MONITORING PLAN

IRB#
Protocol Title

The scope and content of the monitoring plan, as determined by the sponsor-investigator, should be based on such consideration as the objective, purpose, design and complexity of the trial. This monitoring plan will be performed in conjunction with the standard operating procedures for monitoring clinical trials that are established by the given sponsor-investigator. Monitoring will be performed by the sponsor-investigator's appointee.

This Monitoring Plan will be followed in monitoring the sites approved for performance of an Investigational New Drug (IND) or an Investigational Device Exemption (IDE).

PURPOSE:
The purpose of the monitoring plan is to present the [DEPARTMENT/DIVISION NAME]'s approach to monitoring clinical trials. The plan facilitates compliance with good clinical practices, FDA guidelines and regulations which require monitors to verify the following:

- The rights and well-being of participants are protected
- Reported data are accurate, complete and verifiable from source documents
- Trial conducted in compliance with currently approved protocol and other applicable regulatory requirements

This document identifies key monitoring activities and specifies the data to be reviewed over the course of a clinical trial. The clinical trial monitors will conduct monitoring visits in accordance with this plan.

SELECTION AND QUALIFCATION OF MONITORS:
Monitors will be appointed by the sponsor-investigator. Monitors will be trained with scientific and/or clinical knowledge and the sponsor will document his/her qualifications. The Monitor will be familiar with the investigational product, protocol, consent form and any other written information given to the participant, sponsor's SOPs, and GCP and the relevant regulatory requirements.

SITE QUALIFICATION
The Monitor will review the following information at the site qualification visit:

- Latest version of the approved protocol for the study
- Informed Consent Forms and processes
- AE and SAE definitions, reporting procedure and contact information
- CRF completion and maintenance
- Source documentation requirements
- Device accountability requirements

In addition, the Monitor will review the following issues at the study site and include these in a site visit report:

- Principal Investigator qualifications and resources
- Site staffing, facilities, storage and equipment are adequate to safely and properly conduct trial
- Adequacy of and accessibility to participant population
- Access to source documentation
- IRB issues
- Laboratory certifications and normal ranges (if applicable)

- Recommendations for investigational site approval and exclusion from the study.

SITE INITIATION
Once all regulatory documents and approval are received, a site initiation visit will be scheduled. During this visit, the Monitor will review the following with the Principal Investigator and his/her staff as appropriate:

- Study goals and obligations
- Protocol procedures (with particular attention to inclusion/exclusion criteria, enrollment goals, adverse events, primary efficacy variables and GCP compliance)
- Informed consent procedure
- Randomization procedure (if applicable)
- AE/SAE reporting
- CRF completion and error correction/need for adequate source documentation
- Maintenance of the investigator binder and site visit log
- Investigational status of test article and requirements for accountability
- Any other issue as deemed important to the conduct of the study

INTERIM MONITORING VISIT
The first monitoring visit will be performed within [NUMBER] working days of the first [NUMBER RANGE] participants enrolled into the study. The remaining interim monitoring visits will occur every [NUMBER RANGE] weeks thereafter regardless of enrollment at each site.

The following issues will be addressed at each interim visit as appropriate:

- Verify receipt of all documents and supplies needed to conduct study
- Informed consent obtained for each participant
- Source document verification 100%
- CRF completion
- Investigational product accountability
- Check and review of the regulatory binder and all essential documents
- Clinical supply inventory
- SAE reporting
- Enrollment issues and targets
- Protocol amendment and their approval by the IRB
- Significant protocol deviations
- Acceptability of facilities
- Personnel changes
- Updated regulatory documentation
- Any other issue as deemed important to the conduct of the study

Following each monitoring visit, the Monitor will complete follow-up letters and site visit reports within [NUMBER] working days of the site visit date.

CLOSE-OUT VISIT

A close-out visit will be conducted to ensure appropriate documentation is present and complete. The visit will occur after the last subject's case report forms have been completed, study has been closed with reviewing IRB/IEC and all regulatory issues have been addressed. The following issues will be addressed at this visit:

- A complete review of the investigator site file to ensure that all necessary CVs are present and current, all applicable versions of the protocol are present and filled appropriately, all applicable versions of the ICF are present, IRB approval letters are present, all SAEs have been reported to the sponsor and the IRB, and documentation of submission of protocol deviations to the IRB/Sponsor are present, notification and/or final report to the IRB present.
- A copy of the monitoring log is obtained
- A copy of the Delegation of Duties log is obtained
- All CRFs have been completed and appropriately filed
- Device reconciliation records are completed and appropriately filed
- Device shipment and return invoices are present and appropriately filed
- Maintenance and retention of study records are discussed
- Regulatory agency and UC inspection process is discussed

In summary the Monitor will serve an important role in the successful conduct of the study. The relationship between the Monitor and the site staff is strengthened by open effective communication with the Monitor providing training and support to ensure participants' rights and safety as well as data quality and compliance with all applicable regulations of the regulatory authorities.