# SOP 03 Site Staff Qualifications, Training Records and Capability

## 1.1 Purpose

The purpose of this Standard Operating Procedure (SOP) 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 the ICH GCP (and requirements of the Integrated Addendum to this Guideline published by the TGA), the National Statement (or its successor), and the requirements of the Clinical Trials Governance Framework.

ICH GCP requires the Principal Investigator (PI) and other staff involved in a clinical trial to be qualified by education, training, and experience to perform their role and Good Clinical Practice (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. The PI and all staff with significant trial related duties must maintain records of training (including an appropriate level of accredited GCP training) and qualifications. Staff must have appropriate and documented trial-specific training before performing any clinical trial activities.

## 1.2 Scope

This SOP applies to all relevant employees including, but not limited to, visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

## Procedure

3.1 Site Staff Qualifications

**The Principal Investigator must:**

- Be qualified by education, training and experience, including in skills, competencies and training requirements articulated in the National Clinical Trials Governance Framework, 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 2*):
  - current Australian Health Practitioner Regulation Agency (AHPRA) registration details[1].
  - evidence of appropriate GCP training (see Section 3.4)
  - other relevant documentation requested by the Sponsor, the HREC, and/or the regulatory authority.
  - current workplace name and address.

- Ensure all investigational site staff, at both Primary and Satellite Sites, or independent third parties, and external service providers have provided appropriate and current evidence that they are qualified by education, training and experience, including in skills, competencies and training requirements articulated in the National Clinical Trials Governance Framework, to assume responsibilities to perform the delegated study-related duties and functions and that they have the legal authority to do so. Delegation should be consistent with the Roles and Responsibilities specified in the Clinical Trials Governance Framework.
- Ensure all investigational site staff, at both Primary and Satellite Sites, independent third parties and/or external service providers, who have been delegated significant responsibilities have a current CV lodged with the research office/SMF for sighting by the Sponsor and/or regulatory authority.
- Implement procedures to ensure the delegated study-related duties and functions are carried out safely.
- Implement procedures to ensure integrity of all data generated.

ICH GCP requires an Investigator or Institution that retains the services of an individual or party to ensure the individual or party is qualified and where appropriate, credentialed to perform those trial related activities.

All vendors contracted as third-party suppliers of clinical trial services (e.g. IMP shipment, eye tests, laboratory or radiology services, participant identification services) should be assessed as appropriately qualified and credentialed and as having sufficient knowledge and experience to perform their contractual obligations.

Where a Satellite Site requires the services of a third-party provider, the process for contracting that provider should be outlined in the Supervision Plan.

3.2 Site Staff Training Records

**The Principal Investigator must:**

[1] Sponsors may confirm a registration status from the APRHA website so this information does not need to be maintained in the Investigator Site File.

- 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 etc.
- Ensure that for all study specific training provided, there is a record of documents and tools used, including details of who provided the training and when it was provided, by trial specific staff (e.g. on a training record or log - see *Appendix 3* Training Record).
- Ensure all required training is completed and the training record is kept up to date. A copy must be kept at the Primary Site and/or Satellite Sites (when applicable) and available for review on request throughout the entire duration of the clinical research trial.

3.3 Capability

**The Principal Investigator must:**

- When a teletrial is being conducted, the PI, who is always at the Primary Site and never at the Satellite Site, remains responsible for the trial across the cluster.
- Undertake the roles and functions of the Site Principal Investigator specified in the Clinical Trials Governance Framework.
- Demonstrate the potential for recruiting the required number of suitable participants, either from the Primary Site only, or from the Primary Site and 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.
- Ensure that a robust site assessment is undertaken that fully quantifies the capabilities of each Satellite Site to inform the extent to which trial related activities can be delegated to the site. This may include a pre-commencement assessment before a specific trial is proposed so that the process of trial start up is expedited when a suitable trial is identified. For Satellite Sites that have no or limited experience in delivering clinical trials, a staged approach may be undertaken to allow for gradual building of clinical trials capacity and capability (e.g. the Satellite Site is initially involved in less complex trials with greater levels of oversight provided by the Primary Site).

Robust feasibility and study start up processes enable the trial sponsor to verify that the site is an appropriate location at which to conduct the trial.

The process includes an assessment of the strategic fit of the trial and Protocol to the organisation, whether the trial is considered clinically important by the clinicians involved and sufficiently aligns with the Organisation's clinical services plans.

It is also important to ensure the local patient/participant population is not over-researched and there is a sufficient patient/participant population to meet recruitment targets.

A robust feasibility assessment that fully quantifies the capabilities of each Satellite Site is essential to inform the extent to which trial related activities can be delegated to the site.

