Pharmacy Cancer Clinical Trial Initiation Checklist Template

**Verison 1**

**Approved: 06/12/2024 by NCCP Cancer Clinical Trials Pharmacist Subgroup**

* **This checklist in not intended to be used with Advanced Therapy Medicinal Products (ATMPs).**
* **To note, this template is intended to be a guide only; the fields included in this form are not mandatory or exhaustive. Some fields will not be relevant to all cancer clinical trials.**
* **This checklist may be adapted for use at each site as deemed applicable to local practice.**

|  |
| --- |
| **General Information (Refer to feasibility checklist for further general trial information)** |
| Study Protocol Name: | ABC |
| Protocol Number at SIV: | 123 | SIV Date: |  |
| **Clinical Trial Documentation at SIV date** | **Version No.** | **Date of Version** |
| Electronic site file | **[ ]** Yes [ ] No **[ ]** Received  |
| Pharmacy Folder (s) incl. IB / SmPC etc. | **[ ]**  Received  |  |  |
| Pharmacy / Drug Preparation Manual | **[ ]**  Received **[ ]** N/A |  |  |
| IXRS Manual | **[ ]**  Received  **[ ]** N/A |  |  |
| Current Protocol Version | **[ ]** Received  |  |  |
| Sample IMP Labels | **[ ]** Received  |  |  |
| HPRA approval  | **[ ]** Received  |  |  |
| NREC approval | **[ ]** Received  |  |  |
| CRA Contact details  |  |

|  |
| --- |
| **Investigational Medicinal Product (IMP) Details** |
|  | **Medications**  | **Route of Admin** | **Dosage Form / strength** | **Storage Conditions****(Temp/light)** | **Quantity in Initial shipment**  | **Supply route (Local / Central)** |
| A |  |  |  |  |  |  |
| B |  |  |  |  |  |  |
| C |  |  |  |  |  |  |

|  |
| --- |
| **Supply & Ordering** |
| Initial shipment  | Triggered by: **[ ]** SIV **[ ]** Site Activation **[ ]** First patient screened |
| Documents to be received with IMP  | **[ ]** Certificate of analysis **[ ]** QP cert/Batch release **[ ]** SPC**[ ]** Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Reordering process | **[ ]** Manual **[ ]** Form required **[ ]** Lead time\_\_\_\_\_\_\_\_\_\_\_\_**[ ]** Online via IXRS **[ ]** Automatic  |
| Is temperature monitoring required in transit? | **[ ]** Yes [ ] No |
| Are temperature loggers to be retained?  | **[ ]** Yes [ ] No |
| Are shipping cartons to be recovered by courier? | **[ ]** Yes [ ] NoProcess for recovery: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Confirmation of receipt process  | **[ ]** Manual **[ ]** Online via IXRS **[ ]** Form required **[ ]** Automatic  |

|  |
| --- |
| **Accountability** |
| Accountability of IMP | **[ ]** Paper log [ ] Electronic **[ ]** Both |
| Can in-house accountability logs be used?  | **[ ]** Yes [ ] No |

|  |
| --- |
| **Temperature Monitoring** |
| Clarify minimum threshold / interval for alarms  |  |
| Can temperature results be rounded?  | **[ ]** As per local policy **[ ]** As per clinical trial\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] No |
| Process for reporting a temperature excursion  | **[ ]** Electronic form **[ ]** Online portal |
| **Waste disposal** |
| Is there a requirement to retain outer boxes of any presentation of IMP? e.g. vial outers / labels after prep in ACU, pre-filled syringes | **[ ]** Yes [ ] No |
| Can local policy be followed with respect to waste disposal?  | **[ ]** Yes [ ] No |

|  |
| --- |
| **Clinical queries** |
| Drug / kit allocation if trial uses individually numbered stock units | **[ ]** Pharmacy staff **[ ]** Research Nurse [ ] Other staff\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] N/A |
| Dose calculation information | Is there a maximum dose or weight specified for any agents in the trial? |
| Calculation of doses: [ ] Weight should be rounded before dose calculation[ ] Dose should be rounded after calculation based on unrounded weight |
| Timing and frequency of weight measurement:[ ] As per local policy [ ] As per clinical trial \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Recalculation of doses for weight changes during treatment:[ ] As per local policy [ ] As per clinical trial \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| BSA based dosing – Formula  | [ ] CRA informed of local practice  |
| Creatinine clearance - Formula | [ ] CRA informed of local practice  |
| Can calculated doses be rounded to measureable volumes?  | [ ] No [ ]  As per local policy[ ]  As per clinical trial \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Can SOC treatments be dose banded as per local / national policy?  | **[ ]** Yes [ ] No |
| Are there any particular supportive care requirements? Or non-routine test results which need to be reviewed? |  |

|  |
| --- |
| **Aseptic Compounding Unit Details - Table may need to be completed for each drug in clinical trial)** |
| Stability / storage when reconstituted?  |  |
| Can CSTD be used for prep / admin of IMP? | **[ ]** Yes [ ] No |
| Are any special consumables needed for preparation? | [ ] Yes Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] Supplied [ ] To be ordered locally [ ] Not required |
| Is any light protection required during preparation? | **[ ]** Yes [ ] No |
| New drug set up required? If Yes has the NCIS team been informed?  | **[ ]** Yes [ ] No **[ ]** NCIS Informed  |
| Are specific new drug forms required by site ACU | **[ ]** Yes **[ ]** No |
| ACU Specific guide ( may be incorporated into local pharmacy dispensing guide)  | **[ ]** Required **[ ]** Not required |

|  |
| --- |
| **Administration** |
| Is any filter required for administration? | [ ] Yes Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] Supplied [ ] To be ordered locally [ ] No |
| Is any specific giving set required for administration? | [ ] Yes Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] Supplied [ ] To be ordered locally  |
| Is light protection required for administration? | Light protective giving set: **[ ]** Yes **[ ]** NoLine covering: **[ ]** Yes **[ ]** No |
| Is any specific patient monitoring during or post infusion required? |  |
| **General** |
| Pharmacy Budget  | **[ ]** Drafted **[ ]** Agreed with sponsor **[ ]** N/A |
| Sample dispensing labels / worksheet if applicable  | **[ ]**  Not required **[ ]** Completed |
| Local Prescriptions | **[ ]** Not required **[ ]** Completed |
| IXRS Passwords  | **[ ]** Not required **[ ]** Received |
| Material Safety Data Sheet  | **[ ]** Not required **[ ]** Received |
| Documents required as per local site policies (if applicable) | **[ ]** In-house accountability logs **[ ]** Local Pharmacy disp guide (May include ACU guide also)**[ ]** ACU training log **[ ]** Pharmacy training log**[ ]** SIV training log**[ ]** SIV delegation log |

|  |
| --- |
| **Items for follow up** |
| Documents sent to sponsor **[ ]  Calibration certificates [ ]  Waste disposal SOPs [ ]  IMP Management SOPs**Note to file(s) sent to sponsor **[ ]  Temp monitoring [ ]  GCP/CVs [ ]  CSTDs [ ] Superseded protocols / IBs** |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |