Western Health

STANDARD OPERATING PROCEDURE

Receipt and Handling of Investigational Product

Standard Operating Procedure

Western Health

SOP reference	005
Version:	3.0 dated June 2019
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Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	

Amendment History

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

1. AIM

To describe the procedures related to receipt and handling of investigational product.

2. SCOPE

Applicable to all clinical research projects undertaken at Western Health (WH), including Investigator initiated research, collaborative research and all phases of clinical investigation for medicinal products, medical devices and diagnostics for which WH is responsible for the conduct of the trials as a site study

3. APPLICABILITY

Principal Investigator (PI), Associate Investigator(s), research coordinators, Pharmacists, Pharmacy staff and other staff delegated research/trial-related activities by the PI.

4. PROCEDURE

For investigator initiated trials where WH is also the sponsor, obligations owed to or emanating from sponsor should be interpreted to mean WH.

4.1. Receipt and handling of investigational product

Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution. ICH GCP 4.6.1

STEP	ACTION
4.1.1	Where allowed or required, the institution should assign the responsibility for receipt and handling of investigational product to a pharmacist or suitably qualified person who is authorised to dispense study medication and who is under the supervision of the investigator/institution, as indicated on the site signature log. **ICH GCP 4.6.2**

The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should ICH GCP 4.6.3:

STEP	ACTION
4.1.2	Maintain records of the product's delivery and receipt to the study site, the inventory at the site, the use by each participant, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial participants.
4.1.3	Ensure that the investigational product(s) are stored as specified by the sponsor in accordance with applicable regulatory requirement(s). Consideration should be given to how the investigational product shall be securely stored, including restricting access to approved personnel. Records of accountability and storage monitoring (i.e. temperature logs) shall be maintained
4.1.4	Maintain records that document adequately that the participants were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor.

4.1.5	Where permissible, explain the correct use of the investigational product(s) to each participant and should check, at intervals appropriate for the trial, that each participant is following the instructions properly.
4.1.6	A compliance check could include instructing the participants to return empty and partially used containers at their next visit. An assessment would then be made of how much medication has been taken versus the expected amount of medication to be taken. The compliance check will usually also involve asking the participant to describe how and when they are taking the medication

The investigator(s) should:

STEP	ACTION
4.1.7	Ensure that the investigational product(s) are used only in accordance with the approved protocol. **ICH GCP 4.6.5**
4.1.8	Follow the project's randomisation procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s). **ICH GCP 4.7**

5. GLOSSARY

Associate Investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a study site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows). Also referred to as "Sub-Investigator".

Delegate

A person delegated specific but appropriate tasks in relation to the conduct of a clinical trial.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Investigator initiated trial

A clinical trial that is undertaken by the investigator whereby the investigator and/or their institution takes on the role of the sponsor in addition to their role as investigator.

Investigational Product

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Principal Investigator (PI)

An individual responsible for the conduct of a clinical trial at a trial site and ensures that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Protocol

A document that describes the objective(s), design, methodology, statistical considerations and organisation of a clinical trial.

Sponsor

An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

6. REFERENCES

1. Based on VMIA GCP SOP No.005 Version:1.0 Dated 17 September 2007
2. Based on MACH GCP SOP No.005 Version:1.0
3. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, sections 4.6 & 4.7 for Investigator Responsibilities.
4. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, sections 5.12, 5.13 & 5.14 for Sponsor Responsibilities.
5. National Statement on Ethical Conduct in Human Research, (2007).
6. Australian Code of Good Manufacturing Practice (GMP) – Annex 13 Manufacture of investigational medicinal products.

7. AUTHORS/CONTRIBUTORS

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