

2019

HEALTH+MEDICAL RESEARCH

# Close-out at a trial site

Standard Operating Procedure



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## Document details

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## Document approval

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## 1. Purpose

To describe the close-out activities at a trial site. To ensure that sites conducting clinical trials take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements<sup>1</sup>.

## 2. Scope

All clinical trials (except Teletrials)<sup>2</sup> conducted at NSW Public Health Organisations.

## 3. Applicable to

The principal investigator (PI) and all site staff involved in a clinical trial.

Pharmacy for applicable trials and all support departments where clinical trial documentation may be retained.

## 4. Definitions

Refer to SOP-G-01: Glossary of terms.

## 5. Background

Sites participating in clinical trials are closed when all data queries have been resolved and documentation/materials returned to the sponsor\*. For most trials, the sponsor will initiate a close-out meeting which may be conducted via a telephone conference, remote monitoring or an on-site visit. Before study close-out, any issues should be brought to the attention of the sponsor.

*\*In some studies, sponsors may perform a close-out meeting prior all data being collected (e.g. in a trial where the active phase of a study is completed but the site will report long-term follow up data).*

During the close-out meeting, the completion of all key activities is confirmed:

- The completeness of all site documentation pertaining to the trial.
- Plans for archiving the investigator site file, case report forms and source documents.
- IMP accountability including the return or destruction in accordance with the protocol.
- Storage/destruction of trial samples in accordance with the protocol.

- If not already completed, the arrangements for the removal of any excess study materials (e.g. CRFs, lab kits).
- If applicable, on-going responsibilities of the site staff or the site for example collection of patient long-term follow-up data, provision of information in the event of an audit or inspection.
- Plans for dissemination of information to trial participants when results are available.

## Premature termination of a trial

The sponsor may close a trial site for reasons other than the completion of target recruitment. These may include:

- Closure of the trial due to a significant safety issue.
- Closure of a specific site due to its failure to recruit sufficient participants.
- Proven fraud or misconduct.

Organisations/PIs may instigate site closure due to the inability to replace the PI (or other key staff) who; for example, leave the organisation.

Where the decision to prematurely close a trial is made by the organisation, the PI should inform the sponsor/coordinating principal investigator (CPI) as soon as the decision is made. In all cases of premature termination, the PI should promptly inform trial participants and where applicable, their primary care physician of the closure so that appropriate therapy, follow-up or continued care can be arranged.

## 6. Procedure

### Principal Investigator (PI)

Supervise all staff carrying out close-out activities to ensure they are undertaken in accordance with sponsor requirements and local policy.

Sign off the delegation log at the end of the study to confirm that it is complete and accurate.

Ensure all relevant staff and departments are informed when the trial is closed.

Ensure a lay summary of the trial results (usually provided by the sponsor) is disseminated to participants in accordance with the HREC application/trial protocol.

<sup>1</sup> All trials must comply with the principles of GCP (Section 2 of ICH GCP (E6 R2) or Clause 4 of ISO 14155) however sponsors submitting data to regulatory authorities will normally require full compliance with ICH GCP (E6 R2) or ISO 14155 GCP Guidelines.

<sup>2</sup> NSW Health have published an annotated version of these SOPs for sites utilising a Teletrials model.

Ensure appropriate ongoing care of participants if a trial is prematurely terminated.

### **PI or delegate**

Inform relevant staff (e.g. pharmacy and other relevant support departments, referring clinicians, the Research Office) when recruitment has been completed and mark the investigator site file as closed to recruitment.

Inform the Research Office when the trial is closed.

Before the close-out meeting, communicate with the sponsor to confirm the final inventory of study-related materials and to arrange a suitable date for close-out.

Return/destroy unused materials in accordance with sponsor requirements.

Arrange for archiving of all site documents in accordance with SITE SOP-TC-11 and local policy.

## **7. References**

[ICH GCP \(E6 R2\): Good Clinical Practice Guidelines – Annotated by the TGA](#)

## **8. Associated documents**

Close-out checklist – available in the Standard Operating Procedures templates [zip file](#)