

## Data and Safety Monitoring Board/Committee

### Definitions:

A Data and Safety Monitoring Board or Committee (DSMB/C) is comprised of individuals who have appropriate expertise in topic under study. This group is responsible for the following: 1) reviewing, on a regular basis, the data accumulated from an ongoing study or clinical trial; 2) advising the principal investigator or study sponsor of necessary changes to elements of the study that affect subject safety; 3) determining whether there has been any change to the risk-to-benefit assessment during the course of the study; and 4) determining whether the study should continue as designed.

### Overview:

Depending on the complexity and riskiness of a research study and the characteristics of the subject population, it may be appropriate to formally convene a committee of expert consultants to systematically review the ongoing progress of the study. Multi-site clinical trials that include interventions that entail risks to subjects and are funded by NIH MUST have a DSMB. Phase I, II, and III clinical trials funded by NIH may also be required to have a DSMB, particularly if the trial is blinded and involves high risk interventions or includes vulnerable populations (for guidance see: [http://grants.nih.gov/grants/policy/hs/faqs\\_aps\\_dsm.htm#186](http://grants.nih.gov/grants/policy/hs/faqs_aps_dsm.htm#186) ).

There are circumstances when the IRB might determine that other investigators from Pitt/UPMC can serve as members, but a growing number of studies are now including 'independent DSMBs' that include members who have no relationship to either the University or the Sponsor.

The following factors should be taken into account when determining the level of monitoring. 1) the policies of the study sponsor; 2) the number of sites involved (single vs. multicenter) 3) the phase of the study; 4) the public profile of the study; 5) any conflicts of interest; 6) the level of risk to subjects; 7) the study locations; and the study generates data that is blinded.

### Description:

#### Data and Safety Monitoring Board or Committee Members:

The DSMB/C should include experts from relevant medical and scientific specialties and biostatisticians. This may include bioethicists, epidemiologists, and basic scientists. Individuals on a DSMB/C should be free of apparent significant conflict of interest, whether they are financial, intellectual, professional, or regulatory in nature. The appropriate size of the DSMB/C depends on the type of study and types of expertise needed.

## Considerations:

The IRB reserves the right to request a DSMB/C for any study. However, the following are factors that the IRB will consider when making this determination:

- There is a significant likelihood of a serious adverse event to the involved subject
- The study is conducted at multiple sites and the level of risk is greater than minimal
- The study generates data that is blinded or randomized
- The study involves a large number of subjects (Phase III)
- First time use in humans, (Phase I)
- The study involves a gene transfer methodology

## OSIRIS:

Study application

Section 5, question 5.8 Potential Risks and Benefits of Study Participation

Renewal Report

Section 4.0, question 4.12 Data and Safety Monitoring

Required to attach the most current summary report from the Board or Committee

## Consent Document:

Include in the section which discusses who will have access to the participant's identifiable information, the possibility that the Data and Safety Monitoring Board or Committee members may have access.

## Additional Information:

Various funding sponsors also may have additional requirements related to data and safety monitoring which must be considered when preparing your application.

University of Pittsburgh Office of Clinical Research Health Sciences has established an Institutional Data and Safety Monitoring Board (IDSMB) in order to assist in the monitoring of studies

<http://www.clinicalresearch.pitt.edu/irs/services/IDSMB/index.cfm>

National Institutes of Health

<http://nih.gov/>