CLINICAL RESEARCH - INVESTIGATIONAL MEDICINAL PRODUCT RECEIPT AND STORAGE

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that IMP for clinical research is received, processed and stored in compliance with NSW Health, SCHN, regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the receipt, processing and storage of IMP for clinical research.

CHANGE SUMMARY

- Not applicable – New Sydney Children's Hospitals Network Procedure.

READ ACKNOWLEDGEMENT

- Training/Assessment Required – Personnel performing involved in the receipt, processing and storage of IMP for clinical research.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st August 2019	**Review Period**: 3 years
Team Leader:	Clinical Trials Program Manager	**Area/Dept**: Kids Research

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Purpose/Scope

The purpose of this procedure is to ensure that deliveries of IMP for clinical research are received, processed and stored in compliance with NSW Health, SCHN, regulatory and protocol requirements.

It is acknowledged that there may be some variations in the procedure for the receipt and storage of IMP depending upon the protocol-specific requirements dictated by the Sponsor or Delegate, and in accordance with risk-assessments made by Pharmacy, as applicable.

Adherence to this procedure will ensure that:

- Pharmacy personnel receiving deliveries promptly identify that the delivery contains IMP for clinical research purposes; and
- Deliveries of IMP are appropriately processed and stored by the Senior Clinical Trials Pharmacist or Delegate.

The procedure must be followed by all personnel involved in the receipt processing and storage of IMP for clinical research.

Background

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 4.6.1 and 4.6.2, responsibility for IMP at the Site is retained by the Investigator/Institution.

IMP may be provided to the Institution or Investigator by or on behalf of the Sponsor or Delegate for the purposes of conducting approved clinical research. The items supplies will be:

- Stored under the conditions specified by the Sponsor or Delegate, in accordance with all applicable NSW Health, SCHN, regulatory and Protocol requirements;
- Only to be used in accordance with, and for the purposes of, the approved clinical research for which it has been provided; and
- Handled in compliance with all requirements of NSW Health PD2013_043 – Medication Handling in NSW Public Health Facilities.

IMP for clinical research must not be shipped to the Site until all required regulatory approvals are in place.

The Sponsor or Delegate is responsible for notifying the Investigator or Delegate of the intention to ship a delivery of IMP, prior to its release, so the availability of local storage space can be assessed by the Senior Clinical Trials Pharmacist.

Procedure

Receipt

IMP for clinical research must be delivered via a courier or equivalent service, with tracking details, to the Pharmacy shipping address nominated by the Senior Clinical Trials Pharmacist or Delegate within standard operating hours, unless prior arrangements have been made.

On receipt, the receiver will acknowledge receipt of the delivery by SCHN through completion and/or signing of any shipping documentation required.

Deliveries of IMP for clinical research received by personnel other than the responsible Senior Clinical Trials Pharmacist or Delegate must be immediately transferred to the nominated shipping address and the responsible Senior Clinical Trials Pharmacist alerted. The package(s) must not be opened prior to transfer.

Processing

On receipt of the delivery, the IMP for clinical research will be thoroughly inspected by the Senior Clinical Trials Pharmacist or Delegate to confirm the:

- Use of the correct shipping address details and contact person(s);
- Protocol details to which the delivery relates;
- Integrity of the inner and outer packaging;
- Integrity of the required storage conditions during transit, with reference to the IB or equivalent, and any temperature monitoring devices (E.g. Temp-Tale) where provided;
- Integrity of the contents as free of breakages, spoilage or any other damage;
- Validity with reference to the delivery documentation including batch/lot and/or kit number(s), expiry/test-retest date(s) and the quantity supplied, as applicable; and
- Accuracy of any enclosed documentation (e.g. certificates of analysis/release and/or statements of compliance (as applicable)).

The processing of IMP that requires refrigerated, frozen or other special storage conditions, as specified on shipment documentation and/or IB, will be prioritised.

The Senior Clinical Trials Pharmacist or Delegate is responsible for acknowledging receipt of the shipment, and reporting any issues identified, according to the protocol-specific instructions provided by the Sponsor or Delegate.

The IMP Acknowledgement of Receipt Log (Appendix) is recommended for adaptation in the absence of protocol-specific instructions and/or systems being provided by the Sponsor or Delegate.

Whilst awaiting the advice of the Sponsor or Delegate in the event of any issues being identified at inspection, the IMP must be quarantined under appropriate storage conditions, in accordance with the SCHN Procedure – IMP Quarantine.

The Senior Clinical Trials Pharmacist or Delegate is responsible for taking action to rectify any issue(s) identified, in accordance with the instructions of the Sponsor or Delegate, as applicable.

The original of the IMP Acknowledgement of Receipt Log, as well as any corresponding documentation, must be filed in the TMF.

Storage

Full IMP accountability records for any IMP received must be maintained as per SCHN Procedure – Clinical Research - IMP Accountability.

Dedicated storage areas for IMP with temperature monitoring, maintained as per the SCHN Procedure – Clinical Research – IMP Temperature Monitoring, will be provided. Storage areas for IMP will be labelled with the protocol reference number or equivalent. Separate, segregated storage areas will be maintained for quarantined IMP until approved for use or destruction by the Sponsor or Delegate.

IMP will be stored in compliance with NSW Health PD2013_043 – Medication Handling in NSW Public Health Facilities and under the conditions specified by the Sponsor or Delegate.

IMP requiring refrigerated storage (2ºC to 8ºC) will be unpacked (with any gel packs and/or blue ice removed) prior to storage in the refrigerator.

IMP requiring frozen storage that is delivered in packages containing dry ice must be unpacked with reference to the precautions in SCHN Procedure – Clinical Research – Use of Dry Ice and promptly stored in the allocated freezer.

Exemptions

In some instances, the Sponsor, Investigator or their Delegates may recommend the storage of IMP for clinical research in an alternate secure location (e.g. outside of Pharmacy). This may be required if the IMP needs to be accessed in an emergency or outside of standard operating hours. In these cases, the above provisions for appropriate storage still apply.

The Senior Clinical Trials Pharmacist or Delegate will retain responsibility for completing the IMP Storage Location Assessment Form (Appendix) to assess the suitability of the proposed storage location.

The Senior Clinical Trials Pharmacist will be responsible for communicating the outcome of the assessment to the Investigator and Sponsor or Delegate, prior to the IMP being stored.

A copy of the IMP Storage Location Assessment Form as well as any corresponding documentation must be filed in the TMF.

Appendices

IMP Acknowledgement of Receipt Log

IMP Storage Location Assessment Form

Abbreviations and Definitions

IB	Investigators Brochure
C	Celsius
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
NSW	New South Wales
PD	Policy Directive
PSF	Pharmacy Site File
SCHN	Sydney Children's Hospitals Network
TGA	Therapeutic Goods Administration
TMF	Trial Master File

Related Documents

1. NSW Health PD2013_043 - Medication Handling in NSW Public Health Facilities - http://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2013_043
2. SCHN Policy – Clinical Research [DRAFT]
3. SCHN Policy – Clinical Research – Use of Pharmacy Services [DRAFT]
4. SCHN Policy 2014-9027 – Medication Handling in NSW Public Health Facilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3263
5. SCHN Procedure – Clinical Research - IMP Accountability http://webapps.schn.health.nsw.gov.au/epolicy/policy/4631
6. SCHN Procedure – Clinical Research - IMP Quarantine http://webapps.schn.health.nsw.gov.au/epolicy/policy/4630
7. SCHN Procedure – Clinical Research – IMP Ordering and Supply [DRAFT]
8. SCHN Procedure – Clinical Research – IMP Temperature Monitoring [DRAFT]
9. SCHN Procedure – Clinical Research – IMP Transit and Transfer [DRAFT]
10. SCHN Procedure 2019-027 – Clinical Research - Personnel Qualifications and Training Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
11. SCHN Procedure 2019-028- Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624

12. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
13. SCHN Procedure 2019-018 – Clinical Research – Use of Dry Ice - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4640
14. SCHN Procedure 2019-019 – Clinical Research - Use of Fridge(s) and Freezer(s) - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4642
15. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf