**Site Initiation [study] Study**

***Zoom Program***

***\*\**** *Use this template if a site is already recruiting to other PaCCSC/CST/ITCC studies and their overall research capacity and training needs have been assessed and addressed on a previous occasion. \*\**

***Zoom 1: Protocol Overview***

*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 (PI)
* Study Coordinator
* Study Nurse(s)
 |
| **Apologies** |  |

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| --- | --- |
| **Duration** | **Protocol - 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;**Discussion/questions* |
| **4.2 Randomisation and study drug***Procedures, unblinding* |
| **4.3 Schedule and questionnaire overview***Visit schedule; Tests and questionnaires* |
| **4.4 Site implementation and recruitment plan***Referrals and barriers**Recruitment base/pre-screening* |
| **4.5 Sub-Studies***Consent, schedule, assessments* |
| **Other topics (as applicable)** |

**Training slides reviewed at this session:**

[Insert document name for each slide deck presented]

***Zoom 2 – Pharmacy training***

*Day Month Year*

*Time*

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| **Attendees***Please specify name & position of attendees* | IMPACCT Trials Coordination Centre (ITCC) members:* ITCC National Project Officer
* ITCC Project Officer

Site members:* Pharmacist
* Study Nurse
 |
| **Apologies** |  |

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| **Duration** | **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]

**Site Initiation [study] Study**

***Self-training program***

(These items are to be recorded on the Individual or Group Training Record held in the ISF)

|  |  |
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| **Duration** | **Regulations****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* |

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| --- | --- |
| **Duration** | **Monitoring and management****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)* |
| **3.10 Contracts and invoicing** |
| **3.9 Monitoring** |

|  |  |
| --- | --- |
| **Duration** | **Data management** **Topics** |
| **0.5 hour****Study coordinators and nurses** | **5.7 Data Collection Worksheets and CRFs (SOP)- Part A***Data collection and source data requirements**General overview of worksheets and electronic CRFs* |
| **\*The below materials will be available after the Protocol Zoom Session** |
| **1.5 hour****Study coordinators and nurses** | **5.7 Data Collection Worksheets and CRFs- Part B***Completion timepoints and requirements**Study specific worksheets, eCRFs and other associated documents* |
| **5.8 Data entry***REDCap entry* *Data validation**Data corrections* |

**Training slides to be reviewed:**

[Insert document name for each slide deck to be reviewed]