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| Author: |  |
|  |  |
| Protocol Number: |  |
| Study Title: |  |
|  |  |
| Sponsor or Sponsor-Investigator: |  |

This document has been reviewed and approved by:

|  |  |
| --- | --- |
| **Role** | **Signature / Date** |
| Study Monitor |  |
| Study Project Manager |  |
| Sponsor or Sponsor-Investigator (SI) |  |

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**[Template Instruction:**

**Modify each section of the template as per the study protocol and monitoring requirements determined for the study. Include all sections in the Monitoring Plan; if a section or activity is not required for the study, state that it is not applicable.]**

# Monitoring Objectives

**[For CTN studies:]** The objective of this Monitoring Plan is to ensure that the clinical study sites, under the management of the CIHR Canadian HIV Trials Network (the CTN) National Centre or Sponsor/Sponsor-Investigator, are in compliance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines. Adherence to the protocol is expected of every participating centre and will be tracked by CTN XXX’s (protocol number) Steering Committee and periodically by the CTN Data Safety Monitoring Committee (DSMC). Protocol deviations should be documented, reported to the Sponsor/SI and submitted to each site’s Research Ethics Board (REB)/Independent Ethics Committee (IEC) for review as applicable. Any site with repeated major protocol deviations must be brought to the attention of the DSMC. If a participating Site Investigator thinks that adherence to the protocol will in any way be detrimental to a particular participant's health or well-being, the interest of the participant must take precedence.

By agreeing to participate in this study, the clinical site acknowledges that the CTN and DSMC undertake responsibility for overall monitoring of CTN [XXX], which is under the sponsorship of [Sponsor-Investigator’s site or Sponsor]. Qualified individuals from the CTN and/or other individuals acting on behalf of the CTN (herein referred to as the ‘monitor’) will conduct monitoring in compliance with ICH GCP and the CTN’s SOPs and templates.

**[include if CTN involved in Risk Management activities]**

In addition, the CTN and study Sponsor/SI will work together to identify, monitor and mitigate risk over the course of the study. Regular monitoring of study activities is a critical activity to ensure adequate management of risk. Specifically, outcomes of monitoring activities will contribute to the risk indicator dataset for specific risks.

**[For Advancing Health studies:]** The objective of this Monitoring Plan is to ensure that the clinical study sites, under the management of the Centre for Advancing Health Outcomes (Advancing Health), are in compliance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines. Adherence to the protocol is expected of every participating centre and will be tracked by the study sponsor [name of sponsor] or delegate, and periodically by the study Data Safety Monitoring Committee (DSMC), if applicable. Protocol deviations should be documented, reported to the sponsor representative and submitted to each site’s Research Ethics Board (REB)/Independent Ethics Committee (IEC) for review as applicable. Any site with repeated major protocol deviations must be brought to the attention of the DSMC or Sponsor/Sponsor-Investigator. If a participating Site Investigator thinks that adherence to the protocol will in any way be detrimental to a particular participant's health or well-being, the interest of the participant must take precedence.

**[include if Advancing Health involved in Risk Management activities]**

In addition, Advancing Health and study Sponsor/SI will work together to identify, monitor and mitigate risk over the course of the study. Regular monitoring of study activities is a critical activity to ensure adequate management of risk. Specifically, outcomes of monitoring activities will contribute to the risk indicator dataset for specific risks.

By agreeing to participate in this study, the clinical site acknowledges that the Sponsor/Sponsor-Investigator and DSMC undertake responsibility for overall monitoring of the study [study number]. Qualified individuals from Advancing Health and/or other individuals acting on behalf of the sponsor (herein referred to as the ‘monitor’) will conduct monitoring in compliance with ICH GCP and Advancing Health SOPs and templates.

**[For all studies:]**

In general, there is a need for on-site monitoring, before, during, and after the study; however, the Sponsor/SI may determine that central monitoring in conjunction with procedures such as investigators’ training and meetings, and extensive written guidance can assure appropriate conduct of the study in accordance with GCP.

