

## **Coöperative Pediatric Data and Safety Monitoring Board**

The Coöperative Pediatric Data and Safety Monitoring Board was created by the Pediatric GCRC to assist investigators in monitoring the conduct of research protocols. It is designed to monitor protocols where there is a need for greater monitoring than can be reasonably expected of an investigator, usually involves protocols with small study populations (<100), and may include pilot studies and those conducted by young or relatively new researchers. The Coöperative is not designed to monitor multi-site studies, industry sponsored studies, or studies with larger populations (>200).

The Coöperative Pediatric Data and Safety Monitoring Board has been created to move beyond mere compliance with federal and local regulations to provide optimal monitoring which will enhance the ethical conduct of research and provide enhanced protection to research subject. DSMB monitoring may be determined to be beneficial on account of any of several reasons. These include protocols which involve greater than minimal risk, are blinded, randomized, placebo controlled or involve vulnerable populations. In pediatric research all participants are vulnerable. While not all pediatric research protocols require DSMB monitoring, enhanced diligence in monitoring such research is both desirable and prudent. Therefore, the GCRC will place more pediatric protocols under DSMB monitoring than might be expected in an adult population. This is because we are dealing with children, and other people's children.

### **What this DSMB can, and cannot do.**

Institutional Review Boards (IRBs) have statutory authority to approve the conduct of studies as well as suspend or terminate studies. DSMBs are advisory bodies which provide monitoring assistance and make recommendations about the conduct of the study, its continuation, suspension, or termination. DSMBs provide investigators and the IRB of record with copies of all DSMB reports and recommendations.

### **What will the DSMB provide to investigators?**

The Coöperative Pediatric DSMB will provide an infrastructure and expertise in monitoring research protocols. This will be at no additional cost to the investigator and no charges will be made against grant or other protocol funds. The GCRC will provide policy and documentation of the DSMB empanelled for a study as well as assistance in formulating and writing the protocol Data and Safety Monitoring Plan (DSMP). It will also provide assistance in structuring data storage methods for the protocol. Further, the GCRC will arrange for a set of core members for the DSMB which will include a biomedical ethicist, biostatistician and clinician(s) with expertise relevant to the protocol. DSMB meetings will be conducted and documented by the GCRC, and biostatistical reports generated for the DSMB and meeting reports will be provided to the investigator.

Formal DSMB monitoring of research eliminates many concerns that arise in research including, conflicts of interest in researchers who are also treating physicians, possible financial conflicts of interest, and the benefits of independent oversight. In addition, the DSMB can provide documentation to funding sources that the protocol is being conducted in accordance with the highest ethical and scientific standards.

### **What will be required of the investigator?**

The investigator will be expected to work closely with the Coöperative Pediatric DSMB administrator in identifying potential clinician/researchers to act as DSMB members, collaborating in writing the DSMP, formulating stopping rules, and

determining intervals for interim analyses. The investigator must provide the DSMB administrator with the following information.

1. A full, unabridged copy of the protocol.
2. A copy of the most relevant literature, data or other information used to justify or support conduct of the protocol.
3. A list of all tests to be conducted as part of the protocol.
  - Details on which tests are for monitoring patient safety and which are outcome measures.
  - Identification of which labs (if more than one) will perform which tests.
  - Reference ranges for all tests from the lab performing the test.
  - An explanation for why the reference ranges are different from the ranges in a community population if this is the case.
4. Expected rates of AEs and SAEs
  - Background rates in a community population.
  - Background rates in the study population.
5. Immediate DSMB notification of SAEs, and reports of AEs at the determined intervals.
6. Access to the protocol data by the biostatistician for the purpose of conducting interim analyses.
7. Provision of information, clarification, and answers to questions requested by the DSMB administrator, biostatistician, or protocol DSMB members.