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Documentation of Training and Clinical Trial Handover

SOP No:	SOP_CTSU_08
Version No:	2.0
Effective Date:	30 April 2023
Supersedes:	SOP_CTSU_08 Documentation of Training and Clinical Trial Handover Version 1.0 dates 1 July 2020
Review Date:	April 2026

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1.0 Introduction / Background

International Council for Harmonisation (ICH) Good Clinical Practice (GCP) stipulates that each member of the clinical trials team must be 'qualified by education, training and experience to discharge his/her role in the study'. The Principal Investigator (PI) is responsible for supervising any individual or party to whom they have delegated tasks at the clinical trial site.

In order to provide evidence of compliance with this requirement to regulatory authorities, records of clinical trials team experience, education and training are required. The maintenance of up-to-date training records provides a means of demonstrating the adequate training and experience of staff involved in the conduct of clinical trials. Training can be obtained through multiple sources including internal hospital accepted training and certification program(s), external hospital accepted training and certification program(s), and commercially available training.

ICH GCP states that "the investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely". The purpose of a handover is to ensure continuity of operations when the study team member, usually responsible, is not available due to temporary or permanent absence. A handover can be supported by a discussion to explain the status of the tasks, a summary of the work status in an email/ memorandum or, a more detailed Handover Form.

2.0 Objective

To outline the procedure for documenting training undertaken by staff who are conducting clinical trials.

To ensure that handover of clinical trials between staff members occurs and is clearly documented.

3.0 Scope

This SOP applies to all staff involved in clinical trials at South Western Sydney Local Health District (SWSLHD) and the Ingham Institute.

4.0 Ownership and Responsibility

It is the responsibility of the study sponsor to ensure that the PI and other key staff have the necessary expertise and experience to successfully conduct proposed clinical trials.

It is the PIs responsibility to ensure that the staff members who work on their clinical trials have the necessary expertise and experience to successfully conduct proposed clinical trials.

The PI is also responsible for managing the training and development of the clinical trial team and supervising their role in the clinical trial. These duties can be delegated to other members of the clinical trials team but must be documented in the Delegation of Responsibilities Log (FM_007_Delegation of Responsibilities Log) which must be filed in the Investigator Site File (ISF) or e-ISF.

For more information refer to SOP_CTSU_02 Investigator Responsibilities.

It is the responsibility of clinical trial staff to maintain and update their own training records in accordance to professional development.

The Clinical Trials Support Team (CTSU) will provide ICH GCP training, onboarding and ongoing clinical trials training to the clinical trials team. Please contact the CTSU via: SWSLHD-ClinicalTrialsSupportUnit@health.nsw.gov.au to arrange onboarding and further training for new and existing clinical trials staff.

5.0 Associated Documents

- SOP_CTSU_02 Investigator Responsibilities
- SOP_CTSU_09 Investigator Site File and Essential Documents
- FM_006_Protocol Specific Training Log
- FM_007_Delegation of Responsibility Log
- FM_008_Individual Training Log
- FM_009_Essential Documents for the Conduct of Clinical Trials
- FM_028_Handover Form
- FM_025_CTSU Orientation Manual

6.0 Procedure

6.1 Clinical Trial Staff Competency

The CTSU utilises Clinical Trial Competency guidelines to assess the competency of the clinical trials team members. These competencies will be assessed when a new clinical trial team member is employed. This baseline assessment will determine the initial training plan required for that employee. (FM_029_Core Competencies).

Clinical Trial staff members will also receive training in accordance with SWSLHD Policies on the My Health Learning Platform including basic/advanced life support and emergency management. If a staff member is employed by the Ingham Institute, additional orientation requirements such as facility orientation are mandatory.

6.2 Clinical Trial Staff Training

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

- Evidence of TransCelerate accredited ICH GCP Training
- A curriculum vitae (CV) including relevant registration details (where applicable)
- A current job description
- Relevant University degree, Registration and training certificates

All staff CVs are required to be reviewed and updated every two years and maintained within the eISF Veeva Site vault.

ICH GCP training is mandatory within SWSLHD before any staff member commences work on a clinical trial. The training must be TransCelerate accredited. ICH GCP training is valid for three years. Following this time period, a refresher course can be completed. The CTSU can provide this training for all clinical trial teams across the LHD, the Ingham Institute and all associated partners. In the event that there is no scheduled ICH GCP session available, please discuss with the CTSU and they will advise on online training courses. GCP certificates are to be maintained on the eISF.

Relevant study-specific training is required to be documented using a Training Log (FM_006_Protocol Specific Training Log) and filed in the eISF. This document provides evidence of protocol-specific training. The PI is responsible for ensuring that all staff involved in a clinical trial receive protocol-specific training along with all other trial-specific training in a timely fashion upon commencing their role or in the event of an amendment to the trial. This includes relevant supporting departments that are delegated to perform trial-related activities by the PI.

