DATA SAFETY & MONITORING

Description

One of the regulatory criteria for approval is that when appropriate, the research plan makes adequate provisions for monitoring the data to ensure the safety of participants. The IRB requires all moderate risk studies to have a data safety and monitoring plan (DSMP). This plan may include the formation of a data and safety monitoring board or committee (DSMB/C) that will periodically review the study progress for safety and conduct interim analysis.

When an investigator or sponsor designs an appropriate DSMP, the following principles should be considered:

- The monitoring plan should be commensurate with the risks of the study.
- The monitoring plan should be commensurate with the size and complexity of the study.

Initial Submission Requirements

The information provided to the IRB should describe the process and mechanisms in place for assuring the safety of research participants and the oversight of data integrity.

All phase III clinical trials, including sponsored and investigator-initiated trials, require a Data Safety and Monitoring Board or Committee. The following information must be provided to the IRB.

- Who will comprise the Data Safety and Monitoring Committee or Board?
    - The committee should have at least one member with expertise in each of the following areas: statistics, scientific methods, and one non-affiliated member. Members affiliated with the study are non-voting members.
- Describe the board or committee review process.
- What type of reports will be produced (e.g. safety, study progress, interim analysis, etc.)?
- What type of information will be included in these reports?
- How often will they meet?
- Discuss the “stopping criteria” for the study.
- What is the working definition for “adverse events” and “unanticipated problems” for the study and how will they be reported?
- How and when will the committee/board report its findings to the research team, the sponsor, the IRB (*This must be done at least annually)*, and other entities, if applicable?

All other moderate risk interventions need a Data Safety and Monitoring Plan. This includes single-arm trials, early phase or exploratory trials such as Phase I or II, or trials not deemed to require a Board/Committee under relevant regulations and policies. The following information must be provided to the IRB:

- How will the study be monitored?
- Provide the names, affiliations, and expertise of members of the monitoring group. A monitoring group may consist of the PI, someone in addition to the PI, an independent monitor(s) or group who are local but not associated with the conduct of the research or trial.
- How often will the monitoring group meet for review?
- How often will the monitoring group report findings to the IRB (e.g. every 3 months, after every 10 participants, or in response to specific events, etc.)?

- Discuss the "stopping criteria" for the study.
- What is the working definition for "adverse events" and "unanticipated problems" for the study and how will they be reported?
- How and when will the monitoring group report findings to other entities, if applicable?

Reporting Requirements
Researchers must submit reports on events that may represent unanticipated problems involving risks to participants and others (UPs) including unexpected, related adverse events, to the sponsor, FDA, DSMB/C, and the IRB (in accordance with IRB policy).

Monitoring reports (safety, study progress, interim analysis, etc.) generated by the DSMB/C must be provided to the IRB via the Report Form in the ERICA online system. The local PI and IRB should also be provided with information on how to apply the report information to the local participant population. The IRB will evaluate the implications of the reported information, apply that information to the local population(s), and take appropriate action to ensure subject safety.

Continuing Review Requirements
Continuing review of research by the IRB must include consideration of adverse events, unanticipated problems, and interim findings. This information should be provided by the DSMP, including reports and findings from a DSMB/C, when a Continuing Review Application is submitted to the IRB via the ERICA online system. If a current report is not available at the time of Continuing Review, the IRB will review reports submitted since the time of the last review (e.g. during the last year).

Points to Address

Protocol Summary:	**Data Safety & Monitoring**: Please add a Data Safety and Monitoring sub-section. All moderate risk studies require a data safety and monitoring plan, which may involve a committee or board. The information provided to the IRB should describe the process and mechanisms in place for assuring the safety of research participants and the oversight of data integrity. You may describe the plan in this sub-section OR attach a separate document outlining the DSMB/DSMC to the Documents and Attachments page of the application under "Protocol Summary".

References & Links

FAQ	*http://grants2.nih.gov/grants/policy/hs/data_safety.htm*
DSMB Continuing Review Guidance	*http://www.hhs.gov/ohrp/humansubjects/guidance/dsmb.htm*
IRB Reporting Policy	*http://www.research.utah.edu/irb/adverse/index.html*