

Data & Safety Monitoring Plan Guidance

Data and Safety Monitoring

A Data and Safety Monitoring Plan (DSMP) is needed to document safeguards the research team will take to protect the safety of subjects, the validity of the data, and the integrity of the research study. The IRB reviews the plan and determines if the plan has adequate provisions in place for monitoring the data collected to ensure the safety of participants.

For greater than minimal risk research, the IRB requires the investigator to have a Data and Safety Monitoring Plan in place that protects the safety of subjects, the validity of the data, and the integrity of the research study. The IRB reviews the plan and determines if the plan has adequate provisions in place for monitoring the data collected to ensure the safety of participants.

Developing a data and safety monitoring plan may be helpful if the research is considered minimal risk. However, the IRB only requires a plan if the IRB determines that a data and safety monitoring plan is needed to oversee the study.

When developing a DSMP, the investigator should consider the risks of the study and provide an adequate plan to review study data to minimize those risks. The extent to which data (including protected health information (PHI), are monitored should increase as the level of risk to participants increases. Studies involving PHI present elevated data risk and require specific safeguards. The PI and IRB will monitor studies categorized as greater than minimal risk to human subjects. In addition, the project could require additional monitoring by an independent safety monitor or Data Safety Monitoring Board (DSMB). Examples of when a DSMB is needed are described in detail below.

To that end, an investigator should consider the following elements when developing a study specific DSMP:

- **Subject Safety:** monitoring is conducted to avoid or minimize risks (i.e., physical, psychological, or social).
- **Data Integrity:** monitoring is conducted to ensure data is accurate and complete. Monitoring of data assures adherence to the approved clinical study.
- **Subject Privacy:** monitoring is conducted to ensure the individual's rights are protected.
- **Data Confidentiality:** monitoring is conducted to ensure data is secured.
- **Product Accountability:** monitoring is conducted to ensure drug(s) or device(s) are tracked and accounted for.

- **Study Documentation:** monitoring is conducted to ensure that required documentation and reports are on file, accurate, and complete.
- **Study Coordination:** monitoring is conducted to ensure that investigator delegation and communication with the research team are planned and systematic.

In addition to the elements noted above, the plan should explicitly state the individual or committee (but not a student) responsible for monitoring the data, their expertise, and whether such individuals or committee is independent of the research sponsor and the PI of the study.

The DSMP may also include a review of data quality, participant recruitment, accrual, retention, outcome data, results of related studies that may impact the safety of participants, and procedures designed to protect the privacy of subjects.

The DSMP should also outline how often the individuals or committee will review the data, including what documentation will be maintained to demonstrate that the safety review was conducted. (Note: Keep in mind that this information will be reviewed at the time of continuing review. The IRB will want to see that the individuals/committee met at the intervals specified in the DSMP and that associated documentation was maintained as indicated in the initial study submission.)

When adverse events the investigator must review the situation and data. The sponsor may undertake further review of the adverse event. The IRB will review such events per its policy on [Incident Reports](#) as necessary.

Who is responsible for monitoring data and safety?

The individual(s) performing data and safety monitoring will vary depending on the potential risks, complexity, and nature of the study. The Principal Investigator should monitor behavioral research or clinical trials involving surveys or other minimal risk activities.

If you are conducting a clinical trial involving an investigational product, such as an investigational drug or device, data, and safety monitoring may be performed by the research sponsor, a medical monitor, or the contract research organization (CRO) responsible for various study-related activities. There may be times when the Office of Research Integrity will conduct monitoring. This may occur when an investigator is both the investigator and the sponsor of an FDA-regulated clinical trial.

Some research is required to have a Data and Safety Monitoring Board (DSMB) or Data and Safety Monitoring Committee (DSMC), which is an independent monitoring group tasked with completing a review of study data at specified time intervals. DSMB/DSMCs are composed of members whose expertise and experience provide them the ability to identify problems that should be addressed and make recommendations to ensure the safety of research participants. Members of these boards/committees should not possess a conflict of interest with the research, including a financial interest in the study's outcome.

When is a DSMB/DSMC necessary?

The following types of studies are either required or likely to have a DSMB:

- NIH-sponsored Phase 3 clinical trials (as well as some Phase 1 and 2)
- Large, multi-site randomized studies evaluating treatments intended to prolong life or reduce the risk of a major adverse health outcome
- Controlled trials comparing rates of mortality or major morbidity
- When required by the IRB

The FDA recommends the use of a DSMB when an industry-sponsored clinical trial includes:

- A study endpoint that might ethically require termination of the study at interim analysis, where a highly favorable or unfavorable finding is made
- A particular safety concern, such as the administration of treatment by an invasive method (performed solely for research purposes)
- Vulnerable populations such as children, pregnant women, the elderly, terminally ill individuals, or those with diminished capacity
- Individuals at an elevated risk of death or other serious consequences, even with a study objective that addresses a lesser endpoint

Data and Safety Monitoring Plan for Minimal Risk Studies Using PHI

For studies of minimal risk with PHI, researchers should follow the plan listed in Cayuse, e.g., completing and uploading the CITI Health Information Privacy and Security (HIPS) for Clinical Investigators, encrypting all recording devices, etc.

Preparing the Data and Safety Monitoring Plan for Studies of Greater than Minimal Risk

Consider the following seven Human Subject Protection elements when developing a DSMP. Select the DSMP components (as identified in the table below) depending on the level of risk and the nature of the research study.

For greater than minimal risk studies, researchers are strongly encouraged to use the table template below so that all necessary information is included in the DSMP.

NOTE: When PHI is collected, researchers must complete the CITI Health Information Privacy and Security (HIPS) for Clinical Investigators from CITI and upload certificates in the Personnel section of Cayuse.

Protection Element	DSMP Component	Examples of monitoring activities
Subject safety	Specific subject safety parameters	Vital signs, weight, safety blood tests, cardiac status, anxiety, depression scores, etc.
	Frequency of subject safety observations	Weekly telephone follow-up, monthly appointments, observations of subject while in the clinical setting, etc.
	Individual responsible for safety monitoring	Principal investigator, study coordinator, safety monitor, independent monitor, or Data/Safety Monitoring Board, etc.
	Subject stopping rules - under what conditions will a subject be removed from study participation and who will make the decision?	Exclusion criteria, including adverse response to study procedures, pregnancy, stroke, cardiac irregularity, non-compliance with medication, etc. Include procedures for analysis and interpretation of data, etc.
	Study stopping rules - under what conditions will the study be modified or stopped and who will make the decision?	Unanticipated problems involving risks to subjects or others, unexplained adverse outcomes, life threatening adverse events, etc.

Protection Element	DSMP Component	Examples of monitoring activities
	<p>Reporting mechanisms (i.e., deviations, adverse events (AE), serious adverse events (SAE), unanticipated problems involving risks to subjects or others).</p> <p><i>*Follow the steps identified in the the Incident Reports policy located on the IRB website, including the timeliness of any action taken and reporting to the IRB.</i></p>	<p>Plans for reporting to IRB, FDA, Sponsor, participating sites, or Data/Safety Monitoring Board, etc.</p>
Data integrity	Specific data elements to be reviewed	Subject inclusion criteria being met, transcription of data is accurate and complete, units of measure are recorded appropriately, calculations are standardized and performed accurately, etc.
	<p>Frequency of monitoring data, points in time, or after specific number of subjects.</p> <p>When PHI is collected, indicate when PHI is monitored. The timing frequency of monitoring may depend on when data is received.</p>	<p>First 3 subjects and every 20th subject, monthly, quarterly, or annually, etc..</p> <p>When PHI is collected through medical records reviews, monitoring may occur when the data set is received.</p>

Protection Element	DSMP Component	Examples of monitoring activities
	Individual responsible for data monitoring.	Principal investigator, study coordinator, safety monitor, independent monitoring or, etc.
Subject privacy	<p>Under what conditions (time and place) will a subject be consented, interviewed, or telephoned?</p> <p>If PHI is collected:</p> <ul style="list-style-type: none"> • Under what conditions will a subject provide authorization to access PHI using the PHI Authorization form? • NA if study includes a PHI waiver of authorization 	Observations of consenting process, interviewing, or clinical visit performed quarterly on 3 subjects. Request input from 5 subjects related to their experiences regarding privacy expectations, etc.
Data confidentiality	<p>What are the conditions that will protect the confidentiality of the data, including PHI, if collected.</p> <p>When PHI is collected and study procedures include recording devices, describe the encryption process OR when and where PHI transferred to a secure location.</p>	<p>Check for locked file cabinets, secure electronic records, secure location where protected health information is stored.</p> <p>Research team will ensure that the terms of the data sharing agreement and data use agreement are aligned with the DSMP by the terms ^(OBJ)restrictions imposed by the data provider as stated in the data sharing agreement.</p> <p>CITI course “CITI Health Information Privacy and Security (HIPS) for Clinical Investigators” is complete for the PI and co-investigators (upload certificates below).</p> <p>Only the research team will have access to PHI.</p>

Protection Element	DSMP Component	Examples of monitoring activities
Product accountability	Who is responsible for obtaining, storing, preparing, administering, or disposing of the study drug or study device? Who is responsible for overseeing product accountability?	Research Pharmacy, Principal Investigator, Central Pharmacy, Research Laboratory, Nursing, etc.
Study documentation	Study file management	Include study file management guidelines and checklists for monitoring (sampling of study files annually), etc.
Study Coordination	Roles and responsibilities are clarified, education needs are addressed, planned meetings or communications with documented meeting notes/minutes	Annual debriefing to determine if expectations are clear and if educational needs exist. Scheduled meetings are on calendar, and meeting outcomes are noted and available to staff, etc.

May 2023 - safeguards for use of Protected Health Information (PHI) added

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