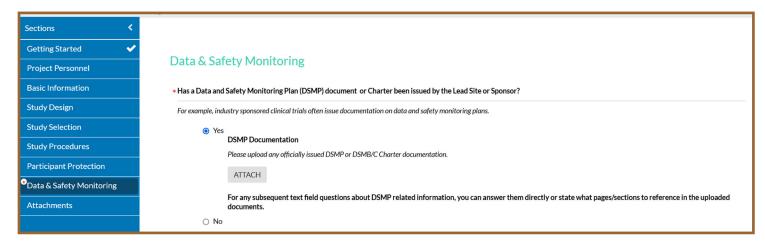
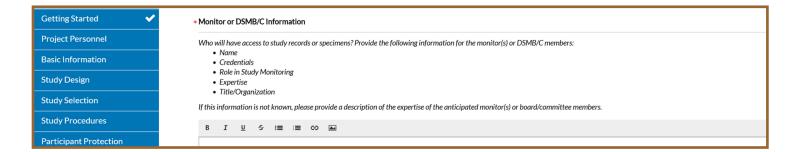
Data and Safety Monitoring

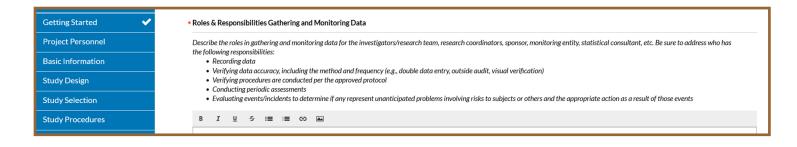
Depending on your responses, additional questions may appear.







Project Personnel	* Objectivity of Monitoring Entity
Basic Information	Explain how the objectivity of the monitoring entity and the monitoring process will be ensured.
Study Design	(E.g., if the monitor is the investigator, the investigator should verify absence of conflict of interest, or when the monitor is from the sponsor, he/she is neither directly nor indirectly involved in the conduct or analyses.)
Study Selection	B I <u>U</u> 5 :≡ :≡ co 📾
Study Procedures	



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Project Personnel	Monitoring Process
Basic Information	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. B
Study Design	
Study Design Study Selection	
Study Procedures	
Participant Protection	
Basic Information	
Study Design	* Frequency of Monitoring and Reporting
Study Selection	Indicate the frequency with which the monitoring entity will review and assess the data and/or events.
Study Procedures	B I <u>U</u> 5 ∷≣ ≔ co a a
Study Design	*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
Study Selection	meeting structure, format, and quorum requirements.
Study Procedures	B I U S ≔ ≔ ⇔ ⊡
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Study Design	* Criteria and Response to Findings
Study Selection	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).
Study Procedures	
Participant Protection	BIU 5 ≔ ≔ ⇔ ⊑
	Communication Findings
Getting Started Control of the started Con	*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,
Project Personnel	etc.).
Basic Information	B I U S ≔ = CO M
Study Design	
Basic Information	
Study Design	* Confidentiality of Data
Study Selection	Describe how the confidentiality of the data provided to the monitoring entity will be maintained.
Study Procedures	B I <u>U</u> 5 ∷≣ ∷≡ co a a
Participant Protection	