CLINICAL RESEARCH - EQUIPMENT AND SUPPLIES – MAINTENANCE AND CALIBRATION

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that equipment and/or supplies for clinical research are maintained and calibrated (if applicable) 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/or 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

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Purpose/Scope

The purpose of this procedure is to ensure that equipment and/or supplies (excluding IMP) for clinical research are maintained and calibrated (if applicable) in accordance with NSW Health, SCHN, regulatory, Protocol requirements as well as the recommendations of the manufacturer.

Adherence to this procedure will ensure that:

- Responsibilities for the maintenance and calibration (if applicable) of equipment and/or supplies for clinical research are clearly defined;
- Equipment and/or supplies remain in good working order and available for use by Investigators or Delegates in accordance with, and for the purposes of, the approved clinical research.

The procedure must be followed by all personnel involved in the use 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.

Such 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.

General use (e.g. shared) equipment and/or supplies at SCHN may also be utilised for the performance of assessments and procedures for clinical research purposes. These items of equipment and/or supplies could be located in a variety of departments, wards and/or clinics owned or accessible to SCHN personnel.

It is recommended that the Investigator assigns some or all duties relating to the maintenance and calibration (if applicable) 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

Maintenance and Calibration

General Use Equipment and Supplies

- General use standard equipment will be maintained and calibrated (if applicable) by the Department of Biomedical Engineering (Biomedical Equipment) or the Maintenance Department (Non-Biomedical Equipment) or Delegate;

- Highly specialised equipment and/or supplies will be maintained and calibrated (if applicable) via the engagement of appropriately qualified, internal or external technicians, in accordance with the recommendations of the manufacturer by the Department responsible for the item(s);
- The frequency of maintenance and calibration (if required) for item(s) of equipment and/or supplies is as defined in AS/NZS3551 (usually annually) unless variation is warranted as a result of risk assessments via the Department responsible;
- Evidence for the maintenance and/or calibration of equipment and/or supplies will be demonstrated through the presence of tags and/or labels indicating the date of testing/re-testing or equivalent;
- Any equipment and/or supplies reported as being faulty or damaged by user(s) will be isolated and labelled by the Department and ideally stored in a segregated location to avoid misuse;
- Original records of the maintenance and calibration (if applicable) of general use equipment and/or supplies will be maintained by the Department responsible for these tasks;
- It remains the Investigator or Delegate's responsibly to request a copy of this documentation for any general use equipment and/or supplies being used for clinical research purposes, to ensure adequate records are maintained in the TMF.

Study-Specific Equipment and Supplies

- If equipment and/or supplies are provided to the Institution or Investigator by or on behalf of the Sponsor or Delegate for the purposes of conducting approved clinical research, the Investigator or Delegate must ensure that adequate measures are in place to guarantee the security, safety and integrity of the item(s) provided;
- The Investigator or Delegate retains responsibility for the liaising with the Sponsor or Delegate to ensure that arrangements for maintenance and calibration (if applicable) are enacted, in accordance with the Agreement(s);
- Maintenance and calibration (if applicable) may be performed via the engagement of appropriately qualified, internal or external technicians, in accordance with the recommendations of the manufacturer by the Investigator or Delegate;
- Arrangements for on-premises maintenance and calibration (if applicable) must be made by the Investigator or Delegate, in consultation with the relevant Department Head or Delegate;
- Any such maintenance and calibration (if applicable) must be performed at the expense of the Sponsor or Delegate in accordance with the SCHN Procedure – Financial Management;
- Evidence for the maintenance and/or calibration of equipment and/or supplies will be demonstrated through the presence of tags and/or labels indicating the date of testing/re-testing or equivalent;

- Any equipment and/or supplies reported as being faulty or damaged by user(s) will be isolated and labelled by the Investigator or Delegate and ideally stored in a segregated location to avoid misuse;
- Original records of the maintenance and calibration (if applicable) of study-specific equipment and/or supplies will be maintained by the Investigator or Delegate and filed as part of the TMF, according to the protocol-specific instructions provided by 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.

Returns

Study-Specific Equipment and Supplies

- At the completion of the clinical research or at the Sponsor or Delegate's request, the Investigator or Delegate will return (unless otherwise agreed), the equipment and/or supplies provided, at the expense of the Sponsor;
- It is not acceptable for equipment and/or supplies to continue to be stored in allocated space(s) after the completion of the clinical research;
- The date on which the equipment and/or supplies are returned must be detailed in accordance with the instructions of the Sponsor or Delegate, if provided, and filed in the TMF.

Appendices

Equipment/Supplies Log

Equipment/Supplies Maintenance & Calibration Log

Abbreviations and Definitions

AS	Australian Standard
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

NZS	New Zealand Standard
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.
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 Standard, AS/NZS3551 - Technical Management Programs for Medical Devices - https://www.standards.org.au/
2. SCHN Policy – Clinical Research [DRAFT]
3. SCHN Policy - Evaluation, Loan or Rental of Biomedical Equipment [DRAFT]
4. SCHN Policy - Testing, Tagging and Labelling of Biomedical Equipment [DRAFT]
5. SCHN Procedure – Clinical Research - Equipment and Supplies – Receipt and Storage [DRAFT]
6. SCHN Procedure – Clinical Research - Financial Management [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