This monitoring plan is written from the perspective of a study with a sponsor that is separate from the investigator. If the investigator is also the sponsor, please adapt the monitoring plan accordingly.

**Monitoring Plan**

Study Title:

IRB Control #:

Sponsor:

Principal Investigator:

Medical Director:

IND #:

Date and Version:

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1. **ABBREVIATIONS**  (delete any which are not pertinent and add any that are specific to plan)

Adverse Event (AE)

Case Report Form (CRF)

Curriculum Vitae (CV

Data Safety Monitoring Plan (DMSP)

Delegation of Authority (DoA) log

Electronic Case Report Form (eCRF)

Electronic Medical Record (EMR)

Good Clinical Practice (GCP)

Informed Consent Form (ICF)

Institutional Review Board (IRB)

Investigational New Drug (IND)

Investigator’s Brochure (IB)

Monitoring Visit Report (MVR)

Principal Investigator (PI)
Serious Adverse Event (SAE)
Site Initiation Visit (SIV)
Standard Operating Procedures (SOP)
Trial Master File (TMF)

1. **MONITORING**

This is a risk based monitoring plan. Monitoring varies with study size and complexity.

The purpose is to:

* Ensure the safety of participants and the protection of their rights
* Ensure quality and integrity of data
* Provide a consistent approach to study conduct

The study should adhere to the requirements described in the protocol, Good Clinical Practices (GCPs), the International Conference on Harmonization (ICH), applicable government regulations, and sponsor Standard Operating Procedures (SOPs).

1. **MONITORING ROLES**

Sponsor Monitor

The sponsor appoints a qualified monitor to review the completion and accuracy of the study data, documents, and activities. The monitor must be qualified by education, experience, and or training on GCPs.

Tasks include:

* Performing monitoring procedures as defined in this document
* Educating the Principal Investigator team members on adherence to the protocol and relevant GCPs.
* Performing site monitoring visits at intervals defined in this document
* Providing monitoring visit reports to PI and sponsor
* Reviewing significant findings with the PI and sponsor
* Communicating safety and/or data concerns to team members in a timely manner
* Working with the study team to address findings
* Participating in the SIV

The monitor must be trained prior to providing monitoring oversite. Training documents include:

Data Safety Monitoring Plan and/or Monitoring Plan

Associated Study Documents

* Protocol
* ICFs
* CRFs
* SOPs
* Investigator Brochure
1. **SITE INITIATION VISIT**

The sponsor and designees conduct the site initiation visit training. At this meeting the sponsor instructs the PI on the obligations of undertaking the clinical trial. Training points include:

* Protocol review
* Regulations
* Informed consent process and expectations
* Participant recruitment
* IRB obligations
* Safety reporting
* Communication between investigator and sponsor

After the SIV, the following documentation will be filed in the regulatory file/binder:

Copy of the SIV sign-in sheet

Copy of the training materials

Official Activation Notice (sent by the sponsor to the PI after the SIV)

1. **TIMING AND FREQUENCY OF MONITORING VISITS**

Monitoring will be performed remotely to the extent possible. The regulatory binder will be stored (in a binder onsite, in Florence ebinders, other). The CRFs will be stored in (RedCap, other). Source documentation will be stored on (paper forms, EPIC emr, Rothman emr). Review of any electronic records may be done remotely. Any records which are kept on paper will be reviewed onsite. The site is expected to keep up with data entry with data entered no later than within \_\_\_ business days.

The site is expected to provide adequate space, time, staff availability, and tools (copier, printer, etc.) for the monitoring visits.

1. **MONITORING VISIT SCHEDULING**

The monitor must assess the monitoring workload and the expected time required for each visit and schedule the upcoming visit with the study team accordingly. The duration and/or frequency of each visit may need to be altered to ensure monitoring milestones are met, or at the request of the sponsor.

At a minimum, monitoring should occur according to the following scheduled:

Onsite monitoring visits should take place

* (Use either enrollment target, time interval, or a hybrid depending on the risk and structure of the study. Be sure to allow enough flexibility to accommodate monitor and site scheduling conflicts.)

