Title: **Monitoring and Oversight Review**
Effective Date: **04/01/08**
Revision Date:

Applicable Regulations:
[21 CFR 50, 54, 56, 312- Responsibility of Investigator/ Sponsor/ IRB]

Purpose of Monitoring and Oversight Review:

The purpose of the monitoring and oversight (M&O) review is to ensure the safety, rights, and welfare of the research subjects and that subjects are not put at unnecessary risk. The monitoring review evaluates the study data separate and independent from external monitoring by entities including the federal government, study sponsor, and contract research organizations. During each monitoring review, the trial conduct, procedure, and processes will be evaluated.

Reason for Monitoring and Oversight Review:

Through monitoring, the M&O Specialist can assess the study staff's knowledge and compliance with the OHRP and FDA regulations as well as GCP guidelines. The specialist will also assess any training needs of the study staff. Any deficiencies with the staff and/or study will be identified and a corrective plan will be designed.

Types of Monitoring and Oversight Reviews:

For cause monitoring review at the direction of the IRB:
  - Multiple protocol violations, deviations, and/or departures from protocol
  - Subject complaint
  - Staff complaint
  - Numerous reportable unanticipated problems
  - Research non-compliance
- Routine, not for cause review (Sites selected without bias based on specific, objective criteria. Please see policy on "Selection of Studies for Routine Monitoring and Oversight Review.")
- COI (Conflict of interest) review
- Study site initiated review

Contacting the site selected:

Contact will be made with the site to inform the Principal Investigator of the purpose and scope of the monitoring and oversight review. The dates and times will be agreed upon by all parties and scheduled. The date of the review will not exceed 60 days from the initial request.

Defined personnel (ie- study coordinator, data manager, etc.) will be requested to be accessible during the visit.

The Principal Investigator will receive a formal written confirmation of the date and time of the review. Within the written confirmation, specific documents will be requested for review.

Historical review:

A request for prior monitor reports from site (if available) will be made to review previous quality assurance findings. The study enrollment log, personnel log, and study monitor log will be requested and reviewed. A review of the study regulatory binder will occur to assure appropriate filing of documents and matching of the site's documents to the IRB study specific regulatory file.

Conduction of Monitoring and Oversight Review:

An interview will be performed to trade introductions and receive detailed information on how the study is being conducted. The responsibilities and roles of the staff members will be discussed. The objectives of the monitor's visit will be discussed and timelines will be established for intermittent meetings and follow-up during and after the review.

A tour of the facility will be performed to examine the equipment being used and their location (i.e. - calibration logs and maintenance logs). Storage areas for case report forms and test articles will be examined for accessibility and security.

A random sample of subject data will be selected to verify protocol compliance, source documentation, and case report form completion. Verification of administration and signing of the study consent form will be completed for all (or a subset) research subjects.

A review and observation of study staff work practices will be performed. Examples of this would be 1) a review of the standard operation procedures for conducting clinical research, 2) the process in which the informed consent is administered, 3) the recruitment process, 4) reporting of serious adverse events, 5) drug accountability and the process for which randomization blind may be broken.

A Closing (Exit) Meeting will be conducted at the end of the scheduled monitoring and oversight review. All significant findings and follow-up items will be discussed. The study staff will be able to respond to the findings and note any corrective action already taken during the review.

Monitoring and Oversight Visit Report

A monitoring and oversight review report will be generated and presented to the IRB Chairpersons and IRB Director at the conclusion of the monitoring review. The IRB Chairs will advise the Monitoring and Oversight Specialist of any follow-up procedures depending on the observations and issues reported. A follow-up letter will be forward to the Principal Investigator. If response is required of the follow-up letter and not received within 30 days of receipt by the Principal Investigator, notification will be forward to the Department Chairman, Assistant Dean of Research, or higher authority as needed (i.e.- Office for Human Research Protection and Food and Drug Administration).

The report will state the current operations within the study being monitored. The report will include noted deficiencies and record the resolution or corrective actions. If improvement, training, or education is needed, the specific area in need will be suggested to the IRB Chairmen.

The letter will serve as documentation for any government audit or inspection.