Department:	**UAMS Institutional Review Board**
Policy Number:	**7.8**
Section:	**Procedures for Study Review**
Effective Date:	**July 31, 2002**
Revision Date:	**August 18, 2004; February 8, 2005; January 24, 2011; August 31, 2020**

SUBJECT: Data and Safety Monitoring

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 determine submitted research satisfies this criterion prior to approval.

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.

DEFINITIONS

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

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.

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.

PROCEDURE

A. Submission requirements
   1. Projects that are greater than minimal risk must include a Data and Safety Monitoring Plan (DSMP) with the initial submission to the IRB.
   2. The DSMP may be a separate document in the submission or incorporated into the protocol.
   3. The content of each plan will vary based on the study's complexity and risk level and should be tailored accordingly. All DSMPs must describe at a minimum:
      a. The specific data that will be monitored. This should always include safety and efficacy data and any associated adverse events.
      b. The methods for collecting safety data, e.g. medical records review, directly from subjects at follow-up visits or phone calls, etc.
      c. The frequency of safety data collection and review.
      d. Who will act as the monitor. The monitor may be an individual or a group..
         i. In some studies, it will be appropriate for the Investigator, or other study team members to serve as monitor. In other studies, the monitor may need to be independent of the Investigator or Sponsor.
   4. Depending on the research, the DSMP may also need to include elements such 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, and whether certain events or endpoints trigger other safety measures to be implemented or immediate study suspension.

B. IRB Review Procedures
   1. To meet the criteria for approval, the convened IRB shall ensure all greater-than-minimal-risk research includes a DSMP adequate for monitoring the data to promote subject safety.
   2. DSMP contents will vary between studies, given the variety of studies reviewed and associated risks.
   3. Reviewers shall:
      a. Verify that the study submission includes a DSMP. The DSMP may include information entered into the e-system submission form, be incorporated into the protocol, and/or be a separate document in the submission. The IRB may consider information from any of these sources, or combinations thereof, in its assessment of the DSMP.
      b. Determine if the provisions outlined in the DSMP are adequate based on nature of the study.
      c. Factors to consider include but are not limited to whether the appropriate data are 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 sufficiently independent.
   4. The IRB has the authority to require the creation of a DSMB if it deems appropriate during its review. Examples of Research that may need a DSMB are below. This list is neither exhaustive nor automatically indicative of a need for a DSMB (since determinations vary), but offers some considerations about potential need for a DSMB, and about the adequacy of a proposed 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.
   5. If no DSMP is submitted or if the protections in the submitted DSMP are inadequate, the study may not be approved. Contingencies for failure to submit a DSMP are major contingencies.

C. IRB reporting related to data and safety monitoring
   1. Events noted as a result of data and safety monitoring and meeting the requirements for immediate reporting under UAMS IRB Policy 10.2 shall be reported to the IRB in accordance with that policy.
   2. Routine monitoring reviews that do not find items subject to immediate reporting under IRB Policy 10.2 shall be reported at continuing review.

REFERENCES

45 CFR 46.111(a)(6)
21 CFR 56.111(a)(6)
AAHRPP Element II.3.B
AAHRPP Tip Sheet 6, *Evaluating Provisions for Monitoring Data and Safety in Proposed Research*
UAMS IRB Policy 10.2, *Information that Must Be Reported to the IRB and IRB Actions*