SOP Number: 130
SOP Title: Site Close Out and Archiving

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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 close-out of a clinical trial at all sites and archiving of trial related documentation at the end of the clinical trial.

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

4.1 Site close-out

4.1.1 Premature Termination or Suspension of a Trial

If the trial is prematurely terminated or suspended for any reason, the investigator must:

- Promptly inform the relevant parties of sponsor, HREC, RGO, Associate/ sub-investigator, any Satellite Site and the TGA by providing a detailed written explanation of the premature termination or suspension.
- Promptly inform the trial participant and their primary care physician where the trial participant has consented, of the termination or suspension and, if applicable, of the investigational product and dose they were administered.
- Assure appropriate therapy and follow-up for the participant's continued care.

4.1.2 Site close-out:

A final close-out of a trial can only be done when the sponsor has reviewed both investigator / institution and sponsor files and confirmed that all necessary

documents are in the appropriate files. The sponsor notifies the investigator close out can occur.

The Investigator must:

- Provide a summary report of the trial's outcome to the HREC, RGO, any Satellite Site and the TGA.
- File documentation and correspondence in the SMF.
- Arrange for archiving of SMF.
- Ensure appropriate final disposition of any Investigational Product/ and other trial related material. This may include return to the Sponsor or destruction of remaining materials.
- Where a Satellite Site was involved: ensure the Satellite Site Supervision Plan is followed regarding the disposition of essential documents during the study. Also ensure that evidence of the manner and frequency of supervision to be undertaken by the Principal Investigator with the Satellite Site staff during the study (eg minutes of calls with satellite staff to review patients and study progress) is filed in the principal site SMF.
- Ensure any Satellite Site retains documentation and correspondence in their SSSF with original or Certified Copy of pre-determined documents sent to principal site.

4.2 Archiving

Study documentation is to be archived as specified in:

i. **ICH GCP E6 (R2) 4.9.5, 5. 5.12**
ii. **Queensland State Archives, Health Sector (Clinical Records) Retention and Disposal Schedule. Section 2.1**
iii. **Australian Code for the Responsible Conduct of Research. Part A, section 2.1**
    - Where the specified archiving period is conflicting, documentation is to be archived for whichever period is the longest.
    - For legal reasons, sites may consider archiving for longer periods or indefinitely.
    - Queensland Government requirements for clinical trial records where the participants are minors are retained for:
        - 15 years from patient/client attaining 18 years of age; AND
        - 10 years after last patient/client service provision or medico-legal action.
    - Queensland Government requirements for clinical trial records where the participants are adults are retained for:
        - 15 years from completion of clinical research/trial; AND
        - 10 years after last patient/client service provision or medico-legal action.

4.2.1 For Paper Records

- Original documents or Certified Copies are to be retained.
- Evident identification (e.g. a document retention sticker) that the medical record forms part of a clinical trial is to be placed on all volumes of the participant's medical record in an appropriate position, without obscuring any information, as guided by local Health Information Management Services practice.
- For commercially sponsored research, archiving arrangements are negotiated with the study sponsor (and the site's Health Information Management Services) prior to study commencement. These details are to be noted in the study contract.
- Identifiable information (e.g. Participant Identification Log and Participant Information Sheet and Consent Forms) is to be archived separately from the main study documents, e.g. with the Principal Investigator – in case identification of participants is required later. A reference to the type and location of these documents is to be filed with the SMF.
- Satellite Sites will archive the original participant identifiable information at site as per above and send a certified copy to the principal site for archiving with the primary site participant identifiable information.
- Where the study documentation will be filed by the sponsor, the site records are NOT TO BE filed with the sponsor study records.

4.2.2 For Electronic Records

- Electronic Medical Records will be archived indefinitely

5 Guidance Documents

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

6 Appendices

Appendix 1: Example Close out check-list