FIU IRB Data and Safety Monitoring Board Guidelines

Note: The following text is meant to assist researchers in understanding what DSMBs are, their functions, and how one is constructed. This text is extracted largely from and summarizes federal guidelines on the use of DSMBs in clinical research. The full text of these guidelines may be found at http://www.niaid.nih.gov/dmid/clinresearch/dsm.htm.

Definition: The Data and Safety Monitoring Board (DSMB) is an independent group of experts that advises the investigators involved in a particular clinical study. The members of the DSMB provide their expertise and recommendations to fulfill several functions. The primary responsibilities of the DSMB are to (a) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and (b) to make recommendations concerning the continuation, modification, or termination of the trial.

Review: In conducting its periodic review, a DSMB may review the following:

- Interim/cumulative data for evidence of study-related adverse events;
- Interim/cumulative data for evidence of efficacy according to pre-established statistical guidelines, if appropriate;
- Data quality, completeness, and timeliness;
- Adequacy of compliance with goals for recruitment and retention, including those related to the participation of women and minorities;
- Adherence to the protocol;
- Factors that might affect the study outcome or compromise the confidentiality of the trial data (such as protocol violations, unmasking, etc.); and,
- Factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study.

At the conclusion of a review, a DSMB may recommend the continuation of the study without change, the modification of the study, or the termination of the study. Recommended modifications of the study may include, among others:

- Modifications of the study protocol based upon the review of the safety data;
- Suspension or early termination of the study because of serious concerns about subjects' safety, inadequate performance or rate of enrollment;
- Suspension or early termination of the study because study objectives have been obtained according to pre-established statistical guidelines.

Membership: The membership of the DSMB should reflect the disciplines and clinical specialties that need to be represented to interpret accurately the data from a particular clinical trial and to fully evaluate participant safety and well being. The number of DSMB members depends on the phase of the trial, range of medical issues, complexity in design and analysis, and potential level of risk but generally consists of three to seven independent members including, at a minimum:

- Expert(s) in the clinical aspects of the disease/patient population being studied (content expert);
- One or more biostatisticians (statistical expert);
- Investigators with expertise in current clinical trials conduct and methodology (research expert) and,
- A member of a community organization.

Meeting Schedule and Content. The frequency of DSMB meetings depends on several study-related factors including: the rate of enrollment, safety issues or unanticipated side effects, availability of data, and, the frequency of interim analyses. Typically, the study's PI is responsible for convening meetings, selecting a venue, and coordinating the distribution of meeting materials to DSMB members and other meeting participants. The agenda for each meeting is generally set by the PI and the DSMB Chair jointly. The initial DSMB meeting should occur preferably before the start of the trial or as soon thereafter as possible. At this meeting the DSMB should discuss the protocol, set triggers for data review or analyses, define a quorum, and establish guidelines for monitoring the study. Guidelines should also address stopping the study for safety concerns and, where relevant, for efficacy based on plans specified in the protocol. At this meeting, the DSMB should also develop procedures for conducting business (e.g., voting rules, attendance, etc.).

Once a study is implemented, the DSMB should convene as often as necessary, but at least once annually, to examine the accumulated safety and enrollment data, review study progress, and discuss other factors (internal or external to the study) that might impact continuation of the study as designed. A DSMB meeting may be requested by DSMB members, the Project Officer (PO), industrial collaborator, IRB, or study Principal Investigator at any time to discuss safety concerns. Decisions to hold *ad hoc* meetings will be made by the PO and DSMB Chair. Face-to-face meetings are preferable but conference calls or videoconferences are acceptable alternatives with the agreement of the DSMB members and PO. In the event a DSMB member cannot attend a meeting, he/she may receive a copy of the minutes of the meeting and either participate by conference call or provide written comments to the DSMB Chair for consideration at the meeting.

Summary Report. The DSMB will issue a written summary report that identifies topics discussed by the DSMB and describes their individual findings, overall safety assessment and recommendations. The rationale for recommendations will be included when appropriate. This report will generally not include confidential information. The DSMB Chair is responsible for drafting, circulating and obtaining approval from other DSMB members of the summary report within two (2) weeks of the meeting. The final summary report will be forwarded by the Principal Investigator to the IRB.