Data Safety Monitoring Board (DSMB)

WHO

The study sponsor or sponsor-investigator selects members to form the committee. The members are typically independent experts in the disease area being studied.

WHAT

A DSMB is responsible for overseeing the study data and the safety of participants. They also provide recommendations on whether to continue, modify or terminate the participants and/or the study.

WHERE

DSMB meetings can occur in person or be conducted via teleconference.

WHEN

The frequency of DSMB meetings depends on factors such as: the rate of enrollment, safety issues and/or availability of data. The initial meeting ideally occurs prior to the start of the study.

WHY

A DSMB is formed to allow for unbiased review and monitoring of clinical studies to ensure the safety of participants and verify that the study meets its scientific objectives.

Things to Remember:

- ✓ Submit DSMB reports to the IRB in a timely manner. This can be done using the report form function or as part of a continuing review submission.
- ✓ Review the Safety Monitoring section of the IRB application regularly and update the DSMB section as necessary (i.e., such as changes to the defined frequency of DSMB meetings or adjustments to the number of board members).
- ✓ File documentation supporting or clarifying why a DSMB meeting was postponed or canceled, if applicable.
- ✓ Track decisions or recommendations made regarding the study by the DSMB and implement if required.

*These reminders may not be applicable for all studies, especially industry sponsored trials.