Tip Sheet 6: Evaluating Provisions for Monitoring Data and Safety in Proposed Research

Related Accreditation Element: II.3.B.

A criterion for approval of research is that, when appropriate, the research protocol or plan makes adequate provisions for monitoring the data collected to ensure the safety of participants. IRBs or ECs should understand the range of possible options for such monitoring.

Recommended Content:

This policy and procedure may stand alone or be part of an umbrella policy and procedure addressing criteria for IRB or EC review.

1. Cite or repeat the criterion for approval pertaining to evaluating provisions for monitoring data and safety found in the relevant laws, regulations, codes, or guidance.
2. Describe the types of information Researchers are asked to provide in the research protocol or plan.
3. Describe the circumstances under which the IRB or EC considers data and safety monitoring to be appropriate.
4. In research involving no more than minimal risk, data monitoring plans are generally not required and should be described as such in the policy and procedure.
5. When the IRB or EC determines that data and safety monitoring is appropriate, describe the types of issues the IRB or EC should consider in evaluating whether the plan is adequate, such as:
    a. Reporting mechanisms.
    b. The frequency of the monitoring, such as points in time or after a specific number of participants are enrolled.
    c. The entity that will conduct the monitoring, such as a data monitoring committee, data and safety monitoring board, medical monitor, Researcher, or independent physician.
    d. The specific data to be monitored.
    e. Procedures for analysis and interpretation of the data.
    f. Actions to be taken upon specific events or end points.
    g. Procedures for communication from the data monitor to the IRB or EC and sites.

Other suggestions:

1. If the IRB or EC uses a checklist, include questions about a plan for data and safety monitoring in the checklist or other supporting forms the IRB or EC uses.
2. Include the data and safety monitoring plan in supporting forms for Researchers, such as an application form.