**Appendix 4**

**Pharmacy Site Feasibility Form**

**Site Name:**

**Protocol:**

***The purpose of this document is to collect essential information on your site IMP management procedures. The information reported will be provided to Insert Sponsor/CTU Name here prior to* the *site activation visit.***

**STUDY LOGISTICS (To be completed by the Trial Manager or Sponsor Pharmacy Representative)**

**Specify if IMP is Blinded: Yes/No**

**Randomisation and Product allocation system:**

**Initial IMP is supplied at: Local Site Activation/ Randomisation of first participant**

**Is IMP automatically supplied or do the site manage further supplies?:**

**Study Equipment is Supplied:**

**Estimated Pre activation visit date:**

**Other Important Information Site to be aware of:**

|  |  |  |  |
| --- | --- | --- | --- |
| **IMPs** | **Formulation** | | **Acceptable Temperate Range** |
|  |  | |  |
| **Key Site Pharmacy Contacts** | | | |
| Pharmacist Name: | | Pharmacy Technician Name | |
| Email: | | Email: | |
| Please specify Pharmacy Team’s availability for Pre-Activation Visit | | Specify Date(s): | |

| **Item** | **Site Pharmacy Team’s Processes & Procedures** | **Checked by Trial Manager/CTU/ Sponsor**  **[Date & Initials]** |
| --- | --- | --- |
| **1.** | **Please provide a contact name & address for IMP deliveries** |  |
| **Pharmacy Response** |  |
| ***2.*** | **Who will check if stock is received in the correct conditions & is suitable for use?** |  |
| **Pharmacy Response** |  |
| ***3.*** | **Will IMP be stored outside of the pharmacy unit (e.g., satellite sites, on ward, private dialysis unit, pharmacy stores)?** |  |
| **Pharmacy Response** |  |
| **4.** | **Will the IMP require any significant transportation that could put the IMP at risk of a temperature excursion?** |  |
| **Pharmacy Response** |  |
| **5.** | **Please describe the method used (manual / electronic) to monitor IMP temperature whilst in storage & how temperature excursions are identified?** |  |
| **Pharmacy Response** |  |

|  |  |  |
| --- | --- | --- |
| **Item** | **Site Pharmacy Team’s Processes & Procedures** | **Checked by Trial Manager/CTU/ Sponsor**  **[Date & Initials]** |
| **6.** | **If manual temperature monitoring is used how frequently is this checked and how is this managed during weekends?** |  |
| **Pharmacy Response** |  |
| **7.** | **ALL temperature excursions outside of the acceptable temperature range (see study logistics above) to be reported to the trial manager/CTU. Who will be responsible for notifying the trial manager/CTU?** |  |
| **Pharmacy Response** |  |
| **8.** | **What procedures are in place to ensure the calibration and maintenance of the pharmacy equipment (refrigerator, thermometer & alarm) are performed according to the manufacturing guidelines?** |  |
| **Pharmacy Response** |  |
| **9.** | **What procedures are in place within pharmacy in the event of a power failure?** |  |
| **Pharmacy Response** |  |
| **10.** | **Is there a back-up refrigerator/freezer in case of an emergency? Where are they located?** |  |
| **Pharmacy Response** |  |
| **11.** | **How will IMP treatment requests be provided to the person dispensing the drug for each patient? (E.g how will they know which batch No. or Med No. to dispense?)** |  |
| **Pharmacy Response** |  |
| **12.** | **If dose is based on weight, is there a robust process in place for updating weight in the prescribing system?** |  |
| **Pharmacy Response** |  |
| **13.** | **Will authorised prescriptions be filed in pharmacy for review by the monitor/trial manager/CTU?** |  |
| **Pharmacy Response** |  |
| **14.** | **How will you ensure IMP remains within the correct storage conditions from dispensing to administration? (E.g. will reconstituted medication have an expiration date/time?)** |  |
| **Pharmacy Response** |  |
| **15.** | **If aseptic units are being used, when is the next shut-down for routine deep cleaning and how long does the shutdown take? Do you foresee any impact this will have on the conduct of this study?** |  |
| **Pharmacy Response** |  |

|  |  |  |
| --- | --- | --- |
| **Item** | **Site Pharmacy Team’s Processes & Procedures** | **Checked by Trial Manager/CTU/ Sponsor**  **[Date & Initials]** |
| **16.** | **What procedures are in place to arrange for unused/used/expired / damaged IMP to be destroyed on site or off site? Please attach SOPs** |  |
| **Pharmacy Response** |  |
| **17.** | **Do you prefer to use your own drug accountability log or the Sponsor’s Accountability Logs? If you intend to use your own, please provide a copy for review.** |  |
| **Pharmacy Response** |  |
| **18.** | **What procedures are in place to ensure new pharmacy staff receives appropriate training for their role and how to manage the IMP for the study?** |  |
| **Pharmacy Response** |  |
| **19.** | **Will pharmacy produce study specific documents / work instructions?  If yes, please list documents below as the monitor will need to review them.** |  |
| **Pharmacy Response** |  |
| **20.** | **Please provide the email address for IMP Notifications for your pharmacy team** |  |
| **Pharmacy Response** |  |
| **21.** | **Please specify if your pharmacy has any internal requirements to be in place before a Pre-Activation visit date can be confirmed?** |  |
| **Pharmacy Response** |  |
| **22** | **Please provide any additional information including relevant SOPs ie. Recall SOP, electronic prescribing CT SOP if used** |  |
| **Pharmacy Response** |  |
| **23** | **Please provide CV and GCP for all members of the trials pharmacy team who will be named on the delegation log** |  |
| **Pharmacy Response** |  |  |

***Site Pharmacy Staff to complete***

***Completed by****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* ***Date:****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

***Print Name:*** *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

***Job Title:*** *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

***Please return completed copy to the Study Manager for review***