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| **SOP#\***  **V9** | **SOP Title** | **Initials and Date Reviewed** |
| **N2 SOPs (001 – 019, 023 – 025)** | | |
| 001\_09 | Standard Operating Procedure (SOP) Administrative Management by Network of Networks |  |
| 002\_09 | Research Team Roles and Responsibilities |  |
| 003\_09 | Research Team Training |  |
| 004\_09 | Clinical Research Protocol Feasibility and Site Selection |  |
| 005\_09 | Study Initiation/Activation |  |
| 006\_09 | Informed Consent Forms |  |
| 007\_09 | Research Ethics Board: Submissions and Ongoing Communication |  |
| 008\_09 | Informed Consent Process |  |
| 009\_09 | Subject Recruitment and Screening |  |
| 010\_09 | Management of Investigational Products |  |
| 011\_09 | Management of Biological Specimens |  |
| 012\_09 | Serious Adverse Drug Reaction Reporting in Clinical Trials |  |
| 013\_09 | Study Monitoring and Communication |  |
| 014\_09 | Clinical Data Management |  |
| 015\_09 | Investigator Study Files and Essential Documents |  |
| 016\_09 | Study Close-Out |  |
| 017\_09 | Audits and Inspections |  |
| 018\_09 | Clinical Trial Application (Drugs) |  |
| 019\_09 | Confidentiality and Privacy |  |
| 023\_05 | Clinical Trial Application (Natural Health Products) |  |
| 024\_05 | Investigational Testing Authorization (ITA) for Medical Devices (non-IVDD) and Manufacturer/Sponsor Obligations |  |
| 025\_05 | Equipment Calibration and Maintenance |  |

\*SOPs 020, 021 and 022 have been re-numbered to SOPs 100, 101 and 102

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| **SOP#**  **V9** | **SOP Title** | **Initials and Date Reviewed** |
| **Investigator-Initiated (IIS) SOPs (100 -109)** | | |
| 100\_07 | CRF Design |  |
| 101\_07 | Study Analysis and Reporting |  |
| 102\_07 | Protocol Development |  |
| 103\_06 | Data Management Plan |  |
| 104\_06 | Database Set-up |  |
| 105\_06 | Database Maintenance and Management |  |
| 106\_06 | File Transfer |  |
| 107\_06 | Database Lock and Archiving |  |
| 108\_06 | System Set-up, Maintenance and Security |  |
| 109\_06 | System Backup and Recovery Planning |  |

**Retention of N2 SOP Training Records:**

The signed N2 SOP Training Records are filed in the Regulatory Binder and retained by designated staff in the [*Name Group. Example: Alberta Children’s Hospital Hematology Oncology Transplant Program Clinical Research Unit*].

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ attest that I have had the opportunity to review and self-train on the relevant Standard Operating Procedures and agree to conduct the study in accordance with them.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Role(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_