32-2. Data Safety and Monitoring Plan - Monitoring the Study

Monitoring the Study

Hide

32-2.1* Indicate the frequency with which the study team will conduct scheduled assessments of study recruitment, data integrity and quality, adverse events, withdrawals, and compliance with protocol plan.

Select one:

- ○ Weekly
- ○ Every two weeks
- ○ Monthly
- ○ Quarterly
- ○ Other

Clear

If other, please specify:

32-2.2* Study oversight and safety monitoring may be required based on the nature, size, and complexity of the study. Indicate the responsible entities.

Select all that apply:

- ☐ No additional monitoring is required – the nature, size, and complexity of this study does not require additional safety monitoring to that provided by the IRB.
- ☐ Independent monitor
- ☐ Internal committee
- ☐ Sponsor
- ☐ Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC)
- ☐ UMHS Cancer Center DSMB
- ☐ Other

If other, please specify:

If no additional monitoring is required, jump to 32-2.3.

32-2.2.1 Provide the names and areas of expertise of those providing this additional monitoring

Note: independent monitor, internal comm Data and Safety Monitoring Board (DSMB etc.

32-2.2.2 Indicate the frequency with which the additional monitoring activities will be conducted.

Select one:

- ○ Annually at the time of the scheduled IRB review
- ○ Monthly
- ○ Quarterly

Clear

Exit Save Continue

Select one:

- ○ Semiannually
- ○ Other

Clear

If other, please specify:

32-2.2.3 Indicate the data that will be reviewed.

Select all that apply:

- ☐ Adverse event review
- ☐ Subject data
- ☐ Enrollment
- ☐ Assessment of minority recruitment
- ☐ Withdrawals
- ☐ Protocol violations/deviations
- ☐ Initiation of early stopping rules
- ☐ Study termination

32-2.2.4 If a DSMB or DSC charter exists, upload it here.

+ Add

Name	Version
There are no items to display	

Additional Help

32-2.3* Monitoring reports will be provided to:

Organization	Reporting Mechanism
☐ IRB (required)	eResearch
☐ Federal oversight agencies (FDA, RAC, etc.)	
☐ Sponsor (federal, industry, private, etc.)	
☐ Other	

If other, please specify:

See Other Reportable Information or Occurrence (ORIO) for guidance on how a when to submit monitoring reports.