32. Data Safety And Monitoring Plan

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Completion of this section is required based on the response provided to question 7-1.10.

The principal investigator (PI) has the ultimate responsibility for the conduct of this research study. The study-specific scientific protocol should include detailed information about tests and procedures employed to safeguard the health and safety of the subjects. Additionally, the PI must prepare a specific data and safety monitoring plan taking into account national guidelines and the study's complexity, risk, and size. The plan should include the administrative processes for recording and evaluating the data quality and integrity. The plan should also specify the responsibilities of research team members and the schedules for reviewing and reporting study progress and adverse events.

Components of this plan relating to the protection of subject privacy and data confidentiality should already have been included in the Confidentiality/Security section of this application.

Additionally, certain members of the research team must complete the PEERRS mandatory training on human subject protection. This includes personnel joining the study team after the initiation of the study.

The Risk Level has been indicated as:

Name	Risk Level	Direct Benefit
There are no items to display		

32.1* Indicate who will provide study information and instructions to the subjects beyond what is included in the informed consent document.

Select all that apply:

- ☐ PI
- ☐ Co-I
- ☐ Study Coordinator/Research Assistant
- ☐ Nursing/Professional Support Staff
- ☐ Other

If other, please specify:

32.2* Indicate who will obtain informed consent from the subjects.

Select all that apply:

- ☐ PI
- ☐ Co-I
- ☐ Study Coordinator/Research Assistant
- ☐ Nursing/Professional Support Staff
- ☐ N/A - Complete waiver of informed consent requested in section 10
- ☐ Other

If other, please specify:

Note: In situations where there is a real or perceived conflict of interest, it may be inappropriate for the conflicted study team member(s) to obtain consent.

32.3* Indicate what mechanism(s) will be used for monitoring subjects and identifying adverse events.

Mechanism (Select at least one:)	Conducted by:
☐ Direct interviews/ physical exams conducted by:	**Select all that apply:** ☐ PI ☐ Co-I ☐ Study Coordinator/Research Assistant ☐ Nursing/Professional Support Staff ☐ Other If other, please specify
☐ Review of lab work, tests, procedures, etc. by:	**Select all that apply:** ☐ PI ☐ Co-I ☐ Study Coordinator/Research Assistant ☐ Nursing/Professional Support Staff ☐ Other If other, please specify
☐ Telephone follow-up conducted by:	**Select all that apply:** ☐ PI ☐ Co-I ☐ Study Coordinator/Research Assistant ☐ Nursing/Professional Support Staff ☐ Other If other, please specify
☐ Self-reporting by subject	Instructions must be included in the Informed Consent Document.
☐ Other	If other, please specify

Reminder: Adverse Events that come to the attention of any member of the study team must be reported to the PI in a timely manner.

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