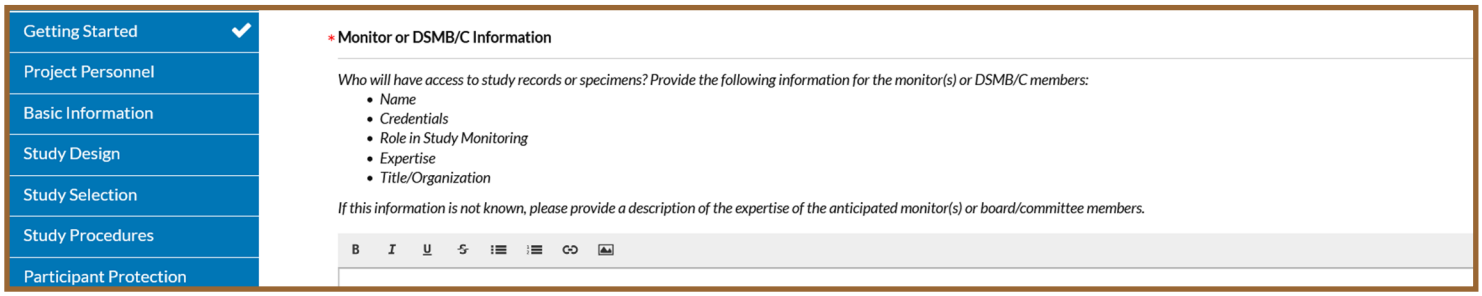
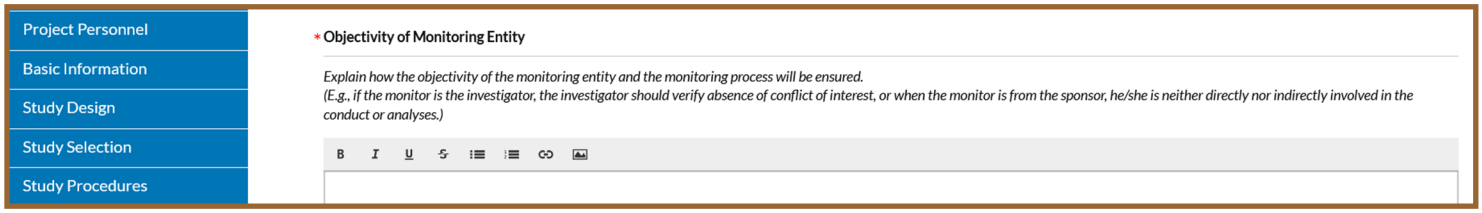
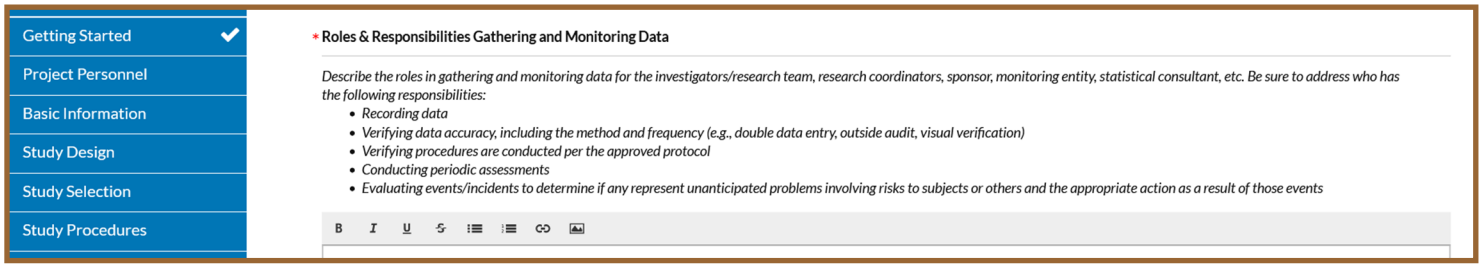
Data and Safety Monitoring

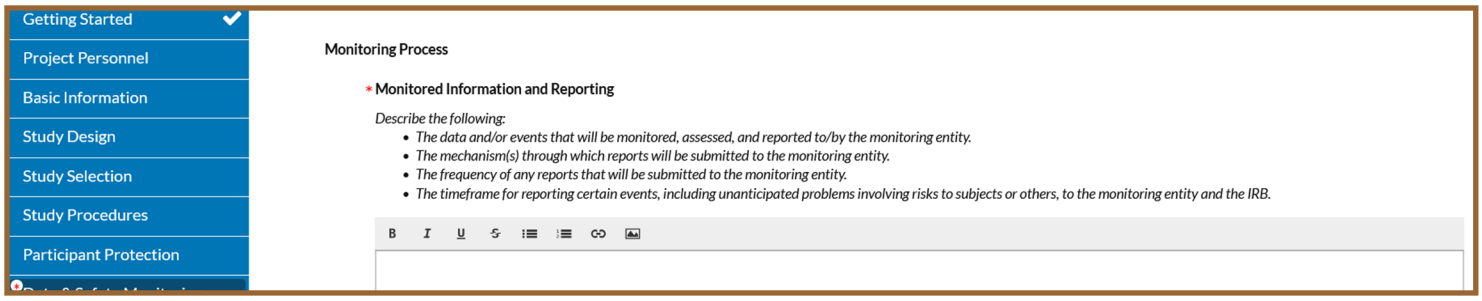
Depending on your responses, additional questions may appear.

