

Criteria Guidelines for the Establishment of Data & Safety Monitoring Boards at Emory University

It is the Principal Investigator's responsibility to insure that individuals participating as subjects in a clinical protocol receive the maximal possible benefit and undergo the minimal possible risk within the parameters of the study. In addition to IRB approval, some protocols benefit from additional oversight.

The following guidelines are designed to assist investigators in determining whether a protocol should have a data & safety monitoring board or committee (DSMB) and, in the event that a DSMB is advisable, how to set up such a committee:

I. The primary responsibility of a DSMB is to make recommendations to the sponsor/investigator concerning the continuation of the study. The board has the mandate to review interim analyses of data and recommend continuation as designed, continuation with major or minor modifications, temporary suspension of enrollment &/or study or study termination.

II. A safety board may be required by the sponsoring organization or the IRB. Additionally, a DSMB is strongly recommended under the following circumstances:

Protocols involving:

1. Highly toxic therapies or dangerous procedures
2. Study populations with high expected rates of morbidity/mortality
3. Gene transfer/ embryonic stem cell research
4. Vaccine/device/drug where FDA IND or IDE is required
5. Blinded or randomized data
6. Vulnerable populations, i.e., children, pregnant women, the cognitively impaired, University/EmoryHealthcare students or employees, prisoners where the study involves more than minimal risk

III. Safety boards should be composed of 3 or more individuals with expertise in the protocol subject, relevant clinical specialties, ethics or statistics. DSMB members should be independent from the investigators & sponsor with no conflict of interest in the outcome of the research.

IV. DSMBs should have a charter or standard operating procedure established prior to beginning enrollment of the study.

V. The purpose of the charter is to define the membership, scope and meeting rules for the board. A charter should contain the following parts:

- A. The membership & function of the DSMB

- B. Specific aim of the study & study design
- C. Patient enrollment
- D. Clinical site locations
- E. Primary efficacy endpoint(s)
- F. Primary safety endpoint(s)
- G. Responsibilities of the DSMB
 - 1.Meeting schedule & format
 - 2.Meeting structure: open session to permit sponsor or investigator interaction, followed by closed session vs. entirely closed

 3. Interim monitoring: for effectiveness, for safety, for conduct
 4. Develop stopping rules to terminate the study when objectives are met
 5. Assure integrity of the study protocol & review data quality, including participant characteristics, timely & complete data submission, data losses and adherence to protocol
 - 6.Record keeping, interim reports, disclosure of board meeting minutes

VI. The board should convene before the onset of the study to review and approve the protocol design, and DSMB charter. Meetings must occur at least annually, but more frequent DSMB reviews are more likely. Meetings should follow the schedule outlined in the charter.

For further information or guidance, the following websites may be of assistance:

<http://www.niams.nih.gov/rtac/clinical/DSMBCharter.htm>

http://www.niaid.nih.gov/dmid/clinresearch/ism_guide.pdf#search='DSMB' <http://www.nida.nih.gov/Funding/GuideDSMB.html>

http://www.nida.nih.gov/funding/DSMB_SOP.html

http://www.amstat.org/sections/SBIOP/br_spr00.pdf#search='DSMB'

http://www.nhlbi.nih.gov/funding/policies/dsmb_est.htm

<http://nccam.nih.gov/research/policies/datasafety/>