SOP Number: 40
SOP Title: Protocol and Investigational Brochure (IB) Requirements

SOP number:	**040**
Version number:	4.0
Effective date:	April 2019
Review due:	April 2021
Author:	Roberta Lusa
Approved by:	A/Director, Health Innovation, Investment and Research Office Office of the Director- General

Amendment History

Version	Date	Author/s	Amendment Details
1.0	1 June 2010	Katrina Brosnan	New
2.0	December 2017	Roberta Lusa & Bernadette Morris-Smith	All sections, incorporating ICH GCP E6 (R2) and teletrials: QH TELETRIAL PILOT VERSION 1.0
3.0	June 2018	Roberta Lusa	All sections, refinement after CRC input: PUBLIC RELEASE VERSION 3.0
4.0	April 2019	Roberta Lusa	Amendments post Round 1 Health Service Directive Consultation.

1 Purpose

To describe the procedures related to the development of a research protocol, an investigational brochure, and amendments to these documents ensuring compliance to ICH GCP E6 (R2).

2 Responsibility / Scope

This Standard Operating Procedure applies to all Queensland Health employees (including visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3 Glossary

For an explanation of acronyms and the definition of terms used in these SOPs, please refer to Chapter Two: Glossary of The Australian ICH GCP SOP Compendium.

4 Procedure

4.1 Protocol content and development

Specific content of a protocol will vary depending on the subject of the research, the level of risk to participants, the phase of research and study design, whether a medicinal product is being researched or a device or a therapeutic intervention. Consequently, the terminology will be different and should be adapted appropriately.

Where the investigator is responsible for the protocol development they must ensure the protocol follows the outline as per ICH GCP E6 (R2) Section 6 CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S). This protocol table of contents is not mandated by QH but it is recommended a trial protocol should generally include the topics listed in the link in the Section 5 of this SOP as it ensures adherence to ICH GCP E6 (R2). However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed may be contained in other protocol referenced documents, such as an Investigator's Brochure.

Where satellite sites will be involved in the study, no specific wording will be required in the protocol, as the following considerations will be addressed in other study-specific documents which may be annexed to the protocol e.g. the site selection report, ethics application, supervision plan, the monitoring manual, laboratory manual, pharmacy manual, safety monitoring manual or a trial specific working guideline. Nevertheless, the following considerations are to be addressed such that protocol deviations are not created.

- The manner in which Informed Consent will be taken is to be clearly described ie face-to-face, videoconference, via telehealth, skype, phone etc.
- Description of how study procedures will be undertaken, e.g. how visits, assessments, collection of data and medical consultations will be conducted i.e. face-to-face or via telehealth or a combination of both.
- Description of storage and handling of Investigational Product, e.g. will the Investigational Product be stored at the Primary Site and shipped to the Satellite Site via appropriate handling and shipping method when a participant is deemed eligible or will Satellite Sites with appropriate facilities store the Investigational Product?
- Description of storage and handling of laboratory samples at Satellite Sites if involved and if relevant e.g. frequency of and timelines between transport of samples to Primary Site or direct to Central or Local laboratory.
- Description of the handling of other study related non-IMP materials
- Description of the roles and responsibilities of investigators and other staff who will be involved in the study at both the Primary and Satellite Sites.

4.2 Investigational Brochure (IB) content and development

Where the investigator contributes to the content and development of the investigator brochure they must ensure the investigator brochure follows the outline as per **ICH GCP E6 (R2) Section 7 Investigator's Brochure.**

This IB table of contents as listed in the link in the reference section of this SOP is not mandated by QH but is recommended for use as it ensures adherence to ICH GCP E6 (R2). The IB should remain up-to-date via annual revision at a minimum, depending on the type of product and its stage of development.

In some situations, for investigational medicinal products, where a product is registered, and has a well-understood pharmacology, a Product Information document may be substituted for an IB, provided that current and comprehensive information about the product under study is available to the investigators. If a product is registered, but is being trialed for a new indication, or in a different population to the approved indication, an IB must be collated with reference to this new indication/population.

4.3 Amendment/s to the Protocol and IB

***The Investigator must inform the HREC*:**

- and obtain acknowledgement of receipt of the updated IB
- and obtain approval of all amendments to the protocol including amendments that:

    a. are proposed or undertaken without prior HREC approval in order to eliminate immediate risks to participants;
    b. may increase the risks to participants; or
    c. significantly affect the conduct of the trial (including changes to the Inclusion / Exclusion criteria).

- as soon as possible of any new safety information from other published or unpublished studies that may have an impact on the continued ethical acceptability of the project or may indicate the need for amendments to the research protocol

Notification to the HREC is HREC specific and the investigator should be familiar with the terms of reference of their ethics committee. Refer to the Australian ICH GCP SOP 50 regarding communication with the HREC.

***The investigator must provide to the RGO*:**

- the HREC approval letter for the amendment(s)
- a copy (if required by the RGO) of all HREC approved amended documents.

and obtain authorisation from the RGO to continue the project where a governance aspect has been affected (if required) including protocol amendments that:

a. are proposed or undertaken without prior HREC approval in order to eliminate immediate risks to participants
b. may increase the risks to participants
c. significantly affect the conduct of the trial (including changes to the Inclusion / Exclusion criteria)
d. pose a risk to the Institution.

Notification to the RGO is site specific and the investigator should be familiar with the processes of their RGO.

5 Guidance Documents

1. Suggested table of contents for an ICH GCP E6(R2) compliant protocol
2. Suggested table of contents for an ICH GCP E6(R2) compliant Investigator's Brochure
3. National Mutual Acceptance. Single Ethical Review of Multi-centre Human Research
4. Projects. MONITORING AND REPORTING TABLES
5. The Australian ICH GCP SOP 50: Communication with Human Research Ethics Committee (HREC), Research Governance Office (RGO), Sponsor and Insurer