CLINICAL RESEARCH - INVESTIGATIONAL MEDICINAL PRODUCT DESTRUCTION

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that unused or unfit IMP, authorised for disposal by the Sponsor or Delegate, is disposed of in compliance with NSW Health, SCHN and regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the destruction of IMP for clinical research.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

- Training/Assessment Required – Personnel performing IMP destruction 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

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

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Purpose/Scope

The purpose of this procedure is to ensure that unused or unfit IMP, authorised for disposal by the Sponsor or Delegate, is disposed of in compliance with NSW Health, SCHN and regulatory and protocol requirements.

This procedure must be followed by all personnel involved in the disposal of IMP for clinical research.

Background

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Sponsor is responsible for maintaining a system for retrieving IMP and documenting the retrieval (e.g. for deficient product recall, reclaim after trial completion, expired product reclaim) (Section 5.1.14.4c).

The Sponsor may elect for unused or unfit IMP for clinical research to be either returned to the Sponsor or Delegate for destruction or sent for secure destruction by the Investigator or Delegate, as per the protocol-specific arrangements made prior to initiation of the clinical research.

Guidance regarding the return of IMP for clinical research to the Sponsor or Delegate for destruction is addressed in the SCHN Procedure - Clinical Research - IMP Transit and Transfer.

Procedure

- The Senior Clinical Trials Pharmacist or Delegate is responsible for ensuring that written authorisation is provided by the Sponsor or Delegate for the disposal of IMP for clinical research by the Site;

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- Tasks related to the disposal of IMP for clinical research by the Site must only be performed after the IMP has been fully accounted for and reconciled as per the SCHN Procedure – Clinical Research - IMP Accountability [DRAFT];
- A full audit trail for all actions taken must be maintained in accordance with the SCHN Procedure – Clinical Research - Record Keeping [DRAFT];
- On receipt of written authorisation, the Senior Clinical Trials Pharmacist or Delegate must update the destruction-related documentation provided by the Sponsor or Delegate;
- The IMP Destruction Certificate (Appendix) is recommended for adaptation in the absence of protocol-specific documentation being provided by the Sponsor or Delegate;
- Documentation must identify the:
    - IMP description (name, strength, form);
    - Batch/lot or kit number(s);
    - Expiry/re-test date(s);
    - Quantity;
    - Date of action;
    - Name and initials of the Senior Clinical Trials Pharmacist or Delegate(s) performing the action; and
    - Name and initials of a witness
- The Senior Clinical Trials Pharmacist or Delegate must ensure that all labels or markings containing participant or prescriber identifying information, including dispensing labels, are removed in full;
- The disposal of IMP for clinical research by the Site will comply with the requirements of the SCHN Policy 2015-9070 – Waste Management and NSW Health PD2017_026 - Clinical and Related Waste Management for Health Services;
- Additional requirements as per the SCHN NSW Health PD2013_043 - Medication Handling in NSW Public Health Facilities – must be complied with for the disposal of IMP for clinical research classified as S8 medications;
- The details of the licensed external waste disposal service provider contracted by SCHN for the management of pharmaceutical waste can be provided to the Sponsor or Delegate, on request;
- The original of the IMP Destruction Certificate, as well as any corresponding documentation, must be filed in the TMF, with a copy provided to the Sponsor or Delegate, if required.

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Appendices

IMP Destruction Certificate

Abbreviations and Definitions

GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
NSW	New South Wales
PD	Policy Directive
S8	Schedule 8
SCHN	Sydney Children's Hospitals Network
TGA	Therapeutic Goods Administration
TMF	Trial Master File

Related Documents

1. NSW Health PD2017_026 - Clinical and Related Waste Management for Health Services - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_026.pdf
2. NSW Health PD2013_043 - Medication Handling in NSW Public Health Facilities - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_043.pdf
3. NSW Health PD 2015_007 - Pharmaceuticals - Preparation in NSW Public Health Facility Pharmacy Services - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3516/
4. SCHN Policy – Clinical Research [DRAFT]
5. SCHN Policy – Clinical Research – Use of Pharmacy Services [DRAFT]
6. SCHN Policy 2014-9027 – Medication Handling in NSW Public Health Facilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3263/
7. SCHN Policy 2015-9008 – Pharmaceuticals - Preparation in Pharmacy Services - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3516/
8. SCHN Policy 2015-9070 – Waste Management - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3649/
9. SCHN Procedure – Clinical Research – IMP Accountability [http://webapps.schn.health.nsw.gov.au/epolicy/policy/4631
10. SCHN Procedure 2019-027– Clinical Research - Personnel Qualifications and Training Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
11. SCHN Procedure 2019-028- Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624
12. SCHN Procedure - Clinical Research - IMP Transit and Transfer [DRAFT].
13. SCHN Procedure – Clinical Research - Record Keeping http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661
14. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf

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