- 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 4* Delegation Log.
  - Staff who as part of routine practice provide ancillary or intermittent care by completing a procedure on a trial patient/participant (i.e. vital signs, electrocardiography (ECG), venepuncture or imaging) generally do not need to sign a Delegation Log (or be listed on a 1572 Form for trials conducted under an Investigational Drug Investigation). However, if a key trial end point is based on reporting from routine care, then this should be clearly reflected in the Delegation Log as in this context, such reporting is considered critical to the trial.
  - 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.

A **Delegation Log** must be used to record which study-related roles and responsibilities have been assigned to each member on the teletrial team. Delegation Logs should be actively maintained (not constructed retrospectively) so there is evidence of appropriate delegation before any trial activities are undertaken. Each entry is signed and dated by the delegates and countersigned by the PI.

A **Supervision Plan** must also be developed before the commencement of a teletrial, which documents the manner and frequency of supervision to be undertaken between the Primary Site and each Satellite Site, and other study staff. It should detail how (and by whom) Satellite Site staff are trained and how they are deemed competent to undertake their delegated duties.

- Where applicable ensure each Satellite Site maintains its own site Delegation Log separate to the Primary Site. Where the PI has delegated such a task to the Satellite Site Associate Investigator, the Associate Investigator will delegate duties appropriately, sign and date the log and send a copy to the Primary Site, when requested. See Appendix 4 Delegation Log.
  - The process for maintaining the Delegation Log across Primary and Satellite Sites may involve the use of wet signatures, scanned copies and/or e-signatures.

- Develop and complete a Supervision Plan before the commencement of a teletrial, which documents the manner and frequency of supervision to be undertaken between the Primary Site and each Satellite Site, and other study staff, especially Associate Investigators and other team members new to the role. The Supervision Plan must include cover for planned leave. See *Appendix 5 Supervision Plan*.

- 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.

3.4 GCP Training

In accordance with the *Clinical Trials Governance Framework*, it is essential that clinical trial Investigators and clinical trial staff with significant delegated trial related responsibilities have access to and undertake training in the principles of GCP as a minimum requirement. 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.

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

- For staff conducting trial related procedures or involved in the care of trial patients/participants, 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 under the oversight of a day ward manager who has undertaken relevant GCP training.
- ward or other 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. Consistent with the Clinical Trials Governance Framework, at a minimum, all trial 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).

# Appendix 2

## Example of a CV

An example of a CV can be found on TransCelerate CV Template.

The CTPRG endorses the use of TranCelerate templates. If the provided link is broken please access the *TransCelerate website* to locate the current template.

# Appendix 3

## Training Record

Complete, sign, date and retain the original Form at the site. Provide a copy of the completed Form to the Sponsor representative.

| **Trainee Name: (Printed)** | | **Trainee Role:** |
|---|---|---|
| **Principal Investigator Name:** | Click or tap here to enter text. | ☒ Principal Investigator (PI) |
| **Protocol Name:** | Click or tap here to enter text. | ☐ Study Coordinator (SC) |
| **Site Number:** | Click or tap here to enter text. | ☐ Associate Investigator (AI) |
| ☐ **Primary**<br>☐ **Satellite** | | ☐ Other (Specify role e.g. Study Nurse) |
| **Training Method:** | ☐ Face to face<br>☐ Video/teleconference<br>☐ eLearning | |

| **Trainee Name: (Printed)** | | **Trainee Role:** |
|---|---|---|
| | ☐ Self-directed<br>☐ Other (see below) | |
| **Other Description:** | Click or tap here to enter text. | |

| Training topic (key) | Trainer Name and Role | Training completed date | Trainer signature and date | Trainee signature and date |
|---|---|---|---|---|
| **Blank cell** | | | | |
| | | | | |

| Key training topics | |
|---|---|
| 1. Protocol (version/date) | 10. IMP handling (version/date) |
| 2. Investigator Responsibilities (version/date) | 11. Laboratory Manual (version/date) |
| 3. Informed consent (version/date) | 12. Source Documentation (version/date) |
| 4. Interactive web response system (IWRS/IVRS) | 13. Monitoring Plan (version/date) |
| 5. ICH GCP E6 R2 (version/date) | 14. Other, specify: |
| 6. CRF completion (version/date) | 15. Other, specify: |
| 7. EDC System (version/date) | 16. Other, specify: |
| 8. Serious Adverse Event (SAE) Reporting (version/date) | 17. Other, specify |
| 9. Safety Monitoring Plan (version/date) | Add rows as needed |

By signing this training record, I attest that I have completed all training topics listed above for my role in the trial. I agree to follow TGA, the National Statement, ICH GCP guidelines, and the National Teletrials Compendium as well as instructions provided in these training topics when conducting this trial. This training was completed before performing any trial responsibilities, and trial related activities. I was given the opportunity to ask questions and received satisfactory clarification.

Signature:

Date: Click or tap to enter a date.

# Appendix 4

## Delegation Log

An example of a Site Signature and Delegation of Responsibility Log can be found on *TransCelerate/SCRS Site Signature and Delegation of Responsibility/*under Form Section.

# Appendix 5

## Supervision Plan

### National Teletrial Supervision Plan: Where a Medical Specialist is an Associate Investigator at the Satellite Site

**Supervision Plan for (xxx) Satellite Site for the Clinical Trial Protocol (xxx)**

#### Introduction

A clinical trial that is conducted using the Teletrial Model involves a cluster of sites. The term 'cluster' refers to all the sites involved in undertaking the clinical trial using the Teletrial Model. The cluster consists of the Primary Site (PS) which assumes overall responsibility for the conduct of the clinical trial and one or more Satellite Sites (SS), conducting the clinical trial under the direction of the Primary Site. A Principal Investigator (PI) is appointed at the Primary Site to take responsibility for overall supervision of the trial across a cluster in accordance with Good Clinical Practice and other trial regulatory requirements.

The level of supervision should be guided by two main factors:

- Whether there are one or more medical specialists at the Satellite Site. In all cases, the level of clinical oversight would mirror what is appropriate for telehealth.
- The level of clinical trial experience of Satellite Site staff, including whether the Lead Associate Investigator at the Satellite Site has prior experience as a Principal Investigator in their own right. The level of clinical trial oversight may reduce as site staff develop competence in clinical trial conduct.

This Supervision Plan provides a framework for the allocation and delegation of duties and functions. The template reflects the need for supervision of most clinical trial activities conducted at the Satellite Site. The PI should develop procedures for reviewing and documenting the performance of delegated tasks (e.g., observation of the performance of selected assessments) in a timely manner. As the Satellite Site becomes more experienced in the conduct of clinical trials, the level of supervision for certain activities can be adjusted accordingly at the discretion of the PI and by mutual agreement. Investigators may also wish to

refer to the TransCelerate Oversight Informational Program, which outlines basic components relevant to PI oversight of clinical trials, and uses scenarios to convey key concepts. Further information is available:

- *Guidance for Use of Principal Investigator Oversight Information Program*; and
- *TransCelerate Investigator Oversight*.

This document is supplementary to the standard suite of documents generated as part of a trial's set-up (e.g. the Clinical Trial Research Agreement, Delegation Log).

| **This Supervision Plan applies to:** | |
|---|---|
| Primary Site | Blank cell |
| Satellite Site | Blank cell |

## Abbreviations

Please refer to *Glossary of Terms* in the Teletrials Compendium for a full list of definitions.

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| **COMMUNICATION** | | | | | |
| Conducting, coordinating and documenting participant visits | | | | | |
| **GUIDANCE: DELETE FROM FINAL DOCUMENT**<br>• Determine whether joint consultations are required based on the whether the SS has a medical specialist Investigator and whether SS staff have prior clinical trial experience (e.g. have demonstrated competencies in the conduct of key trial procedures).<br>• When there is a medical specialist at a SS who has been an Investigator in a prior trial, the PI (in liaison with the sponsor) may deem joint consultations unnecessary and instead, may provide oversight through regular trial meetings.<br>• The person responsible should document the consultation in the medical records, or for Source Data not relevant to a participant's clinical care, in the participant's trial file as described in the Source Data Location List*. The visit number/status, date, delivery mode, persons present, all actions assigned to individuals etc. Is to be included.<br>**The location of trial documentation may be dependent on how the trial has been set up (e.g. whether the Sponsor intends to monitor the SS directly, whether the SS Investigator has direct access to the electronic records of the PS, etc.)*<br>Further information and guidance can be found in appendix 8 examples 1 and 2, and at:<br>• *Guidance for use of principal investigator oversight information program*; and<br>• *Transcelerate investigator oversight*. | | | | | |
| Coordinating regular trial meetings to discuss participants | | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| and trial progress (e.g. using telehealth or videoconference) | | | | | |

**GUIDANCE: DELETE FROM FINAL DOCUMENT**

The frequency and duration of trial meetings will be dependent on the nature and complexity of the trial and the number of participants recruited. The following agenda items are to be discussed, and minutes (with clear allocation of actions) to be produced and filed in both the PS and SS Trial Files. Any minutes relating to the clinical care of individual participants are also to be filed in the participant medical records at both the PS and the SS.

- Overall status of the study
- Overall status of the site (staffing etc.)
- Overall status of each participant enrolled at the Satellite Site including any safety concerns
- New study updates, information or communications from the study Sponsor or CRO

Any issues from the Satellite Site are to be followed up and resolved in timely manner.

| | | | | | |
|---|---|---|---|---|---|
| Coordination of Sponsor Monitoring Visits | | | | | |

**GUIDANCE: DELETE FROM FINAL DOCUMENT**

If the Sponsor conducts SS monitoring visits, liaison with the SS Coordinator and Pharmacist will be arranged as appropriate. The PS should be made aware of all visits and PS staff may wish to be present via telehealth as required.

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| Arranging sponsor visits to the Satellite Site | | | | | |
| **EDUCATION AND COMPETENCE** | | | | | |
| Ensuring all staff at the Satellite Sites are trained in appropriate aspects of the trial and GCP and are competent to perform their role | | | | | **See National Teletrial Compendium *SOP 03 for further details*** |
| Ensuring staff are aware of and understand any relevant SOPs | | | | | |
| Ensuring staff are aware of/trained on amendments | | | | | |
| **STAFF COVERAGE** | | | | | |
| Arranging for back up staff as required at the Satellite Site | | | | | |
| **CLINICAL CARE DECISIONS** | | | | | |
| Allocating responsibility for trial related management decisions | | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| and management of hospitalised participants at the Satellite Site (e.g. progression, need for additional investigations) | | | | | |
| **FUNDS MANAGEMENT** | | | | | |
| Managing payments to Satellite Sites | | | | | |
| **RESEARCH GOVERNANCE AT THE SATELLITE SITE: INITIAL APPLICATION** | | | | | |
| Creating a Satellite Site SSA application (where applicable) | | | | | |
| Creating site-specific documentation | | | | | |
| Obtaining local site HoD sign-off | | | | | |
| Submitting to the local site RGO | | | | | |
| Responding to local site RGO queries | | | | | |
| **RESEARCH GOVERNANCE AT THE SATELLITE SITE: START UP** | | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| Satellite Site start up (General) | | | | | |
| Satellite Site start up (Pharmacy) | | | | | |
| Satellite Site start up (Pathology) | | | | | |
| Satellite Site start up (Medical Imaging) | | | | | |
| Providing other trials related equipment | | | | | |
| Contracting third party provider/supplier | | | | | |
| **INVESTIGATIONAL MEDICINAL PRODUCT (IMP) FOR SATELLITE SITE (AMEND IF DEVICES TRIAL)** | | | | | |
| Transporting IMP to the Satellite Site | | | | | |
| Ordering of IMP | | | | | |
| Receiving and storing IMP | | | | | |
| Dispensing of IMP | | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| Reconciling IMP | | | | | |
| Training pharmacy staff (e.g. in the requirements of the pharmacy manual) | | | | | |
| **SCREENING OF POTENTIALLY ELIGIBLE PARTICIPANTS AT THE SATELLITE SITE** | | | | | |
| Screening (inclusion/exclusion criteria) | | | | | |
| **CONSENT PROCESS AT THE SATELLITE SITE** | | | | | |
| Consenting either remotely or at the Satellite Site | | | | | |
| Documenting consent in participant's medical records | | | | | |
| **ESSENTIAL DOCUMENT MANAGEMENTS/CRF ENTRY FOR PARTICIPANTS RECRUITED AT THE SATELLITE SITE** | | | | | |
| Storing/managing Source Documents | | | | | |
| **RANDOMISATION** | | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| Randomising a participant onto the trial | | | | | |
| Managing paper CRF data entry | | | | | |
| Managing e-CRF data entry | | | | | |
| Storing Essential Documents at the Satellite Site as per GCP and SOP 08 of Compendium | | | | | |
| **PARTICIPANT STUDY INVOLVEMENT AT THE SATELLITE SITE** | | | | | |
| Scheduling of next visit | | | | | |
| Notifying participant of next visit | | | | | |
| Scheduling of study tests/procedures | | | | | |
| Booking of study tests/procedures with relevant department(s) | | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| Managing trial visit requirements (e.g. physical exam, tests, processing samples for shipping etc) | | | | | |
| Conducting trial consultations and assessments as per Protocol | | | | | |
| **SAFETY REPORTING OCCURRING AT THE SATELLITE SITE** | | | | | |
| Reporting safety events to Sponsor | | | | | |
| Reporting safety events to the Satellite Site RGO | | | | | |
| Reporting safety events to the HREC (if required) | | | | | |
| **DEVIATIONS AND SERIOUS BREACHES AT THE SATELLITE SITE** | | | | | |
| Reporting Protocol deviations to the Sponsor | | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| Managing Serious Breaches occurring at the Satellite Site | | | | | |
| **RESEARCH GOVERNANCE AT THE SATELLITE SITE: AMENDMENTS** | | | | | |
| Managing amendments of site-specific documentation | | | | | |
| Obtaining local site HoD sign-off (if required) | | | | | |
| Submitting to the local site RGO | | | | | |
| Responding to local site RGO queries | | | | | |
| **STUDY CLOSE-OUT AT THE SATELLITE SITE** | | | | | |
| Satellite Site close-out | | | | | |
| Satellite Site close-out (Pharmacy) | | | | | |
| Satellite Site close-out (Pathology) | | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF | | | | COMMENTS |
|---|---|---|---|---|---|
| | PS RESPONSIBLE | SS WITH DIRECT SUPERVISION FROM PS | SS WITH SUPPORT FROM PS | SS RESPONSIBLE | |
| Satellite Site close-out (Medical Imaging) | | | | | |
| Managing Satellite Site archiving of trial documentation | | | | | |

