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

#### Monitoring the Study

**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:

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**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:*

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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

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**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*

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Note: independent monitor, internal comm

Data and Safety Monitoring Board (DSMB etc.)
Select one:
- Semiannually
- Other

If other, please specify:

32-2.3.3 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

32-2.4 If a DSMB or DSC charter exists, upload it here.

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

32-2.3 Monitoring reports will be provided to:
- IRB (required)
- Federal oversight agencies (FDA, RAC, etc.)
- Sponsor (federal, industry, private, etc.)
- Other

If other, please specify: