# SOP Number: 20
# SOP Title: Investigator Responsibilities

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| Author: | Roberta Lusa |
| Approved by: | A/Director, Health Innovation, Investment and Research 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. PUBLIC RELEASE VERSION 4.0 |

# 1 Purpose

To define the Investigator responsibilities associated with undertaking a clinical trial which are not listed in other AUSTRALIAN ICH GCP (including Teletrials) SOPs.

# 2 Responsibility / Scope

This standard 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. The responsibilities described in this SOP are extra to and are to be read in conjunction with investigator responsibilities defined in all other AUSTRALIAN ICH GCP (including Teletrials) SOPs.

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, located at the front of the AUSTRALIAN ICH GCP (including Teletrials) Standard Operating Procedures (SOP) Compendium.

# 4 Procedure

Investigator responsibilities include those listed in this SOP as well as those listed in all other AUSTRALIAN ICH GCP (including Teletrials) SOPs. To avoid duplication those listed in other SOPs are not repeated here.

## 4.1 Investigator Responsibilities (CPI, PI and SI)

### 4.1.1 Before the Research Project Commences

***The Investigator must***:

- Declare in writing any conflicts of interest, or payments they will receive from other parties with any relationship to the study and notify the sponsor.
- Ensure any payment received for undertaking the trial is noted in the Participant Information Sheet and Consent form.
- Demonstrate that adequate participant recruitment is possible.
- Demonstrate adequate staffing levels to ensure success of the study at the site.
- Be thoroughly familiar with the appropriate use of the investigational product as described in the protocol, in the current Investigator's Brochure for medicines or Product Information for devices and in other information sources provided by the

Sponsor.

- Be provided with the registration number of the trial once it is registered on a publicly accessible World Health Organization compliant clinical trials registry before the first participant is recruited to the study.

### 4.1.2 During the course and at the completion of the Research Project

***The Investigator must***:

- Sign all trial related documentation, such as documents requiring an end date, indicating the research project is completed including but not limited to: Delegation Log, training log, Supervision Plan, agreements, progress reports, eCRF/CRF, SAE reports, etc.
- Ensure all trial related staff and Third-Party Providers have been informed of research project closure, results and publication plan.
- Inform participant's primary care physician (where participant has consented to do so) of research project closure, results and, if applicable, the treatment the participant was allocated for notation in the participant's medical record.
- Record in the participant's medical record at the institution the treatment the participant was allocated (if applicable).
- Follow the Teletrials Clinical Consultation User Guide to enable the telehealth process to be successfully used and correctly reimbursed.
- Document any deviation from the Protocol as per sponsor's guide
- Ensure they notify the sponsor, HREC and RGO if they leave the institution, in writing with either their new place of employment and contact details or who their replacement is with contact details for recording on all archiving related documentation.
- Ensure study related documents are archived according to SOP 130.

## 4 Guidance Document

1. AUSTRALIAN ICH GCP (including Teletrials) SOPs 20-130
2. Teletrials Clinical Consultation User Guide