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| **[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** |

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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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