

2019

HEALTH+MEDICAL RESEARCH

Clinical trial training and qualification

Standard Operating Procedure



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The NSW Ministry of Health has developed these resources as a guide to support public health organisations in developing local governance around clinical trials. The resources should not be relied upon as a complete summary of obligations on public health organisations in relation to clinical trials and are not intended to circumvent clinical judgment or replace locally developed clinical trials policies. Public health organisations are encouraged to seek legal or other advice if there is any uncertainty around compliance with clinical trials requirements.

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1. Purpose

To describe the requirements for clinical trial training and the documentation of staff training and qualifications. To ensure that sites conducting clinical trials take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements¹.

2. Scope

All clinical trials (except Teletrials)² conducted at NSW Public Health Organisations.

3. Applicable to

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

Relevant support department staff.

The Research Office.

4. Definitions

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

5. Background

ICH GCP requires the PI and other staff involved in a clinical trial to be *qualified by education, training, and experience* to perform their role and GCP auditors/inspectors look for evidence that staff have received training commensurate with their roles and responsibilities.

The PI is the person responsible, either individually or as a leader of the researchers at a site, for the conduct of research at that site and should be able to demonstrate they can assume the PI role. Evidence may include previous research experience, knowledge of research field, expertise in the procedures involved, training in research methods (including informed consent) and GCP training.

The PI and all staff with significant trial-related duties must maintain records of training and qualification including:

- Evidence of GCP Training (TransCelerate accredited GCP training) *
- A curriculum vitae (e.g. TransCelerate CV template) including Australian Health Practitioner Regulation Agency (AHPRA) registration details (where applicable) **

- A current job description
- A training file/training record.

** Where the organisation provides GCP training for site staff as part of its quality assurance processes, the training should meet the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma.*

***Sponsors may confirm a registration status from the APRHA website so this information does not need to be maintained in the investigator site file.*

Trial-related training

Staff must have appropriate trial-specific training before to performing any clinical trial activities. Depending on their role, this may include training on the protocol, investigator's brochure and trial-related procedures and equipment. Training may take any form (e.g. self-directed learning, remote/online training or face-to-face training). The PI should be confident that all staff are competent and where applicable, credentialed to perform their assigned tasks (e.g. obtaining consent, operating complex equipment, venepuncture). For staff with significant trial-related duties, trial-specific training may be carried out at a trial initiation meeting. Members of the team not able to attend the trial initiation meeting should complete alternative training before the start of trial-related activities.

When trial documents are amended (e.g. a protocol, participant information and consent forms, investigator's brochure), the PI should ensure the new information is disseminated to relevant staff in a timely fashion and that staff understand the changes.

GCP training

Knowledge of GCP should be provided in a way that is proportionate to the individual's role and level of trial activity. A trial risk assessment can be used to inform and justify the level of training; however, the following minimum requirements apply:

- **Staff with significant trial-related duties (all trials)**

Core trial staff should receive TransCelerate-accredited GCP training. Refresher GCP training should also be available to trial staff, at appropriate intervals to ensure that staff maintain awareness of current clinical trial standards and legislation.

¹ 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.

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

- **Ancillary staff involved in trials with novel/non-routine interventions**

For staff conducting trial-related procedures or involved in the care of trial patients, GCP training may be in an abbreviated format; for example, taking the form of a short departmental trial awareness sessions covering relevant requirements such as:

- recording adverse events
- documenting activities in source notes
- notifying protocol deviations and adverse events to the core trial team
- escalating any other issues identified to the core trial team.

Staff provided abbreviated GCP training include:

- pharmacy staff involved in general dispensing, under the oversight of a trial pharmacist who may perform training on relevant trial/GCP requirements.
- laboratory/diagnostic staff undertaking routine tests used in a trial, under the oversight of a lead contact who may perform training on relevant trial/GCP requirements.
- chemotherapy nurses with only the role of administering investigational products
- ward staff performing routine activities within their scope of practice.

- **Ancillary staff involved in standard care trials**

Trials involving routine treatment (e.g. comparative effectiveness trials) often involve large numbers of healthcare professionals that are suitably qualified to undertake the trial by virtue of the prior education, training and experience, and work to quality systems outlined in their professional codes of practice. If deemed appropriate through risk assessment, staff should be made aware of the trial/relevant GCP principles (e.g. at routine meetings, short trial awareness sessions or provision of written materials).

Written procedures

Trial staff should be familiar with any local policy, procedures (SOPs) or work instructions that are relevant to their role.

6. Procedure

Principal Investigator (PI)

Be able to demonstrate appropriate education, training, and experience where applicable, credentialing to assume the role of PI.

Assess the training and competency requirements of trial staff and ensure staff are suitably qualified by education, training, and experience to perform their trial-related duties.

Have an adequate number of trained/qualified staff for the duration of the trial including adequate cover/back-up of core staff.

Maintain a Delegation Log to document the role of all staff with significant trial-related duties.

Ensure records of all training and competency (central or personal records) are kept in accordance with local policy.

PI's delegate

Be confident that all trial tasks are within the individual's scope of practice and raise concerns if appropriate.

Be able to demonstrate appropriate education, training and experience, and where applicable, credentialing to perform trial activities.

Research Office

Ensure all relevant staff are aware of, and have appropriate knowledge of the suite of State-wide clinical trials SOPs in accordance with local policy.

If providing centralised training (e.g. GCP) keep records who has been trained.

7. References

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

[The National Clinical Trials Governance Framework \(Draft\)](#)

8. Associated documents

Personal Training Records Template – available in the Standard Operating Procedures templates [zip file](#)

[TransCelerate Delegation Log](#)

[TransCelerate CV Template](#)