



Site Monitoring Report

Study Title:	
Principal Investigator:	
Research Site:	
Qualified Investigator:	
Date Monitoring Performed:	
Site Monitoring Performed By:	

Key Research Site Personnel Present for Monitoring Visit

Name	Title	Available During Discussions (Y/N)
	Qualified Investigator	
	Research Coordinator	
	Pharmacist	
	Etc...	

Activity	Y	N	N/A	Comments
Study Team Meeting				
1. Review of the site visit agenda with the Investigator and study staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Review of previous site visit outstanding items to addressed for the next visit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Review of subject accrual status and enrollment objectives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Review of protocol and any amendments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Facilities				
1. Tour of study facilities (i.e. clinic, laboratory, pharmacy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Collection and storage of biological samples	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Shipping of samples	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Investigational product storage (i.e. secure, locked place with proper storage conditions, if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Investigational product accountability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Ensure the site has adequate supplies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Data Review			
1. Informed Consent Review (if the ICF has been updated ensure active patients are re-consented with updated ICF)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Review of screening log	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Enrolled participants meet inclusion/exclusion criteria	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Visits and procedures are performed at the correct times	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Randomization order and assignment of subjects to treatment are maintained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Source Documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. CRF Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Regulatory Documentation Review			
1. Ensure regulatory compliance with the applicable regulations (i.e. ICH, IRB, Health Canada)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Verify the protocol and all amendments have approval granted from the IRB	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Verify the ICF has been approved by the IRB (as well as any amendments)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Review study staff CVs and licenses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Review Laboratory Accreditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Review regulatory agency documentation (Health Canada, FDA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Ensure all adverse events and serious adverse events have been reported to the IRB and Sponsor as per applicable regulations and guidelines.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Safety Review			
1. Evaluate the accurate reporting for all safety measures (i.e. abnormal lab values, physical exam findings, abnormal findings on any procedure report)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Review all adverse event data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Review all serious adverse event data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



4. Ensure notifications to the IRB are filed for all adverse events and serious adverse events	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Record Retention				
Provide instructions and confirm the research site has a plan for record retention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ensure record retention storage documentation is filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Summary

Post monitoring visit summary including:

- *Site recruitment activities (screening, enrolment)*
- *SAEs*
- *Protocol violations, deviations*
- *deficiencies, including actions taken and resolution*

Written by:

Name

Date