CLINICAL RESEARCH - INVESTIGATIONAL MEDICINAL PRODUCT QUARANTINE

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that unused or unfit IMP for clinical research identified by clinical research personnel, the Sponsor or Delegate, or the manufacturer as requiring quarantine is managed in compliance with NSW Health, SCHN, regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the handling of IMP for clinical research.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

- Training/Assessment Required – All personnel involved in the handling 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

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Background

IMP for clinical research may be deemed to be unfit for a variety of reasons, including, but not limited to:

- Deviations to required storage conditions including temperature excursions;
- Expiry;
- Recall; and/or
- Breakage, spoilage or any other damage.

Supplies of unused or unfit IMP for clinical research may require quarantine to protect against unintended use prior to their return to the Sponsor or Delegate or secure destruction by the Investigator or Delegate.

All records related to the quarantine of IMP will be maintained in accordance with the SCHN Procedure – Clinical Research – Record Keeping.

Procedure

Placing IMP into Quarantine

- The Senior Clinical Trials Pharmacist or Delegate is responsible for recording the details of any unused or unfit IMP identified on the IMP Quarantine Notice (Appendix);
- The IMP Quarantine Notice will reference the IMP (name ,strength, form), date placed into quarantine, quantity, batch/lot number(s), kits number(s) (if applicable); and the reason for quarantine;
- Unused or unfit IMP will be stored under the required storage conditions, in its original packaging, and an additional sealable container or bag, in dedicated quarantine storage areas within Pharmacy;
- The quarantine storage area(s) will be clearly marked and segregated from any storage areas used for any IMP suitable for use and/or any clinical research participant returns;
- The IMP Quarantine Notice (Appendix) will be placed with the unused or unfit IMP being placed into quarantine, in such a way that the details are clearly visible within the sealed container or bag;
- The Senior Clinical Trials Pharmacist or Delegate is responsible for promptly reporting any quarantine actions to the Sponsor or Delegate, as per the protocol-specific instructions of the Sponsor or Delegate;
- The IMP Quarantine Notice, as well as any other documentation or correspondence, is to be retained in the TMF and a copy returned to the Sponsor or Delegate(s), as required.

Releasing IMP from Quarantine

- The Senior Clinical Trials Pharmacist or Delegate is responsible for ensuring that written authorisation is provided by the Sponsor or Delegate for the release of IMP from quarantine;
- On receipt of written authorisation, the Senior Clinical Trials Pharmacist or Delegate will update the IMP Quarantine Notice noting the resolution and date of removal from quarantine;
- The IMP Quarantine Notice, as well as any other documentation or correspondence from the Sponsor or Delegate approving or disapproving use of IMP, is to be retained in the TMF and a copy returned to the Sponsor or Delegate(s), as required.

Appendices

IMP Quarantine Notice

Abbreviations and Definitions

GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
NSW	New South Wales
PD	Policy Directive
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 Destruction [DRAFT]
7. SCHN Procedure – Clinical Research - IMP Receipt and Storage [DRAFT]
8. SCHN Procedure – Clinical Research – IMP Temperature Monitoring [DRAFT]
9. SCHN Procedure 2019-027 – Clinical Research - Personnel Qualifications and Training Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
10. SCHN Procedure 2019-028 - Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624
11. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
12. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf