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DATA AND SAFETY MONITORING PLANS

Emory IRB Webinar

4/11/2024

OBJECTIVES



Define Terms



Clarify IRB
Expectations



Review Guidance
and Templates



Highlight
Resources

DATA SAFETY MONITORING PLAN (DSMP)



DATA SAFETY MONITORING PLAN (DSMP)



A plan that covers review of participant safety, welfare; and data integrity; and



Site monitoring to ensure data accuracy and protocol compliance. Based on risk level of the study, this may be conducted by a person/group independent from the study.

DATA SAFETY MONITORING BOARD OR COMMITTEES

- The DSMB/DMC evaluates research data on an ongoing basis to assure participant safety and study integrity. The primary goal is to assess for any significant trends and unexpected events that may constitute an unanticipated problem. The DSMB/DMCs also considers performance of overall study operations and any other relevant issues, as necessary. After reviewing the study progress they will make recommendations concerning the continuation, modification, or termination of the trial.





WHAT IS MONITORING?

- Monitoring is an ongoing process of overseeing the progress of a study from start to finish
- It is a quality control tool for determining whether study activities are being carried out as planned and whether there are any unexpected safety concerns.
- Monitoring enables study teams to identify and correct any deficiencies in study conduct, record keeping, or reporting.



SO, WHAT ARE THE IRB'S EXPECTATIONS?

- Every study requires a plan with some level of data and safety monitoring. Even a study deemed “minimal risk” by the IRB will need to outline plans to protect data and ensure the safety and confidentiality of research participants.
- The Data and Safety Monitoring Plan (DSMP) should be based on a risk assessment of critical data and processes that are necessary for human participant protection and integrity of the investigation.
- A study that involves **more than minimal risk** (requiring full board review) will have additional requirements depending on the level of complexity.
- The IRB will always consider the level of risk and burden a participant may experience in a study when determining additional requirements for a plan.

WHEN IS A DSMB/DMC REQUIRED?

- DSMB/DMC *may* be needed in the following scenarios:
 - There is a large study population, or there are multiple study sites.
 - The trial is intended to provide definitive information about effectiveness and/or safety of a medical intervention.
 - Prior data suggests that the intervention being studied has the potential to induce unacceptable toxicity.
 - The trial evaluates mortality or another major endpoint, such that inferiority of one treatment arm has safety and effectiveness implications.
 - If it would be ethically important for the trial to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed.

* A DSMB is usually implemented if two or more of the above considerations apply.

The following types of studies are **required** to follow the Emory DSMP guidelines:

- Investigator-initiated, or Emory-led, or
- Multi-site studies where Emory is not the lead site and the study is not monitored by a CRO.

EMORY SPECIFIC REQUIREMENTS

COMPLEXITY AND RISK CATEGORIES

The IRB will consider the level of risk and burden a participant may experience in a study when determining additional requirements for studies involving more than minimal risk. We refer to these combined attributes as “complexity.”



LEVELS OF COMPLEXITY

Medium complexity

- Behavioral interventions and studies involving sample collection or imaging done during a single interaction with a study participant, or
- Studies where the probability of harm is limited to the immediate circumstances of the research encounter.
- Studies using Transcranial magnetic stimulation (TMS) , wearable devices.

High Complexity

- Phase I –III clinical interventional studies (toxicity/safety/dose finding/effectiveness); and
- Other studies that may not be under an IND or IDE, where a participant is exposed to risk for an extended period, or for which the risk might change with time.
- Device studies under an Abbreviated IDE (Non-Significant Risk Devices)

* This is further broken down into two categories. “A” and “B”.

HIGH COMPLEXITY, CATEGORY A

- A Phase I/II/III trial (toxicity/safety/dose finding/effectiveness) under an IND or significant risk IDE or
- A clinical study without an IND or IDE that the IRB determines is high-risk due to the procedures involved.



HIGH COMPLEXITY, CATEGORY B

- A clinical trial using a drug or device under its FDA-approved indication.
For example: A comparative effectiveness trial of two standard-of-care interventions
- Expected to be IND/IDE Exempt or under an Abbreviated IDE without other interventions that elevate the study to Category A.
- Under an IND where the intervention does not pose significant risk to the participants. These studies may use a drug (approved or not) that does not significantly increase morbidity or mortality
For example: A radiotracer study where the risk is limited to a single scan
- Using software or an algorithm that may potentially inform clinical care *without other interventions that elevate the study to Category A.*



MONITORING EXPECTATIONS

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- For medium complexity studies, the IRB may approve site Monitoring conducted via assessment. This is a process for self-assessment of protocol compliance and data integrity, which can be part of an overall DSMP. There is a Self-Assessment tool that is available for use by teams.
 - For high-complexity studies, monitoring should be conducted by a designated study monitor, an experienced, knowledgeable person *who is independent of the study team*. The responsibility for site monitoring may be delegated by the study sponsor to a Contract Research Organization (CRO).

- In addition to the criteria previously outlined, as applicable, these studies are required to engage a CRO working in the study country, and/or to consult with legal counsel regarding compliance with the country's clinical research regulations.

HIGH-COMPLEXITY CLINICAL TRIALS WITH INTERNATIONAL SITES

THE QUESTIONNAIRE

Does this study evaluate or direct the use of a device?

For example: use of a TMS device, wearable devices that collect medical data, etc.

Yes → Regardless of the overall study risk, a monitoring plan is required. Continue to #1

No → **What is the overall study risk level?**

No more than minimal risk (*example: non-invasive sampling or imaging without contrast, blood draws*) → The study not required to follow DSMP guidance. Stop here and upload a copy of this completed questionnaire with the study protocol.

