CLINICAL RESEARCH - INVESTIGATIONAL MEDICINAL PRODUCT ACCOUNTABILITY

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure consistency in the performance of accountability tasks for IMP used in clinical research, in compliance with NSW Health, SCHN, regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the conduct of clinical research involving IMP.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

Training/Assessment Required – Personnel performing accountability tasks for IMP used in 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 consistency in the performance of accountability tasks for IMP for clinical research, in compliance with NSW Health, SCHN, regulatory and protocol requirements.

Adherence to this procedure will ensure that:

- Detailed records of all occasions of the receipt, dispensing and return of IMP for clinical research are maintained;
- IMP for clinical research is managed in accordance with the protocol-specific instructions of the Sponsor or Delegate; and
- IMP for clinical research is only used in accordance with, and for the purposes of, the approved clinical research for which it has been provided.

The procedure must be followed by all personnel involved in performing accountability tasks for IMP used in 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.

The Investigator or Delegate is responsible for ensuring that detailed records of the receipt, dispensing and return of IMP for clinical research are maintained, and that IMP is only used in accordance with the approved protocol.

The records will serve as evidence that clinical research participants were dispensed the appropriate IMP, at the appropriate dose(s) and intervals, as defined by the protocol.

Procedure

- The Senior Clinical Trials Pharmacist or Delegate is responsible for maintaining accountability records detailing the receipt , dispensing and return of IMP for clinical research, as per the protocol-specific instructions of the Sponsor or Delegate;
- All accountability records will be maintained in accordance with the SCHN Procedure – Clinical Research – Record Keeping [DRAFT];
- Accountability records will include the specific details of the IMP (name ,strength, form), date(s), quantities, batch/lot number(s), expiry/test-retest date(s), and/or kit number(s) (as applicable);
- Adaptation of the IMP Accountability Logs (Master and Participant-Specific) (Appendix) is recommended in the absence of protocol-specific instructions and/or templates being provided by the Sponsor or Delegate;
- A blank copy of the IMP Accountability Logs (or equivalent), will be filed in the TMF at initiation of the clinical research to allow additional pages to be used for contemporaneous record keeping, as required;
- Any discrepancies identified though the performance of accountability tasks must be promptly reported according to the protocol-specific instructions of the Sponsor or Delegate;
- All discrepancies must be investigated until their resolution, and the outcome(s) and/or resolutions, agreed with the Sponsor or Delegate, clearly documented and filed in the TMF;
- Accountability tasks will continue until the Sponsor or Delegate has reviewed and authorised the final reconciliation of IMP for clinical research at the time of the close-out visit or equivalent;
- The original accountability records, and any corresponding documentation, must be retained in the TMF and a copy returned to the Sponsor or Delegate, where required.

Appendices

IMP Accountability (Master) Log

IMP Accountability (Participant-Specific) Log

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 https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_043.pdf
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 Destruction [DRAFT]
6. SCHN Procedure – Clinical Research – IMP Quarantine [DRAFT]
7. SCHN Procedure – Clinical Research - IMP Ordering and Supply [DRAFT]
8. SCHN Procedure - Clinical Research – IMP Preparation and Dispensing [DRAFT]
9. SCHN Procedure – Clinical Research – IMP Receipt and Storage [DRAFT]
10. SCHN Procedure – Clinical Research – IMP Temperature Monitoring [DRAFT]
11. SCHN Procedure – Clinical Research - IMP Transit and Transfer [DRAFT]
12. SCHN Procedure 2019-027 – Clinical Research - Personnel Qualifications and Training Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
13. SCHN Procedure 2019-028 - Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624
14. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
15. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf