Department: UAMS Institutional Review Board
Policy Number: 7.8
Section: Procedures for Study Review
Effective Date: July 31, 2002
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SUBJECT: Data and Safety Monitoring Plans

I. Policy

A criterion for approval of research is that when appropriate, the research makes adequate provisions for monitoring the data to ensure the safety of subjects. The IRB must evaluate whether submitted research satisfies this criterion.

Research that is submitted as, or determined to be, greater than minimal risk must provide a plan for monitoring the data to ensure the safety of the subjects. The plan should be tailored to fit the expected risk level, complexity, phase and size of the particular study

Research determined to be minimal risk does not require provisions for data and safety monitoring to protect subjects.

II. Definitions

A. Data and Safety Monitoring Plan (DSMP): A DSMP describes how the Investigator plans to oversee the research subject's safety and welfare.

B. Data and Safety Monitoring Board (DSMB): A DSMB is an independent committee set up to monitor data throughout the study to determine if continuation of the study is appropriate scientifically and ethically.

C. Data and Safety Monitor (DSM): An individual assigned to conduct interim monitoring of accumulating data from research activities to assure the continuing safety of research participants, relevance of the study question, appropriateness of the study, and integrity of the accumulating data. The individual should have relevant medical, ethical and scientific, and monitoring expertise.

III. DSMP CONTENT AND SUBMISSION PROCESS

A. Investigators submitting research that is greater than minimal risk must submit a Data Safety Monitoring Plan to the IRB with initial submission. This may be a separate document in the submission or incorporated into the protocol. The content of each plan will vary based on the complexity and risk level of the study and should be tailored accordingly. All DSMPs must contain at a minimum:

1. The specific data that will be monitored. This should always include safety and efficacy data and any associated events.

   Depending on the complexity of the research, the plan may also need to include such things as assessments of data quality, timeliness, participant recruitment, accrual and retention, procedures for analysis and interpretation of the data, how adverse events will be characterized, whether certain events or endpoints trigger other safety measures to be implemented.

2. Identification of the Monitor. This may be a person or group.

   In some studies, it will be appropriate for the Investigator, or other member of the study team, to serve as monitor. In other studies, the monitor may need to be independent of the Investigator or Sponsor.

3. The frequency of the monitoring. Identify if the monitoring will occur at specific time points, such as quarterly or every six months, or if it is based on milestones, such as after every 5 subjects or if a certain event occurs.

4. Procedures for communication from the monitor to the IRB. This should address that the IRB will be promptly provided with information from the monitor.

This may be the normal processes for communicating with the IRB if the Monitor is part of the study team or it may require that the Investigator provide the IRB with monitoring reports from an outside Monitor.

IV. IRB REVIEW

A. In order to meet the criteria for approval, the convened IRB must ensure that all research which is greater than minimal risk submits a DSMP with adequate provisions for monitoring the data to ensure the safety of subjects. The adequacy of a plan will vary from study to study. For studies determined to be greater than minimal risk, reviewers should:

1. Verify that the study submission includes a DSMP. The DSMP may be an ARIA generated document based on the submission form, incorporated into the protocol or a separate document in the submission.

2. Determine if the provisions outlined in the DSMP are adequate based on nature of the study.

Factors to consider include but are not limited to whether the appropriate data is being monitored, whether the monitoring is frequent enough, whether the monitor needs to be independent, whether a DSMB is needed or if there is one whether it is independent enough.

Research that may indicate the need for a DSMB is listed below. Being on the list does not require a DSMB but is one factor to take into account in determining the adequacy of submitted DSMP.

a. Study involves highly toxic therapies or dangerous procedures.
b. Study expects high rates of morbidity or mortality.
c. It would be ethically important for the study to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed.
d. Study involves a large study population or is conducted at multiple sites.

3. If no DSMP is found or if the protections in the submitted DSMP are inadequate, the study may not be approved. Contingencies for failure to submit a DSMP must be classified as major revisions required.