SOP Number: 60
SOP Title: Site Initiation

SOP number:	**060**
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 site initiation of a clinical trial at all sites.

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

4 Procedure

Site Initiative

Prior to initiation of the study, the investigator must:

- mutually agree with the Sponsor a scheduled date, time and location for the Study Initiation Visit at the Primary Site.
- review all study related documentation and be familiar with the Investigational Product and protocol.
- ensure that all relevant staff involved with the study, (Sub-Investigator, pharmacist, Clinical Research Coordinator and others as appropriate including trial related staff at a Satellite Site), have been advised of the meeting and are able to attend either in person or via videoconference.
- be in possession of all required approvals and authorisations to conduct the research project.
- ensure a Supervision Plan is in place, that documents the manner and frequency of supervision to be undertaken with other trial staff, especially those new to the role, and, where relevant, trial related staff at a Satellite Site. A Supervision Plan is to be created for each Satellite Site.
- under the teletrials model a satellite site is not initiated until such time a potentially eligible participant is identified.

During the Initiation Visit the investigator must ensure the following are available and/or addressed:

- Study Master File containing all required essential documents and review arrangements for organising and maintaining study files. (Satellite Site Study File in the case of the PI initiating a Satellite Site)
- a list of all study personnel attending the initiation meeting on an attendance log/training log with full name, signature, date and the method attended i.e. in person or via videoconference
- original, signed and dated curricula vitae of all study personnel involved in the study at the site and any satellite sites for which the Investigator has responsibility
- other documents such as, financial disclosures, training logs, medical licenses and other essential documents as per Sponsor requirements.
- a contact list with names and contact details of all study personnel from both Primary and Satellite Site, Sponsor and Independent Third-Party service providers is available.
- timeline for shipment, delivery and receipt of Investigational Product and other study related supplies to site
- a laboratory manual, where applicable, clearly defining sample handling instructions and processes, shipping procedures, documentation handling, contact list of all laboratories involved and any other laboratory activity to be undertaken during the course of the trial
- a pharmacy manual clearly defining any activity linked to the handling or the IMP/IMD
- any specialised equipment required will be available throughout the period of the trial, e.g. centrifuge, freezer, etc.
- the eCRF, completion guidelines and that they are accessible by all sites
- training in all aspects required by the protocol is recorded on Training Log
- archiving of study records at the end of the study
- subsequent training for staff not in attendance at the Initiation Visit. Such initiation training can be conducted remotely where feasible. It is critical however, that this training is undertaken and documented before they commence activities in the study.
- Supervision plan
- Under the teletrials model when a satellite site is initiated, the Satellite Site Study File is set up and all above steps apply at that time

At the conclusion of the initiation the investigator must:

- File the sponsor's initiation visit report/letter in the SMF
- Ensure that the staff at the Satellite Site files all communication and documentation in the SSSF

5 Guidance Documents

Nil extra to Chapter 4 Guidance documents

6 Appendices

Appendix1 Example Initiation check-list