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| **SOP#\***  **V10** | **SOP Title** | **Initials and Date Reviewed** |
| **N2 SOPs (001 – 019, 023 – 025)** | | |
| 001\_10 | Standard Operating Procedure (SOP) Administrative Management by Network of Networks |  |
| 002\_10 | Research Team Roles and Responsibilities |  |
| 003\_10 | Research Team Training |  |
| 004\_10 | Clinical Research Protocol Feasibility and Site Selection |  |
| 005\_10 | Study Initiation/Activation |  |
| 006\_10 | Informed Consent Forms |  |
| 007\_10 | Research Ethics Board: Submissions and Ongoing Communication |  |
| 008\_10 | Informed Consent Process |  |
| 009\_10 | Participant Recruitment and Screening |  |
| 010\_10 | Management of Investigational Products |  |
| 011\_10 | Management of Biological Specimens |  |
| 012\_10 | Adverse Event/ Drug Reaction Documentation, Assessment and Reporting |  |
| 013\_10 | Study Monitoring and Communication |  |
| 014\_10 | Clinical Data Management |  |
| 015\_10 | Investigator Study Files and Essential Documents |  |
| 016\_10 | Study Close-Out |  |
| 017\_10 | Audits and Inspections |  |
| 018\_10 | Clinical Trial Application (Drugs) |  |
| 019\_10 | Confidentiality and Privacy |  |
| 023\_06 | Clinical Trial Application (Natural Health Products) |  |
| 024\_06 | Investigational Testing Authorization (ITA) for Medical Devices (non-IVDD) and Clinical Site Obligations |  |
| 025\_06 | Equipment Calibration and Maintenance |  |

\*SOPs 020, 021 and 022 have been re-numbered to SOPs 100, 101 and 102 in May 2011

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| **SOP#**  **V10** | **SOP Title** | **Initials and Date Reviewed** |
| **Investigator-Initiated (IIS) SOPs (100 -109)** | | |
| 100\_08 | CRF Design |  |
| 101\_08 | Study Analysis and Reporting |  |
| 102\_08 | Protocol Development |  |
| 103\_07 | Data Management Plan |  |
| 104\_07 | Database Set-up |  |
| 105\_07 | Database Maintenance and Management |  |
| 106\_07 | File Transfer |  |
| 107\_07 | Database Lock and Archiving |  |
| 108\_07 | System Set-up, Maintenance and Security |  |
| 109\_07 | 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_