The maximum effort will be taken to complete the monitoring tasks mentioned in the monitoring plan. This may not be achieved due to any reasons including early termination of the study, financial constraints, and time constraints. The monitoring plan will be updated if necessary to reflect any changes made during the study period.

[If other countries are involved, the CTN/Advancing Health SOPs and templates may or may not be used; if external SOPs and templates are used, this should be specified. For example, In {other country}, monitoring activities will be performed according to this Monitoring Plan and {external monitor’s} monitoring SOPs. In some cases, the CTN/Advancing Health forms and/or procedures will be used in order to be in line with overall study procedures. The forms/procedures that are affected will be noted in this Monitoring Plan.]

# Project Monitoring Contacts

**[List appropriate contact information]**

|  |
| --- |
| **[Sponsor or Sponsor-Investigator]** |
| Name | Title | Phone | Email |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **[CIHR Canadian HIV Trials Network or Advancing Health]** |
| Name | Title | Phone | Email |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **[External Study Monitor]** |
| Name | Title | Phone | Email |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Site Visit Objectives

### Compliance with GCP and Study Protocol

The purpose of these visits is to assess compliance with ICH GCP guidelines for the conduct of clinical studies. The monitor will also assess compliance and adherence to the protocol as well as investigator involvement in order to report on overall site performance.

The Investigator should not implement any deviation from the study protocol without prior agreement by the Sponsor/SI and prior approval from their REB/IEC unless satisfying the exception criteria described in the ICH GCP (see section 4.5 of the GCP).

### Risk-Based Monitoring

* **Monitoring Critical Data and Processes**

SAMPLE TEXT (to be modified as needed)

Case Report Forms (CRFs) will be reviewed for completeness and source verification (if applicable) of critical data for all enrolled participants will be performed either on-site or remotely. Sponsor/SI will identify the list of critical processes and data and provide it to the monitor. The list may include the following:

1. Signed Informed Consent Forms

2. Eligibility criteria

3. Drug Accountability

4. Critical efficacy endpoints

5. Protocol-required safety assessments

6. Evaluating, documenting, and reporting serious adverse events, participant deaths, and withdrawals, especially when a withdrawal may be related to an adverse event

7. Conduct and documentation of procedures essential to trial integrity (e.g., ensuring the study blind is maintained).

If necessary, 100% source data verification may be performed for some participants due to poor site performance at the request of Sponsor/SI.

* **Risk Assessment**

SAMPLE TEXT (to be modified as needed)

Note: Include only if Risk Plan has not been / will not be developed.

After identifying critical data and processes, Sponsor/SI should perform a risk assessment to identify and understand the nature, sources, and potential causes of risks that could affect the collection of critical data or the performance of critical processes.

The identified risks should be assessed and prioritized by considering the following:

* + - * The likelihood of errors occurring
			* The impact of such errors on human participant protection and trial integrity
			* The extent to which such errors would be detectable

Sponsor/SI should use the results of the risk assessment in developing the monitoring plan (e.g., determining which risks may be addressed through monitoring, determining the types and intensity of monitoring activities best suited to addressing these risks).

A monitoring plan ordinarily should focus on preventing or mitigating important and likely risks, identified by the risk assessment, to critical data and processes. The types (e.g., on-site, centralized), frequency (initial assessment and training versus throughout the study), and extent (comprehensive versus targeted or random review of certain data) of monitoring activities will depend on a range of factors, considered during the risk assessment.

### Essential Documents

The monitor will ensure that the appropriate documents are on file by either on-site or remote monitoring. The Sponsor/SI is responsible for maintaining the Trial Master File (TMF). Each participating site (Investigator/Institution) is responsible for maintaining the Investigator Site File (ISF). The Sponsor/SI and the site (investigator/institution) should maintain a record of the location(s) of their respective essential documents including source documents. ***[See SOPPM\_17 – Essential Documents Management for additional details. Update the table below as needed.]***