Signatures to the agreement of the Supervision Plan

| | | | |
|---|---|---|---|
| **PI SIGNATURE:** CLICK OR TAP HERE TO ENTER TEXT. | **DATE:** CLICK OR TAP TO ENTER A DATE. | **SS LEAD AI SIGNATURE:** CLICK OR TAP HERE TO ENTER TEXT. | **DATE:** CLICK OR TAP TO ENTER A DATE. |

# Glossary

| TERM | DESCRIPTION |
|---|---|
| **ADE** | Adverse Device Effect |
| **ADR** | Adverse Drug Reaction |
| **AE** | Adverse Event |
| **AHPRA** | Australian Health Practitioner Regulation Agency |
| **AI** | Associate Investigator |
| **ARPANSA** | Australian Radiation Protection and Nuclear Safety Agency |
| **ARPANSA Code of Practice** | ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research |
| **CAPA** | Corrective and Preventative Actions |
| **CASA** | Civil Aviation Safety Authority |
| **CIOMS** | Council for International Organizations of Medical Sciences |
| **CPI** | Coordinating Principal Investigator |
| **CRA** | Clinical Research Associate |
| **CRC** | Clinical Research Coordinator |
| **CRF** | Case Report Form |
| **CRO** | Contract Research Organisation |
| **CTA** | Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme) |
| **CTN** | Clinical Trial Notification scheme |
| **CTPRG** | Clinical Trials Project Reference Group |
| **CTRA** | Clinical Trial Research Agreement |
| **CV** | Curriculum Vitae |
| **DSMB** | Data and Safety Monitoring Board |
| **EMR** | Electronic Medical Record |
| **GCP** | Good Clinical Practice |
| **HHS** | Hospital and Health Service |
| **HREC** | Human Research Ethics Committee |
| **IATA** | International Air Transport Association |

| | |
|---|---|
| **ICH** | International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use |
| **IP** | Investigational Product |
| **IMD** | Investigational Medicinal Device |
| **IMP** | Investigational Medicinal Product |
| **IVRS** | Interactive Voice Response System |
| **IWRS** | Interactive Web Response System |
| **National Statement** | National Statement on Ethical Conduct in Human Research (NHMRC) |
| **NHMRC** | National Health and Medical Research Council |
| **NMA** | National Mutual Acceptance |
| **PI** | Principal Investigator |
| **PICF** | Participant Information and Consent Form |
| **PMS** | Post Registration or Marketing Surveillance Study |
| **RGO** | Research Governance Officer |
| **SADE** | Serious Adverse Device Effect |
| **SAE** | Serious Adverse Event |
| **SMF** | Study Master File |
| **SSA Form** | Site Specific Assessment Form |
| **SSI** | Significant Safety Issue |
| **SSSF** | Satellite Site Study File |
| **SUSAR** | Suspected Unexpected Serious Adverse Reaction |
| **TGA** | Therapeutic Goods Administration |
| **UR** | Unit Record |
| **USADE** | Unanticipated Serious Adverse Device Event |
| **USM** | Urgent Safety Measure |

## ○ Revision Chronology

| **Document History** | | | |
|---|---|---|---|
| Version | **Effective Date** | **Summary of Changes** | **Author** |
| **1.0** | *13/11/2025* | Initial Version | Katie Ozdowska |