# DSM Review by the National Cancer Institute (NCI)

All NCI-designated cancer centers conducting clinical research are required to have an institutional data and safety monitoring plan. The purpose of the plan is to improve participant protection and trial conduct, as well as to provide a template for center investigators developing DSM plans for individual trials.

All institutional DSM plans undergo 2 separate, but required, reviews. Applicants must submit a general description of the DSM plan for peer review as part of the grant application, in accordance with NIH policy. A full copy of the plan is usually provided at the site visit. For further information on this aspect of review, see http://www.cancer.gov/clinicaltrials/patientsafety/dsm-guidelines/page2.

The second review is by NCI OCC program staff based on criteria listed below. These reviews are distinct from one another; to have an NCI-approved DMSP does not obviate the need for approval by peer review, or vice versa.

## Data and Safety Monitoring Plans Review Criteria

1. Adequacy of the plan for monitoring progress of trials and safety of participants

   *Committee Structure and Relationships*

   Plan describes:
   - Persons and/or committee responsible for oversight,
   - Composition and membership of the committees,
   - Relationship of these committees to others (e.g., scientific review committee, IRB, etc.)

   Committee structures and relationships are illustrated with diagrams or organization charts.

   *Conflict of Interest*

   Plan describes:
   - Conflict of interest rules regarding review of protocols that involve committee members.
   - Policies that apply when study investigators have conflicts of interest with, or financial stakes in, the research outcome; and how these conflicts are managed.

   *Monitoring and Oversight*

   Plan describes:
   - The process and frequency for monitoring patient risks and reporting study progress, safety, accuracy and integrity of data, protocol compliance, adverse events, etc.
   - The process of feedback to the investigator and committee follow-up.
   - How the major classes of trials (i.e., treatment, prevention, cancer control, intervention, etc.) will be accommodated.
   - Different levels of oversight based on the degree of risk (i.e., phase 1, 2, or 3, etc.) involved for the participants and the size and complexity of the trial.

- How confidentiality of data (e.g., assignments to arms of randomized and blinded studies, etc.) are assured in the review process.
- What the monitors or oversight committees look for in terms of progress and safety of participants.
- The processes and reporting functions in place for multi-center trials, if applicable (other than Cooperative Group), i.e., how the trial will be coordinated with respect to data and safety monitoring and patient safety issues; how adverse events will be reported to participating sites and their respective IRBs.
- Information flow and processes are illustrated by flow diagrams or tables.

2. Adequacy of the plan for assuring compliance regarding the reporting of adverse events (AEs).

   Plan describes:
   - Methods, processes, guidelines for reporting AEs and the follow-up procedures for quality control of the AE reporting system.
   - If applicable, for multi-center trials coordinated by the institution, the procedures by which the institution centrally collects from and reports AEs to all appropriate regulatory agencies, and the co-investigators at participating institutions.

3. Adequacy of the plan for assuring that any action resulting in a temporary or permanent suspension of an NCI-funded clinical trial or trial investigator is reported to the NCI Program Director responsible for funding the trials, and other appropriate agencies.

4. Adequacy of the plan for assuring data accuracy and protocol compliance.

   Plan describes:
   - Guidelines and procedures for quality assurance audits of clinical trials, data integrity and protocol adherence, i.e., who is responsible for audits, the method and frequency of selection of trials for audits, percentage of patients to be selected and how the audit information is used.
   - How the discrepancies in audit (e.g. data integrity; missing information, scientific misconduct) are resolved or if unresolved, how these issues are reported to the appropriate regulatory agencies.