The following documentation should be on file in the TMF and the ISF:

|  |  | **TMF**  | **ISF** |
| --- | --- | --- | --- |
| **1** | **Study Logs** |  |  |
| * Participant Screening Logs
* Participant Enrollment Logs
* Participant Identification Code List
* Delegation of Authority Signature Log
 | X (where required) N/AN/AX | XXXX |
| **2** | **Protocol and Agreements** |  |  |
| * Protocol & Protocol Amendments (all approved versions)
* Qualified Investigator (QI) signature page
* Signed agreement between involved parties
* CTN/Advancing Health Authorization Letter (If applicable)
 | XXXX | XXXX |
| **3** | **Investigational Agent and Safety Information** |  |  |
| * Product Monograph / Investigator’s Brochure (all versions)
* Notification by Sponsor and/or Investigator (as applicable) to Regulatory Authority(ies) of USADRs/Safety Reports/Information
* Notification by Investigator to Sponsor/SI of Serious Adverse Event (SAE) Reports
* Notification by Sponsor/SI to Investigator(s) of safety information
 | XXXX | XXXX |

|  |  |  |  |
| --- | --- | --- | --- |
| **4** | **Participant Information** |  |  |
| * Approved Informed Consent Forms (ICFs), all versions (blank templates)
* Approved Case Report Forms (CRFs), all versions (blank templates)
* Source Documents
* Approved Participant Information, all versions
* Approved advertising for participant recruitment, all versions
* Signed ICFs
* Signed, dated, and completed CRFs
* CRF Corrections
 | XXN/AXN/AN/AXX | XXXXXXXX |
| **5** | **Ethics Approvals** |  |  |
| * Submissions and associated documents
* Approvals (incl. updates to approvals)
* Membership List (incl. updates)
 | XXX | XXX |
| **6** | **Ethics Communication** |  |  |
| * Communications
 | X | X  |
| **7** | **Regulatory Agency** |  |  |
| * Approvals
* Correspondence
* Audit certificate (at study close), if applicable
 | XXX | XX (where required)N/A |
| **8** | **Investigator Information** |  |  |
| * CV (Investigator and sub-Investigators, signed and dated)
* Medical/Nursing License (signed & dated) (as applicable)
* Site Personnel Contact Information Sheet
* Financial Disclosure Form(s) (if required)
* CTN/Advancing Health Confirmation of Participation Form (If applicable)
* Qualified Investigator Undertaking (if applicable)
* Insurance statement (if applicable)
 | XXXXXXX | XXXXXXX |

|  |  |  |  |
| --- | --- | --- | --- |
| **9** | **Study Drug Management** |  |  |
| * Shipping & receiving records
* Dispensing records
* Storage (e.g. temperature logs)
* Destruction records
* Instructions for handling of IP(s)
* Decoding procedures (if applicable)
* Sample of Label(s)
* Certificate(s) of Analysis of Investigational Product(s) Shipped
* Treatment allocation records (at study close)
 | XXX XXXXXX | XXXX (if destroyed at site)XXN/AN/AN/A |
| **10** | **Laboratory** |  |  |
| * Normal Values (from lab reports is acceptable)
* Certifications and Accreditations (incl. updates)
* Records of retained body fluids/tissue samples inventory
* Documentation of sample shipment (e.g., waybills, specimen forms)
 | XXXX | XXXX |
| **11** | **Study Correspondence** |  |  |
| * With CTN/Advancing Health - Sponsor/SI
* With monitor
* With sites
* Other correspondence
 | XXXX | XXXX |
| **12** | **Study Staff Training** |  |  |
| * Investigator Meeting/SIV training documentation
* Ongoing Site Training
* General Training (e.g. GCP, Division 5, TCPS2)
 | XXX | XXX |

|  |  |  |  |
| --- | --- | --- | --- |
| **13** | **Monitoring Visits** |  |  |
| * Visit Confirmation Letter
* Approved Monitoring Visit Reports
* Signed Follow-up Letters
* Monitor Site Visit Log
 |  XXXX | X X X X |
| **14** | **Miscellaneous** |  |  |
| * Supplemental Protocol instructions (Operations Manual, etc.)
* Site SOPs
* Notes-to-File
* Protocol Deviations
* Shipping and receiving records for trial-related materials
* Master Randomization List
 | XXXXXX |  X X X X X N/A |

