1. Purpose
The purpose of this Monitoring Plan is to describe the rationale and process for the collection, recording, and verification of data for NICHD Protocol # ____________

2. Objectives
   a. To establish a monitoring plan to ensure the protocol data are in compliance with Good Clinical Practice (GCP), NICHD Institutional Review Board (IRB) and Data Safety Monitoring Committee policies, and Federal regulations.
   b. To ensure the validity, accuracy and integrity of the data

3. Study Staff Responsibilities
   Indicate delegated responsibilities. Delegation of responsibility may be documented on a study staff Signature and Delegation of Responsibility Log.

4. Source Documentation and Case Report Forms
   Indicate who is responsible for data collection and how often he/she/they will review the data for accuracy and completeness.
   Summarize monitoring activities: who will conduct the monitoring, indicate what will be monitored, the frequency of monitoring and how the findings/observations will be documented. Consider adding a flow chart to further illustrate the process.
   Specify, if there is an outside monitoring group (e.g. sponsor’s monitor, CRO) who is responsible for ensuring data accuracy and integrity.

5. IRB and DSMC Documentation
   Indicate who is responsible for maintaining IRB Correspondence. Specify which IRB approved documents will be maintained as part of the study.

6. FDA Documentation
   Indicate who is responsible for maintaining FDA Correspondence. Specify which FDA documents will be maintained as part of the study, including forms 1571 and 1572 and other correspondence (e.g., annual reports, amendments, safety reports).

7. Adverse Event Procedures and Documentation
   Indicate the process for identifying, recording and reporting adverse events (per sponsor, IRB, and FDA reporting guidelines).

8. Study Completion
   Specify how the study close-out process will occur (e.g., maintenance of study files and data retention.)