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| **Cooperative Group:** | **Principal Investigator:** |
| **Institution:** | **Qualified Investigator** (*If different from PI)***:** |

I authorize the following personnel to assume the indicated study tasks and procedures for all \_ [name of cooperative group]\_\_\_\_\_studies approved at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (site). As the Principal Investigator/Qualified Investigator (PI/QI), I understand that this in no way alters my responsibility as defined by ICH-GCP, the sponsor, Health Canada, applicable regulations, and the clinical trial agreement. Individuals have been assigned roles based on appropriate education and training.

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| **Name (N) and Role (R)**  (PRINT CLEARLY) | **Training**  **GCP**  **Div 5** | **Full Signature** | **Initials** | **Delegated Study Responsibilities**  *Write Numbers (see list)* | **Dates of Study Involvement**  *(yyyy-mmm-dd)* | **PI/QI Signature**  to Authorize Delegation and affirmation of identity of individual | **Date of Signature**  *(yyyy-mmm-dd)* | **PI/QI Signature for End of Study or End of Role** | **Date of Signature**  *(yyyy-mmm-dd)* |
| **N** | **GCP □** |  |  |  | **Start** |  |  |  |  |
| **R** | **Div5 □** | **Stop** |
| **N** | **GCP □** |  |  |  | **Start** |  |  |  |  |
| **R** | **Div5 □** | **Stop** |
| **N** | **GCP □** |  |  |  | **Start** |  |  |  |  |
| **R** | **Div5 □** | **Stop** |
| **N** | **GCP □** |  |  |  | **Start** |  |  |  |  |
| **R** | **Div5 □** | **Stop** |
| **N** | **GCP □** |  |  |  | **Start** |  |  |  |  |
| **R** | **Div5 □** | **Stop** |
| **N** | **GCP □** |  |  |  | **Start** |  |  |  |  |
| **R** | **Div5 □** | **Stop** |
| **N** | **GCP □** |  |  |  | **Start** |  |  |  |  |
| **R** | **Div5 □** | **Stop** |
| **Instructions:** Identification of study role may include sub-investigator, study nurse, clinical/research nurse, study coordinator, pharmacist (when appropriate, technician, nurse practitioner, physician assistant, resident, and data recorder). List individual’s delegated study-related tasks (ICH GCP 4.1.5) as described in the Responsibility List. Signatures/Initials required for all persons authorized to make entries and/or corrections to Case Report Forms (ICH GCP 8.3.24). When tasks are delegated by the PI/QI, the PI/QI is responsible for providing adequate supervision and training of those to whom tasks are delegated. PI/QI affirmation and delegation, by means of signature and date above, must occur after individual has completed all required training and prior to conducting any study-related tasks.  **Note**: If a research team members’ role changes, reassign remaining study-related tasks from the Responsibility List to a qualified site research team member by creating a new line and include the new start date. | | | | | | | | | |

**Principal Investigator Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **\* Delegated Study Responsibilities (Duties)** | | | |
| 1. Obtain Informed Consent/Assent | 6. Instruction on Study Drug Administration | 11. CRF completion and correction | 16. Document Protocol Deviations |
| 2. Patient Screening | 7. Dispensation of Study Drug | 12. Data/Query Resolution | 17. Trial-related Medical Decisions |
| 3. Physical Examination & History | 8. Study Drug Accountability | 13. REB Communication | 18. Eval. of Trial-related Lab Reports |
| 4. Patient Randomization | 9. Assess & Assign Causality for AEs/SAEs | 14. Essential Regulatory Documents | 19. Ordering Investigational Agents |
| 5. Patient Follow-Up Visits | 10. Collecting and Reporting of AEs/SAEs | 15. QIU Labeling | 20. Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |