CLINICAL RESEARCH - INVESTIGATIONAL MEDICINAL PRODUCT PRESCRIPTIONS

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that prescriptions for IMP for clinical research are created, approved, completed and authorised, in compliance with NSW Health, SCHN, regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the creation, approval, completion and authorisation of prescriptions for IMP used in clinical research.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

- Training/Assessment Required – Clinical research personnel involved in the creation, approval, completion and authorisation of prescriptions 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 that prescriptions for IMP used in clinical research are created, approved, completed and authorised, in incompliance with NSW Health, SCHN, regulatory and protocol requirements.

The procedure must be followed by all personnel involved in the creation, approval, completion and authorisation of prescriptions for IMP used in clinical research.

Procedure

Creation

- All prescriptions used in clinical research must meet the requirements of the NSW Health PD2013_043 – Medication Handling in NSW Public Health Facilities;
- The creation of protocol-specific prescription template(s) may be required in circumstances where:
  - The Sponsor has not provided a prescription template(s) for use; or
  - The Sponsor or Delegate has provided prescription template(s) that do not comply with local regulatory or other operational requirements; or
  - The standard Hospital prescription does not clearly delineate the prescription as being for clinical research purposes and/or allow all necessary aspects of the protocol to be adequately captured.
- If the creation of protocol-specific prescription template(s) is required, the Senior Clinical Trials Pharmacist or Delegate will prepare a draft, in consultation with the Investigator and Sponsor or Delegate;

- Adaptation of the IMP Prescription template (Appendix) is recommended to ensure consistency in capturing all pertinent information for clinical research prescribing, including, but not limited to:
  - Protocol details (number, full title)
  - Site number
  - Principal Investigator's name
  - Participant ID number/code
  - Participant height/weight and BSA (if applicable)
  - Arm/group allocation (if applicable/appropriate to disclose)
  - Protocol visit and/or time point (e.g. Visit 1 – Month 1 - Day 28)
  - IXRS pack or kit reference code(s) (if applicable)
  - Clinical Research Coordinator/Nurse name and contact details

Approval

- The protocol-specific prescription template(s) created must be reviewed and approved by the Investigator as well as the Sponsor or Delegate, prior to finalisation;
- A full audit trail, including appropriate version control, must be maintained in accordance with the SCHN Procedure – Clinical Research - Record Keeping;
- The protocol-specific prescription template(s) approved, as well as any corresponding documentation such as approvals, must be filed in the TMF;
- In the event of amendments to the protocol and/or systems that materially affect the validity of protocol-specific prescription template(s), a modified version of the protocol-specific prescription template(s) must be created, according to the procedure outlined above.

Completion & Authorisation

- All prescriptions used in clinical research must be completed and authorised (including signed and dated) by the Investigator or Delegate;
- The Investigator or Delegate must ensure that prescriptions used in clinical research are clear, legible and not open to misinterpretation.

Appendices

IMP Prescription

Abbreviations and Definitions

BSA	Body Surface Area
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
ID	Identification
IMP	Investigational Medicinal Product
IXRS	Interactive Voice/Web Response System
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 2019-027 – Clinical Research - Personnel Qualifications and Training Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
6. SCHN Procedure 2019-028 - Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624
7. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
8. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf