

2019

HEALTH+MEDICAL RESEARCH

# Delegation of duties by the principal investigator

Standard Operating Procedure



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## Document approval

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## 1. Purpose

To describe the procedure for delegating clinical trial duties and functions to appropriately qualified staff. 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 clinical trials with significant trial-related duties.

## 4. Definitions

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

## 5. Background

ICH GCP states that the PI has overall responsibility for the conduct of a trial at a trial site and must supervise any individual or party to whom they have delegated trial-related duties and functions. These responsibilities are outlined in Section 4 of ICH GCP. To perform this role, the PI must be:

- qualified by education, training, and experience to take responsibility for the trial at the site.
- thoroughly familiar with the study protocol and the investigational product(s).
- aware of, and compliant with GCP and any applicable regulatory requirements relating to clinical trial conduct.

The PI must maintain a list of appropriately qualified persons to whom the PI has delegated trial-related duties known as a Delegation Log. The Delegation Log will be kept in the Investigator Site File and a copy should be provided to the sponsor on request. Delegation Logs should be actively maintained (not constructed retrospectively) so there is evidence of appropriate delegation before any trial activities are undertaken.

### Who should sign the Delegation Log?

ICH GCP requires staff with *significant trial-related duties* to sign the Delegation Log. These are staff who make a direct and significant contribution to the data.

Staff who as part of routine practice provide ancillary or intermittent care by completing a procedure on a trial patient (i.e. vital signs, electrocardiography (ECG), venepuncture or imaging) do not need to sign a Delegation Log (or be listed on a 1572 Form for trials conducted under an Investigational Drug Investigation).

Where service departments (e.g. pharmacy, laboratories, radiology) are involved in trial-specific activities (e.g. dispensing investigational medicinal products), the PI may delegate the role of supervising and training departmental staff to a Named Person (e.g. a clinical trial pharmacist). This person would train all staff on any aspects of GCP/the protocol relevant to their role.

## 6. Procedure

### Principal Investigator (PI)

Ensure that individual trial-related duties and functions are defined, established and allocated appropriately (e.g. medical decisions are made by medical staff) and that each member of staff understands and accepts their role.

Maintain a Delegation Log, countersigning each person's entry before they undertake any trial activities to confirm that they are qualified by *education, training and experience* to perform their role.

Ensure the Delegation Log is updated in a timely fashion as personnel join or leave the study team or when an individual's study role changes.

At the end of the study, sign the declaration to confirm the information in the Delegation Log is accurate and complete.

Ensure sufficient staff to provide adequate medical cover and appoint a deputy to provide back up when absent.

Supervise any individual or party delegated significant trial-related duties and functions.

Follow Organisational policy when trial-related activities are contracted to external vendors.

### PI's delegate

Be comfortable that any delegated tasks are within their scope of practice and that they are competent to perform their role. If necessary, raise any concerns with the PI.

<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.

## 7. References

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

[National Statement on Ethical Conduct in Human Research \(2018\)](#), as amended

[Australian Code for the Responsible Conduct of Research \(2018\)](#)

[Guidance for Industry Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects \(FDA\) Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator \(Form FDA 1572\)](#)

## 8. Associated documents

[TransCelerate Delegation Log](#)

[TransCelerate CV Template](#)