

SOP Number: 30

SOP Title: Site Staff Qualifications, Training Records and Capability

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AUSTRALIAN ICH GCP (Including Teletrials) SOP 30
Site Staff Qualifications, Training Records and Capabilities

PUBLIC RELEASE VERSION 4.0

<http://www.health.qld.gov.au/hiro>

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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.

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1 Purpose

The purpose of this Standard Operating Procedure is:

- a) to ensure the appropriate documentation of clinical research site staff qualifications and training records are completed and maintained up to date during the course of the study, and
- b) to ensure the provision of resources to perform clinical research at all clinical research sites, according to the principles of ICH GCP and the NHMRC National Statement on Ethical Conduct in Human Research (2007) - Updated 2018.

2 Responsibility / Scope

This Standard Operating Procedure 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 Standard Operating Procedures, please refer to Chapter Two: Glossary located at the front of the Australian ICH GCP Standard Operating Procedures Compendium.

4 Procedure

4.1 Site Staff Qualifications

The Principal Investigator must:

- Be qualified by education, training and experience, including GCP training, to assume ultimate responsibility for the proper conduct of the research.
- If required by the local site RGO submit a current Curriculum Vitae (CV) to the RGO if not submitted previously and at any time the CV changes including (see Appendix 1):
 - current Australian Health Practitioner Regulation Agency (AHPRA) registration details.
 - other relevant documentation requested by the sponsor, the HREC, and/or the regulatory authority (e.g. current GCP training).
 - Current workplace name and address



- Ensure all investigational site staff, at both Primary and Satellite Sites, or Independent Third Party, and External Service Providers are qualified by education, training and experience, including GCP training, to assume responsibilities to perform the delegated study-related duties and functions.
- Ensure all investigational site staff, at both Primary and Satellite Sites, or Independent Third Party, who has been delegated significant responsibilities has a current CV in the research office/SMF for sighting by sponsor and / or regulatory authority. (see Appendix 1)
- Implement procedures to ensure the delegated study-related duties and functions performed are carried out safely.
- Implement procedures to ensure integrity of any data generated.

4.2 Site Staff Training Records

The Principal Investigator must:

- Ensure all required staff, including new staff involved during the course of a study, who assist with the clinical trial are informed about and trained on the protocol, any Investigational Product, and their research-related duties and functions. This can be in the form of an Initiation meeting held by any communication means e.g. via face-to-face, skype, videoconference, telehealth means etc.
- Record the study specific training given, documents and tools used, to whom and when e.g. on a training record or log. (see Appendix 2)
- Ensure the training and training record are kept up to date, kept at the Primary Site and Satellite Sites (when applicable) and available for review on request throughout the entire duration of the clinical research trial.

4.3 Capability

The Principal Investigator must:

- Demonstrate a potential for recruiting the required number of suitable participants, either from the principal site only or from associated Satellite Sites, within the specified recruitment period. This may be in the form of de-identified participant recruitment listings or other documented written or printed evidence.
- Have sufficient time to properly conduct and complete the research within the specified period.
- Have an adequate number of qualified staff and adequate facilities for the foreseen duration of the research.
- Maintain a record identifying appropriately qualified persons to whom they have delegated significant research-related duties (on a “per person” basis) such as a Delegation Log (see Appendix 3)
- Where applicable ensure each Satellite, Site maintains their own site Delegation Log separate to the Primary Site. The sub-investigator will delegate duties appropriately, sign and date the log and send a copy to the principal site, when



- requested (see Appendix 3a)
- Develop and complete a supervision plan before the commencement of a clinical research study that documents the manner and frequency of supervision to be undertaken between Primary Site and Satellite Site and other study staff, especially sub-investigators and other team members new to the role. The supervision plan must include cover for planned leave (see Appendices 4&5)
 - Provide oversight, as outlined in the supervision plan, to any third party to whom any study-related duty or function is outsourced and take responsibility for any study-related duty or function performed and any data generated by the third party.

5 Guidance Documents

Key Guidance documents – Chapter 4 of The Australian ICH GCP (including Teletrials) SOP Compendium

6 Appendices

- Appendix 1 TransCelerate Curriculum Vitae Template
<http://www.transceleratebiopharmainc.com/wp-content/uploads/2018/03/CV-Template-1.pdf>
- Appendix 2: Example Training Record
- Appendix 3: TransCelerate Delegation Log Principal Site.
<http://myscrs.org/learningcampus/site-management-modules/>
- Appendix 3a: TransCelerate Delegation Log Satellite Site
<http://myscrs.org/learningcampus/site-management-modules/>
- Appendix 4: Example Supervision Plan MS Word
- Appendix 5: Example Supervision Plan MS Excel