**\* If another country is involved in the study, additional country-specific documentation may be required.**

# Frequency of Interim Monitoring Visits

***SAMPLE TEXT (to be modified as needed)***

On-site or remote monitoring will be performed by the assigned monitor, if applicable. The first monitoring visit will take place [e.g. within approximately one month after a site randomizes its second participant or approximately within the first six months from the time the first participant is enrolled, i.e., randomized.] Additional site monitoring visits will be scheduled [e.g. at minimum on an annual basis] for each site provided that there are active participants that require monitoring. [This will include a final visit before study closure, preferably when all vital data should have been completely validated].

# Site Initiation Training

*[TO BE MODIFIED AS NEEDED – MOSTLY APPLICABLE ONLY IF CTN/ADVANCING HEALTH IS RESPONSIBLE FOR SITE INITIATION]*

The study PM or delegate may conduct site initiation training for all sites. This training may be conducted on-site or remotely via teleconference; refresher training will be performed as needed. All sites that attend the on-site and/or teleconference trainings must record training on the training log.

### Timing

Sites are eligible for initiation training at a time deemed appropriate by the Sponsor and the study PM. However, the site may not officially start the study until the requirements below (b) are met. The study PM will inform the monitor appropriately. The monitor may be asked to perform initiation or assist with initiation.

### Initiation Training Activities

The initiation training activities will be performed as per the CTN/Advancing Health SOPs: SOPPM\_14 Site Initiation and Training, SOPPM\_16 Protocol Deviation Management and the approved study-specific Project and Monitoring Plans. The full agenda will include the following topics as applicable:

* Introduction, background information and protocol rationale
* Protocol overview
* Investigator responsibilities
* Study drug and pharmacy responsibilities
* Randomization process and web demonstration
* Study visits
* CRFs
* Data management
* Administration
* Enrolment and study procedures
* Adverse events (AEs) and Serious Adverse Events (SAEs)
* Study communications

Following the completion of the site initiation training, sites will not be able to screen patients until all of the following criteria are met:

* All regulatory documents complete
* REB/IEC approval received, as applicable
* Site contract has been fully executed
* CTN/Advancing Health Authorization Letter and supplies have been received.

Once all of these criteria are met, the site will officially be able to screen and enrol patients into the study.

### Initiation Training Report

The Site Initiation Visit Report (see Appendix A) will be prepared for all on-site and telephone Site Initiation Visits conducted and will be reviewed by the study PM or delegate. Once the report is finalized, the study PM will sign and date the report. The original signed/finalized reports will be maintained within the TMF.

# Interim Monitoring Visits

A Monitoring Visit Report will be generated after each visit. Reports identifying significant problems (e.g., data collection, excessive loss to follow-up, protocol deviations, GCP noncompliance, concerns about safety, etc.) will be referred to the study PM (and, if necessary, reviewed by the study’s Medical Monitor, the SI and the DSMC) to assist in resolving the problem and to suggest an appropriate action.

### Pre-visit Communication

A Monitoring Visit Confirmation Letter (see Appendix B) will be sent to the QI and any relevant site staff in order to document the date, time, duration and agenda (list of monitoring tasks to be done) for the visit. The monitor will inform the site staff of what will be reviewed during the visit. Refer to SOPPM\_06 - Study Monitoring for additional information on pre-visit communication.

### Interim Monitoring Visit Activities

Each monitoring visit will average [X] hours on site.

In case the monitor is unable to cover the workload contemplated in this plan, additional monitoring visits or co-monitoring visits may be conducted as needed, depending on issues encountered at the site based on the Sponsor/SI’s approval. The monitor will prepare the Monitoring Agenda (list of monitoring tasks to be done at the site visit) as per the monitoring plan. The monitor may confirm the Monitoring Agenda with the Sponsor/SI, before sending the Monitoring Visit Confirmation Letter to the site.

During the visit, the monitor will conduct activities described in sections 3 a, b, and c of this plan.

