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| **[Insert Name of Department/Group Responsible for Monitoring Trial]**MCRI, The Royal Children’s HospitalFlemington Road, Parkville, VIC 3052Phone: (+61) 3 9936 6328 | **MONITORING VISIT REPORT** |

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