More than minimal risk → Continue to #1

1. Does the study involve: Invasive sample collection or imaging with contrast?

For example: studies involving an MRI with contrast, bone marrow sample collection for research purposes, or CSF or biopsy material collection in the context of a clinical encounter.

Yes → This is a *Medium Complexity* study and should follow requirements in [Monitoring Table 1](#). Upload a copy of this completed questionnaire with the study protocol.

No → Continue to #2

2. Is the study either:

- A Phase I/II/III trial (toxicity/safety/dose finding/effectiveness) under an IND or significant risk IDE or
- A clinical study without an IND or IDE that the IRB determines is high-risk due to the procedures involved?

Yes → This is a *High Complexity, Category A* study and will need to follow the requirements of [Monitoring Table 2](#). Upload a copy of this completed questionnaire with the study protocol.

3. Is the study one of the following?

- A clinical trial using a drug or device under its FDA-approved indication.
For example: A comparative effectiveness trial of two standard-of-care interventions
- Expected to be IND/IDE Exempt or under an Abbreviated IDE without other interventions that elevate the study to Category A.
- Under an IND where the intervention does not pose significant risk to the participants. These studies may use a drug (approved or not) that does not significantly increase morbidity or mortality
For example: A radiotracer study where the risk is limited to a single scan
- Using software or an algorithm that may potentially inform clinical care without other interventions that elevate the study to Category A.
 - Yes** → This is a *High Complexity, Category B* study and will need to follow the requirements of [Monitoring Table 3](#). Upload a copy of this completed questionnaire with the study protocol.
 - No** → Please send an email to irb@emory.edu to schedule a time to speak with IRB staff for assistance in determining DSMP requirements for your study.

MONITORING TABLES

- Based on the category, it will direct completion of the corresponding monitoring table to collect study specific details.
- As a reminder, FDA regulations also apply to FDA-approved drugs and devices when the use of a drug or a device is being evaluated during the study. As a result, the tables will collect additional details for studies that are FDA regulated.



DSMP Requirement	How this Requirement is Met	Frequency	Responsible Party(ies)
Site Monitoring at pre-determined intervals: The Principal Investigator has a responsibility to ensure that the study is following all aspects of the protocol.	<i>There should be a standard operating procedure to review data (whether a sample or 100%) at pre-determined intervals to ensure that there is adequate documentation of critical elements such as eligibility criteria.</i>	<p>At a minimum, a review is required annually when no one has been enrolled or the study is in long term follow up.</p> <p><i>Additional interim monitoring at least once every 12-24 weeks based on the site activity, and more as needed, to include the possibility of remote monitoring.</i></p> <p><i>Frequency of review may occur more often, based on the milestones of the research, such as:</i></p> <ul style="list-style-type: none"> • <i>Initiation of initial enrollment</i> • <i>During participant interventions</i> 	<p><i>Delegate a responsible party for each requirement below*. Self-assessment is NOT acceptable. An experienced, knowledgeable person who is independent of the study team should serve as monitor. A Contract Research Organization (CRO) may be used. Consult the IRB Office regarding acceptable qualifications for the independent monitor, if not using an outside expert such as a CRO.</i></p>
Real-time review of participant data during initial data collection.		<i>Expectation is that this happens at the time of data collection</i>	
100% review of regulatory files			
100% review of consent forms			
Review of credentials, training records, the delegation of			



PROTOCOL DETAILS

You will be directed to “Check the box for the study’s risk level”

No more than minimal risk - Study not required to follow DSMP guidance, may delete the rest of this section. (Non-invasive sampling or imaging, blood draws, etc. are likely minimal risk if all procedures fall clearly within these categories. If all study procedures do not fall into these categories, and you still believe your study is minimal risk, consult with IRB staff.)

More than minimal risk – Continue below.

- Review our Data and Safety Monitoring Questionnaire and insert the relevant monitoring table at the end of this section. Also upload the completed questionnaire in the “Basic Study Information” smartform section in eIRB, question #8, as a separate document.

SELECT THE RISK CATEGORIZATION, AS DETERMINED BY THE QUESTIONNAIRE

Select one of the following (do not delete this table; review the guidance document for definitions):		
<input type="checkbox"/>	Medium Complexity	
<input type="checkbox"/>	High Complexity Category A	
<input type="checkbox"/>	High Complexity Category B <i>If choosing this category for a study under an IND or IDE because you believe the study intervention does not significantly impact morbidity or mortality, please provide your rationale:</i>	

REMINDERS

- The IRB will ultimately determine the risk level of the study.
- Make sure your study also contemplates study stopping rules.
- Best practice is to document any reviews conducted by the study team, even when there are external monitors. Teams can use the Self-Assessment Tools to document.





RESOURCES

- [Data and Safety Monitoring Plan Requirements](#): details current requirements for all studies reviewed by the Emory IRB.
- [Data Safety Monitoring Plan Requirements Questionnaire](#): provides the insert chart for the protocol as well as some guiding questions.
- [DSMB Guidance](#)
- [NIH Policy on Data and Safety Monitoring](#)

QUESTIONS?

General Inquiries:

<https://www.irb.emory.edu/about/contact/general-inquiries.html>

Via listserv: IRB@emory.edu

Study-specific inquiries: Please contact your study analyst directly.

For Education/Outreach questions, Complaints from study participants, Compliance, and Adverse Event issues, please contact the [Education and Quality Assurance Team](#).

