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| **SIGNATURE AND DELEGATION OF DUTIES** | | | | | | | | | | |
| **Protocol Name/No:** |  | | | | | | | | | |
| **Study Sponsor:** |  | | | | **Site Name:** | | | | | |
| **Name of Principal Investigator** | | **Principal Investigator’s Signature** | | | **Principal Investigator’s Initials** | **Start**  **(dd/mmm/yyyy)** | | | **End**  **(dd/mmm/yyyy)** | |
|  | |  | | |  |  | | |  | |
| **Staff with delegated duties/tasks** | | | | | | | | | | |
| **Print Name** | | **Signature** | | **Initials** | **Study Role (e.g.**  **study nurse, pharmacist)** | **Task(s)**  **Delegated** | | **Authorised/Confirmed by the Principal Investigator** | | |
| **Start Date** (dd/mmm/yyyy)**/**  **Initials** | | **End Date** (dd/mmm/yyyy)**/**  **Initials** |
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| 1. Coordinates HREC communications 2. Screens/recruits study participants 3. Obtains Informed Consent (inc. sign off) 4. Confirms eligibility (inclusion/exclusion 5. Obtains medical history 6. Performs physical examination 7. Maintains essential documents 8. Activities related to regulatory submissions 9. Conducts study visit procedures | | | 1. Makes study related medical decisions 2. Evaluates study related test results 3. Performs study related assessments 4. Assesses AEs / SAEs 5. Reports SAEs 6. Prepares/dispenses study drug/device (investigational product) 7. Activities related to code break 8. Stores study drug and monitors temperature 9. Collects Samples | | | | 1. Makes entries / corrects e/CRFs 2. Processes biologic sample and ships sample 3. Signs off e/CRFs 4. Resolves data queries 5. Manages study drug/device accountability 6. Randomisation (e.g. IVRS) 7. <additional categories > | | | |