CCTS Data Safety Monitoring Board

Criteria for Studies that Require a Data and Safety Monitoring Board

- **Studies must be using other CCTS Services (i.e., Regulatory, Clinic Space, BAL, etc.) in order to utilize the CCTS DSMB.**
- If the study has a DSMB there is no need to utilize the CCTS DSMB.
- **All phase 3 trials** – NIH requires a DSMB for all phase 3 clinical trials. Generally, these trials are large, masked, involve multiple sites, and are intended to change medical practice or product labeling. These characteristics warrant a high level of impartial scrutiny.
- **Phase 1 or 2 trials that involve masked interventions** – The use of a DSMB ensures oversight of participant safety while the clinicians involved in conducting the study remain blinded to outcome and safety data.
- **Multi-center clinical studies** – Multi-center studies involve multiple institutions following the same protocol. This imposes a level of complexity which will benefit from impartial scrutiny of safety, study conduct and data quality/integrity, to ensure that all sites are conducting study procedures in a similar, uniform manner.
- **Large randomized multi-site studies to prolong life or reduce risk** – Large studies to evaluate treatments intended to prolong life or reduce risk of a major adverse health outcome such as a cardiovascular event or recurrence of cancer.
- **Clinical trials of high risk interventions or clinical studies where the outcome assessment is invasive or involves more than minimal risk** – Studies of high risk interventions (e.g., gene transfer studies; drug with significant toxicities) should be monitored by a DSMB. Trials that involve testing of new interventions where limited safety data is available are also considered high risk. In addition, studies where the measured outcome is used solely for research purposes and is invasive or could potentially have adverse effects should utilize a DSMB. Please note that the concept of minimal risk is not up to the investigator, but is defined in 45 CRF Subpart A, SEC 46 102.
- **Clinical studies involving vulnerable populations that are more than minimal risk** – The term “vulnerable populations” generally encompasses children, pregnant women, prisoners, elderly or terminally ill individuals, or those with diminished mental capacity. Generally, such studies should be monitored by a DSMB; however, in a single center study if the intervention or outcomes assessment poses only minimal risk, it may be acceptable to have a Safety Monitor, rather than a DSMB. Such exceptions should be discussed with the appropriate funding agency program staff.
- **Controlled trials** – Trials of any size that compare rates of mortality or major morbidity.
- **Clinical Studies that have a funding source that require a DSMB (not a plan)** in their RFA.

All studies should be approved for acceptance by the CCTS DSMB prior to including the CCTS DSMB in your grant application or Research Description. Once accepted you will be provided with the CCTS DSMB template language for use in your grant or Research Description.

All studies must be accepted by the CCTS DSMB **PRIOR** to initiation of the study.