STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_020

SOP Title: Storage of clinical trial medication (outside of pharmacy)

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Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	27-May-2016	Initial Version	09-Feb-2016
2	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

STANDARD OPERATING PROCEDURE (SOP)

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SOP Title: Storage of clinical trial medication (outside of pharmacy)

1. PURPOSE AND CONTEXT

1.1 To describe the procedures for storing clinical trial medication outside of the pharmacy.

1.2 Covers the procedures to follow for assessing and approving a clinical trial medication storage area outside of the pharmacy. The term clinical trial medication will cover investigational medicinal products (IMPs), and other medicinal products which may be provided by the sponsor for a specific trial (e.g. non-investigational medicinal products - nIMPs). The procedure includes:

- Assessment of the need to store clinical trial medication outside of the pharmacy
- Identification and assessment of a proposed clinical trial medication storage area and associated temperature monitoring equipment
- Approval of clinical trial medication storage area and associated temperature monitoring equipment
- Creating study specific instructions for clinical trial medication management outside of the pharmacy
- Periodic pharmacy monitoring of clinical trial medication storage area outside of the pharmacy

2. DEFINITIONS

PI - Principal Investigator. The lead person at a single site designated as taking responsibility within the research team for the conduct of the study. Responsible for all aspects of the study conduct at the site.

3. PROCEDURE and RESPONSIBILITIES

3.1 Assessment of the need for storage of clinical trial medication outside pharmacy

3.1.1 There are circumstances where it may be necessary to store clinical trial medication outside of pharmacy. For example, in some trials it may be necessary to store clinical trial medication on the ward or another location in the trust where they can be accessed in an emergency by the principal investigator (PI) or research nurses. Assess the need for storing clinical trial medication outside of pharmacy as part of the pharmacy feasibility assessment of a clinical trial.

3.2 Assessment of a proposed storage area for clinical trial medication and associated temperature monitoring equipment

3.2.1 Arrange to visit the proposed storage area with the PI or a member of the research team as delegated by the PI.

3.2.2 Discuss and agree the following:

- Access - restricted access to relevant trial staff
- Suitability - size of storage area and need for segregation of stock
- Temperature monitoring - device, calibration, logs and frequency of recording
- Process for temperature monitoring and reporting of temperature excursions
- Process for recording and accountability of clinical trial medication
- Process for ensuring expiry date checks
- Process for ordering, supply and delivery of clinical trial medication
- Process for prescribing and dispensing clinical trial medication in line with the trial's requirements
- Process for handling returns and disposal/destruction of clinical trial medication
- Process for periodic environmental checks and review accountability records by pharmacy

3.2.3 Document the assessment process using the *Clinical trial medication storage area assessment form* (Form 03).

3.3 Approval of clinical trial medication storage area and associated temperature monitoring equipment

3.3.1 If the storage area is deemed unsuitable, identify an alternative storage area by following steps 3.2.1 to 3.2.2.

3.4 Creating study specific instructions for clinical trial medication management outside of the pharmacy

3.4.1 The pharmacist/technician delegated the task of trial set-up for the trial concerned should create a comprehensive set of study specific instructions for use by staff outside of pharmacy, including but not limited to:

- Storage location of clinical trial medication, including a description of the storage location and how to access the storage area (e.g. where keys are located) as well as a statement on the acceptable storage temperature range.
- Procedure for temperature monitoring, including what equipment to use, frequency of monitoring, documentation requirement, and actions to take in the event of a temperature excursion and how this should be documented
- Procedure for ordering and receipt of clinical trial medication, including information on documentation requirement.
- Procedure for transferring clinical trial medication from pharmacy to storage location, including information on documentation requirement.

- Procedure for prescribing, dispensing and checking of clinical trial medication, including information on documentation requirement.
- Procedure for accountability logs completion
- Procedure for expiry date checking, including information on frequency of checks, documentation requirement, and actions to follow if clinical trial medication is found to be out of date.
- Procedure for handling returned/used clinical trial medication, including information on storage location, the frequency at which used clinical trial medication should be returned to pharmacy (where applicable), disposal of clinical trial medication (where applicable), and documentation requirement.
- Procedure for pharmacy monitoring, including information on the frequency of monitoring, and a description of all tasks to be completed at such visits.
- Responsibility and accountability in the implementation of the study specific instructions
- Record of trained personnel

Note: Quarantine of clinical trial medication should always be handled by pharmacy staff. The possible need for quarantine (e.g. in the event of a temperature excursion or expired stock) should be highlighted to pharmacy by non-pharmacy staff through following the study specific instructions. Always store quarantined stock in pharmacy.

3.4.2 Outline the roles and responsibility for both pharmacy and non-pharmacy staff in the study specific instructions. Where appropriate, consult relevant non-pharmacy staff when creating study specific instructions.

3.4.3 Authorisation of the study specific procedure is the responsibility of the lead clinical trial pharmacist and PI for the trial.

3.5 Periodic pharmacy monitoring of clinical trial medication storage area outside of the pharmacy

3.5.1 At regular intervals in accordance with the decision made as part of the pharmacy feasibility assessment of a clinical trial, arrange to visit the clinical trial medication storage area with the PI or a member of the research team as delegated by the PI.

3.5.2 Undertake a review of temperature records, accountability logs and other relevant documentation to check that the study specific instructions are being followed.

3.5.3 Document the monitoring visit in a report, highlighting any action points arising from the visit.

3.5.4 Provide a copy of the report to the PI.

3.5.5 Where necessary, inform the sponsor of any issues and/or report as a pharmacy clinical trial incident.

3.5.6 Follow up any action points arising from the monitoring visit with the PI and research team, ensuring these points are addressed within a stated time period.

3.5.7 File the monitoring visit report with the relevant correspondence in the pharmacy site file.

	Responsibility	Undertaken by	Activity
1	Chief Pharmacist	Clinical Trials Pharmacist	Ensure correct procedures are followed
2	Clinical Trials	Staff involved	Temperature monitoring and reporting of temperature

	Pharmacist	with the day to day management of IMP's	deviations.
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Clinical trial medication storage area assessment form (Form 03)

5. TRAINING

- The Clinical Trial details, which are specific to each individual trial, must have been read

6. REFERENCES

For more detailed guidance/reference, refer to:

- Section 6.14 of the MHRA Good Clinical Practice Guide, 2012.
- Professional Guidance on Pharmacy services for clinical trials, National Pharmacy Clinical Trials Advisory Group, Version1, October 2013.
- The safe and secure handling of medicines: A team approach. A revision of the Duthie Report (1988) led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society". March 2005.