**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** |  |

|  |  |
| --- | --- |
| **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** |

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| --- | --- |
| **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]