Clinical trial staff are required to maintain a list of appropriately qualified persons to whom the Investigator has delegated significant trial-related duties. The list is unique to each clinical trial conducted and is documented in the form of a Delegation of Responsibilities Log (FM_007_Delegation of Responsibilities Log). Please review SOP_CTSU_02 Investigator Responsibilities for more details.

On appointment to the clinical trials team, the Lead Investigator/Manager or delegate will schedule an orientation session with the CTSU. This can be arranged by emailing swslhd-clinicaltrialssupportunit@health.nsw.gov.au.

For all new Clinical Trial Coordinators (CTC), the CTSU will tailor the orientation and support required depending on the level of experience of the new staff member. The CTSU will also support the Lead PI/Research Director to allocate clinical trials for a new member of the team, based on previous experience and qualifications. Further training may be provided to bring the clinical trial team member up to the required level for specific tasks. Upskilling Trials staff is also centrally coordinated by the CTSU team.

Each Investigator, Clinical Trials Coordinator and associated clinical trials team members are required to review and acknowledge the SWSLHD/Ingham Institute Standard Operating Procedure (SOPs). The record of acknowledgement is tracked by the CTSU meeting the National Accreditation training and compliance standards.

Before the clinical trial activation for recruitment, the Sponsor will organise a Site Initiation Visit (SIV) meeting to train all clinical trial team members. Clinical trial team members must attend the meeting for a thorough understanding of the clinical trial. This training will be documented on the Protocol Specific Training Log. For more information please refer to SOP_CTSU_10 Site Initiation and Activation.

6.3 Ancillary Staff

For staff conducting clinical trial-related procedures or involved in the care of clinical trial patients, ICH 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 clinical trial team.

Staff that can be provided abbreviated ICH GCP training include:

- Pharmacy staff involved in general dispensing, under the oversight of a clinical trial pharmacist who may perform training on relevant protocol and ICH GCP requirements
- Laboratory/diagnostic staff undertaking routine tests used in a clinical trial, under the oversight of a lead contact who may perform training on relevant protocol and ICH GCP requirements
- Radiology staff undertaking routine tests used in a clinical trial, under the oversight of a lead contact who may perform training on relevant protocol and ICH GCP
- Chemotherapy and day care nurses with only the role of administering investigational products
- Ward staff performing routine activities

Clinical trials involving routine treatment (e.g. comparative effectiveness trials) often involve large numbers of healthcare professionals that are suitably qualified to undertake the clinical 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 clinical trial and ICH GCP principles (e.g. at routine meetings, short trial awareness sessions or provision of written materials). If required by the trial team the above staff should complete a ICH GCP course that is certified by TransCelerate.

6.4 Handover Training

If a team member is planning extended leave, or is resigning from their position they are responsible to ensure that the proper handover is given to the incoming clinical trial team member or delegate identified. The incoming clinical trial team member or delegate should be briefed within a suitable amount of time before the person departs. In the event that there is no one identified the Lead Investigator/Delegate should discuss this with the CTSU to ensure a plan to mitigate any risk is facilitated before the staff member leaving.

In addition to verbal handover a documented Handover Form (FM_028_Handover Form) is mandatory prior to their departure. This form includes the following:

- Training on protocol and required websites to facilitate the trial

- eISF location and any outstanding filing requirements or pending amendments/reports
- Information regarding clinical trial subjects, documents and all clinical trial-related activities
- Outstanding data entry and/or data queries
- Notification to the sponsor/CRA of the clinical trial team changes
- Notification to the active participants of the clinical trial team changes
- Provide a list of clinical trial-specific contacts (e.g., sponsor, monitor, vendors etc)
- The outgoing person has to make sure that the documentation concerned for the tasks is up to date and easily available, and if needed, revise it when preparing the handover.

For trial staff going on extended leave, the outgoing clinical trial team member is required to complete the same handover documentation using the Handover Form (FM_028_Handover Form) to the relieving trial coordinator.

When the clinical trial member returns from extended leave, a handover from the reliving coordinator is required to be prepared to provide relevant updates on the trial following leave.

All handover correspondence must be filed in the eISF under correspondence in accordance with SOP_CTSU_09 Investigator Site File and Essential Documents.7.0

7.0 References

ICH GCP (E6 R2): Good Clinical Practice Guidelines - Annotated by TGA

8.0 Amendment history

Version	Date	Amended or Updated By	Details of Amendment
1.0	1 July 2020	Kelsey Dobell-Brown	Due to operational changes and accreditation requirements.
2.0	April 2023	Kelsey Dobell-Brown	Due to operational changes and accreditation requirements.

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