### Data Query Process

After Data Management or the monitor has generated queries, site staff will be asked to resolve all queries. It will be the responsibility of the monitor, the study PM, and Data Management to help ensure that all queries are resolved by the site.

### Protocol Deviations

Protocol non-compliance will be documented in the Monitoring Visit Report.

### Monitoring Visit Report

The Monitoring Visit Report (see Appendix C) will be prepared by the monitor for all on-site interim monitoring visits and reviewed by the study PM/delegate (if applicable) and the Sponsor/SI. Once the report is finalized, the monitor and the study PM/delegate (if applicable), and the Sponsor/SI will sign and date the report. The original signed/finalized reports will be kept in the TMF (see Section 3b).

### Follow-up Communication

A Monitoring Visit Follow-up Letter (see Appendix D) will be sent to the site in a timely manner. The purpose of the letter is to document any issues identified during the visit, to address any questions that may have been asked, to review what was accomplished during the visit and to discuss the status of the study.

### Ongoing Study Communications

In between interim monitoring visits, most of the communication will be between the Sponsor/SI and the site, however, the monitor will communicate with the site staff if necessary or as requested by the study PM. Discussion topics may include, but are not limited to, the following:

* Ensure SAEs/AEs have been reported as per protocol
* Remind site that data is to be entered into the CRF promptly (if needed)
* Discuss enrolment status
* Maintain site involvement
* Communicate any administrative information (including resolution of outstanding issues in latest Monitoring Visit Follow-up Letter)
* Resolve outstanding study issues (queries, deviations, pending reports, study materials, lab issues, etc.)
* Answer any outstanding questions.

Relevant site contact communications should be documented and filed in the TMF and ISF as applicable. These may be, but are not limited to, the following:

* Calls made to site personnel
* Calls received from site personnel
* Faxes sent to sites (e.g., individual and mass or blast faxes)
* Faxes received from sites
* Emails sent to sites in place of or in follow-up to phone
* Emails received from site personnel.

The monitor should document any conversation they believe is significant to the study timeline, regulatory considerations, protocol adherence, participant safety, issues team members should be made aware of and major decisions. The monitor will remind sites to file all relevant emails, fax transmittals, and letters in the study correspondence binder/file.

The information documented should be specific and include key points discussed.

# Close-Out Monitoring Visit/Activities

### Timing

Close-out Visits will be conducted for activated sites as instructed by the study PM. The timing may vary, however Close-out Visits will most likely be prior to database lock to ensure completion of all query resolution for the study, or at the discretion of the study PM.

### Pre-visit Communication

An email confirmation will be sent to the QI and any relevant site staff in order to document the date, time, duration and brief agenda for the Close-out Visit if applicable. The monitor will inform the site staff what will be reviewed during the visit with a Monitoring Visit Confirmation Letter similar to the one used for the monitoring visits and attached to this Monitoring Plan.

### Close-out Monitoring Visit/Activities

The Close-out Visit should ideally be performed on site. The procedures listed below should be completed as applicable whether or not there is an on-site Close-out Visit:

* AEs/SAEs recorded in the source documents and CRFs
* SAEs documented and reported to the Sponsor/SI, expedited reports (forwarded by the Sponsor or SI) submitted to the local Research Ethics Board (REB)/Independent Ethics Committee (IEC)
* CRFs completed in accordance with the source documents
* All protocol deviations are identified, reviewed, verified and approved
* Corrections to the data, source documents, and/or CRFs completed
* Outstanding questions from previous monitoring visits, audits or inspections addressed
* Essential study documents completed, verified and provided to the TMF
* Accountability logs for all investigational products, used and unused, completed and copies retained with the essential study documents and provided to the TMF
* Destruction of investigational product by the local pharmacy (if requested) performed according to the institution’s written destruction procedure and documentation provided to the Sponsor/SI and study files
* Return of randomization code envelopes or lists to the Sponsor/SI, according to the protocol, or other written instructions
* Return of unused CRFs and other used/unused study-related paper/electronic material to the Sponsor/SI or destruction of material on-site, in accordance with local procedures for destruction of confidential documents as requested by the Sponsor/SI
* Return of all equipment and supplies to the Sponsor/SI unless otherwise arranged
* Return of all laboratory specimens (blood, tissues, etc.) to the Sponsor/SI for evaluation and storage unless otherwise described in the protocol or other written instructions

Discuss the following issues with the QI and/or appropriate site personnel:

* Outstanding issues or action items arising from the Close-out Visit
* Participant follow-up requirements, including post-study AEs/SAEs (in compliance with the protocol)
* Procedures for handling data clarifications that may arise; and
* Record retention/storage requirements.

