Sponsor Responsibilities In Investigator Initiated Studies

Standard Operating Procedure
Office of Health and Medical Research
Queensland Health

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Amendment History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author/s</th>
<th>Amendment Details</th>
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<tbody>
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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 define Sponsor Responsibilities in the conduct of Investigator Initiated studies.

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 Procedure

Where the Investigator is acting in the capacity of sponsor.

4 Procedure

4.1 Sponsor Responsibilities

The sponsor for an investigator initiated study may be an individual (eg the investigator or department head), a company (e.g. a not-for-profit) an organisation (e.g. a charity) or an institution (e.g. a public hospital). Each institution will have its own policy regarding the sponsorship role. All Queensland Health sites are covered by this SOP.

Before Study Commencement, the Sponsor is Responsible for:

- Ensuring that Quality Assurance and Quality Control systems are in place so that trials are conducted and data is gathered and reported in compliance with GCP, the trial protocol, institutional approvals and any TGA requirements. ICH GCP 5.1.1, ICH GCP 5.6.3
- Securing agreement from all involved parties to ensure direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities. ICH GCP 5.1.2
- Ensuring that no omissions occur which might disentitle themselves, the Hospital or HREC / site Governance Officers, to such indemnity as could otherwise be available under the QGIF Agreements with Queensland Health.
- Selection of the appropriate investigator(s) and institution(s) to conduct and complete the trial according to GCP standards. ICH GCP 5.5.1
- Definitive, unambiguous allocation of trial-related duties and responsibilities to trial-related staff. ICH GCP 5.7
- Ensuring provision of appropriate insurance and indemnity for the trial and trial-related staff, as well as measures for participant compensation for trial-related injury. ICH GCP 5.8.1, ICH GCP 5.8.2
- Ensuring the confirmation of endorsement from the relevant HREC(s) / Governance Offices and notification of the approvals to the TGA. ICH GCP 5.11.
- Ensuring that funding arrangements are declared in the NEAF and Governance applications, and that the appropriate MA Clinical Trial Research Agreement (CTRA) is used.
- Trial design and appropriate analysis. ICH GCP 5.4
• Data handling, record keeping, and overall trial management. **ICH GCP 5.5**

• Archiving and retention of all records relating to the study for a period of at least 15 years from the end of the Trial (i.e. completion of data analysis) in the case of adults and at least 25 years from the end of the Trial (i.e. completion of data analysis) in the case of children.  

• Ensuring that agreements made with the investigator/institution and any other parties involved with the clinical trial, are in writing. **ICH GCP 8.2.6**

• Ensuring that there is clear definition as to the ownership of any Intellectual Property that may arise from the project.  

**During the Study the Sponsor is Responsible for:**

• Ensuring medical expertise is on hand for trial-related medical queries or participant care. **ICH GCP 5.3, ICH GCP 4.3.1**

• Ensuring that Investigational Products are available to participants free of charge.

• Taking appropriate urgent safety measures (with investigator) where necessary.

• Keeping records of all adverse events reported by investigators. **ICH GCP 5.18.4(m) (iii)**

• Ensuring appropriate manufacture, packaging, labelling/coding and distribution to trial sites of all investigational medicinal products. **ICH GCP 5.13**

• Ongoing safety evaluation and AE/ADR reporting as described earlier in this document. **ICH GCP 5.16.1**

• Compliance with Monitoring/Audit/Inspection requirements. **ICH GCP 5.20.1**

• Notification of any premature termination of the trial in question. **ICH GCP 4.12.2, ICH GCP 5.21**

• Completion of the Clinical Study Report. **ICH GCP 5.22, ICH GCP 8.4.8**

## 5 Glossary

**Adverse drug reaction (ADR)**

Adverse drug reactions concern noxious and unintended responses to a medicinal product.

**Adverse event (AE)**

Any untoward medical occurrence in a participant administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product.

**Clinical Trials Agreement (CTA)**

An agreement governing the safety and efficacy of outside collaborators, proprietary biologics or pharmaceutical compounds in clinical studies.

**European Union (EU)**
An organization of European countries.

**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.

**Governance Office/r**

The Office or coordinated function within a Public Health Organisation which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the District CEO / delegate as to whether a research project should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance).

**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.

**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.

**Investigator initiated trial**

A clinical trial that has the following characteristics:

- A pharmaceutical/device company is not acting as the sponsor for the purposes of the CTN application.
- A pharmaceutical/device company is not fully funding the conduct of the study, that is, making payment to the relevant hospital or investigator.
- The clinical trial addresses relevant clinical questions and not industry needs.
- The principal investigator or the Hospital/Institution is the primary author and custodian of the clinical trial protocol.
Serious adverse event (SAE)

Any untoward medical occurrence that at any dose:

- Results in death.
- Is life-threatening.

(NOTE: The term "life-threatening" in the definition of "serious" refers to an event/reaction in which the participant was at risk of death at the time of the event/reaction; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe).

- Requires inpatient hospitalisation or results in prolongation of existing hospitalisation.
- Results in persistent or significant disability/incapacity.
- Is a congenital anomaly/birth defect.
- Is a medically important event or reaction.

Sponsor

An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing 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.

Therapeutic Goods Administration (TGA)

Australia's regulatory agency for medical drugs and devices.

6 References

1. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, section 5.