

MELBOURNE HEALTH	OFFICE FOR RESEARCH		
	STANDARD OPERATING PROCEDURE: SOP005		
	Receipt and Handling of Investigational Product		
Prepared by	Sarah Rickard	Position	Manager of Research Governance
Authorised by	Angela Watt	Position	Director Research Governance and Ethics

1. AIM

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

2. SCOPE

Applicable to all clinical research projects undertaken at Melbourne Health, including investigator initiated research, collaborative research and all phases of clinical investigation of medicinal products, devices and diagnostics.

3. APPLICABILITY

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

4. PROCEDURE

4.1 Receipt and handling of investigational product

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

The investigator(s) should:

- Liaise with the Melbourne Health (MH) Clinical Trials Pharmacy (CTP) at the RMH site to organise the CTP to undertake receipt and handling of the investigational products (s) according to the protocol and applicable CTP policies (PCY12.03, PCY12.07 and PCY12.08).
- In certain cases and where specific HREC and Office for Research approval has been granted, investigators may assign some or all of the investigator's/institutions duties for investigational product(s) accountability at the trial site(s) to an appropriate individual within the research team who is under the supervision of the investigator/institution. The Melbourne Health Clinical Trials Drug Management Protocol must be used in this instance.

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

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- Maintain records of the product's delivery and receipt to the trial 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.
- 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.
- 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.
- 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.
- 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.

4.3 The investigator(s) should:

- Ensure that the investigational product(s) are used only in accordance with the approved protocol.
- Follow the trial'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).

5. GLOSSARY

Delegate

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

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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.

Human Research Ethics Committee (HREC)

A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

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.

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 authorization 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.

Investigator

An individual responsible for the conduct of a research projects including clinical trials at a research/trial site and ensures that it complies with GCP guidelines. If a research/trial is conducted by a team of individuals at a research/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.

Sub Investigator

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

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6. REFERENCES

1. MH Research Policy MH18
2. 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.
3. 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.
4. National Statement on Ethical Conduct in Human Research, (2015).
5. Australian Code of Good Manufacturing Practice (GMP) – Annex 13 Manufacture of investigational medicinal products.

7. APPENDICES

Appendix 1: SOP Change Log

Appendix 2: Example IP accountability log

DOCUMENT END

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APPENDIX 1: SOP CHANGE LOG

<i>Version No.</i>	<i>Reason for Issue</i>
1	First issue
2	26/9/2013: 4.1 Updated for MH Clinical Trials Drug Management Protocol
3	28/2/2017: Review and minor updates

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