Transfer of IMP between Pharmacy clinical trials and a storage location outside of Pharmacy clinical trials

This form is to be used in conjunction with SOP Pharm/S76 – Dispensing the IMP outside of Pharmacy

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED**

All staff should regularly check the R&D Unit’s website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

|  |  |
| --- | --- |
| SOP Reference: | Pharm/F91 |
| Version Number: | 3.0 |
| Author: | Poppy Cottrell-Howe |
| Implementation date of current version: | 20th December 2019 |

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| --- | --- | --- |
| Approved by: | Name/Position: | Stuart Parkes (Deputy Chief Pharmacist) |
| Signature: | C:\Users\szparkes\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Word\SP Signature.jpg |
| Date: | 21st November 2019 |
|  | Name/Position: | Sarah Sheath, SOP Controller |
|  | Signature: |  |
|  | Date: | 25th November 2019 |

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| This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise |

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

|  |  |  |
| --- | --- | --- |
| Version | **Date Implemented** | **Details of significant changes** |
| 1.0 | 12th September 2013 |  |
| 2.0 | 26th July 2016 | No changes. |
| 3.0 | 20th December 2019 | Change of author. Change to link for R&D website, amended form to include the details of two previously used forms Pharm/F92 and Pharm/F93 these are now obsolete. |
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Transfer of IMP between Pharmacy clinical trials

and a storage location outside of Pharmacy clinical trials

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name of Study | | | | |  | | | | | | |
| EudraCT number | | | | |  | | | | | | |
| Description of IMP  (name, strength, form and pack size) | | | | |  | | | | | | |
| Temperature conditions required | | | | |  | | | | | | |
| **Purpose of Transfer**  (Please tick below) | | | | | | | | | | | |
| IMP leaving pharmacy to an approved location outside of pharmacy  ❑ | | | Expired/damaged/unused  IMP returning to pharmacy from an outside location  ❑ | | | | | Patient returns or empty packaging returning to pharmacy for reconciliation from an outside location  ❑ | | | |
| **Departing** location of IMP | | |  | | | | | | | | |
| **Arrival** location of IMP | | |  | | | | | | | | |
| **Details of transferred IMP**  **Only complete sections if applicable for transfer** | | | | | | | | | | | |
| Batch/lot number(s) | Expiry date(s) | | | Kit/pack  Number(s) | | | Patient trial ID number(s) | | Patient Initials | | Quantity transferred  (or state if empty containers) |
|  |  | | |  | | |  | |  | |  |
| **This section confirms that the IMP described above has been selected for**  **transfer between two locations and has been prepared for safe and secure transportation** | | | | | | | | | | | |
| Date of Transfer | | Time prepared for transfer | | | | Print name | | | | Signature | |
|  | |  | | | |  | | | |  | |

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| **Receiving IMP at arrival location**  This section confirms that the above details of the IMP transferred to the stated  arrival location are correct.  If there is any discrepancies state them below and the actions taken to resolve in the box provided. | | | |
| Date received | Time received | Print name | Signature |
|  |  |  |  |
| If applicable -  State any discrepancies that have occurred during the transfer and list the actions taken to resolve. | | | |
|  | | | |

Ensure accountability logs are updated on both the departing and arrival locations