CLINICAL RESEARCH - EQUIPMENT AND SUPPLIES – RECEIPT AND STORAGE

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that equipment and/or supplies for clinical research are received, processed, evaluated and stored in compliance with NSW Health, SCHN, regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the use and/or management of equipment and supplies for clinical research.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

- Read Acknowledge Only – All personnel involved in the conduct of clinical research involving equipment and/or supplies.

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 March 2019	**Review Period**: 3 years
Team Leader:	Clinical Trials Program Manager	**Area/Dept**: Kids Research Institute

TABLE OF CONTENTS

Purpose/Scope

The purpose of this procedure is to ensure that deliveries of equipment and/or supplies (excluding IMP) for clinical research are received, processed, evaluated and stored in compliance with NSW Health, SCHN, regulatory and Protocol requirements.

Adherence to this procedure will ensure that:

- Investigators or Delegates receiving deliveries promptly identify that the delivery contains equipment/supplies for clinical research purposes;
- Deliveries of equipment and/or supplies are appropriately processed, evaluated and stored by the Investigator or Delegate.

The procedure must be followed by all personnel involved in the receipt and storage of equipment and/or supplies for clinical research.

Background

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 4.2.3, the Investigator should have access to adequate facilities, including any equipment and/or supplies required to conduct approved clinical research properly and safety.

Equipment and/or supplies may be provided to the Institution or Investigator by or on behalf of the Sponsor or Delegate for the purposes of conducting approved clinical research. The items supplies will be:

- Stored under the conditions specified by the Sponsor or Delegate, in accordance with all applicable NSW Health, SCHN, regulatory and Protocol requirements; and
- Only to be used in accordance with, and for the purposes of, the approved clinical research for which it has been provided.

It is recommended that the Investigator assigns some or all duties relating to the receipt and storage of equipment and supplies for clinical research to appropriately qualified and trained personnel operating under their supervision, in accordance with the SCHN Procedure –Clinical Research – Personnel Roles and Responsibilities [DRAFT].

Procedure

Pre-Receipt

Prior to the initiation of clinical research, the Investigator or Delegate is responsible for contacting the Department of Biomedical Engineering with regards to any clinical research that involves the supply of biomedical equipment, so that the suitability of items intended to be provided can be assessed.

Arrangements for the provision of equipment must be documented in an Agreement(s), detailing the responsibilities for:

- Proper use;
- Ownership;
- Insurance and indemnity;
- Associated costs;
- Training and/or certifying users (including the development, provision, access and ownership to any associated resources);
- Quality assurance (e.g. accountability);
- Storage (including any security requirements);
- Maintenance and calibration; and
- Transfer, transit and/or return(s).

The Sponsor or Delegate is responsible for notifying the Investigator or Delegate of the intention to ship a delivery of equipment and/or supplies, prior to its release, so the availability of local storage space can be assessed.

Receipt

Equipment and/or supplies must be delivered to the shipping address nominated by the responsible Investigator or Delegate within standard operating hours, unless prior arrangements have been made;

On receipt the receiver will acknowledge receipt of the delivery by SCHN through completion and/or signing of any shipping documentation required and notification of the addressee.

Processing

On receipt of the delivery, the equipment and/or supplies will be thoroughly inspected to confirm the:

- Use of the correct shipping address details and contact person(s);
- Protocol details to which the delivery relates;
- Integrity of the inner and outer packaging;
- Integrity of the required storage conditions during transit (if applicable);
- Integrity of the contents as free of breakages, spoilage or any other damage; and
- Validity with reference to the order and delivery documentation including shipment reference number(s), expiry/test-retest date(s) and the quantity supplied, as applicable.

The processing of equipment and/or supplies that require refrigerated, frozen or other special storage conditions, as identified by the presence of markings, wording and/or symbols on the package(s), will be prioritised.

The Investigator or Delegate is responsible for acknowledging receipt of the package, and reporting any issues identified at inspection to the Sponsor or Delegate, according to the protocol-specific instructions provided by the Sponsor or Delegate.

The Equipment and/or Supplies Acknowledgement of Receipt Log or equivalent is recommended for adaptation in the absence of protocol-specific instructions being provided by the Sponsor or Delegate.

Whilst awaiting the advice of the Sponsor or Delegate in the event of any issues being identified at inspection, the equipment and/or supplies must be clearly marked as 'Not For Use' in their storage location.

The original of the Equipment and/or Supplies Acknowledgement of Receipt Log or equivalent, as well as any corresponding documentation, must be filed in the TMF.

