**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 |  | PIsSub PIsStudy staffInterested clinical teams |
|  | Session 5 | Data management |  | Study staff  |