SOP Number: 80
SOP Title: Case Report Forms and Source Documents

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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 related to the completion of (electronic) case report forms, and maintenance of Source Documents.

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. All study personal 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 in the Australian ICH GCP (including Teletrials) Standard Operating Procedures (SOP) Compendium.

4 Procedure

4.1. Completion of Case Report Forms (CRFs and eCRFs)

Where electronic medical records (EMR) are used, a validation system is required with an inbuilt correction and audit trail feature. In the case where there is no inbuilt validated audit trail, printed records of the changes and corrections (e.g. data queries) must be retained

The Investigator must:

- Ensure the accuracy, completeness, legibility, (including any changes or corrections) and timeliness of data recording adheres to the protocol and monitoring plan requirements and also the supervision plan.
- Ensure that any party delegated to perform data entry or signing for data completeness is recorded on the delegation log and is trained to perform those trial-related duties and functions.
- Ensure that changes to the paper source document do not obscure the original entry, are traceable and explained (i.e. an audit trail should be maintained).

4.2. Source Documents

The Investigator must:

- Maintain adequate source documents and trial records including all key observations on each of the site's trial participants.
- Store all trial-related documents in a Study Master File / Satellite Site Study File as required by the applicable regulatory requirement, sponsor and protocol and take measures to prevent accidental or premature destruction of these documents.
- Ensure, for both paper and electronic documents, all changes, corrections and amendments are tracked, and version dates and numbers, are updated to reflect the changed data and to maintain the integrity of the data. An explanation of the changes is noted in a record of change.
- Ensure all staff are aware that, upon request, direct access to all trial related records is given to the monitor, auditor, HREC, Governance officer or regulatory authority, to enable source data verification, sponsor audits or regulatory inspection. Direct access is stipulated in the CTRA and outlined to the participant via the PICF.
- Ensure that for telehealth consultations, the call is documented in the participant's medical record at each site by agreeing in the supervision plan where the original and Certified Copies are stored. The written record will include a brief summary of the consultation; follow up instructions and that the visit was conducted via telehealth as per current version of the Teletrials Clinical Consultation User Guide.
- For paper records, ensure that a Certified Copy of any key essential documentation generated at the satellite site is sent to the primary site for filing in the SMF e.g. SAE reports, to allow remote monitoring by sponsor and for auditing and inspection purposes. These can be sent via email or post.
- Where Electronic Medical Records (EMR) are in use, ensure that access to the patient's trial related information is limited to authorised users only. Where access cannot be limited measures must be put in place to ensure the patient's privacy and confidentiality are respected eg print the trial related information, sign as a Certified Copy and place in a paper record for access by Sponsor, regulatory inspectors and auditors etc.

5 Guidance Documents

1. NHMRC Australian Code for the Responsible Conduct of Research (Part A, Section 1
2. Queensland State Archives, Health Sector (Clinical Records) Retention and Disposal Schedule. Section 2.1
3. Queensland Government Contracts Directory GovNet (Queensland Health Only)
4. Teletrials Clinical Consultation User Guide