### Close-out Visit Report

The Close-out Visit Report (see Appendix E) will be prepared by the monitor and then reviewed by the study PM/delegate (as applicable) and the Sponsor/SI. Once the report is finalized, the monitor, the study PM/delegate (as applicable), and the Sponsor/SI will sign the report. The final Close-out Visit Report will be filed in the TMF.

*INCLUDE AS APPLICABLE:*

For sites in other countries, the signed/finalized reports will be forwarded to the study PM.

### Follow-up Communication

A follow-up letter will be sent to the site in a timely manner. The purpose of the letter is to remind the QI of their responsibilities and to document any outstanding issues from the visit. The format of the letter will be similar to the Monitoring Visit Follow-up Letter (see Appendix D) and should include information on when/how final Close-out will be completed and state that the study PM or delegate will send the final Close-out Letter.

### Close-out Letter

Once the study PM or delegate has confirmed with Data Management that the site may be closed, the study PM or delegate will provide the site with a Close-out Letter (see Appendix F), including the following information as applicable:

* Anticipated timing of receiving any outstanding payments
* Anticipated timing for availability of the final report
* Feedback regarding site performance in the clinical study
* Required storage period for the archived study (study site to inform the Sponsor/SI of the location of the file archive)
* Possibility of Sponsor and government audits and additional queries
* Publication policy

**g) Annual/Final Reports to REBs/IECs**

The monitor will ensure that the annual reports and a final report are submitted to the REB/IEC, as required and if applicable.

# Centralized (Remote) Monitoring

*[Keep this section if remote monitoring is performed. Modify accordingly.]*

Centralized (Remote) monitoring may be conducted during the site initiation, throughout the study period, and during the site closeout. The findings will be conveyed to the study monitor if other study personnel (e.g., data manager) do the remote monitoring.

The Study Monitor will complete appropriate training to use the Sponsor/SI’s remote monitoring tools (i.e. File sharing platforms). The sites will share only redacted source documents for remote monitoring while using the File sharing platforms. Any source documents shared electronically for monitoring should be accessible to the monitor only (e.g. read access). The Study Monitor will strictly follow the privacy regulations when they review the Electronic Medical Record / Source documents remotely.

* Review of validated electronic TMF / ISF - The monitor will review the essential documents remotely and ensure that essential documents are on file.
* Review of Electronic Medical Record – The monitor will perform source data verification remotely.
* Appropriately qualified and trained persons (e.g., data managers, monitors) will remotely review the accumulating data to:
	+ Identify missing data, inconsistent data, and protocol deviations.
	+ Evaluate for systematic or significant errors in data collection and reporting at a site or across sites; or potential data manipulation or data integrity problems.
	+ Select sites and/or processes for targeted on-site monitoring.

# SAE (Serious Adverse Event) Reporting

Serious Adverse Event: An Adverse Event that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death.

The monitor will ensure that all SAEs noted during a monitoring visit or through other communication with the site, are reported to the study PM or Delegate (as applicable) within 24 hours of learning that the event occurred.

All SAEs are to be reported to:

**Attention**: [Study Project Manager or Delegate name]

**Phone:**  [add number]

**Fax:** [add number]

**E-mail**: [add email]

**[Attach necessary study-specific forms or reference applicable SOP or template.]**

# Appendix A: Site Initiation Visit Report

# Appendix B: Monitoring Visit Confirmation Letter

# Appendix C: Monitoring Visit Report Form

# Appendix D: Monitoring Visit Follow-Up Letter

# Appendix E: Close-out Visit Report

# Appendix F: Close-out Letter