



## Does my protocol need a Data and Safety Monitoring Plan?

Intervention studies (referred to in the regulations as clinical trials) involving human subjects may require a Data and Safety Monitoring Plan (DSMP). Clinical trials include behavioral or biomedical intervention studies.

The HHS regulations require that studies involving human subjects have a monitoring plan when appropriate (45 CFR 46.111). NIH requires that all clinical trials supported by NIH have a DSMP. Data and Safety Monitoring Boards (DSMB) are used for clinical trials involving significant risk. An observational study, or a study that does not test an intervention, is not a clinical trial and does not require a DSMP.

The Institutional Review Board (IRB) at Marquette may require a DSMP for an intervention study, regardless of the funding source of the research. The determination of the need for a DSMP or DSMB may be made by the research sponsor or the IRB.

## Definitions

**Clinical Trial:** A prospective study of human subjects designed to answer questions about **biomedical or behavioral interventions**; these may include drugs, treatments, devices, or behavioral or nutritional strategies or new ways of using known treatments to determine whether they are safe and effective.

**Human Subject:** Living Individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

**Data and Safety Monitoring Plan (DSMP):** A plan that describes protections for research participants and data integrity, and oversight for clinical trials at a level that is commensurate with the risks of participating in the clinical trial. That is, the method and frequency of monitoring is directly related to the possible harms to research participants in the clinical trial. The DSMP can be as simple as the investigator submitting safety and adverse event information to the IRB or as complex as having a Data and Safety Monitoring Board (DSMB).

## What should a Data and Safety Monitoring Plan include?

- A description of the type of data or events that will be monitored including a definition of an adverse event
  - Events may be broken down into categories (i.e. mild, moderate, severe) if appropriate
- Who will be responsible for monitoring (for example, the primary investigator (PI), Co-PIs, other research team members)
  - This should include the reporting structure if monitoring is not done by the PI
- Monitoring Plan – Policies and Procedures for adverse event reporting
  - Type of action that will be taken if there is an adverse event. Different actions may be defined for different types of events (i.e. mild, moderate, etc.)
  - Time frames for reporting (for example, the PI will report to the IRB every month) and/or frequency of reports (for example, data will be reported after data collection is complete on 50 and 100 participants)  
**\*\*\*Report adverse events to the IRB immediately using the Adverse Event Reporting Form.\*\*\***
- If applicable, a definition of specific triggers or *stopping rules* that will dictate when some action is required. *Stopping rules* are predetermined guidelines that are used to determine that the study should be altered or stopped, based on review of study related events that occur during the conduct of the study. Stopping rules should be specific about the endpoints that will be used and the decisions that will be made.
- As appropriate, procedures for communicating with the IRB, the study sponsor, and other appropriate entities.

## References:

National Cancer Institute, Data and Safety Monitoring Guidelines <http://www.nci.nih.gov/clinicaltrials/conducting/dsm-guidelines/page2>

NIH Guide: NIH Policy for Data and Safety Monitoring <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

NIH National Institute of Allergy and Infectious Diseases, Create a Data and Safety Monitoring Plan <http://www.niaid.nih.gov/ncn/clinical/humansubjects/hs12.htm>

NIH National Institute of Allergy and Infectious Diseases, Glossary of Funding and Policy Terms and Acronyms <http://www.niaid.nih.gov/ncn/glossary/default2.htm>

NIH National Library of Medicine, Requirements for Data Safety and Monitoring Plans Guidelines for NLM Grant Applications <http://www.nlm.nih.gov/ep/dsm.html>

NIH Protecting Human Research Participants <http://phrp.nihtraining.com/index.php>

NYU School of Medicine Institutional Review Board Guidance for Data Monitoring Plans [http://www.med.nyu.edu/irb/information\\_sheets/data.html](http://www.med.nyu.edu/irb/information_sheets/data.html)

University of Kentucky, Resources on Data and Safety Monitoring <http://www.research.uky.edu/ori/QIP/DSMP.htm>

University of Washington, Researchers Guide, Data and Safety Monitoring Plans <http://www.washington.edu/research/guide/dsmp.html>