

Data Safety Monitoring Plan/Charter

1. The Reviewing IRB reviews select key elements of the DSMP and determines whether or not they are sufficient.
2. Relying Institutions are not permitted to modify these sections, but are permitted to add additional information to meet institutional requirements prior to submission to the Reviewing IRB.
3. Suggested key elements of the DSMP:
 1. The monitoring entity and their responsibilities
 2. The type of data or events that are to be captured under the monitoring plan
 3. The time frames for reporting adverse events and unanticipated problems to the monitoring entity
 4. The frequency of data assessments or events captured by the monitoring plan
4. Target return time for review of IRB documents:
 - 15-21 days
5. Significant modifications:
 - a. **Pre-approval** Modifications to DSMP: input of all sites is sought by the main PI before the protocol is finalized. Any Relying Institution Modification to the DSMP are submitted to the Reviewing IRB
 - b. **Post approval** Reviewing IRB reviews the changes to the DSMP via Amendment submission, the approved protocol is distributed to the Relying Institutions post approval. Sites can't alter DSMP based on Relying Institution preferences.