

### ELEMENTS OF A DATA MONITORING PLAN

#### Definitions

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**Data Monitoring:** The regular evaluation of data and documentation collected during a study to ensure both adherence to the approved investigative plan and the validity of data collected (White 2007).

#### Federal Research Regulations and IRB Policy

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The Common Rule and FDA regulations state that the IRB may only approve research if there are adequate provisions for monitoring the data collected to ensure the safety of subjects (45 CFR 46.111(a)(6) & 21 CFR 56.111(7)).

NIH policy states that every clinical trial should have provisions for data and safety monitoring (NIH 1979).

#### IRB Policy

A data monitoring plan is required for all studies, no matter the risk level. The IRB requires that the full data monitoring plan be *summarized* in the IRB application. The study team must maintain the *full* data monitoring plan as part of the study operating procedures.

#### Description

A data monitoring plan must have provisions to monitor individual data points collected for data analysis, as well as required study documentation, such as IRB and sponsor documentation, consent documents, adverse event reports, etc.

Elements of a data monitoring plan are discussed in detail below and include:

- Who is responsible for performing the data monitoring?
- How often will monitoring be performed?
- What components of the study will be monitored?
- How will monitoring be documented and responded to appropriately?

#### Who is responsible for performing the data monitoring?

One or more individuals may be responsible for monitoring all or specific aspects of the study data. These individuals may be internal to the study or may be independent of the study team.

When writing this section of the plan, include:

- Justification that the number of individuals responsible for monitoring is enough to accomplish the monitoring activities.
- Justification that an independent monitor is or is not needed.
  - An independent monitor can view the data and documentation objectively, providing unbiased feedback to the study team. An independent monitor may also have monitoring-specific expertise, which allows the monitor to complete the review efficiently but thoroughly.
- The division of study components (see below) that are reviewed by each individual with monitoring responsibilities.
  - For example, the study coordinator reviews the consent and eligibility documentation, while the independent monitor reviews the case report forms and data set.

#### How often will monitoring be performed?

Monitoring should be conducted at an appropriate frequency to ensure that:

- Additional risks to subjects can be identified in a timely manner such that decisions can be made about their care;

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- Safety concerns about the study can be identified in a timely manner such that decisions can be made about the conduct of the study;
- Research documentation is complete;
- Data collection is complete, with as few missing data points as possible;
- Data is collected accurately, with no errors;
- Research data is valid, capturing all appropriate information that can be used to answer the research question.

The frequency of monitoring may need to be increased for any of the following factors:

- The anticipated enrollment rate is high
- The number of data points being collected is large
- The eligibility criteria and the consent process is complex
- The study does not have a pre-programmed data entry failsafe

When writing this section of the plan, include justification that the intended frequency of monitoring satisfies all of the points described above.

### **What components of the study will be monitored?**

In general, the following components can be monitored for all types of studies:

#### ***Regulatory documentation***

This includes all documentation that must be maintained according to federal regulations, IRB policy, and institutional policy.

- For example: all versions of the protocol, all IRB correspondence and approvals, all sponsor correspondence, all FDA correspondence, etc.

#### ***Site operations***

This includes all documentation of required qualifications and training of research staff, as well as documentation that study procedures were only performed by qualified personnel.

#### ***Protocol compliance***

This includes documentation that all study procedures, from recruitment/enrollment through study closure, have been completed in compliance with the study protocol and study operating procedures.

#### ***Subject research records***

This includes documentation all procedures for each participant have been performed and all required data points have been accurately recorded for each participant.

Depending on the design and procedures in a study, there may be other components that require monitoring. The following list serves as an example of other components that can also be monitored as applicable:

#### ***Informed consent documentation***

This includes documentation that all participants have provided informed consent, using a consent process and a consent document approved by the IRB.

#### ***Safety information***

This includes documentation that all adverse events and problems have been recorded in the study record and appropriately reported to the IRB, the sponsor, the FDA, etc. This also includes documentation that each event and problem has been considered by the PI and necessary oversight bodies to ensure that decisions are made to protect the safety of participants.

#### ***Drug or device accountability***

This includes documentation that an investigational drug/device used in the study is appropriately accounted for at all times during the study.

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### ***Tissue banking management and sample processing***

This includes documentation that all samples have been appropriately collected, processed, stored, and released according to the study protocol and consent document.

### ***Randomization procedures***

This includes documentation that all participants were randomized according to the procedures described in the approved protocol.

Each component has a number of different items that must be confirmed in the study documentation. See Appendix A for a sample table that outlines some components and the types of items that can be confirmed.

Monitoring should be done in a systematic fashion, ensuring that all appropriate components are reviewed. The IRB has self-assessment worksheets that outline various components and the items that can be confirmed during monitoring. However, there are components for which the IRB does not provide worksheets, because of the specific nature of study requirement. The study team is advised to create their own study-specific monitoring worksheets in order to fulfill the needs to the study, based upon the study protocol and study operating procedures.

### **How will monitoring be documented and responded to appropriately?**

After a monitoring review has been completed, a written report of the findings should be created. The PI should consider the findings with other members of the study team and determine if corrective actions are necessary, which may include:

- Amending the protocol or consent form
- Re-consenting participants
- Additional data collection from participants
- Withdrawal of participants from the study

Any changes made to IRB-approved documents or information must be submitted to the IRB via an amendment application.

The PI must also determine whether the findings and corrective actions must be reported to any of the following entities, as applicable:

- IRB
- Study sponsor
- Safety monitoring entity, such as a DSMB
- Regulatory agencies, such as the FDA

### **Points to Address**

#### **New Study Application:**

**1. Data Monitoring Plan page:** Answer the questions by providing a summary of the overall data monitoring plan for the study.

### **References & Links**

*Article: Monitoring the Monitors*

*White S, Field L, Wolf D. Monitoring the Monitors. Applied Clinical Trials. September 2007; p52-60*

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**Research Guidance Document**

*NIH Guidance*

*NIH Guide for Grants and Contracts, Volume 8, No. 8 (1979)*

*Investigator Self-Assessment  
Worksheets*

To be updated

*Data and Safety Monitoring  
Guidance (IRB)*

To be updated

**Appendix A:**

**Sample Table of Study Components, Items for Review, and Documentation**

*This is an example only. This is not meant to be a comprehensive list of study components to review, nor does it reflect universal documentation to be reviewed for each component.*

<b>Study component</b>	<b>Items to be reviewed for this component</b>	<b>Study documents to be reviewed for this component</b>	<b>Monitoring review documentation</b>
Regulatory Documentation	All versions of approved protocol in study file	Regulatory binder, protocol section	IRB self-assessment worksheet titled "Regulatory Documentation"  Study SOP procedures checklist
	All versions of approved consent forms in study file	Regulatory binder, consent section	IRB self-assessment worksheet titled "Regulatory Documentation" -- OR -- Study SOP procedures checklist
	(etc.)	(etc.)	(etc.)
Site Operations	Documentation of PI involvement in conducting and supervising the study	See informed consent process checklist, eligibility criteria checklist, study meeting minutes, etc.	IRB self-assessment worksheet titled "Site Operations" -- OR -- Study SOP procedures checklist
	Responsibilities and tasks are delegated to qualified personnel	See delegation log, IRB application, and study SOP	IRB self-assessment worksheet titled "Site Operations" -- OR -- Study SOP procedures checklist
	(etc.)	(etc.)	(etc.)
Protocol Compliance	Inclusion/Exclusion criteria met per IRB approved protocol	See approved protocol, eligibility criteria checklist, and individual participant source documentation	IRB self-assessment worksheet titled "Protocol Compliance" -- OR -- Study SOP procedures checklist

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	Screening, study procedures, etc. performed per IRB approved protocol	See IRB approved protocol, CRFs titled "Visit 1" and "Visit 2", and individual participant source documentation	IRB self-assessment worksheet titled "Protocol Compliance" -- OR -- Study SOP procedures checklist
	(etc.)	(etc.)	(etc.)

*Additional rows can be added to this table to include all components that require monitoring.*

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