**Trial Specific Pharmacy/IMP Handling Manual Review**

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| Study Details | | | | | | | | | | |
| Study name |  | | | | | | | | | |
| Type of study |  | | | | | | | | | |
| IMP/agent name |  | | | | | Dose/quantity received | |  | | |
| Type of stock | Standard stock |  | Ring fenced standard stock | | |  | Supplied for trial |  | Other  *(list)* |  |
| Number/time points of dispensing according to protocol |  | | | | | Any special dispensing instructions | |  | | |
| Pharmacy performing manufacturing step (✓) | Yes |  | | No |  | If yes please list  *(e.g. CT labelling, re-packaging, blinding)* | |  | | |
| IMP/agent storage location (✓) | Pharmacy |  | | Ward |  | Other  *(please list)* | |  | | |
| IMP/agent storage temperature (°C) |  | | | | | Other special storage instructions | |  | | |
| Emergency Unblinding responsibility (✓) | Pharmacy |  | | PI |  | Unblinding system | |  | | |

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| Manual Details | | | |
| Name of document reviewed *(if multiple documents make up manual please list all documents reviewed)* |  | Version (date) |  |

*Note: Required content of pharmacy manual/IMP handling instructions will vary according to study design, IMP formulation, IMP storage requirements and risk adaption. The following table should be used as a guide for the checks required. Checks should be made against the protocol and other associated documents e.g. SmPC/IB or sIMPD where appropriate to ensure pharmacy manual/IMP handling instruction processes are in line with approved documentation. Where information is marked as n/a justification must be recorded in the comments box provided.*

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| Manual Review | | | | |
| (✓) | Yes | No | N/A | Comments |
| Study title |  |  |  |  |
| Study identifier (e.g. EudraCT Number, site R&D number) |  |  |  |  |
| Study team contact details |  |  |  |  |
| Sponsor |  |  |  |  |
| Description/summary of trial design |  |  |  |  |
| Description of IMP/agent including:   * Name * Strength * Formulation * Manufacturer |  |  |  |  |
| Description of any comparators |  |  |  |  |
| Description of any NIMPs |  |  |  |  |
| It is clear what stock the IMP and any comparators or NIMPs are coming from |  |  |  |  |
| Pharmacy set-up/activation/RGL process |  |  |  |  |
| Approved label |  |  |  |  |
| Shipment receipt process |  |  |  |  |
| IMP storage requirements *(Include temperature excursion escalation process)* |  |  |  |  |
| Randomisation process |  |  |  |  |
| Prescription process *(Ensure dose prescribed matches protocol)* |  |  |  |  |
| Dispensing process *(Ensure number and time points of dispensing matches protocol)* |  |  |  |  |
| Returns process |  |  |  |  |
| Accountability log completion |  |  |  |  |
| Emergency resupply process *(e.g. if IMP lost/damaged)* |  |  |  |  |
| Destruction process  *(Include Sponsor approval requirements)* |  |  |  |  |
| Any pharmacy required manufacturing steps are clearly defined |  |  |  |  |
| Ordering process |  |  |  |  |
| Unblinding process |  |  |  |  |
| Recall process |  |  |  |  |
| Pharmacy file requirements |  |  |  |  |
| Monitoring requirements |  |  |  |  |
| Archiving requirements |  |  |  |  |
| Additional requirements *(please list)*: |  |  |  |  |

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| Review Completion | | | | | | | | | | |
| If study is running in Lothian content approved by NHSL pharmacy? (✓) | Yes |  | | No |  | | N/A | | |  |
| Comments |  | | | | | | | | | |
| Final pharmacy manual version approved *(if multiple documents please list)* |  | | | | | | | | | |
| Protocol used for review | Version | |  | | Date | | | |  | |
| Name of reviewer |  | | | | | | | | | |
| Signature |  | | | | | Date | |  | | |