CLINICAL RESEARCH - INVESTIGATIONAL MEDICINAL PRODUCT PREPARATION AND DISPENSING

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that IMP for clinical research is prepared and dispensed in accordance with NSW Health, SCHN, regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the preparation and dispensing of IMP used in clinical research.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

- Training/Assessment Required –Personnel performing IMP preparation and dispensing for clinical research.

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

TABLE OF CONTENTS

Purpose/Scope

The purpose of this procedure is to ensure that IMP for clinical research is prepared and dispensed in accordance with NSW Health, SCHN, regulatory and protocol requirements.

Adherence to this procedure will ensure that IMP is accurately and safely prepared, dispensed (including packaged and labelled) and released to clinical research participants in a timely manner, as per the protocol.

The procedure must be followed by all personnel involved in the dispensing (including packaging and labelling) of IMP used in clinical research, as applicable.

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.

Preparation and dispensing practices for IMP for clinical research requires additional safeguards from standard clinical care practices due to the:

- Range and complexity of dosing regimens;
- Absence of full knowledge of adverse events /or anticipated outcomes from use in a given population; and
- The need to maintain the integrity of randomisation and/or blinding practices (as applicable).

Procedure

Preparation

- Prior to dispensing, the Senior Clinical Trials Pharmacist or Delegate will ensure that a record of the IMP for clinical research has been generated within the SCHN dispensing system, iPharmacy;
- The Investigator or Delegate must notify the Senior Clinical Trials Pharmacist or Delegate in the event that a potential clinical research participant is identified for screening and the outcome from screening, once known;
- The Investigator or Delegate will prepare and provide a prescription (electronic or paper) for dispensing IMP in accordance with the SCHN Procedure – Clinical Research – IMP Prescriptions;
- If IMP is to be administered by SCHN personnel the Investigator or Delegate will prepare a Medication Administration Record (MAR).
- The provision of the MAR and prescription is to be completed in advance of the proposed protocol-specific visit, where feasible. In such cases, the Investigator or Delegate must inform the Senior Clinical Trials Pharmacist of any cancellations and/or changes to the proposed visit date.

Review

- The Senior Clinical Trials Pharmacist or Delegate is responsible for thorough review of the prescription (electronic or paper) to ensure the entries are complete, legible, consistent and appropriately authorised;
- Special attention will be given to ensure consistency with the requirements of the current protocol and/or existing records relating to the clinical research participant, including IXRS (if applicable);
- Incomplete, unclear, inconsistent or incorrect prescriptions (electronic or paper) will be promptly returned to the Investigator or Delegate for correction;
- Any anomalies identified will be promptly communicated, discussed and clarified with the Investigator or Delegate, prior to the Senior Clinical Trials Pharmacist proceeding to dispensing.

Dispensing

- The Senior Clinical Trials Pharmacist or Delegate will perform dispensing in accordance with the protocol-specific instructions provided by the Sponsor or Delegate and all NSW Health, SCHN and regulatory requirements;
- The tasks performed will include, but are not limited to:
    - Collection of the IMP for clinical research required from its storage location;
    - Confirmation that the IMP is viable through visual inspection and cross-checking of the expiry or test-retest date

- Preparation of the IMP under appropriate conditions as per protocol requirements (e.g. sterile products must be produced in the aseptic suite);
- Packaging and labelling the IMP according to all applicable regulations and/or protocol requirements, ensuring the integrity of the blind (if applicable);
- Entering the details of the dispensing into the dispensing system, iPharmacy;
- Requesting that the dispensed IMP is checked against the prescription and all applicable regulations and/or protocol requirements by a second Pharmacist; and
- Updating all accountability records and/or systems, as per the SCHN Procedure – Clinical Research – IMP Accountability and SCHN Procedure – Clinical Research - Record Keeping.

- Once the IMP is ready for release, the Senior Clinical Trials Pharmacist or Delegate will notify the Investigator or Delegate;
- The Investigator or Delegate will ensure that counselling and/or education regarding the safe and appropriate use of the IMP, in accordance with the protocol, is provided;
- Supplementary counselling and/or education may be delivered verbally by the Senior Clinical Trials Pharmacist or Delegate, if responsible for the release of IMP to the clinical research participant;
- Any supplementary counselling and/or education will not replace nor negate the provision of any protocol-specific participant-facing information that has been approved for use by the responsible HREC and RGO;
- The Investigator will check, at intervals appropriate to the protocol and/or as outlined by the Sponsor and/or Delegate, that clinical research participants are following the instructions correctly and taking any action(s) required to remediate issues.

Abbreviations and Definitions

HREC	Human Research Ethics Committee
ICH	International Conference on Harmonisation
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
IXRS	Interactive Voice/Web Response System
MAR	Medication Administration Record
NSW	New South Wales
PD	Policy Directive
RGO	Research Governance Office
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. NSW Health PD 2015_007 - Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3516/
3. SCHN Policy – Clinical Research [DRAFT]
4. SCHN Policy – Clinical Research – Use of Pharmacy Services [DRAFT]
5. SCHN Policy 2014-9027 – Medication Handling in NSW Public Health Facilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3263/
6. SCHN Policy 2015-9008 - Pharmaceuticals - Preparation in Pharmacy Services - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3516
7. SCHN Procedure – Clinical Research – IMP Accountability http://webapps.schn.health.nsw.gov.au/epolicy/policy/4631
8. SCHN Procedure – Clinical Research – IMP Quarantine [DRAFT]
9. SCHN Procedure – Clinical Research – IMP Ordering and Supply [DRAFT]
10. SCHN Procedure – Clinical Research – IMP Prescriptions [DRAFT]
11. SCHN Procedure – Clinical Research - IMP Receipt and Storage [DRAFT]
12. SCHN Procedure – Clinical Research – IMP Transit and Transfer [DRAFT]
13. SCHN Procedure 2019-027 – Clinical Research - Personnel Qualifications and Training Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
14. SCHN Procedure 2019-028 - Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624
15. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
16. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf
17. TGA - PE009-13 - The PIC/S guide to GMP for medicinal products - TGA interpretation and expectations for demonstrating compliance - Version 1.0, December 2017 - https://www.tga.gov.au/sites/default/files/pe009-13-pics-guide-gmp-medicinal-products.pdf
18. TGA - Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-Operation Scheme – Guide to Good Manufacturing Practice for Medicinal Products Annexes - https://www.tga.gov.au/sites/default/files/manuf-pics-gmp-medicines-annexes.pdf
19. TGA - Standard for the Uniform Scheduling of Medicines and Poisons - https://www.tga.gov.au/publication/poisons-standard-susmp