

# Series 703 Data and Safety Monitoring | Institutional Review Board

## The Institutional Review Board from Series 703 of Data & Safety Monitoring

### I. Responsibility to Monitor

Investigators are in the best position ensure the safety of participants both during study procedures and once they have been completed. Adequate monitoring activities ensure that participant safety is not compromised during their active participation in research. In some cases, it is appropriate to continue monitoring participant safety after the research interactions with participants have ended or via the data, as well.

### II. Circumstances Requiring Data & Safety Monitoring

A data & safety monitoring plan is required for all greater than minimal risk research. In addition, a reviewer might determine during the protocol review that a data & safety monitoring plan is appropriate for minimal risk research. If such a determination is made, the basis for that determination will be documented by the IRB reviewer. An adequate data & safety monitoring plan includes at least the following elements:

1. Who will conduct the monitoring (e.g. the researcher, an independent reviewer, a data & safety monitoring board, etc.)
2. The specific data to be monitored
3. The procedure for analyzing and interpreting the data
4. The frequency and timing of monitoring
5. How monitoring will be reported to the IRB and at what intervals
6. Actions that will be taken
7. Any other reporting that will be undertaken related to data & safety monitoring

### III. Monitoring by Sponsor

If a research sponsor will engage in data & safety monitoring, reports generated by the sponsor should be provided to the IRB absent prospective agreement to the contrary.

### IV. Data & Safety Monitoring Boards

Some greater than minimal risk research might require oversight by a Data & Safety Monitoring Board (DSMB). A Data & Safety Monitoring Board is an independent group of experts that advises both the study team as well as the IRB regarding the safety of a particular study or set of studies. The members of the DSMB are selected by the research team, but approved by the IRB, and serve in an individual capacity and provide their expertise and recommendations. The primary responsibilities of the DSMB are to

1. Periodically review and evaluate the accumulated study data for participant safety, study conduct, and study progress, and
2. Make recommendations to the study team and the IRB concerning the continuation, modification, or termination of the study.

The DSMB considers study-specific data as well as relevant background knowledge about the population or procedures under study. No member of the DSMB should have direct involvement in the conduct of the study. Furthermore, no

member should have financial, proprietary, professional, or other interests that may affect impartial, independent decision-making by the DSMB.