Evaluation

Items of biomedical equipment and/or supplies will require evaluation to ensure the item(s) are compliant with applicable safety and quality standards (AS3551), as well as approved for use by the TGA.

The item(s) must be provided to the Department of Biomedical Engineering at receipt, along with a copy of the executed Agreement referencing the item(s), any prior correspondence with the Department during the planning stage and the TGA conformity assessment certificate(s), if available.

The item(s) must be made accessible to the Department of Biomedical Engineering at a mutually agreed time for evaluation. Whilst evaluation is pending, the item(s) must be clearly marked as 'Not For Use' in their storage location.

After evaluating the item(s), the Department of Biomedical Engineering will be responsible for:

- Communicating the outcome of the evaluation to the Investigator or Delegate; and
- Maintaining documentation related to the evaluation of the item(s) including tagging of the item with a Safety Test Label to indicate the approved period of safe usage;
- Providing a copy of any documentation to the Investigator or Delegate for filing in the TMF.

Storage

Space for the storage of equipment and/or supplies for clinical research in the Clinical Research Centre is allocated at the project assessment stage via the SCHN CRC Operations Committee. At the time such approved items are placed, the Operations Team should be notified to ensure the item(s) are included in the asset list.

Space for the storage of equipment and/or supplies outside of the Clinical Research Centre or in addition to previously allocated space(s), must be sought via the responsible Head of Department or Delegate prior to any placement of the item(s).

Equipment and/or supplies placed in common areas must be labelled with the protocol reference number, Investigators name, SSA reference number, and approved storage location.

The details of the item(s), as well as their approved storage location should be detailed in accordance with the protocol-specific instructions of the Sponsor or Delegate. The Equipment and/or Supplies Log or equivalent is recommended for adaptation in the absence of protocol-specific instructions being provided by the Sponsor or Delegate.

The original of the Equipment and/or Supplies Log or equivalent, as well as any corresponding documentation, must be filed in the TMF.

Exemptions

In some instances, the Sponsor, Investigator or their Delegates may recommend the storage of equipment and/or supplies for clinical research in an alternate location (e.g. outside of SCHN).

In these cases, the provisions for assuring equipment and supplies are received, processed, evaluated and stored in compliance with NSW Health, SCHN, regulatory and Protocol requirements, still apply.

The Investigator or Delegate will retain responsibility for assessing the proposed storage area for the equipment and/or supplies to ensure it is safe, secure and compliant with all requirements.

Appendices

Equipment and/or Supplies Acknowledgement of Receipt

Equipment and/or Supplies Log

Abbreviations and Definitions

Biomedical Equipment	Any instrument, apparatus or appliance, including software, whether used alone or in combination which makes physical or electrical contact with the patient or transfers energy from or to the patient, or detects such energy transfer to or from the patient, and is intended to diagnose, treat or monitor the patient.
Equipment	Any instrument, apparatus or appliance, including software, regardless of its intended purpose.
IMP	Investigational Medicinal Product
NSW	New South Wales
NUM	Nurse Unit Manager
PD	Policy Directive
Safety Test Label	A label attached to biomedical equipment and its associated detachable mains supply cable (if applicable) indicating the next test date, the service entity undertaking the test and that testing has been completed in accordance with AS/NZS3551.
SCHN	Sydney Children's Hospitals Network

Software	A program or a set of instructions and applications used to manage and control various functions of a device such as a computer.
SSA	Site Specific Assessment
Supplies	Item(s) provided for the purposes of clinical research that do not meet the definition of Equipment.
TGA	Therapeutic Goods Administration
TMF	Trial Master File

Related Documents

1. Australian Regulatory Guidelines for Medical Devices (ARGMD) Version 1.1 dated May-2011 - https://www.tga.gov.au/sites/default/files/devices-argmd-01.pdf
2. Australian Standard, AS/NZS3551 - Technical Management Programs for Medical Devices - https://www.standards.org.au/
3. SCHN Policy – Clinical Research [DRAFT]
4. SCHN Policy - Evaluation, Loan or Rental of Biomedical Equipment [DRAFT]
5. SCHN Policy - Testing, Tagging and Labelling of Biomedical Equipment [DRAFT]
6. SCHN Procedure – Clinical Research - Equipment and Supplies – Maintenance and Calibration [DRAFT]
7. SCHN Procedure – Clinical Research - Investigational Medicinal Product Receipt and Storage [DRAFT]
8. SCHN Procedure – Clinical Research - Personnel Qualifications and Training Records – [DRAFT]
9. SCHN Procedure - Clinical Research – Personnel Roles and Responsibilities [DRAFT]
10. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
11. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf