Receipt and Handling of Investigational Product

Standard Operating Procedure

Office of Health and Medical Research
Queensland Health

SOP reference: 005
Version number: 1
Effective date: 01 June 2010
Review due: May 2011
Author: Katrina Brosnan
Approved by: Dr Jane Jacobs, Director, Research Ethics and Governance Unit

Amendment History

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Based on, and with permission of the Victorian Managed Insurance Authority – VMIA GCP SOPS
Reviewed by the QH Clinical Research Coordinators Network May 2010
1 Purpose
To describe the procedures related to receipt and handling of investigational product.

2 Responsibility / Scope
This standard applies to all Queensland Health employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff.

3 Applicability
Principal Investigator / Associate/sub-Investigator(s), Research Coordinators, Pharmacists, Pharmacy staff and other staff delegated trial-related activities by the Principal Investigator.

Applicable to all clinical investigation of medicinal products, medical devices and diagnostics.

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. ICH GCP 4.6.1

According to the Health (Drugs and Poisons) Regulation 1996, a registered nurse or clinical nurse (or other clinical research coordinator) is NOT authorised to dispense investigational product. http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HealDrAPOR96.pdf

The investigator(s) should:

- (Where allowed/required), assign some or all of the investigator's/institutions duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual 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 and who is authorised to dispense study medication, should (ICH GCP 4.6.3):

- 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 that participants were provided the doses specified by the protocol.
The investigator(s) should:

- Ensure that the investigational product(s) are used only in accordance with the approved protocol. **ICH GCP 4.6.5**
- 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). **ICH GCP 4.7**

5 Glossary

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.

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 a 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 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, one investigator should be designated as the responsible leader of the team and should be called the site 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 / Associate Investigator**

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, clinical research coordinators. The P.I. will designate who will be nominated as Associate Investigators for that site.

### 6 References

1. 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.

### 7 Appendices

Appendix 1: [Example IP accountability log](word doc)
QH SOP 5 Appendix 1  Investigational Product (IP) Accountability Record

Section 1 – Investigational Product Details

<table>
<thead>
<tr>
<th>Investigational Product:</th>
<th>Dosage Form:</th>
<th>Lot Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Protocol Number:</td>
<td>Strength / Unit:</td>
<td>Expiry Date:</td>
</tr>
<tr>
<td>Participant ID Code:</td>
<td>Research Coordinator:</td>
<td>Used IP:</td>
</tr>
</tbody>
</table>

Section 2 – Storage Details

<table>
<thead>
<tr>
<th>Room / Location:</th>
<th>Storage Requirements:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ambient ☐ / 2-8°C ☐ / Other ☐ ____________</td>
</tr>
</tbody>
</table>

Form Notes

Section 3 – Transaction History

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Transaction Details</th>
<th>Balance of IP</th>
<th>Balance of used IP</th>
<th>If Transaction = RECEIVE or RETURN</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Time</td>
<td>Subject IDENTIFIER</td>
<td>Performed by (Initials)</td>
<td>Checked by (Initials)</td>
<td>IN</td>
</tr>
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<td></td>
<td></td>
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Received, Dispensed or Returned

☐ Received
☐ Balance carried over

IN OUT TOTAL IN OUT TOTAL

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<tr>
<td></td>
<td></td>
<td>IN</td>
<td>OUT</td>
<td>TOTAL</td>
<td>IN</td>
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Accountability Record Complete: Yes ☐  Balance carried over to new record ☐  All IP returned (ie. TOTAL Balance is zero) ☐

Research Coordinator (or delegate): ___________________________ Date: ___/___/____  Page _____ of _____