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SOP Title: Communication with Human Research Ethics Committee (HREC), Research Governance Office (RGO), Sponsor and Institution's Insurer.

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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 relating to communication with the HREC, RGO, Sponsor and Insurer.

2 Responsibility / Scope

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, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice. This SOP takes into consideration the Single Ethical Review Processes adopted by Queensland Health.

3 Glossary

For an explanation of acronyms and the definition of terms used in these SOPs, please refer to Chapter Two: Glossary, located at the front of the Queensland Health Standard Operating Procedures (SOP) Compendium.

4 Procedure

Communication with the HREC and RGO is illustrated in a tabular form in the National Mutual Acceptance. Single Ethical Review of Multicentre Human Research Projects. MONITORING AND REPORTING TABLES.

4.1 Communication with Reviewing HREC

When communication regarding key decision points is verbal, the initiating party should follow up verbal communication with written correspondence/e-mail and send to the call recipient. The title of the letter / e-mail should include the term “FILE NOTE” followed by a text string which should include the decision topic. Such documentation must be filed in the Study Master File (SMF) and where applicable in the Satellite Site Study File (SSSF).

4.1.1 Prior to study Commencement, the Investigator (CPI/PI/SI) must:

- Choose a reviewing HREC who’s approval is acceptable to the institution/s where the clinical study is being undertaken.
- Understand the reviewing HREC requirements, submission processes and be aware of their meeting and submission dates to better liaise with sponsors.
- Be familiar with the relationships between HREC review and approval, governance authorisation and any other processes/approvals that need to be in place (e.g. does the HREC have subcommittees, is a *Public Health Act* Application required, is approval from QCAT required) before any study start

up activities can commence. This process and approval flow will be required by Sponsors, auditors and inspectors.
- Submit an ethics application as per the reviewing HREC submission process
- Include in the relevant section of the ethics application that the trial may be undertaken using Telehealth with Satellite Sites, if applicable, and that the informed consent process and/or some or all study assessments will be undertaken using Telehealth, face to face consultation or a combination of both.
- Submit any other application as per that process found on the relevant website (e.g. PHA, QCAT, QGIF).
- Ensure all documentation and correspondence pertaining to the submission and approval processes is filed in the SMF e.g. correspondence to and from the HREC, RGO or other body (e.g. QCAT, PHA, QGIF).

4.1.2 During the study, the investigator (CPI/PI/SI) must:

- No longer submit individual reports of AEs, SAEs, SUSARs, USADEs and six-monthly line listings to the reviewing HREC unless otherwise advised.
- Submit all documents/reports/summaries according to the requirements and timelines as stipulated on the respective reviewing HREC approval letter including but not limited to: sponsor reports of accumulated safety data outcome analyses; proposed changes to the protocol; major violations; annual progress reports; and unforeseen events that might affect continued ethical acceptability of the trial.
- Immediately notify the reviewing HREC of any notification received from a participant in a trial that they intend to initiate a claim against either the Sponsor and/or the Institution.
- File all documentation in the SMF/SSSF.

4.1.3 At the end of the study, the investigator (CPI/PI/SI) must:

- Submit a trial termination/closeout report according to the requirements and timelines as required by the respective reviewing HREC. This may be stipulated in the approval letter and/or on their website.
- File all documentation in the SMF/SSSF.

4.2 Communication with the Research Governance Office (RGO)

For the purpose of this SOP the Clinical Trial Research Agreement (CTRA), other site specific trial-related documentation and the Site-Specific Assessment (SSA) Form constitute a research governance application for the primary site. Similarly, for the satellite site, a research governance application consists of the sub-contract, the SSA sub-form and other site-specific trial-related documentation. This application may be submitted to the RGO in parallel to the HREC submission if all governance related documentation is available and completed correctly. In this case the final document to be provided to the RGO is the HREC approval. This has the advantage of enabling an RGO review in parallel to the HREC review, and allows a timelier RGO authorisation which may lead to expedited study start up. It is important to note, that HREC approval must be obtained and submitted to the RGO, prior to the final RGO authorisation being granted.

4.2.1 Prior to study commencement, the investigator (CPI/PI/SI) must:

- Submit the CTRA, the SSA Form and any other required documentation to the RGO.
- Ensure all documentation and correspondence pertaining to the submission and approval processes is filed in the SMF.
- Ensure each satellite site in the cluster (whether in a different HHS to the principal investigator or the same HHS) completes a clinical trial sub-contract and an SSA sub-form which is a subsection of the main SSA and submits to their RGO.
- Await site specific RGO authorisation before any study related activity can occur at that site.
- Ensure the satellite site files all documentation in the SSSF.

4.2.2 During the trial, the investigator (CPI/PI/SI) must:

- Submit all governance related documents/reports/summaries to the relevant RGO according to the requirements and timelines as stipulated on the respective RGO website including but not limited to: changes to the CTRA/sub-contract; budget; any change that might affect continued financial acceptability of the trial; any change that may increase institution risk.
- Immediately notify the RGO of any notification received from a participant in a trial that they intend to initiate a claim against either the Sponsor and/or the Institution.
- Ensure the satellite site files all documentation in the SSSF.

4.2.3 During the trial, the investigator (CPI/PI/SI) must:

- Notify the RGO the trial has terminated/closed.
- File all documentation in the SMF/SSSF.

4.3 Communication with the Research Governance Office (RGO)

- notify the sponsor within 24 hours of discovery of any Serious Adverse Events (SAE) involving trial participants under the care of the investigator and where relevant notify the PI in parallel
- notify the sponsor promptly regarding any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants and where relevant notify the CPI/PI/SI. Communication must be followed up with written report/email and filed in the SMF/SSSF
- notify the sponsor of any Protocol Violation (which may include significant deviation from the protocol) and where relevant notify the CPI/PI/SI (see Appendix 1)
- be available to meet with sponsor to discuss study progress, issues and safety
- provide the sponsor with copies of all correspondence from the reviewing HREC and / or RGO
- immediately notify the sponsor of any notification received from a trial participant that they intend to initiate a claim against either the sponsor and/or the Institution.

4.4 Communication with Institution's Insurer

If the Institution is notified or becomes aware that a trial participant intends to make a claim against the Institution or Sponsor for injuries arising as a result of participating in a clinical trial undertaken at the Institution or any of the Satellite Sites under supervision by the Institution, the Institution must promptly notify the Institution's insurer in writing that such an action is intended.

In QH the institution's insurer is QGIF.

4.5 Communication with QH Solicitor, Sponsor and CPI/PI/SI

If the Investigator is notified or becomes aware that a trial participant intends to make a claim against the Institution or Sponsor for injuries arising as a result of participating in a clinical trial undertaken at the Institution or any of the Satellite Sites under supervision by the Institution, the Investigator must promptly notify the following in writing that such an action is intended:

- the relevant QH Solicitor,
- the CPI/PI/SI as relevant, and
- the Sponsor.

5 Guidance Documents

1. NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods November 2016
2. NHMRC Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods 2018
3. NHMRC Guidance on the Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods 2018
4. National Mutual Acceptance. Single Ethical Review of Multicentre Human Research Projects. MONITORING AND REPORTING TABLES
5. SOP 120: TGA Notification and SAE Reporting Requirements

6 Appendices

- Appendix1 Example Protocol Deviation Log