

**Department:** UAMS Institutional Review Board  
**Policy Number:** 7.8  
**Section:** Procedures for Study Review  
**Effective Date:** July 31, 2002  
**Revision Date:** August 18, 2004

**SUBJECT: Data and Safety Monitoring**

Data Safety Monitoring is considered an essential part of good research practices.

The purpose of Data and Safety Monitoring is to provide for oversight of the study to assure that the protocol is being followed, data is credible, adverse events are examined, and that the confidentiality and safety of subjects is being protected. The principal investigator is responsible for submitting a data safety monitoring plan appropriate for each study. The IRB is responsible for approving the plan and subsequent review of appropriate reports related to data safety monitoring, including but not limited to reports from Data Safety Monitoring Boards.

Various types of Data Safety Monitoring Plans are required dependent upon the type of study.

**NIH Supported Trials**

NIH supported trials require a data safety monitoring plan. At a minimum these plans should include a description of the reporting mechanisms of adverse events to the IRB, the FDA and the NIH. Investigators must ensure that the NIH is informed of actions, if, any, taken by the IRB as a result of its continuing review. The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the trial. The degree of the detail in the plan depends upon the risk to the subject, the vulnerability of the subjects and the organization of the trial. The NIH considers the following elements essential to the Data Safety Monitoring Plan:

- Monitoring the progress of trials and safety of participants
- Plan for assuring compliance with reporting of adverse events
- Plans for assuring that any action resulting in a temporary or permanent suspension of a funded clinical trial is reported to the NIH institute.
- Plans for assuring data accuracy and protocol compliance

In addition to a Data Safety Monitoring Plan, NIH generally requires a Data Safety Monitoring Board (DSMB) be established for Phase III trials. A DSMB may also be required for Phase I or II drug trials, some behavioral clinical trials, if

multiple study sites are involved, if the treatment is blinded, if the study tests a high risk intervention or is conducted in vulnerable populations.

The purpose of the DSMB is to monitor the safety of the interventions and validity and integrity of the data from the trial.

Reference: NIH Guidance *Further Guidance on a Data and Safety Monitoring for phase I and Phase II Trials* 6/5/00

Reference: NIDA Guidance *Guidelines for Developing a Data and Safety Monitoring Plan* NIDA website

### **Initial New Drug Studies (IND) regulated by the FDA**

When an investigator holds the IND for a drug involved in research, the FDA requires an IND Monitoring Plan. This type of monitoring is more intensive than most DSMPs.

When an investigator holds the IND for a drug involved in research, the FDA requires studies under that IND to be monitored and an IND monitoring plan be prepared and followed. This monitoring plan must verify that:

- the rights and well-being of human subjects are protected,
- the reported trial data are accurate, complete and verifiable from source documents,
- the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with Good Clinical Practice (GCP), and with applicable regulatory requirement(s).

The number of monitors appointed by the sponsor should be sufficient to oversee study conduct. Monitors must be appropriately trained, should have the scientific and/or clinical knowledge needed to adequately monitor the progress of a clinical trial, and their qualifications must be documented.

Monitors must be thoroughly familiar with:

- the investigational product(s),
- the protocol,
- the written informed consent form,
- any other written information provided to the subjects,
- the sponsor's Standard Operating Procedures (SOP),
- Good Clinical Practice guidance, and
- the applicable regulatory requirement(s).

There must be a written plan for monitoring IND studies to assure the integrity of the data, safety of the subjects and that each person involved in the monitoring process carries out their duties. The monitor must be an individual who is not involved in the study and monitors may not enter or correct data on case recording forms. Any deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements must be reported to the investigator and the investigator must take appropriate action designed to prevent recurrence of the detected deviations.

Monitors should not report directly to the investigator. The FDA recommends that alternate reporting structures for monitors or the use of independent monitors.

Sponsor/investigators should consult with the Office of Research Compliance regarding IND submissions and preparations of monitoring plans. The IRB will refer sponsor/investigators to ORC if this has not been done prior to submission of the study.