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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 >
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