



Data Safety Monitoring (DSM)

The IRB is responsible for determining if a study needs formal ongoing monitoring of data to ensure that research subjects will be protected. This responsibility stems from DHHS and FDA regulations stating a criterion for study approval be that "when appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects" ([45 CFR 46.111\[a\]\[6\]](#))

Data Safety Monitoring Requirements

This IRB follows guidelines set out by the National Cancer Institute (NCI), as they are the most comprehensive of the NIH guidelines. The NIH (NCI model) says that "All clinical trials supported or performed by NCI require some form of monitoring." Risk and complexity are identified as the most important determinants of the degree and method of monitoring.

- **Early studies (non-therapeutic, Phase I, Phase II) are allowed great flexibility in monitoring;** it is specifically allowed that the PI do the monitoring. However, the policy requires written policies and procedures, and also requires that "regardless of the method used, monitoring must be performed on a regular basis."
- **All Phase-III studies require a formal DSM plan,** which may mean the establishment of a Data Safety Monitoring Board(DSMB) at the sponsoring institute or at the study site or at the lead institution of a multi-center trial.
Note: Low-risk behavioral and nutritional trials may not require a DSMB.

Data Safety Monitoring Boards (DSMB)

A DSMB is an independent committee set up specifically to monitor data throughout the duration of a study to determine if continuation of the study is appropriate scientifically and ethically. For more about the origins and functioning of DSMBs, see resources below.

Factors that suggest a Data Safety Monitoring Board (DSMB) is needed:

1. A large study population.
2. Multiple study sites. *It is more difficult to recognize a pattern of increased or unusual problems when investigators treat small fractions of the population separately.*



3. Highly toxic therapies or dangerous procedures.
4. High expected rates of morbidity or mortality in the study population.
5. High chance of early termination of the study.

Board Composition and Functioning with the IRB

The [NCI guidelines](#) set forth requirements for DSMB composition and function; note that it is required that a majority of the members be drawn from outside the institution (or institute) conducting the study. Membership is usually comprised of:

- experts in the fields of medicine and science that are applicable to the study,
- statistical experts,
- lay representatives, and
- other who can offer an unbiased assessment of the study progress

The DSMB is not specifically required to communicate with the IRB, but the intent is clear that the important information get to the IRB: "The study leadership will provide information on cumulative toxicities and relevant recommendations to the local principal investigators, to be shared with their IRBs."

Resources for Data Safety Monitoring

National Cancer Institute

- [Data and Safety Monitoring Guidelines](#)
- [Data and Safety Monitoring Example Plans](#)

National Institutes of Health

- (Draft) [Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees](#)
November, 2001
- [Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials](#)
June 5, 2000
- [NIH Policy for Data and Safety Monitoring](#)
June 10, 1998



**University of Pennsylvania ♦ Institutional Review Board
Guidance on Data and Safety Monitoring Plans**