Assessing an area for Investigational Medicinal Product storage outside of Pharmacy

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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| SOP Reference: | Pharm/F89 |
| Version Number: | 4.0 |
| Author: | Dominic Burns |
| Implementation date of current version: | 13th February 2023 |

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| Approved by: | Name/Position:  | Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager |
| Date: | 25th January 2023 |
|  | Name/Position: | Sarah Sheath, SOP Controller |
|  | Date: | 16th January 2023  |

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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.

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| Version | **Date Implemented** | **Reviewers** | **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 of link to R&D website |
| 4.0 | 13th February 2023 | Dominic BurnsPoppy Cottrell-Howe | Change of Author. Change of Trust name. |
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**Assessing an area for Investigational Medicinal Product storage**

**outside of Pharmacy**

**Brief description of the clinical trial and Investigational Medicinal Product**

|  |  |
| --- | --- |
| Name of clinical trial |  |
| EudraCT number |  |
| Description of IMP (name, strength, form, pack size) |  |
| Temperature storage requirements of IMP |  |

**Proposed storage requirements of the Investigational Medicinal Product**

|  |  |
| --- | --- |
| Room location (department, area, room number) |  |
| Pharmacy access codes required for the room (if applicable) |  |
| Is there a dedicated, secure, lockable cupboard/fridge/freezer to store the IMP separate from normal hospital stock?If not state what the arrangements will be to ensure the IMP is stored securely.  |  |
| Describe the IMP storage area (state whether a lockable cupboard, fridge or freezer will be used) |  |
| How will access be controlled to the area where the IMP will be stored? |  |
| Is there enough space in the cupboard/fridge/freezer for the quantity of IMP expected to be required during the trial? |  |
| If applicable, there a suitable lockable area to store patient returns separate from unused IMP?If not state what the arrangements will be to ensure returns are stored securely.  |  |
| Describe the storage area available for patient returns, if applicable. |  |

**Temperature monitoring requirements of the Investigational Medicinal Product**

|  |  |
| --- | --- |
| Is the area air conditioned (if IMP needs to be stored at room temperature)? Or is there good air circulation? |  |
| Has the cupboard/fridge/freezer been temperature monitored for two weeks?If not seek sponsor approval. |  |
| Method of temperature monitoring |  |
| Has the temperature remained with an acceptable range as defined by the protocol during the two weeks? If not seek sponsor approval or try other storage locations. |  |
| Lowest temperature recorded during the two weeks |  |
| Highest temperature recorded during the two weeks |  |
| How often will the pharmacy clinical trials team temperature monitor the area (through temperature logger download)? |  |
| How often will the research team temperature monitor the area manually? |  |

*Attach the temperature graphs associated with the temperature monitoring described above to this form.*

**Confirmation of suitability for use**

|  |  |
| --- | --- |
| Has the suitability of the area and temperature monitoring arrangements been discussed and agreed with a member of the research team? |   |

|  |
| --- |
| Any comments  |

|  |
| --- |
| I confirm that the area described is/is not suitable for use for the trial (*delete as applicable)* |
| Print  |   |
| Sign  |  |
| Date |   |