**DIVISION OF RESEARCH AND INNOVATION**

**Clinical Research Facility**

|  |
| --- |
| Treatment Room Temperature Excursion Form (see GOSH/ICH/SOP/CRF/001) |

**Excursion location (delete Y/N as appropriate)**

|  |  |  |  |
| --- | --- | --- | --- |
| Fridge | Y / N | Ambient | Y / N |

**Excursion description**

|  |
| --- |
|  |

**Action Log**

|  |  |  |  |
| --- | --- | --- | --- |
| Actions  | Action Completed By | DateDD-MMM-YY | Time(24hr) |
| Excursion occurred | N/A | **DD-MMM-YY** |  |
| CRF Nurse in Charge informed |  | **DD-MMM-YY** |  |
| Impacted stock labelled as quarantined |  | **DD-MMM-YY** |  |
| CRF Pharmacist informed |  | **DD-MMM-YY** |  |
| Event resolved | N/A | **DD-MMM-YY** |  |
| Safety assessment completed by CRF Pharmacist (see Appendices 1 and 2) |  | **DD-MMM-YY** | N/A |

**Form completed by:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Signature** | **Date****DD-MMM-YY** |
| CRF Nurse in Charge (or delegate) |  |  | **DD-MMM-YY** |
| CRF Pharmacist |  |  | **DD-MMM-YY** |

**Appendix 1: Quarantine log for impacted IMPs (if applicable)**

|  |  |
| --- | --- |
| **IMP(s) Impacted****(To be completed by CRF Nursing Staff)** | **Assessment** **(To be completed by CRF Pharmacist)** |
| **R&D Number** | **IMP Name** | **Batch Number(s)** | **Storage Location** | **Assessment Date** | **Assessment Decision** | **Action Date** |
|  |  |  | * Fridge
* Ambient
 | **DD-MMM-YY** | * Safe to use, remove from quarantine
* Safe to use with shortened shelf life, remove from quarantine
* Not safe to use, return to pharmacy for disposal
 | **DD-MMM-YY** |
|  |  |  | * Fridge
* Ambient
 | **DD-MMM-YY** | * Safe to use, remove from quarantine
* Safe to use with shortened shelf life, remove from quarantine
* Not safe to use, return to pharmacy for disposal
 | **DD-MMM-YY** |
| **Completed by CRF Nurse In Charge (or delegate):**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date**  |
|  |  | **DD-MMM-YY** |

 | **Completed by CRF Pharmacist:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
|  |  | **DD-MMM-YY** |

 |

**Appendix 2: Quarantine log for impacted non-IMPs**

|  |  |
| --- | --- |
| **Non-IMP(s) Impacted****(To be completed by CRF Nursing Staff)** | **Assessment** **(To be completed by CRF Pharmacist)** |
| **Medicinal Product Name** | **Batch Number(s)** | **Storage Location** | **Assessment Date** | **Assessment Decision** | **Action Date** |
|  |  | * Fridge
* Ambient
 | **DD-MMM-YY** | * Safe to use, remove from quarantine
* Safe to use with shortened shelf life, remove from quarantine
* Not safe to use, return to pharmacy for disposal
 | **DD-MMM-YY** |
|  |  | * Fridge
* Ambient
 | **DD-MMM-YY** | * Safe to use, remove from quarantine
* Safe to use with shortened shelf life, remove from quarantine
* Not safe to use, return to pharmacy for disposal
 | **DD-MMM-YY** |
| **Completed by CRF Nurse In Charge (or delegate):**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date**  |
|  |  | **DD-MMM-YY** |

 | **Completed by CRF Pharmacist:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
|  |  | **DD-MMM-YY** |

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