Data Safety Monitoring Plan Requirements Questionnaire for Investigator-Initiated Studies

Please complete the below questionnaire to determine which monitoring table best fits your study monitoring requirements.

**Upload your completed questionnaire in the protocol section of eIRB**. **If a monitoring table is required**: complete the corresponding monitoring table and insert in your study protocol under the section titled “Plans to Monitor the Data to Ensure the Safety of Participants and Integrity of the Data.” **Note: The IRB will ultimately decide on the risk level of the study and may require additional plan details.**

**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.](#_Monitoring_Table_1) Upload a copy of this completed questionnaire with the study protocol.

[ ]  **No 🡪** Continue to #2

1. **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.](#_Monitoring_Table_2) Upload a copy of this completed questionnaire with the study protocol.

[ ]  **No 🡪** Continue to #3

1. **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.](#_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 Table 1

Address the specific details below even where there is template text present. Please read the guidance in the gray row first to help inform the plan details. Do not edit any pre-populated answers as these are the IRB’s expectations.

If a requirement is not applicable, please provide rationale. Note that the identified monitor(s) should be listed on the study’s delegation of authority log.

|  |  |  |  |
| --- | --- | --- | --- |
| **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.  | *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.*  | *Based on risk,* ***a review is required at least annually when participants have been enrolled****.**Frequency of review may occur more often, based on the milestones of the research, such as:** *Initiation of initial enrollment*
* *During participant interventions*
* *When all participants are in long-term follow-up*
 | *Delegate a responsible party for each requirement below.* Self-assessment is acceptable.\**Self-assessment*: a process for self-assessment of protocol compliance and data integrity which can be part of an overall DSMP. See Emory’s self-assessment tool on [this page.](https://www.ctac.emory.edu/) *Note: Everyone on the study team responsible for review of data at the time of collection.* |
| Real-time review of participant data during initial data collection. |  | *Expectation is that this happens at the time of data collection* |  |
| 100% review of consent forms |  |  |  |
| Review of credentials, training records, the delegation of responsibility logs (if applicable) |  |  |  |
| Comparison of case report forms (CRF) to source documentation for accuracy and completion |  |  |  |
| Review of documentation of all adverse events |  |  |  |
| Monitoring of critical data points (eligibility, study endpoints, etc.) |  |  |  |
| **For FDA regulated studies, the following requirements apply:\*** | **How this Requirement is Met** | **Timing, frequency, and intensity of monitoring** | **Responsible Party(ies)** |
| Monitoring methods (may include centralized, on-site, and self-assessment) |  |  |  |
| \*Note: FDA regulations also apply to FDA-approved drugs and devices when the use of a drug or a device is being evaluated in the course of the study. To learn more: <https://www.irb.emory.edu/guidance/faqs/index.html> |

# Monitoring Table 2

Address the specific details below even where there is template text present. Please read the guidance in the gray row first to help inform the plan details. Do not edit any pre-populated answers as these are the IRB’s expectations.

If a requirement is not applicable, please provide rationale. Note that the identified monitor(s) should be listed on the study’s delegation of authority log.

|  |  |  |  |
| --- | --- | --- | --- |
| **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.  | *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.* | ***At a minimum, a review is required annually when no one has been enrolled or the study is in long term follow up.*** *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.**Frequency of review may occur more often, based on the milestones of the research, such as:** *Initiation of initial enrollment*
* *During participant interventions*
 | *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.* |
| Real-time review of participant data during initial data collection. |  | *Expectation is that this happens at the time of data collection* |  |
| 100% review of regulatory files |  |  |  |
| 100% review of consent forms |  |  |  |
| Review of credentials, training records, the delegation of responsibility logs (if applicable) |  |  |  |
| Comparison of case report forms (CRF) to source documentation for accuracy and completion |  |  |  |
| Review of documentation of all adverse events |  |  |  |
| Monitoring of critical data points (eligibility, study endpoints, etc.) |  |  |  |
| Laboratory review of processing and storage of specimens |  | *Reviewed at first and close-out visits and at least biannually* |  |
| Assessment of laboratory specimens stored locally |  |  |  |
| Test article accountability review |  | *Reviewed at first and close-out visits and at least biannually* |  |
| Accountability logs, dispensing records, and other participant records  |  | *At least biannually* |  |
| **For FDA regulated studies, the following requirements apply:\*** | **How this Requirement is Met** | **Timing, frequency, and intensity of monitoring** | **Responsible Party(ies)** |
| Monitoring methods (may include centralized, on-site, and self-monitoring) |  |  |  |
| \*Note: FDA regulations also apply to FDA-approved drugs and devices when the use of a drug or a device is being evaluated in the course of the study. To learn more visit: <https://www.irb.emory.edu/guidance/faqs/index.html>For international studies, you are required to engage a CRO that is working in the site country and/or to consult with Emory’s legal counsel regarding compliance with the country’s clinical research regulations. |

# Monitoring Table 3

Address the specific details below even where there is template text present. Please read the guidance in the gray row first to help inform the plan details. Do not edit any pre-populated answers as these are the IRB’s expectations.

If a requirement is not applicable, please provide rationale. Note that the identified monitor(s) should be listed on the study’s delegation of authority log.

|  |  |  |  |
| --- | --- | --- | --- |
| **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.  | *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.*  | *At a minimum, a review is required annually when no one has been enrolled or the study is in long term follow up. Additional risk-based interim monitoring may be required at least once every 12-24 weeks based on the site activity, to include the possibility of remote monitoring. A longer frequency could be acceptable with justification about risk to participants.**Frequency of review may occur more often, based on the milestones of the research, such as:** *Initiation of initial enrollment*
* *During participant interventions*
 | *Delegate a responsible party for each requirement below.* Self-assessment is acceptable.\**Self-assessment*: a process for self-assessment of protocol compliance and data integrity which can be part of an overall DSMP. See Emory’s self-assessment tool on [this page.](https://www.ctac.emory.edu/)  |
| Real-time review of participant data during initial data collection. |  | *Expectation is that this happens at the time of data collection* |  |
| 100% review of regulatory files |  | *Reviewed at a minimum of first and close-out visits* |  |
| 100% review of consent forms |  |  |  |
| Review of credentials, training records, the delegation of responsibility logs (if applicable) |  |  |  |
| Comparison of case report forms (CRF) to source documentation for accuracy and completion |  |  |  |
| Review of documentation of all adverse events |  |  |  |
| Monitoring of critical data points (eligibility, study endpoints, etc.) |  |  |  |
| Laboratory review of processing and storage of specimens |  | *Reviewed at first and close-out visits and at least biannually* |  |
| Assessment of laboratory specimens stored locally |  |  |  |
| Test article accountability review |  | *Reviewed at first and close-out visits and at least biannually* |  |
| Accountability logs, dispensing records, and other participant records  |  | *At least biannually* |  |
| **For FDA regulated studies, the following requirements apply:** | **How this Requirement is Met** | **Timing, frequency, and intensity of monitoring** | **Responsible Party(ies)** |
| Monitoring methods (may include centralized, on-site, and self-assessment) |  |  |  |
| \*Note: FDA regulations also apply to FDA-approved drugs and devices when the use of a drug or a device is being evaluated in the course of the study. To learn more visit: <https://www.irb.emory.edu/guidance/faqs/index.html>For international studies, you are required to engage a CRO that is working in the site country and/or to consult with Emory’s legal counsel regarding compliance with the country’s clinical research regulations. |