Communication with HREC, Trial Sponsor and Insurer
(Sponsored Clinical Trials Only)

Standard Operating Procedure
Office of Health and Medical Research
Queensland Health

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Amendment History

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1 Purpose
To describe the procedures related to communication with the HREC, Governance Office, Trial Sponsor and Insurer.

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.

Applicable to all sponsored clinical trials.

3 Applicability
Coordinating Principal Investigator / Principal Investigator / Associate (Sub) Investigator, Clinical Research Coordinators and delegate(s).

4 Procedure

4.1 Communication with Reviewing HREC / Governance Office
Prior to study commencement, the investigator(s) should:

- Understand the Institutional HREC and Governance requirements and processes to better liaise with sponsors – e.g. on application approval processes, documents, understanding legal requirements, understanding specific institutional site requirements on wording in consent forms etc. QH HREC SOPS

- Be aware of how frequently the reviewing HREC meets, which documents are required for various submissions, the submission dates for HREC / Governance reviews, what the approval process is and the documentation involved as well as the number of copies of the document(s) required for submission. QH REGU Website

- Ensure they are familiar with the relationship between HREC review and Approval, and Governance Authorisation, in addition to any other processes (e.g. does the HREC have subcommittees, is a Public Health Act Application required, is approval from QCAT required?) since this may be required to be described to sponsors, auditors, inspectors. QH RUG

- Ensure the Reviewing HREC is registered with AHEC and is constituted in accordance with the National Statement. For a list of HREC’s registered with the NHMRC, go to: http://www.nhmrc.gov.au/health_ethics/hrecs/hreclist.htm

- Have filed in the Site Master File, the written and dated approval/favourable opinion from the Reviewing HREC for the trial protocol, written informed consent form, consent form updates, Participant recruitment procedures (e.g. advertisements), and any other written information to be provided to Participants prior to the commencement of the trial. This must be in the form of an ethics approval letter which must state the version number and dates of documentation approved for use. GCP 8.2.7

- Obtain written and dated Authorisation from the local Governance Office to conduct the project at that site. QH RUG
• As part of the application to the Reviewing HREC, provide the HREC with a current copy of the Investigator’s Brochure and if updated during the trial, the investigator/institution should supply an updated copy to the HREC. ICH GCP Sect. 7

• Be familiar with the procedure for submitting protocol amendments and amendments to the informed consent form and understand the time periods associated to obtain approval following submission of amendments. QH RUG

**During the project, the investigator(s) should:**

• Provide to the Reviewing HREC or Governance Office all documents subject to review during the trial, including any serious or unexpected adverse events, proposed changes in the protocol and unforeseen events that might affect continued ethical acceptability of the project. ICH GCP 3.1.2.; QH RUG

• Submit written summaries of the trial status to the Reviewing HREC annually, or more frequently, if requested by the HREC. The frequency will be stated in the original approval letter from the HREC. All relevant study staff should understand the reporting requirements for their HREC including protocol deviations and safety reporting. ICH GCP 8.3.19

• Report to the Reviewing HREC and/or site Governance Office any serious adverse event that is experienced during the trial by any participant under the care of the investigator within 15 days of the investigator becoming aware of same. ICH GCP 8.3.17; QH RUG

• Notify the Reviewing HREC / Site Governance Office of any Serious Adverse Events that occur during the course of the study in accordance with the Protocol, and relevant Institutional and Jurisdictional ethical and regulatory guidelines. This includes “Dear Investigator” letters and at least six monthly line listings of all safety reports. ICH GCP 8.3.17; QH RUG

**NB:** CIOMs reports are no longer required for HREC / Governance review, unless requested by local HREC / Governance office.


• Notify the Reviewing HREC / Site Governance Office of any adverse events that occur during the course of the Study in accordance with the local HREC / Governance guidelines, the protocol, and relevant Institutional and Jurisdictional ethical and regulatory guidelines. QH RUG

4.2 Communication with the Trial Sponsor

The investigator(s) should:

• Notify the sponsor within 24 hours of discovery of any Serious Adverse Events involving trial Participants under the care of the investigator. ICH GCP 4.11; 8.3.16

• Provide written reports promptly to the sponsor, the Reviewing HREC and, where applicable, the local Governance Office on any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants. ICH GCP 5.16.2; 5.17; 4.11.1

• Notify the sponsor or their delegate of any protocol violation (which may include significant deviation from the protocol). ICH GCP 4.5; 8.3.11
• Be available during the study to meet with sponsor delegates to discuss study progress, issues and safety. ICH GCP4.2.2; 5.6.3
• Provide the Sponsor with copies of all correspondence from the reviewing HREC and / or site Governance Office. ICH GCP 5.11. ICH GCP Section 8
• Immediately notify the site Governance Office of any notification received from a research participant that they intend to initiate a claim against either the Sponsor and/or the Institution. In addition, the Trial Sponsor, and Reviewing HREC must also be notified as soon as possible. QH RUG

4.3 Communication with the Insurer (QH RUG)

Obligation of the Institution:
If notified that a research participant intends to make a claim against the institution or study sponsor for injuries arising as a result of participating in research, the institution should:
• Notify the District Solicitor (if there is one) that such an action is intended. The District Solicitor should report this advice to QGIF in accordance with the claims procedure agreed between Queensland Health and QGIF.
• Notify the Study Sponsor of the intended claim.
• Notify the Principal Investigator / Coordinating Investigator of the intended claim.

5 Glossary

Clinical Research Coordinators
A research worker who works at a clinical research site under the immediate direction of a Principal Investigator, whose research activities are conducted under Good Clinical Practice guidelines. May also be called “Clinical Trial Coordinator” or “Research Coordinator”. (ARCP Definition.)

Coordinating Investigator
A lead investigator who coordinates the conduct of a trial at more than one site and who coordinates HREC notifications, Amendments to Protocols and other trial related paperwork, and ensures that all sites comply with GCP guidelines.

Delegate
A person delegated specific but appropriate tasks in relation to the conduct of a clinical trial. Delegation must be evidenced in writing.

QCAT
Queensland Civil and Administrative Tribunal (http://www.qcat.qld.gov.au/). An independent body established by the Guardianship and Administration Act 2000 to appoint decision makers to protect the rights of adults with impaired decision-making capacity. Impaired decision making capacity can be as a result of an intellectual or psychiatric disability, an acquired brain injury, an illness such as dementia or a combination of these.
Governance Office(r) / Function
A body which reviews Site Specific Applications for research to be conducted at a local institution – to ensure all governance aspects of a research project are in order.
The National Statement requires that all research proposals involving human participants be subject to Governance review.

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.

QGIF
Queensland Government Insurance Fund, which is a part of Queensland Treasury and is the insurer of Queensland Government agencies, including Queensland Health.

QH HREC SOPS

QH RGO SOPS
A set of Standard Operating Procedures approved by Queensland Health (QH) for use by QH Research Governance Officers undertaking the review and authorisation of proposed research projects to be carried out at QH sites. Go to: http://www.health.qld.gov.au/ohmr/documents/rgo_sops.pdf.

QH RUG

Reviewing 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.

Serious Adverse Event (SAE)
Any untoward medical occurrence that, at any dose:
a. results in death;

b. is life-threatening;

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

c. requires in-patient hospitalisation or prolongation of existing hospitalisation;

d. results in persistent or significant disability/incapacity; or

e. is a congenital anomaly/birth defect; and fits the SAE criteria as specified in the relevant clinical trial protocol.

Medical or scientific judgment should be exercised in deciding whether reporting is appropriate in other situations – in accordance with protocol requirements - such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the Participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug abuse.

Serious Adverse Event (SAE) - device

Serious Adverse Event for medical devices: any adverse medical occurrence that:

a. lead to a death;

b. lead to a serious deterioration in health of a study participant user or other. This would include:
   • a life threatening illness or injury.
   • a permanent impairment of body function or permanent damage to a body structure.
   • a condition requiring hospitalisation or increased length of existing hospitalisation.
   • a condition requiring unnecessary medical or surgical intervention e) foetal distress, foetal death or a congenital abnormality/birth defect.

c. might have led to a death or a serious deterioration in health had suitable action or intervention not taken place.

This includes:
   • a malfunction of a device such that it has to be modified or temporarily/permanently taken out of service.
   • a factor (a deterioration in characteristics or performance) found on examination of the device.

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.

QH GCP SOP 3: Communication with HREC, Trial Sponsor and Insurer
Prepared by the Research Ethics and Governance Unit May 2010
Based on, and with permission of the Victorian Managed Insurance Authority – VMIA GCP SOPS
Reviewed by the QH Clinical Research Coordinators Network May 2010