

**Human Research Protections Institutional Review Board**

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# Data Safety Monitoring

The purpose of this guidance is to explain the role and requirements of a Data Safety Monitoring Plan (DSMP) and to define monitoring entities as they relate to human subjects research.

A DSMP is required for all studies involving human subjects, including minimal risk studies that only review medical records. The complexity of the DSMP should be tailored to the nature, size, and complexity of the research protocol, the expected risks of the research, and the type of subject population being studied. Since only secure, confidential, and valid data can substantially contribute to scientific knowledge, a DSMP should ensure the accuracy, integrity, and security of the emerging data, as well as a plan to identify any safety signal for harm. A plan must always be submitted to the IRB, regardless of the monitoring approach (as described below).

## Components of a DSMP



**Definitions:**

### Data monitoring:

Includes the methods for monitoring and ensuing the accuracy, security, and validity of the data.

#### Safety Monitoring:

Includes the methods to ensure the safety of the subjects. The details and protections for this part of the plan should be calibrated to the likely harms associated with the research.

### **Data Safety Monitoring Plan:**

A plan that describes how the investigator(s) or monitoring entities will oversee the data during the trial to ensure that safety of subjects is constantly monitored and the data is reviewed for completeness and integrity. The plan may also establish rules for stopping recruitment and treatment of individuals due to an earlier than expected signal for efficacy or futility.

### Monitoring entity:

An identified individual or group assigned to conduct regular monitoring of accumulated 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.

**1**Ensuring compliance with the reporting requirements for recommendations for study continuation or for reporting unanticipated problems involving risk to subjects or others (including but not limited to serious adverse events)

**2**Including how the data will be monitored, the specific data elements and time points that will be monitored, and how the accuracy and security of the collected data will be ensured and remain in compliance with the IRB-approved protocol.

**3**Stopping rules are predetermined guidelines that are used to determine that the study should be altered or stopped, based on review of study-related outcome data and adverse events that occur during the conduct of the study. Stopping rules should be specific for specific (usually the primary) endpoints that will be used, and the recommended decisions to be made. Studies may be stopped, for example, when there is a greater than expected rate of morbidity or mortality or when the experimental arm of a head-to-head comparison study is shown to be better or worse than the standard care arm based on a priori statistical criteria.

## Consideration for Protocol Design

| **Study Elements**  | **Study Implementation Tools** |
| --- | --- |
| * Inclusion/Exclusion—Clear eligibility criteria that ensure enrollment of subjects with an appropriate level of risk to benefit
* Methods/Procedures—Include procedures to collect relevant data on safety and to evaluate safety
* Stopping Rules—Criteria for discontinuing or suspending enrollment or even the entire trial in the event of an emerging safety concern or signal for efficacy or futility
* Statistical Analysis—Complete analytic plan for both efficacy and safety endpoints that ensures that the trial is adequately designed to achieve the state objectives
 | * Case report forms with sufficient detail to ensure capture of relevant details of adverse and reportable events
* Reporting Forms that include clear directions and criteria for reporting unanticipated problems involving risk to participants to the relevant IRB(s), sponsor(s) and regulatory agency(ies)
* Data management SOP that ensures case report forms are submitted, entered, processed, summarized, and monitored at an appropriate frequency
* Statistical Analysis Plan to detail the statistical design and analytic strategy for the trial and for statistical monitoring activities.
* DSM SOP—outlining data and safety review procedures with clear delineation for reporting responsibilities and reporting intervals
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Certain groups, such as the [NIH](https://grants.nih.gov/policy/humansubjects/policies-and-regulations/data-safety.htm) or [CTSI](http://www.med.nyu.edu/ctsi), may have specific instructions regarding the DSMP for research that is sponsored or conducted by such groups and may impact your protocol, study implementation and DSMP. Make sure to check with your sponsor.

## Monitoring Entities

Depending on the needs of the study the monitor can be any of the following:

| Entity  | Responsible Party  | Monitoring Frequency—General Examples | Research Type—General Examples |
| --- | --- | --- | --- |
| Investigator | PI or Co-I | * Annually
 | * Single-site
* Small number of participants
* Minimal risk
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| Independent Monitor/Monitoring Group | Individual or group not involved in the design or conduct of the research  | * May need to be more frequent than annually
* After X number of subjects enrolled
* After interim analysis
 | * Single-site
* Small number of participants
* Low-risk interventions
* Double-blind study groups
* Randomized
* Phase I or Phase II
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| Independent Data and Safety Monitoring Board (DSMB)/Data Monitoring Committee (DMC) | Committee or Board comprised of experts in the research field under study, in the conduct and ethics of clinical trials, as well as in the study design and analysis methods. Members may not be involved in the design and conduct of the research. | * More frequent than annually (e.g. every 3 months)
* After X number of subjects enrolled
 | * Multi-site
* Large number of participants
* Higher risk interventions or vulnerable populations
* Randomized study design
* Double-blind study groups
* Phase II, Phase III, or implementation trials (group randomized or stepped wedge)
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Regardless of the monitoring entity, the Principal Investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under their care and for ensuring that the study is conducted at their investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

## Reporting to the IRB

Whichever monitoring entity is right for your study, the IRB will require defined reporting schedule at regular intervals to the IRB. After each meeting of the monitoring entity, the lead or Chair should send a brief summary report to each investigator. The report should document that a review of data and outcomes across all centers took place on a given date. It should summarize the review of the cumulative toxicities reported from all participating sites without specific disclosure by treatment arm. It should also inform study investigators of the monitoring entities’ conclusions with respect to progress or need for protocol modifications. The investigator is required to transmit the report to their local IRB.