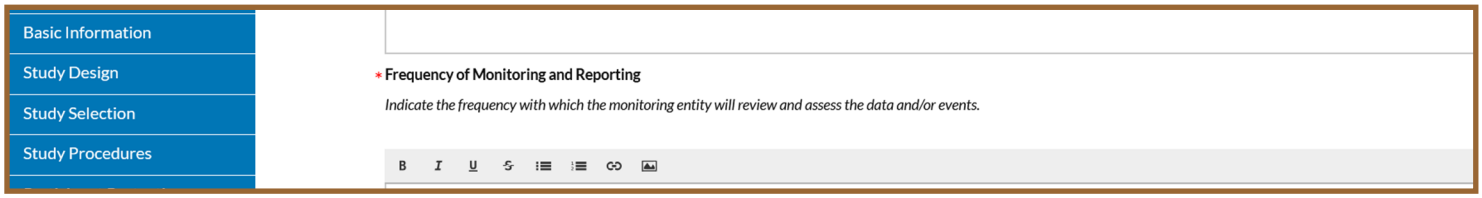


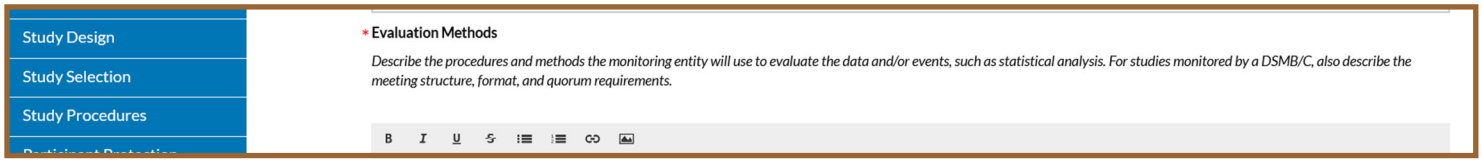




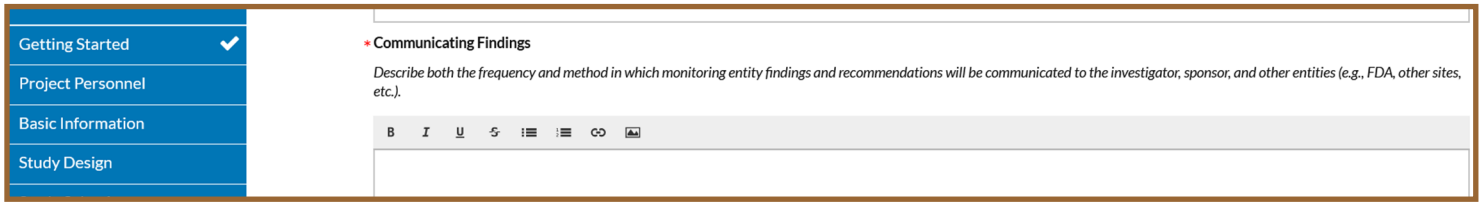



Getting Started
Project Personnel
Basic Information
Study Design
Study Selection
Study Procedures
Participant Protection
Monitoring Process
* Monitored Information and Reporting
Describe the following:
The data and/or events that will be monitored, assessed, and reported to/by the monitoring entity.
The mechanism(s) through which reports will be submitted to the monitoring entity.
The frequency of any reports that will be submitted to the monitoring entity.
The timeframe for reporting certain events, including unanticipated problems involving risks to subjects or others, to the monitoring entity and the IRB.


Basic Information
Study Design
Study Selection
Study Procedures
* Frequency of Monitoring and Reporting
Indicate the frequency with which the monitoring entity will review and assess the data and/or events.


Study Design
Study Selection
Study Procedures
* Evaluation Methods
Describe the procedures and methods the monitoring entity will use to evaluate the data and/or events, such as statistical analysis. For studies monitored by a DSMB/C, also describe the meeting structure, format, and quorum requirements.


Study Design
Study Selection
Study Procedures
* Criteria and Response to Findings
Describe the criteria and plan for taking action in response to monitoring entity findings (e.g., reporting, stopping rules, protocol changes, or modifying subsequent monitoring activities).


Getting Started
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* Communicating Findings
Describe both the frequency and method in which monitoring entity findings and recommendations will be communicated to the investigator, sponsor, and other entities (e.g., FDA, other sites, etc.).


Basic Information
Study Design
Study Selection
Study Procedures
Participant Protection
* Confidentiality of Data
Describe how the confidentiality of the data provided to the monitoring entity will be maintained.