[Insert Name of Department/Group Responsible for Monitoring Trial] MCRI, The Royal Children's Hospital Flemington Road, Parkville, VIC 3052 Phone: (+61) 3 9936 6328	**MONITORING VISIT REPORT**
Site Principal Investigator: [Insert full name]	
Study Site: [Insert full name of organisation, City and State]	**Date:** [Insert date(s) of visit]
Protocol: [Insert official title of the protocol]	
Monitor(s): [Insert Monitor name and affiliation]	

	Check if present
Principal Investigator: [Insert full name]	☐
Sub-investigator: [Insert full name]	☐
Research Nurse: [Insert full name]	☐
Study Coordinator: [Insert full name]	☐
Data Coordinator: [Insert full name]	☐
Pharmacist: [Insert full name]	☐
Other: [Insert full name and role]	☐

Clinical Site	**Yes**	**No**	**Comments**
Have there been any investigator/sub-investigator changes since the last visit? (If yes, ensure CV on file and HREC notified)	☐	☐	
Have there been any changes in other staff members since the last visit?	☐	☐	
(If yes, have the new staff members been trained? Are tasks appropriately delegated?)	☐	☐	
Does the facility remain adequately staffed?	☐	☐	

Does the site continue to have the resources and commitment to conduct the study?	☐	☐	
Protocol	**Yes**	**No**	**Comments**
Is the investigator adhering to the approved protocol/amendments in: *Subject screening and enrolment?*	☐	☐	
Schedule of events?	☐	☐	
Administration of investigational product?	☐	☐	
Laboratory requirements?	☐	☐	
Safety requirements?	☐	☐	
Efficacy requirements?	☐	☐	
Informed Consent	Yes	No	Comments
Is the investigator adhering to the informed consent process in: *Each subject has a properly signed, dated and witnessed HREC- approved consent?*	☐	☐	
There is written documentation that the study was explained to each participant and questions were answered?	☐	☐	
Consent was obtained prior to study-related procedures?	☐	☐	
The correct version of the consent was signed (current HREC-approved)?	☐	☐	
Revised versions of the consent have been signed by all participants, if applicable?	☐	☐	
Deviations to the consent process are documented and all applicable parties have been informed?	☐	☐	

Patient Recruitment	Yes	No	Comments
Is patient recruitment satisfactory?	☐	☐	
Number of participants: *Screened:* *In treatment:* *In follow-up:* *Completed:* *Withdrawn:*			
Source Documents	Yes	No	Comments
Are original source documents available?	☐	☐	
Do the medical records/source documents: *Reference the study?*	☐	☐	
Indicate the participant is receiving an investigational product?	☐	☐	
Contain progress notes, lab reports, concomitant therapies and adverse medical experiences?	☐	☐	
Document any modifications to investigational product dose?	☐	☐	
Were any protocol deviations noted?	☐	☐	
Was the PI notified of protocol deviations?	☐	☐	
Are deviations filed in the patient's chart?	☐	☐	
Is follow-up complete on previously reported SAEs?	☐	☐	
Did PI/delegate conduct AE review in a timely manner?	☐	☐	
For all AEs, were the AE review outcomes	☐	☐	

(causality, expectedness, seriousness, severity) appropriate?			
Were there any new SAEs?	☐	☐	
Were all SAEs reported to the Sponsor within 24 hours of becoming aware of the event?	☐	☐	
Were there any SUSARs? Were they reported to PI, RGO and TGA within the required timeframes?	☐	☐	
Were there any SSIs, including USMs?	☐	☐	
Were all SSIs/USMs reported to stakeholders within the required timeframes?	☐	☐	
Were there any DLTs?	☐	☐	
Were all DLTs reported to Sponsor in a timely manner?	☐	☐	
Data Integrity & Privacy			
Has personal identifying information been transferred to portable drives that have security measures in place to ensure no unauthorized access?	☐	☐	
Are computer files containing study data protected by passwords?	☐	☐	
Are all computer files containing study data stored on a secure network drive where they are regularly backed up?	☐	☐	
For all paper-based source documents, has identifying information been removed and replaced with a participant ID code?	☐	☐	
Is the participant ID code stored separately from all participant source documents and with	☐	☐	

access restricted to authorized members of the study team?			
Case Report Forms	**Yes**	**No**	**Comments**
Patients reviewed: *For those participants whose CRF was reviewed, list the participant ID number here.*	☐	☐	
Is data entry in the CRF and source documents being completed in a timely manner and up-to-date?	☐	☐	
Are the CRFs available for review?	☐	☐	
Is there satisfactory resolution of CRF discrepancies and errors?	☐	☐	
Were all AEs, con meds and intercurrent illnesses recorded in the CRFs?	☐	☐	
Were all patient withdrawals reported and explained in the CRFs?	☐	☐	
Have queries been reviewed, resolved and returned in a timely manner?	☐	☐	
Are the CRFs accurate and consistent with the source documents?	☐	☐	
Investigational Product	**Yes**	**No**	**Comments**
Is investigational product stored properly?	☐	☐	
If refrigeration/freezing required, are daily temperatures documented?	☐	☐	
Is the retest/expiration date current?	☐	☐	
Did the site confirm receipt of the investigational product and is the documentation maintained at the site?	☐	☐	

Is the investigational product being prepared, administered and disposed of according to study procedures?	☐	☐	
Are the drug accountability records current and accurate?	☐	☐	
Is there a sufficient supply of investigational product?	☐	☐	
Laboratory	**Yes**	**No**	**Comments**
Are lab certifications and normal ranges current?	☐	☐	
Are lab facilities, equipment and storage areas adequate?	☐	☐	
Are temperature logs maintained for frozen samples?	☐	☐	
Are lab supplies adequate and current (expiration dates of tubes)?	☐	☐	
Have all samples been collected, processed and sent to the appropriate lab?	☐	☐	
Have copies of requisitions and sample inventories been retained?	☐	☐	
Have the lab reports been reviewed by the investigator in a timely manner?	☐	☐	
Regulatory Documents	**Yes**	**No**	**Comments**
Are all required regulatory documents current and filed at the site [e.g. CTN, evidence of clinical trial registration and maintenance of the record, submission of safety reports to TGA (if applic)]??	☐	☐	

Have progress reports been sent to the HREC, if required?	☐	☐	[Provide date of all annual progress reports (due on anniversary of initial ethics approval]
Has the current version of the IB been submitted to the HREC?	☐	☐	
Have protocol deviations been submitted to the HREC, if required?	☐	☐	
Have all SSIs, USMs and SUSARS been submitted to the HREC, local Research Governance Office and TGA, if applicable?	☐	☐	
Is the Screening Log current and accurate?	☐	☐	
Is the Delegation Log current and accurate?	☐	☐	
Were any regulatory documents collected during the visit?	☐	☐	
Administrative	**Yes**	**No**	**Comments**
Was the principal investigator or sub-investigator available for a meeting?	☐	☐	
Was the Monitor Log signed?	☐	☐	
Visit Details:			
Comments:			
Action Items:			
Have all action items from the previous visit been completed?	☐ *Yes*	☐ *No*	☐ *NA*

List any items that require action by the site staff, monitor or sponsor below. Alternatively, action items can be included above in the comments field for each question.		
Item:	**Task Owner Initials**	**Target Completion Date:**

Monitor Name / Signature:	**Date**
Name / Signature on behalf of the Sponsor:	**Date**