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

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

|  |  |  |
| --- | --- | --- |
| **SOP#**  **V7** | **SOP Title** | **Initials and Date Reviewed** |
| **Investigator-Initiated (IIS) SOPs (100 -109)** | | |
|  | CRF Design |  |
|  | Study Analysis and Reporting |  |
|  | Protocol Development |  |
|  | Data Management Plan |  |
|  | Database Set-up |  |
|  | Database Maintenance and Management |  |
|  | File Transfer |  |
|  | Database Lock and Archiving |  |
|  | System Set-up, Maintenance and Security |  |
|  | 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_