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<tr>
<th>Title of Standard Operating Procedure:</th>
<th>RDSOP24 Sourcing Pharmacy Services from Pharmacy Providers</th>
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<tr>
<td>Document Summary:</td>
<td>This procedure is to be used to assess if a pharmacy is suitable to run a trial, which includes the dispensing of IMP and / or NIMP.</td>
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All Trust R & I SOPs |
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<tr>
<th>Minimum Monitoring Requirement</th>
<th>Frequency</th>
<th>Process for monitoring</th>
<th>Evidence</th>
<th>Responsible Individual(s)</th>
<th>Response Committee(s)</th>
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1. Introduction

All clinical trials of an investigational medicinal product (CTIMP’s) must adhere to The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments.

Pharmacies that dispense Investigational Medicinal Products (IMPs) must comply with the principles of Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) and the over-arching Clinical Trials Regulations, as well as conform to The Medicines Act 1968.

Non-Investigational Medicinal Products (NIMP’s) “fall under general medicines legislation and GMP rather than the Clinical Trials Regulations. In this way, NIMP’s that are authorised medicinal products are governed by the requirements of Directive 2001/83/EC, including Title IV, which contains the GMP requirements”. [Medicines and Healthcare products Regulatory, 2012].

2. Purpose

This procedure is to be used to assess if a pharmacy is suitable to run a trial, which includes the dispensing of IMP and / or NIMP.

3. Roles and Responsibilities

3.1 Duties within the organisation

It is the responsibility of the Research & Innovation Office to make Trust R & I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R & I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R & I SOP
it is the responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

The Research & Innovation Office is responsible for managing Trust R & I SOPs including their approval, dissemination and archiving. All Trust R & I SOPs must be made available via Q-Pulse and published on the Trust website.

4. Procedure

4.1 Pharmacy Location

a. Discuss with the investigator which pharmacy department(s) they had planned to dispense the IMP and any NIMP’s.

b. Discuss with the investigator which pharmacy department(s) would be more convenient for clinical trial participants or research staff to collect dispensed IMP and any NIMP’s.

4.2 Pharmacy Facilities

a. The pharmacy must be able to provide the following:

• appropriate facilities for the type of CTIMP (particularly where the trial involves radiopharmaceuticals or Advanced Therapy Medicinal Products such as gene therapy or cell therapy)
• facilities meeting accepted health and safety standards
• safe and secure storage of IMP and any NIMP’s
• sufficient storage to enable IMP and any NIMP’s to be stored separately from normal pharmacy stock
• space to ensure each CTIMP has its own storage area within the pharmacy
• sufficient storage to allow expired, recalled or returned IMP and/or NIMP to be stored separately from any unused IMP and any NIMP’s and normal pharmacy stock
• segregated areas for IMP and any NIMP’s in quarantine (quarantined medication should be clearly identified in addition to being segregated from working stock).
• segregated space in a safe and secure controlled drugs cupboard for IMP and any NIMP’s classed as controlled drugs
• for IMP that must be stored in a fridge:
- a fridge that only stores IMP and any NIMP’s
- either a fridge designated to that CTIMP or a separate shelf within the fridge designated to the CTIMP
- the fridge must have a calibrated temperature monitoring device that records the current temperature and minimum and maximum temperatures. The temperature monitoring device must have a minimum/maximum temperature memory function (or be able to produce reports or data to show the temperature has been maintained within the correct temperature range). The temperature monitoring device should also have a reset function. There should be an alarm system to alert staff if the temperature falls outside the specified range
- the fridge must have a working lock
- Ideally, there should be a backup power supply, but if this is not possible there must be a contingency plan to deal with ‘power cuts’

- for IMP that must be stored in a freezer:
  - a freezer that only stores IMP and any NIMP’s
  - either a freezer designated to that CTIMP or a separate compartment within the freezer designated to the CTIMP
  - the freezer be must have a calibrated temperature monitoring device that records the current temperature and minimum and maximum temperatures. The temperature monitoring device must have a minimum/maximum temperature memory function (or be able to produce reports or data to show the temperature has been maintained within the correct temperature range). The temperature monitoring device should also have a reset function. Ideally there should be an alarm system to alert staff if the temperature falls outside the specified range
  - Ideally, there should be a backup power supply, but if this is not possible there must be a contingency plan to deal with ‘power cuts’.
  - the freezer must have a working lock

- regular temperature monitoring and recording
- records of temperature monitoring of IMP storage facilities for filing in the CTIMP pharmacy file
- temperature monitoring devices should have a valid calibration certificate
- clean and dry storage areas
- appropriate lighting, temperature, humidity and ventilation so as to protect the IMP and any NIMP’s during any manufacturing and/or storage, and to maintain the accurate functioning of any equipment being used
• storage areas that are designed and equipped to provide maximum protection against the entry of insects or other animals
• an environment which minimises the risk of contamination of IMP and any NIMP’s
• premises which are carefully maintained, ensuring that repair and maintenance operations do not present a hazard to the quality of IMP and any NIMP’s
• premises with access restricted to authorised personnel
• lockable facilities
• adequate preparation areas
• appropriate disposal
• equipment that is calibrated / recalibrated every year (or as recommended by the CTIMP sponsor) and maintained.

4.3 Pharmacy Services

a. The pharmacy must be able to dispense IMP and any NIMPs as agreed in the CTIMP protocol and in-line with legal requirements, local standard operating procedures and policies, and good clinical practice.

b. The pharmacy must be able to label IMP in a manner that conforms to good manufacturing practice and Annex 13.

c. If IMP is to be packed down from bulk IMP stock, check with the clinical trials pharmacy team that they can do this under Exemption 37. If the pharmacy cannot pack down IMP, then approach a different pharmacy or consider sending the bulk IMP to a licensed manufacturing unit to be packed down and labelled (there will be additional costs incurred).

4.4 Pharmacy Processes

a. The pharmacy should have the following SOPs in place to cover the following procedures or agree to use SOPs written by GMMH or the CTIMP sponsor

• Pharmacy approval of a CTIMP.
• Receipt and recording of the safe delivery of IMPs.
• Safe handling and storage of IMPs.
• Temperature monitoring and reporting of temperature deviations.
• Risk assessment of storage areas for IMPs outside of pharmacy.
• Quarantine of IMPs.
• Expiry date relabelling.
• Code breaking (unblinding).
• Preparation and dispensing of IMPs in accordance with professional standards (including dispensing against an appropriate prescription, maintaining drug accountability records and ensuring that all IMPs are labelled with the appropriate pharmacy label).
• Return and disposal of unused IMPs.
• Reconciliation of IMPs.
• Drug alerts and recalls of IMPs
• Maintaining a pharmacy CTIMP file.
• Training of clinical trial pharmacy personnel.
• Archiving of CTIMP documentation.

4.5 Pharmacy Personnel

a. The pharmacy must have a dedicated clinical trials team.
b. Pharmacy personnel working on the CTIMP must have had good clinical practice training within the last 2 years.
c. Pharmacy personnel must be trained on the protocol and dispensing procedure for each CTIMP.
d. Pharmacy must hold training records and signature logs for staff involved in CTIMP activity (these records should be readily available for inspection if required).
1. References and Bibliography


