
It is the policy of the GWU IRB that all clinical trials, regardless of phase, include a data oversight and safety-monitoring plan. The purpose of a data oversight and safety-monitoring plan is to ensure the safety of subjects and the validity and integrity of data associated with a particular study. Data oversight and monitoring plans should vary depending on the nature, size, risk (low risk vs. high risk intervention) and complexity of the clinical trial (single-site vs. multi-site). The oversight and monitoring plan may be conducted by various individuals/groups and in various ways. For example, the PI of a small Phase I or II study involving a low-risk intervention may be qualified to monitor the progress of such a study. Alternatively, an independent Data Safety Monitoring Board (DSMB) may be the only entity qualified to monitor the progress of a Phase I or II clinical trial involving multiple sites, blinding, high-risk interventions or vulnerable populations.

As part of the IRB review process, the GWU IRB will assess the appropriateness and adequacy of a study’s proposed data oversight and safety monitoring plan (or the justification as to why such a plan is not possible) based on the following criteria:

1. Whether the proposed plan is commensurate with the nature, size, and complexity of the clinical trial as well as the degree of risk involved in the study.
2. The timeliness of the planned monitoring. Annual monitoring for low risk studies vs. quarterly monitoring for high-risk studies.
3. How the monitoring conclusions are reported to the IRB, as well as how often they are reported.
4. Whether the individual/entity conducting the monitoring activities has the expertise to accomplish the monitoring mission. For studies
requiring a monitoring group, the group should consist of clinical trial experts, biostatisticians, bioethicists, and clinicians knowledgeable about the disease and treatment under study.

5. The mechanisms for reporting adverse events to the IRB, FDA, and NIH, as applicable.