CLINICAL RESEARCH - INVESTIGATIONAL MEDICINAL PRODUCT TEMPERATURE MONITORING

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that the quality and integrity of IMP for clinical research is maintained through consistent temperature monitoring practices of IMP storage locations;
- 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 – 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

TABLE OF CONTENTS

Purpose/Scope

The purpose of this procedure is to ensure that the quality and integrity of IMP is maintained through consistent temperature monitoring practices of IMP storage locations, in compliance with NSW Health, SCHN, regulatory and protocol requirements.

Adherence to this procedure will ensure that:

- A valid, continuous record of temperature is available for all locations used for the storage of IMP for clinical research; and
- Temperature deviations are promptly identified, escalated and acted upon, as appropriate, in consultation with the Sponsor or Delegate.

The procedure must be followed by all personnel involved in the handling 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 for clinical research must be stored under suitable storage conditions at all times, as per the SCHN Procedure 2019-009 – Clinical Research – IMP Receipt and Storage. Continuous temperature monitoring of the locations used for IMP storage is vital to assuring the integrity and quality of IMP.

The Investigator or Delegate is responsible for ensuring that any deviations from this procedure, due to the approved storage of IMP in locations outside of Pharmacy, are appropriate documented and filed in the TMF.

Procedure

Systems

- Continuous temperature monitoring of refrigerators and freezers used for the storage of IMP for clinical research is provided via the Matos Monitoring System;
- Continuous temperature monitoring of ambient storage areas used for the storage of IMP for clinical research is provided via the Building Management System (BMS);
- Fridges, freezers, and associated monitoring systems are maintained in accordance with the SCHN Procedure 2019-010 – Equipment and/or Supplies – Maintenance and Calibration;
- The acceptable temperatures for IMP storage locations are as follows: Ambient: 15ºC to 25ºC, Refrigerated: 2ºC to 8ºC, Frozen: -15°C and -25°C or as otherwise defined;
- Notifications are issued by the Matos Monitoring System via SMS in the event of temperature breaches, power failures and/or network failure for action by designated personnel;
- The use of separate temperature loggers (e.g. temp-tales) for protocol-specific temperature monitoring of IMP in shared Pharmacy storage locations is not permitted.

Monitoring

- The Senior Clinical Trials Pharmacist or Delegate will access and review temperature monitoring records for designated IMP storage locations on a daily basis (with the exception of weekends and public holidays);
- The minimum and maximum temperature for each IMP storage location will be recorded on the IMP Temperature Monitoring Log (Appendix) and a cumulative graph(s) of temperature generated at the end of each month;
- Where continuous temperature monitoring occurs, a weekly print-out of the graphs will be filed in a central folder;
- The IMP Temperature Monitoring Log and cumulative graph(s) will be stored in a master file accessible to the Pharmacy personnel responsible for the designated IMP storage location(s);
- Complete temperature records will be made available for inspection by Sponsors or Delegates on request to the Senior Clinical Trials Pharmacist or Delegate, or at routine monitoring visits;

Excursions

- In the event of a true temperature excursion, the Senior Clinical Trials Pharmacist is responsible for:
    - Determining the cause of the excursion and instigating corrective action, if feasible;

- Promptly reporting the excursion according to the protocol-specific instructions of the Sponsor or Delegate, and providing a copy of the IMP Temperature Monitoring Log and/or cumulative graph;
- Placing the IMP into quarantine in accordance with the SCHN Procedure – Clinical Research - IMP Quarantine until such time that further instruction is received from the Sponsor or Delegate; and
- If the IMP is deemed to be unfit for use, advising the Investigator or Delegate of the temperature excursion so that alternative arrangements can be made for any imminent visits requiring dispensing (if applicable);

- False temperature excursions, displaying as sharp peaks on the cumulative graph(s), may occur due to opening or closing the fridge and/or freezer during re-stocking. Such excursions will only be reported if substantiated by the receipt of an alert from the Matos Monitoring System;
- If no alert is received, the Senior Clinical Trials Pharmacist will initial and date the corresponding graph(s) noting the occurrence as a 'False Temperature Excursion';
- The original of the IMP Temperature Monitoring Log, graphs and any corresponding documentation, must be filed in the TMF, and a copy provided to the Sponsor or Delegate, as required.

Faults

- In the event of a suspected fault to the temperature monitoring system(s), the Senior Clinical Trials Pharmacist is responsible for:
  - Notifying designated personnel to request that checks of the power, air conditioning, and/or associated systems are undertaken (as appropriate); and
  - Placing the IMP into quarantine in accordance with the SCHN Procedure – Clinical Research - IMP Quarantine until such time that further instruction is received.

Appendices

IMP Temperature Monitoring Log

Abbreviations and Definitions

BMS	Building Management System
C	Celsius
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
ISF	Investigator Site File

IMP	Investigational Medicinal Product
NSW	New South Wales
PD	Policy Directive
SCHN	Sydney Children's Hospitals Network
SMS	Short Message Service
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 2019-010 – Clinical Research - Equipment and/or Supplies - Maintenance and Calibration - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4622
6. SCHN Procedure – Clinical Research - IMP Accountability http://webapps.schn.health.nsw.gov.au/epolicy/policy/4631
7. SCHN Procedure – Clinical Research IMP Receipt and Storage http://webapps.schn.health.nsw.gov.au/epolicy/policy/4628
8. SCHN Procedure – Clinical Research – IMP Quarantine http://webapps.schn.health.nsw.gov.au/epolicy/policy/4630
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