**Site Initiation [study] Study**

**Zoom Program**

*\*\* Use this template if a site has* ***not*** *previously been involved in another PaCCSC/CST/ITCC study and overall research training needs have been assessed and addressed in addition to study specific training. \*\**

***Session 1 – Pharmacy training***

*Day Month Year*

*Time*

|  |  |
| --- | --- |
| **Attendees**  *Please specify name & position of attendees* | IMPACCT Trials Coordination Centre (ITCC) members:   * National Manager * National Project Officer * Other   Site members:   * Pharmacist * Study Coordinator(s) * Study Nurse |
| **Apologies** |  |

|  |  |
| --- | --- |
|  | **Pharmacy initiation – ITCC team**  **Topics** |
| **1 hour**  **Trial pharmacists** | **Protocol summary**  **Study Drug and pharmacy procedures**  *Storage and handling*  *Preparation and dispensing*  *Accountability; Destruction* |
| **Pharmacy folder** |

**Training slides reviewed at this session:**

[Insert document name for each slide deck presented]

***Session 2 – Regulations***

*Day Month Year*

*Time*

|  |  |
| --- | --- |
| **Attendees**  *Please specify name & position of attendees* | IMPACCT Trials Coordination Centre (ITCC) members:   * National Manager * National Project Officer * Other   Site members:   * Principal Investigator * Study Coordinator * Study Nurse(s) |
| **Apologies** |  |

|  |  |
| --- | --- |
| **Times** | **ITCC team**  **Topics** |
| **1.5 hour**  **Study coordinators and nurses** | **2.1 Overview of Trials and Regulations**  *ICH GCP; HREC; TGA* |
| **2.2 Roles, Responsibilities, Communication (SOP)**  *Sponsor; Site Investigator; Research staff*  *Absence process – contingency plans* |
| **2.3 Standard Operating Procedures**  *Understanding; Implementation* |
| **2.6 Adverse Event Assessment and reporting (SOP)**  *CTCAE NCI criteria; ITCC reporting, HREC reporting* |

**Training slides reviewed at this session:**

[Insert document name for each slide deck presented]

***Session 3 – Monitoring and Management***

*Day Month Year*

*Time*

|  |  |
| --- | --- |
| **Attendees**  *Please specify name & position of attendees* | IMPACCT Trials Coordination Centre (ITCC) members:   * National Manager * National Project Officer * Other   Site members:   * Principal Investigator * Study Coordinator(s) * Study Nurse(s) |
| **Apologies** |  |

|  |  |
| --- | --- |
| **Times** | **ITCC team**  **Topics** |
| **2 hours**  **Study coordinators and nurses** | **3.4 Record keeping**  **Documentation and study filing**  *Master files; Essential documents; Investigator Site Files* |
| **3.5 Consent process**  *HREC / RGO / local site requirements*  *Documentation of consent*  *Consent procedure(s)* |
|  | **3.9 Monitoring** |
| **3.10 Contracts and invoicing** |
| **General discussion and commencement plans** |

**Training slides reviewed at this session:**

[Insert document name for each slide deck presented]

***Session 4 – Protocol***

*Day Month Year*

*Time*

|  |  |
| --- | --- |
| **Attendees**  *Please specify name & position of attendees* | IMPACCT Trials Coordination Centre (ITCC) members:   * National Manager * National Project Officer * Coordinating Principal Investigator * Other   Site members:   * Principal Investigator * Study Coordinator * Study Nurse(s) |
| **Apologies** |  |

|  |  |
| --- | --- |
| **Times** | **Coordinating Principal Investigator and ITCC team**  **Topics** |
| **1.5-2 hours**  **Required attendance by all PIs and coordinators** | **4.1 Protocol review**  *Background; Study design*  *Inclusion/exclusion criteria*  *Learnings from [other study], early results* |
| **4.2 Schedule and questionnaires**  *Visit schedule; Tests and questionnaires* |
| **4.3 Randomisation and study drug**  *Procedures, unblinding* |
| **4.4 Site implementation and recruitment plan**  *Referrals and barriers*  *Recruitment base/pre-screening* |
| **4.5 Sub-studies**  *Selection and Consent;*  *Schedule and assessments* |
| **Other topics (as applicable)** |

**Training slides reviewed at this session:**

[Insert document name for each slide deck presented]

***Session 5 – Data Management***

*Day Month Year*

*Time*

|  |  |
| --- | --- |
| **Attendees**  *Please specify name & position of attendees* | IMPACCT Trials Coordination Centre (ITCC) members:   * National Manager * National Project Officer * Other   Site members:   * Principal Investigator * Study Coordinator * Study Nurse(s) |
| **Apologies** |  |

|  |  |
| --- | --- |
| **Time** | **ITCC team**  **Topics** |
| **2 hours**  **Study coordinators and nurses** | **Data Collection Worksheets and CRFs (SOP) - 7**  *Completion timepoints and requirements*  *Worksheets, Electronic CRFs and other associated documents* |
| **Data entry - 8**  *REDCap entry*  *Data validation*  *Data corrections* |

**Training slides reviewed at this session:**

[Insert document name for each slide deck presented]

***SCHEDULE OF SESSIONS – [study] Study***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date and time** | **Session number** | **Topic area** | **Presenters** | **Attendees** |
|  | Session 1 | Pharmacy |  | All clinical trials pharmacists |
|  | Session 2 | Regulatory |  | Study staff |
|  | Session 3 | Monitoring and management |  | Study staff |
|  | Session 4 | Protocol and implementation |  | PIs  Sub PIs  Study staff  Interested clinical teams |
|  | Session 5 | Data management |  | Study staff |