Overview of Study Monitoring Services

Study monitoring is an important component of study conduct that is designed to ensure compliance with the protocol, Good Clinical Practice, Federal and local regulations, and institutional policies. Where the investigator is serving as the sponsor, study monitoring also offers protection to the investigator and the institution. In many cases, a developed Study Monitoring Plan is a required element of NIH grant applications involving proposed clinical research studies. The process of study monitoring begins in the protocol development phase when a monitoring plan is developed and monitoring continues through to study closure. This guideline describes standards for implementing study monitoring.

Monitoring Services

The Clinical Research Center (CRC) at Boston Children’s Hospital offers monitoring services for investigators in need of independent monitoring. CRC monitors are experienced clinical research professionals that have completed competency-based monitoring education. Priority for monitoring is given to faculty acting as the regulatory sponsor of an IND or IDE clinical trial to aid those investigators with fulfilling federal regulatory requirements to perform safety monitoring. The numbers of staff that monitor studies is small. Therefore, studies are monitored on a first come, first served basis. If BCH personnel are not available to monitor an investigator’s study The Clinical Research Center staff can provide investigators with the names of experienced outside individual monitors or contact information for companies that offer monitoring services for interventional trials involving drugs and devices.

The CRC’s Monitoring Program uses a risk-based monitoring approach. Risk-based monitoring assesses all risks related to a study which informs the development of a proper plan for risk management that includes systematic monitoring and controlling/mitigating risks through the conduct of the study. The intensity and frequency of monitoring varies across studies and among sites depending on the phase of the trial, complexity of the protocol, disease being evaluated, experience of the investigator and study team, number of subjects enrolled, site performance and sponsor monitoring SOPs. Likewise, the number and location of sites and rate of enrollment are considered when monitoring a study. Site monitor visits can be broken down into four types: pre-study visits, initiation visits, periodic monitoring visits, and close-out visit.

A suggested Monitoring Visit Schedule would include:

- Site assessment review and staff training
- Study initiation visit
- First monitoring visit to be scheduled no more than 8 weeks after the first subject is enrolled or after a determined number of subject have met a specific milestone.
- Interim monitoring visits at least every 12 – 24 weeks based on the site activity and as specified in the approved, study-specific Monitoring Plan
- Other monitoring as needed or requested
Pricing of Monitoring Services

- Pricing of monitoring is dependent on elements such as: phase of the trial, complexity of the trial and risk posed to human subjects, single versus multiple participating sites and numbers of subjects enrolled. The monitoring services that are offered to BCH investigators are intended to be a service. The pricing has been structured to be as economical as is feasible. The rate for study monitoring that is conducted by the staff of the Clinical Research Center is $65.00/hour. The costs include: Development of the monitoring plan, time spent conducting the monitoring visits, report preparation and time to meet with investigators and study teams to review the findings and develop corrective action plans, where needed. The monitoring staff of The Clinical Research Center will work with investigators and the staff of the Clinical Trials Business Office to construct a monitoring budget.

Monitoring visits will be scheduled at a frequency that adheres to the schedule of events described in the monitoring plan and as deemed appropriate and determined from assessment of study compliance and individual study team needs.

External Monitoring Services for Hire

- Investigators can access the assistance of outside monitoring vendors. Below is a list of experienced study monitors who contract independently with individual investigators as well as a company that help investigators locate study monitoring services. There are both other out monitoring vendors and independent monitors that investigators are welcome to contract with.

Vendor

- MonitorForHire: https://www.monitorforhire.com/
  MonitorForHire is a patented, resource management tool for locating and contracting available, independent clinical research monitors (CRAs) for CROs, Pharmaceutical, Biotech and Medical Device industries, and Academic Institutions.

Independent Monitors

- Independent study monitors who investigators can contact who have agreed to have their names posted and may be available to do independent monitoring:
  - Matthew Hodgson @: crmatthew@gmail.com.
    Phone: 215-510-0032
  - David Bowling @: david.bowling@childrens.harvard.edu
    Phone: 617.699.8559
**Monitoring Visit Activities**

The monitoring visit activities will be defined in accordance with the protocol and documented in the Monitoring Plan. The findings of the monitoring visits will be documented in the Monitoring Visits Report(s) and reviewed with the investigator and study team.

**To Further Discuss Monitoring for Your Study**

To further discuss study monitoring for your protocol, please contact Cindy Williams: Lucinda.williams@childrens.harvard.edu