The Monitor must make every attempt to schedule visits per the monitoring schedule. If the monitor is unable to schedule the monitoring visit within the timeframe identified, the monitor must proactively communicate this with the sponsor. Deviations from the monitoring plan should be communicated to the sponsor as determined in the study-specific roles and responsibilities within \_\_\_ business days of identification.

1. **MONITORING VISIT PROCEDURES**

Best practice is to monitor the following on an ongoing basis.

* Review the informed consent process, including all ICFs to verify consent was obtained in accordance with regulations and guidelines
* Review all participants’ eligibility including those who have been withdrawn and verify there is an explanation for each withdrawal (NOTE: “Participant Decision” is an adequate explanation as participants are not required to give a reason for withdrawal. Participants may be asked for specific reason.)
* Verify all study personnel are performing all activities required by the protocol consistent with the Delegation of Authority (DoA) log
* Ensure all adverse events and serious adverse events are captured accurately
	+ Verify that all AEs/SAEs are recorded and reviewed by a licensed clinician as listed on the Form FDA 1572. It is required of the PI or licensed Sub-Investigator (SI) to evaluate attribution (relatedness), expectedness, and seriousness
	+ Verify that AEs/SAEs are reported in a timely manner per protocol, sponsor instructions, and local regulatory requirements
	+ Verify investigational product accountability and disposition
		- Dispensed by authorized study personnel
		- Dispensed/administered to an eligible study participant
		- Dispensed/administered at protocol-specific doses and time points
		- Regulatory binders should include dispensing/administration and disposal logs for products
		- Product should be disposed of according to the protocol, pharmacy manual, or SOP
		- Based on an assessment of risk, \_\_\_\_\_\_\_% source data verification should be conducted for \_\_\_\_\_\_\_% of participants. Based on findings, the sponsor may require a 100% SDV of all participants’ data. 100% source data verification is not required. The percentage of monitored data and what was monitored should be determined based on risk. For example, 100% of all primary endpoint datapoints and 30% of all secondary endpoints will be monitored or 100% of all primary endpoints and 100% source data verification for every fifth participant.
		- Regulatory binder
		- All essential documents (protocol, ICFs, IBs, recruitment materials, and CRF templates)
		- IRB submissions, approvals, and correspondence
		- Study Personnel files (COIs, CVs, medical licenses
		- Training records (protocol, amendments, CITI GCP, biomedical research, any special procedure training)
		- Study screening and enrollment logs
		- Delegation of Authority log
		- 1572s
		- Protocol deviations, exceptions, and unanticipated problems
		- Timeliness of data entry
		- Discussion and timely resolution of monitoring findings with PI and study team
		- IRB and sponsor reporting requirements
		- Any safety concerns and reporting procedures
		- Any internal or external audit reports and resolution of findings
1. **MONITORING LOG**

The monitoring log will be signed on each day of an onsite monitoring visit. This is filed in the regulatory binder.

1. **MONITORING VISIT REPORT (MVR)**

The monitor prepares the MVR and submits it to the sponsor and the PI. MVRs should be done within \_\_\_\_\_\_\_business days of the monitoring visit.

The MVR includes:

* Date(s) of the visit
* Name of the monitor
* Sponsor name
* PI name
* List of study personnel present during the visit
* Summary of what the monitor reviewed
* A description of any findings, may be documented in the MVR or in queries in the electronic database, if applicable
* Conclusions and actions to be taken by the study team, recommended actions to secure compliance
* Resolution and/or follow-up on observations from previous visits
1. **COMMUNICATING SAFETY CONCERNS**

Safety concerns must be shared promptly with the sponsor by the monitor. The monitor must verify that SAEs are reported in a timely manner to the sponsor per protocol, sponsor instructions, and regulatory requirements.

1. **MANAGING NON-COMPLIANCE**

The sponsor must act promptly to resolve non-compliance. The monitor is expected to remind the site of its responsibilities as documented in the SIV training materials. This includes, but is not limited to, reporting AEs/SAEs and protocol deviations as specified in the protocol, keeping up to date with data entry, and responding to monitoring queries/findings.

1. **MEDICAL DIRECTOR**

Name:

Phone:

Email: