Data and Safety Monitoring (DSM) Tables

**Follow the instructions in the “Data and Safety Monitoring” section of your study protocol and insert the appropriate Data Safety Monitoring Table into your study protocol**.If you are still unsure which Data and Safety Monitoring (DSM) Table to use, send an email to irb@emory.edu to determine the appropriate selection.

# Instructions for Completing the DSM Table

**Do not alter the information already entered into the Monitoring Table.** The left columns describe each required Monitoring Activity. For each activity, the required minimum frequency for completion and the extent of each activity, if predetermined, are listed in the table.

**For each Monitoring Activity, indicate the person or group responsible for completing the activity and, if not predetermined, indicate the extent to which the required activity will be completed.**

* *For example*: For the activity of “comparison of case report forms (CRFs) to source data” you could indicate that 20% of all CRFs will be reviewed and that the study nurse will be responsible for this activity.

Under “responsible parties and additional notes,” you may also insert additional information, such as plans to complete the monitoring activity more often than the minimum-required frequency. In the rare cases that a Monitoring Activity is not applicable, provide clear rationale for the inapplicability in this column.

**You must respond to each question under the Compliance Monitoring Overview section.** Keep in mind the following, when selecting the appropriate Compliance Monitoring type:

* **Contract Research Organizations (CROs)** should be described further in the study submission. Describe the CRO in the study protocol and upload any relevant details about the CRO operations to the study submission.
* **Independent Study Monitors (ISMs)** must be experienced and knowledgeable in the area and operate independently of the study team. To implement an ISM, you must demonstrate that the ISM has acceptable qualifications.
* **Self-Monitoring assessments** can be completed using the [self-assessment forms overseen by Emory CTAC](https://www.ctac.emory.edu/). Self-assessments are not allowed for High Complexity, Category A studies.

**Important Reminder: The Principal Investigator maintains ultimate responsibility for ensuring that all details of the completed Data Safety Monitoring Table are followed.**

# Monitoring Table 1: High Complexity Studies, Categories A and B

Complete the Monitoring Table as described under the instructions on page 1, keeping in mind the following frequency requirements for High Complexity studies:

**The required frequency for monitoring activities is based on the study’s milestones.** Studies are considered to have “*no active interventions”* and require less-frequent monitoring when one of the following applies:

* Zero participants have been enrolled
* All participants have either completed study interventions or are in long-term follow-up only
* The remaining research activities are limited to data analysis only

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| --- | --- | --- | --- |
| **Monitoring Activity** **(High Complexity)** | **Required frequency** | **Extent of Activity** | **Responsible Parties and Additional Notes** |
| **No Active Interventions** | **Active Interventions** |
| **Review of data and forms for completion and accuracy** | Confirmation of participant eligibility and documentation in enrollment log | At the time of consent completion and at least annually | 100% of enrollments |  |
| Consent forms reviewed for completion | At the time of consent completion and at least annually | 100% of consent forms  |  |
| Comparison of Case Report Forms (CRFs) to source data | At least annually | At least every 6 months |  |  |
| **Review of study events, critical data points, and study checkpoints** | Review of test article dispensing records (i.e., drug and device handling/use)  | When opening and closing to enrollment | At least every 6 months | 100% review of all records |  |
| Confirm that all possible adverse events have been assessed and follow-up is documented | At least annually | At least every 6 months | 100% of possible events |  |
| Monitor to ensure no study-stopping rules are met | At least annually | At least every 6 months |  |  |
| Monitoring progress toward next interval/phase or study endpoint | At least annually | At least every 6 months |  |  |
| **Review of regulatory files and study management processes** | Confirm credentials and training records of study team | During team member updates and at least annually | 100% of study team members |  |
| Review of delegation of authority (DOA) logs | During team member updates and at least annually | Complete DOA log |  |
| Laboratory protocols, equipment, and specimen storage | When opening and closing to enrollment | At least every 6 months |  |  |
| Other regulatory files (e.g., protocols, consents, training logs, etc.) | At least annually | At least every 6 months | All files |  |
| **Compliance Monitoring Overview** |
| **Who will assess compliance with the stated monitoring plans?** | [ ]  Self-Monitoring *(NOT permitted for High Complexity, Category A)*[ ]  Independent Study Monitor (ISM)[ ]  Contract Research Organization (CRO)  |
| **If FDA-regulated:** Indicate the [Monitoring Method(s)](https://www.fda.gov/media/116754/download) to be used *(check all that apply)* | [ ]  On-site [ ]  Self-monitoring[ ]  Centralized (remote) [ ]  N/A[ ]  Other *(describe)*:  |
| **If there are international research sites:** How will you ensure clinical research compliance? | [ ]  CROs with the site country[ ]  Consultation with Emory Legal Counsel [ ]  N/A |
| Reminder: **The Principal Investigator maintains responsibility for ensuring that all activities in this Monitoring Table are followed** |

# Monitoring Table 2: Medium Complexity Studies

Complete the Monitoring Table as described under the instructions on page 1.

|  |  |  |  |
| --- | --- | --- | --- |
| **Monitoring Activity** **(Medium Complexity)** | **Required frequency** | **Extent of Activity** | **Responsible Parties and Additional Notes** |
| **Confirmation of participant eligibility and documentation in enrollment log** | At the time of consent completion and at least annually | 100% of enrollments |  |
| **Consent forms reviewed for completion** | At the time of consent completion and at least annually | 100% of consent forms  |  |
| **Comparison of Case Report Forms (CRFs) to source data** | At least annually |  |  |
| **Confirm that all possible adverse events have been assessed and follow-up is documented** | At least annually | 100% of possible events |  |
| **Confirm credentials and training records of study team** | During team member updates and at least annually | 100% of study team members |  |
| **Review of regulatory files and study management processes** | During team member updates and at least annually |  |  |
| **Compliance Monitoring Overview** |
| **Who will assess compliance with the stated monitoring plans?** | [ ]  Self-Monitoring[ ]  Independent Study Monitor (ISM)[ ]  Contract Research Organization (CRO) |
| **If FDA-regulated:** Indicate the [Monitoring Method(s)](https://www.fda.gov/media/116754/download) to be used *(check all that apply)* | [ ]  On-site [ ]  Self-monitoring[ ]  Centralized (remote) [ ]  N/A[ ]  Other *(describe)*:  |
| **If there are international research sites:** How will you ensure clinical research compliance? | [ ]  CROs with the site country[ ]  Consultation with Emory Legal Counsel [ ]  N/A |
| Reminder: **The Principal Investigator maintains responsibility for ensuring that all activities in this Monitoring Table are followed** |