# Office for Research

**SOP-RTM-04**

## IMP RECEIPT, STORAGE, DISPENSING, RETURN AND DESTRUCTION

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**DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION**

## 1. PURPOSE:

The purpose of this SOP is to describe the procedures related to receipt, storage, dispensing and return/destruction of Investigational Medicinal Products (IMP) at Epworth HealthCare (Epworth).

## 2. BACKGROUND

N/A

## 3. SCOPE:

All clinical trials conducted at Epworth involving unapproved medicinal products.

## 4. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in the research activity at Epworth.

## 5. RESPONSIBILITIES:

Sponsor –responsibilities include supply of IMP to site unless otherwise stated in the study agreement, providing information on storage, preparation and usage of IMP, updating the protocol, Investigator Brochure and information to the HREC and site, and submission of the Clinical Trials Notification to the Therapeutic Goods Administration (TGA).

Principal Investigator (PI): is responsible for IMP accountability at the trial site(s) . The PI can delegate at their discretion certain trial duties to suitably qualified individuals acting within their scope of practice at Epworth. Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

All study staff are responsible for ensuring appropriate receipt, storage, dispensing and return/destruction of Investigational Medicinal Products (IMP) at Epworth HealthCare (Epworth).

## 6. DEFINITIONS:

N/A

## 7. PROCEDURE:

### 7.1 Receipt and handling of IMPs

The PI should:

a. Ensure only professionally qualified pharmacists and qualified staff (in accordance with Epworth Medication Management Policy) are delegated the tasks associated with the overall day-to-day on-site management of IMPs used in clinical trials.

b. Liaise with the nominated Clinical Trials Pharmacy (CTP) at Epworth (Slade Pharmacy) to organise receipt and handling of the IMP(s) according to the protocol and applicable CTP SOPs.

c. Ensure that only CTP staff undertake receipt, handling, accountability, storage, management, and other related activities associated with the IMP.

d. Ensure that if transport between the CTP and treatment areas is required, and this cannot be undertaken at the time by a pharmacist, only clinically trained staff working within their scope of authorised practice may transport IMP after it has been dispensed to them by a trials pharmacist.

e. Ensure that all IMP is adequately labelled to ensure it is clearly associated with a specific clinical trial and a specific clinical trial participant[1].

## 7.2 Storage and General Management of IMP

a. IMP should be received, handled, repackaged, reconstituted, physically accounted for, stored at, dispensed from, and/or destroyed only within premises that are registered under Victorian law[2,3] to undertake these activities.

b. Under no circumstances should IMP that are schedule 8 and 9 poisons and/or drugs of dependency be stored anywhere other than the CTP.

c. Temperature logs recording the ambient or refrigerated temperature of areas or equipment used in the storage of IMP must be maintained by the CTP or clinical research staff (if stored elsewhere to the CTP).

d. IMP will be managed in a manner that ensures it is discrete from non-research products and maintained in a locked, restricted access facility.

e. Instructions given in the Pharmacy Manual and/or clinical trial Protocol document must be followed for any activities associated with the storage, handling, and any required reconstitution of the IMP.

## 7.3 Prescription of IMP for dispensation

a. Prescriptions of IMP can only be written, authorised and signed by a qualified and registered medical practitioner working as the PI or as a delegated sub-investigator.

## 7.4 Dispensing of IMP

a. Instructions on dispensing of an IMP, which is intended to be taken orally, should be provided directly to the recipient by a qualified pharmacist or qualified medical practitioner who is working on the clinical trial and is on the delegation log.

b. Dispensing of an IMP, which is intended to be administered via subcutaneous, intramuscular, intradermal, or intravenous routes, is understood to mean transferring it from an approved storage facility to an approved treatment area (e.g. hospital ward, day medical unit, operating theatre) for subsequent administration by a medical practitioner or registered nurse working on the trial.

c. Appropriate documentation must be kept of trial IMP logged in and out of pharmacy and to dispensing location. The IMP must be traceable from receipt of IP to dispensing/administration to participant. All personnel must be appropriately qualified.

d. While medically qualified staff and pharmacists may dispense directly to patients, only registered nurses or medical practitioners may administer trial IP to participants for treatment.

### 7.5 Dispensing IMP

a. Records must be maintained of receipt, storage and dispensing device/diagnostic IMP.

### 7.6 Ordering of IMP

a. IMP should be ordered as per the trial Protocol or Pharmacy Manual.

### 7.7 Administration of IMP

a. IMP must only be administered according to administration guidelines in the clinical trial protocol and/or the associated Pharmacy Manual.

b. IMP must only be administered per protocol by qualified and professionally registered individuals authorised to do so under Australian law. Examples include medical practitioners and registered nurses delegated to this task by the PI.

### 7.8 Return and destruction of IMP

a. Processes, conditions and costs for the return and destruction of IMP, primarily drugs and devices, should be agreed upon between Epworth and the Sponsor and stated clearly in the Protocol and/or the Clinical Trial Research Agreement. This must be in accordance with the TGA Act.

### 7.9 Emergency unblinding

a. If a trial is blinded (either single- or double- blinded), the establishment of the emergency unblinding procedure is the responsibility of the Sponsor and should be clearly and easily understandable within the trial Protocol.

b. It is the Epworth staff's responsibility to understand emergency unblinding procedures prior to the commencement of a trial.

## 8. REFERENCES:


1. Australian clinical trial handbook – labelling medicines. https://www.tga.gov.au/book-page/manufacturing

2. Drugs, Poisons and Controlled Substances Regulations 2017 S.R. No. 29/2017. http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/b05145073fa2a882ca256da4001bc4e7/C3217A0343C6A914CA25812200151801/$FILE/17-029sra%20authorised.pdf

3. Drugs, Poisons and Controlled Substances Act 1981. http://classic.austlii.edu.au/au/legis/vic/consol_act/dpacsa1981422/

4. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Annotated with TGA comments.

5. Australian Commission on Safety and Quality in Health Care National Clinical Trials Governance Framework (Governance Framework).


## 9. RELATED DOCUMENTS:

N/A

## 10. VERSION CONTROL

| Document History | | | |
|---|---|---|---|
| **Version** | **Date** | **Summary of Changes** | **Author** |
| 1.0 | 8/5/2019 | N/A - First Issue | Helen Christensen |
| 2.0 | 19/6/2024 | Update header, formatting throughout and version control table.<br>Insert section 2. Background, 5. Responsibilities and 6. Definitions.<br>Move responsibilities from Section 7 to Section 5: Responsibilities.<br>Insert sponsor, PI and study staff responsibilities. | Sarah Rickard |