

Drexel University
ESTABLISHING A
DATA SAFETY MONITORING BOARD

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Data Safety Monitoring: 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\[a\]\[6\]](#)). In general, all studies posing more than minimal risk should consider a data safety monitoring plan (DSMP). As warranted, the Drexel University IRBs may require a DSMP be provided as condition for protocol approval to assure the safety and welfare of its participants.

DSMP: It describes how the Principal Investigator plans to oversee the human subject's safety and welfare. The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the trial. Sponsors may impose stricter requirements. The intensity and frequency of monitoring should be tailored to fit the expected risk level, complexity, and size of the particular study.

DSMB: A DSMB is a formally appointed independent group consisting of at least three (3) members assigned to conduct interim monitoring of accumulating data from research activities to assure the continuing safety of human subjects, relevance of the study question, appropriateness of the study, and integrity of the accumulating data. Membership should include expertise in the relevant field of study, statistics, and research study design.

The FDA guidance document, defines a DSMB as "a group of individuals with pertinent experience that reviews on a regular basis accumulating data from an ongoing trial. The DSMB advised the sponsor regarding the continuing safety of current participants and those yet to be recruited, as well as the continuing validity and scientific merit of the trial." <http://www.fda.gov/cber/gdlns/clindatmon.htm#1> There are other names for committees that monitor accumulating data (e.g., Data Monitoring Committee).

While it is important to remember that all studies require careful monitoring, the Drexel University IRBs may require a DSMB when a study is investigator-initiated and intends to provide definitive information about the effectiveness or safety of a medical intervention (drugs, device and biologics) and comparative therapies to test the efficacy of one intervention over the other. Other circumstances in which the IRB may require a DSMB are studies involving large populations, multiple sites, and studies having the potential to induce unacceptable toxicity.

DSMB Membership: The PI or trial sponsor generally appoints the DSMB. However, in certain circumstances a Drexel University IRB may form its own DSMB to monitor a specific study. When appointing individuals to a DSMB, the following should be considered: relevant expertise, experience in clinical trials, experience as a member of other DSMBs, and a lack of conflict. A DSMB may consist of as few as 3 members, but this number should be large enough to include a representation of all needed skills and experience. In general the committee may be composed of clinicians, medical ethicist, pharmacologist, epidemiologist, biostatistician and appropriate representation of gender and ethnic groups.

DSMB Responsibilities and Reports: The primary responsibility of the DSMB is to safeguard the interest of study participants. Therefore, the DSMB must approve the safety measures in the protocol to preserve the study credibility and facilitate the availability of timely and reliable findings to the broader clinical community. In particular, the DSMB will provide written documentation assuring that it is in agreement with the data safety monitoring plan (DSMP).

The DSMB written documentation includes:

- Review the progress of the study carefully as often as necessary for side effects and tolerability
- Review all adverse event reports and provide appropriate consultation or summary of adverse events
- Provide reports to the IRB summarizing oversight activities, and
- Any concerns on subject safety and recommendations.

If you are in need of additional guidance please contact a representative from Human Research Protection directly at 215-255-7857.

Further Reading

DSMP

<http://www.cancer.gov/images/Documents/f69cebbb-fe0b-4f89-bee3-1609c2f5197b/StJudePLAN.pdf>

<http://www.cancer.gov/images/Documents/f69cebbb-fe0b-4f89-bee3-1609c2f5197b/DukeDSMPLAN.pdf>

<http://www.cancer.gov/images/Documents/f69cebbb-fe0b-4f89-bee3-1609c2f5197b/NorrisCottonDSMPlan.pdf>

<http://www.cancer.gov/images/Documents/f69cebbb-fe0b-4f89-bee3-1609c2f5197b/WisconsinDSMPlan.pdf>

DSMB

[Guidance for Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees March \(2006\)](#)

[National Cancer Institute Data and Safety Monitoring Guidelines](#)

[Policy for the National Cancer Institute for Data and Safety Monitoring of Clinical Trials](#)

[The DUOM IRB Policies and Procedures: Section 4.15: Data and Safety Monitoring Plans](#)

[NIH Guidance on Data and Safety Monitoring for Phase I and II Trials \(June 2000\)](#)

[Decision Tree for Data and Safety Monitoring Plan Ellenberg, Susan S., Thomas R. Fleming, and David L. DeMets. Data Monitoring Committees in Clinical Trials: A Practical Perspective. Chichester, England: John Wiley, 2003.](#)