

“Data and Safety Monitoring Plans (DSMPs)”

The purpose of data and safety monitoring is to protect the safety of participants and ensure the integrity of the research data. All studies involving human subjects require some level of data and safety monitoring with the method and level being commensurate with the degree of risk to subjects and the size and complexity of the study.

For “**minimal risk**” projects, the plan would generally consist of (1) the type of data or events that will be monitored: e.g., recruitment, accrual rates, response and retention rates, and events and problems involving risks to subjects or others, etc., (2) identification of the individual(s) responsible for monitoring the data collected, (3) the frequency of review (i.e., whether review will be conducted at specific time intervals or whether it will be conducted after a certain number of subjects are enrolled), (4) a description of how the privacy, confidentiality and safety of the data will be accomplished, and (5) additional details depending on the nature of the research being conducted.

All “**greater than minimal risk**” projects require a detailed DSMP. A summary of the requirements appears below. For full details, see “Data and Safety Monitoring” on the HSIRB website: <http://www.research.buffalo.edu/rsp/irb/hsirb/default.cfm>

Elements of a DSMP

DSMPs must be written to include sufficient information to enable the HSIRB to determine whether the plan is appropriate for the research being conducted. DSMPs should generally include the following information:

General:

- Types of data or events that will be monitored
- Identification of the individual(s) responsible for the monitoring
- Procedures for disclosing conflicts of interest of the monitor(s)
- Frequency of review
- Procedures for communicating the outcome of DSM reviews to the HSIRB, study sponsor, or other entities

Safety Issues:

- Description of the plan for reporting events and problems to the HSIRB and others and how those events and problems will be managed

Data integrity:

- Procedures to facilitate the accuracy of data collection and ensure the validity of data

Data and Safety Monitoring Board (DSMB):

- When the study has a DSMB, information about the board’s monitoring activities and the board members



- **The method and level of data and safety monitoring is relative to the degree of risk to subjects and the size and complexity of the study**



Determining the Appropriate Level of Monitoring

DSMPs should be developed for each study according to the nature, size, subject population, complexity, and potential and expected risks associated with participation in the research.

The level of monitoring required is related to the degree of risk posed by the research and ranges from monitoring by the principal investigator or group of investigators to the establishment of an independent Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC).

The types of risks to consider include:

- Physical
- Psychological
- Social
- Legal
- Economic
- Invasion of Privacy / Breach of Confidentiality