Data and Safety Monitoring Policy

I. MONITORING DEFINITION
The collection, review, and analysis of data as the project progresses to ensure the appropriateness of the research, its design, and subject protections.

II. MONITORING PRINCIPLES
A. All clinical investigation requires monitoring.
B. The CCI/IRB will generally accept the monitoring plan for externally sponsored research, and reserves the right to review the plan on an ad hoc basis. Sponsor reports must be submitted to the Primary Review Committee (CCI or IRB) within 30 days of receiving the DSM Report.
C. Monitoring should be performed according to a predetermined schedule.
D. The frequency, intensity and mechanism of monitoring depend on the level of risk and the size and complexity of the study.
E. Monitoring should provide information, as appropriate, concerning the performance of individual centers, interim results of the study for evidence of efficacy or adverse events, and possible early termination of the study because of early attainment of study objectives, safety concerns, or inadequate performance.
F. The primary responsibility of the monitoring committee is the health and safety of the research participants.

III. MONITORING PLAN - ELEMENTS AND DESIGNS
The CCI/IRB will review and approve the monitoring plan, as well as the appropriateness of the individuals for Data Safety Monitoring activities on a case-by-case basis. Consideration will be given to the need for expertise and independence from the investigator, the department or the institution.
A. ELEMENTS:
   i. The overall elements of the monitoring plan will vary depending on the potential risks, complexity, and nature of the trial.
   ii. The monitoring plan must:
      1. Define the authority of the monitoring group with regard to advising or making final decisions concerning continuation, revision or discontinuation of the research project.
      2. Include the process for making such recommendations or decisions.
      3. The monitoring plan is to include, as appropriate:
         a. The specific procedures that will be used to monitor for and report adverse events, protocol violations and deviations.
         b. The timing and frequency of data analysis.
c. Periodic Assessment of the following:
   i. Participant recruitment and retention, to assure the feasibility of meeting recruitment projections.
   ii. Data quality and timeliness.
   iii. Participant risk versus benefit, taking into consideration the impact of new scientific or therapeutic developments.
   iv. Trial site performance.
   v. The procedure and schedule for timely reporting to sponsors and the CCI/IRB.

B. DESIGNS:
   i. For studies involving no greater than minimal risk, the signed assurances of the PI included in the CCI/IRB Research Application form, including the policy for reporting internal and external adverse events, constitute a sufficient plan.
   ii. For Phase I and Phase II drug or device studies involving a single site and small numbers of study subjects, close monitoring by the study investigator may be adequate. Alternatively, one or two independent individuals may serve this role. More intense monitoring would be appropriate if the study is blinded or employs particularly high-risk interventions or vulnerable populations.
   iii. For Phase I and Phase II drug or device studies involving multiple sites, a central DSM entity would be most appropriate for performing ongoing monitoring.
   iv. For Phase III, multiple site drug or device trials, an external Data and Safety Monitoring Board is generally required.
   v. For single site studies presenting more than minimal risk and involving diagnostic, physiologic, biochemical, metabolic or genetic observations or interventions, close monitoring by the study investigator may be adequate.
   vi. For behavioral intervention or observation studies presenting more than minimal risk, close monitoring by the study investigator may be adequate.
   vii. For high risk and complex studies, the CCI/IRB may require additional monitoring, such as:
       1. The addition of one or two individuals not involved in the study who would join the PI as a monitoring committee.
       2. An internal Data Safety Monitoring Committee.
       3. A full External Data Safety Monitoring Board.
       4. An external Data and Safety Monitoring Board for multiple sites studied.
IV. PROCEDURAL GUIDELINES FOR PROTOCOLS REQUIRING THE ESTABLISHMENT OF A DATA SAFETY MONITORING COMMITTEE FOR RESEARCHER-INITIATED PROTOCOLS AND EXTERNALLY SPONSORED PROTOCOLS HAVING NO MONITORING COMMITTEE:

The DSM Committee is required to meet and review the approved protocol prior to enrolling research participants.

A. The DSM Plan will stipulate:
   i. The composition of the DSM Committee.
   ii. The frequency of committee meetings.
   iii. The material to be reviewed at each meeting.

B. The DSM Committee is required to record minutes of the meetings. The minutes are to include the following:
   i. Attendance.
   ii. Summary of the discussion.
   iii. Findings, (e.g., research may begin or continue, recruitment is halted, actions needed to re-open recruitment, etc.).

C. When the DSM Committee concludes that the protocol should continue, unmodified, the DSM Committee will send the investigator and the CCI/IRB the minutes. No further action is required.

D. When the DSM Committee concludes that recruitment should be stopped:
   i. The DSM Committee will send the investigator and the CCI/IRB the minutes with directive to suspend recruitment immediately.
   ii. The DSM Committee and the CCI/IRB will copy each other on all written and electronic communications.
   iii. The CCI/IRB Chair or designee will review the DSM Committee recommendations, and if in agreement, the CCI/IRB will notify the investigator, in writing, affirming the DSM Committee action, and directing the investigator to submit an amendment to implement the required changes.
   iv. Depending on the nature of the changes, the amendment will receive expedited or full committee review.

E. When the DSM Committee concludes that changes to the protocol and/or the informed consent are required, but recruitment may continue:
   i. The DSM Committee will send the investigator and the CCI/IRB the minutes.
   ii. The CCI/IRB Chair or designee will review the DSM Committee recommendations, and if in agreement, the CCI/IRB will notify the
investigator, in writing, to submit an amendment to implement the required changes.

iii. Depending on the nature of the changes, the amendment will receive expedited or full committee review.

F. The researcher is required to include all DSM Committee reports as attachments to the Progress Report at the time of recertification.

G. GREATER THAN MINIMAL RISK STUDIES HAVING NO DSM COMMITTEE:

In the rare instance in which the CCI/IRB has determined that a protocol that is slightly greater than minimal risk does not require a DSM Committee, the researcher must submit a DSM Plan for review and approval by the CCI/IRB.

References:
General Clinical Research Center: http://ictr.aecom.yu.edu/
http://www.niaid.nih.gov/dmid/clinresearch/policy.htm

Approved 9/7/04
Revised 12/6/04, 3/07
CCI/IRB Joint Policy - approved
Administrative revision 10/22/07