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Managing Medical Devices

SOP No.: SOP_CTSU_016

Version No.: 2.0

Effective Date: 1 June 2023

Supersedes: SOP_CTSU_016 Managing Medical Devices Version 1.0 dated 1 July 2020

Review Date: 29 May 2026

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Date	June 2023	June 2023	June 2023
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1.0 Introduction / Background

A medical device is any instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. This includes artificial body parts (prostheses), any surgical, diagnostic or monitoring equipment/devices, as well as advanced, implanted devices such as pacemakers and neuro-stimulators.

Medical devices are classified based on their intended use, invasiveness, duration of use, and the risks and potential harms associated with their use. The Therapeutic Goods Administration (TGA) Australia provides an overview of the classes on their website.

Device trials must be conducted in accordance with ISO standard 14155 on the Clinical Investigation of Medical Devices on human subjects under the Therapeutic Goods (Medical Devices) Regulations (2002). However, many of the principles of ICH-GCP are also found in the device regulations and standards.

2.0 Objective

To describe the requirements for the inventory/receipt, storage, returns and destruction of a medical device being used for a clinical trial in accordance with ISO standard 14155, principles of ICH GCP and all other appropriate regulatory requirements.

3.0 Scope

This SOP applies to all staff involved in clinical trials at SWSLHD and the Ingham Institute.

4.0 Ownership and Responsibility

This SOP applies to those members of the study team involved in the process of receipt, storage, dispensing, and return or destruction of Investigational Product (IP). These include the following:

- Principal Investigator (PI)
- Clinical Trial Coordinator (CTC)
- Research Nurse
- Support Staff

5.0 Associate Documents

SOP_CTSU_02 Investigator Responsibilities

FM_35_Participant Medical Device Accountability Log

FM_36_ Medical Device Receipt and Returns Log

6.0 Procedure

Before a clinical trial involving a new device commences, the proposed study and device must undergo a review and notification process to ensure the safety of study participants. The following steps are required;

6.1 The proposed clinical trial and associated documents must be reviewed and approved by a Human Research Ethics Committee (HREC)

6.2 The site(s) at which the trial is proposed to take place will perform a Research Governance review, in order to decide if the study is appropriate for the site to conduct. This process takes into consideration the feasibility of the clinical trial at the site. Refer to SOP_CTSU_04 Clinical trial start up for further guidance.

6.3 If the device is new or unapproved the Sponsor must notify or submit an application via the Clinical Trial Notification (CTN) or Clinical Trial Application (CTA) scheme to the Therapeutics Goods Australia (TGA) prior to the clinical trial being conducted at the site. If the device is already approved and will be used as per its approved use, then neither of these is required. The decision regarding which scheme to use relies on the availability and quality of preclinical safety data for the device that is provided by the Sponsor to the TGA.

6.4 Receipt and Inventory of the clinical trial device

Upon receipt of the study device, inventory the shipment, ensuring that the information on the packing slips matches exactly with what has been sent to the site.

Document verification of the following information where applicable and as directed in the protocol. Ensure that the following items are documented in a separate log;

- Receipt date
- Lot, serial, or model numbers as applicable
- Device type/batch number or code mark as applicable
- Quantity per carrier/container

Ensure the device(s) labelling clearly states investigational use and includes any applicable warnings or precautions. Under no circumstances do not re-label, deface, or change the labelling without prior written permission of the Sponsor. If the sponsor includes a form in the shipment to acknowledge receipt, obtain the appropriate signature and forward the form to the sponsor as soon as possible. At this point also document and inform the

Sponsor/CRO of any concerns regarding the clinical trial device and have this rectified as soon as reasonably possible.

Retain a copy of shipping documents and packing slips and file in the appropriate section of the Investigator Site File (ISF) or eISF.

6.5 Storage of the clinical trial device

Ensure inappropriate or inadvertent use of the device does not occur by storing the study device in a secure environment with access limited to essential research personnel. Maintain a storage area temperature log, if appropriate.

Ensure the study device is stored in the appropriate environmental conditions and temperature in accord with details in the protocol or supplied by the sponsor in a supplementary document

6.6 Use and dispensing of the clinical trial device

Ensure that each time the study device is used/dispensed, the applicable device accountability form is completed using the FM_035 Participant Investigational Device Accountability log.

The log will facilitate the required documentation which includes, but is not limited to:

- Quantity and lot number dispensed
- Name and signature of the individual dispensing study device
- Protocol number and Principal Investigator name
- Date and time dispensing

Ensure that study device supplies are adequate and within the appropriate expiration date. Inform the Monitor/CRA when additional supplies are required and arrange delivery to the site.

6.7 Monitoring of the clinical trial device

In accordance with the clinical trial protocol and manufacturer guidelines provided by the Sponsor, ensure appropriate measures are taken at assigned intervals for maintenance of the device such as ensuring the appropriate storage of the device and ensuring calibration requirements are met.

6.8 Return/Destruction of the clinical trial device

At the end of the study, ensure all documentation regarding the receipt, storage, dispensing, and return of used containers is complete, accurate, and ready for review and verification at the monitors/CRA's study close-out visit.

Ensure that unused study device is available for the monitor to inventory and prepare for return shipment to the sponsor.

In any instance where the unsuccessful use of the medical device, or at the end of the study, follow the sponsor's instructions for containing/packaging the device for a return shipment as appropriate. If any containers/units are missing, document the reasons.

Each time return of the study device to the sponsor is necessary, the applicable device form is documented using FM_036_Medical Device Receipt and Returns Log

Destruction of the study device at the site requires written authorization from the Sponsor/CRO and adherence to NSW Health Policy and guidelines. The destruction of the Medical device is required to be documented using the FM_036_Medical Device Receipt and returns Log.

Maintain a copy of all accountability logs and associated documentation in the appropriate section of the electronic Investigator Site File (eISF)

7.0 References

ICH GCP (E6 R2): Good Clinical Practice Guidelines - Annotated by TGA

National Statement on Ethical Conduct in Human Research (2018)

Australian Code for the Responsible Conduct of Research (2018)

Australian regulatory guidelines for medical devices (ARGMD)

8.0 Amendment History

Version	Date	Amended by	Details of Amendment
1.0	1 July 2020	Kelsey Dobell-Brown	Due to operational changes and accreditation requirements, inclusive of changing the naming convention of GCP to SOP_CTSU
2.0	1 June 2023	Kelsey Dobell-Brown	Review of V1.0 to update any superseded links and processes

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