New Zealand Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Handling Investigational Products				
SOP Number:	SOP-05	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose

To describe the procedure for the management of all aspects of the investigational product (IP), either medicinal product or device. Management includes but is not limited to the receipt, storage, accountability, preparation and administration, shipment, and destruction of investigational products.

2. Scope

This SOP applies to all members of the study team involved in the handling and shipping of IP, including the Primary Site (PS) and all the Satellite Site (SS) study team.

3. Responsibilities

3.1 IP accountability rests with the Principal Investigator (PI), at both the PS and SS, however, the PI may delegate the responsibility for IP management to the site (PS or SS) pharmacist or other appropriately qualified members of the study site team (i.e., Research Nurse). The investigator, pharmacist, or appropriately qualified non-pharmacist must ensure:

3.1.1 The IP is used only in accordance with the approved protocol

3.1.2 The IP is received, stored, prepared, administered, shipped, and destroyed in accordance with the trial protocol, pharmacy manual, applicable regulatory requirements, and as specified by the sponsor. Consideration must be given to the security of the IP with restricted access to approved personnel.

3.2 Contracted Service to External providers - IP management must follow any processes agreed upon between the site(s), the contracted provider, and the sponsor. These may include but are not limited to Clinical Trial Agreements and existing contracts, approved quote documents/agreements, trial specific End-to-End (E2E) Process Documents, trial specific protocols, and Pharmacy Manuals.

4. Background

N/A.

5. Quality Management

All study personnel involved in the clinical study must operate within their scope of practice.

6. Supporting and Related Documents

SOP-04 Delegation of Duties
Decentralised Clinical Trials NZ NZ Glossary
Decentralised Clinical Trials NZ NZ Terms

7. Definitions

Refer to Decentralised Clinical Trials NZ Glossary
Decentralised Clinical Trials NZ Terms

8. Procedure

8.1. Prescribing

All prescriptions for the use of IP for clinical trials are completed in accordance with standard hospital prescription procedures, the study protocol, and/or Pharmacy Manual, and any applicable legislation.

8.2 Receipt and storage of investigational product

8.2.1 Ensure that the investigational product is received from the sponsor and stored respecting correct temperature control and provide maintenance and calibration records for storage equipment (e.g., refrigerators, thermometers) in accordance with sponsor requirements.

8.2.2 Ensure that any deviation to the required temperature, storage conditions, or potential defect/issue with the investigational product is notified to the sponsor in a timely manner and in accordance with the study protocol and/or Pharmacy Manual, following study site quarantine processes where applicable.

8.3 Transportation of investigational product to a satellite site (SS)

8.3.1 The shipment of product to the SS can be from either PS or Sponsor as detailed in the supervision plan.

8.3.2 Where the investigational product needs to be transported to, or returned from, a SS destination, the appropriate transfer method is to be used according to the protocol and sponsor's guidelines.

8.3.3 Correct documentation must accompany the shipment and must be filed accordingly.

8.3.4 The SS pharmacy that is receiving the IP will follow the process for IP management as outlined in the site-specific Supervision Plan.

8.4 Maintain records

The investigator, pharmacist or appropriately qualified non-pharmacist must maintain records of all aspects of the management of the IP. These records at a minimum should include dates, quantities, batch/serial/kit numbers, expiration dates (if applicable), and the unique code numbers of the trial participant.

8.5 Provide counselling on the use of IP

The investigator, pharmacist, or delegated study team member must explain the correct use of the IP to each participant and should check, at the intervals appropriate for the trial, that each participant is following the instructions properly.

8.5.1 When a participant is collecting medication from a SS under the Decentralised Clinical Trials NZ model, the satellite pharmacy must follow the process for IP management as outlined in the SS-specific Supervision Plan.

8.5.2 Study staff from the PS may be required to provide instructions and counselling on IP use over the phone if appropriate study staff are not available at the SS.

8.6 Randomisation and unblinding of investigational product

The investigator, pharmacist, or delegated study team member must follow the trial's randomisation and / or registration procedures for a non-randomised trial.

8.6.1 If the trial is blinded, the investigator must promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the IP.

8.7 Returns, reconciliation and destruction of investigational product

8.7.1 The return, reconciliation and destruction of IP (used and unused packets will be followed according to the supervision plan.

8.8 Recalls of investigational product

8.8.1 Procedures for retrieving IP and documentation of retrieval should be agreed upon by the sponsor, in collaboration with the manufacturer or importer where different. The investigator and monitor need to understand their obligations under the retrieval procedure.

8.8.2 The sponsor should ensure that the supplier of any comparator or other medication to be used in a clinical trial has a system for communicating to the sponsor the need to recall any product supplied.

9. Corrective Actions

All Decentralised Clinical Trials sites must follow this SOP. If a site is not able to follow the Decentralised Clinical Trials NZ SOP-05, this must be documented in Supervision Plan **/** individual site processes.

10. Training and Distribution

Training will be conducted at the Site Initiation Visit (SIV) by the study monitor on behalf of the sponsor or by the PI or delegate as appropriate to the delegated role. This can be performed either face-to-face or virtually and recorded on the training log.

11. Document Control & Change History

This SOP will be reviewed at least every 2 years.
If you have any queries regarding the information in this document, please forward details to the Decentralised Clinical Trials NZ Project Manager

Changes	Justification

12. External Related Documents/References

- VCCC-TT-SOP-01a v1.0: Teletrials Overarching Processes Developed by VCCC and PCCTU (based on COSA Australasian Tele-trials model) October 2018 https://vcccalliance.org.au › assets › Teletrials
- COSA Australasian Teletrial Model https://www.cosa.org.au/media/332607/introduction-to-the-cosa-australasian-tele-trial-model.pdf
- National Standard Operating Procedures for Clinical Trials, in Australia. 2020. https://www.health.gov.au/resources/collections/the-national-teletrials-compendium

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Internal Document Management

***Not for publication with the SOP

This page should be completed and retained with the master copy of the document, but should not be published for shared, public-facing documentation.

Formatting: All documents should be in Arial, with the main body being size 11.

****DOCUMENT IDENTIFICATION: Every Document must contain a footer in the format shown on this document in order for documents to be uniquely identifiable. All stand-alone Procedure/work instruction documents must contain a footer in this format****

SOP should not include a reference to a person's name but should be limited to the use of position titles/roles only.

1. Document Management

SOP Title:					
SOP Number:		**Version:**		**Effective Date:**	
Document Owner:		**Review Cycle:**		**Supersedes SOP:**	(if no document superseded, state 'New SOP')
Reviewed By:	(Name, position, organisation)			**Document Location:**	(Link to cloud based location)

2. Document History

Changes	Justification
New Document	