	TITLE: Clinical Trial Standard Operating Procedure 03: Site Staff Qualifications, Training Records and Capability		
Document Type:	Procedure	**Approved by:**	CMO & EDMS
Directorate:	CMO & Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Clinical Trials Coordinator

DO NOT USE THIS STANDARD OPERATING PROCEDURE IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION.

The definitive versions of all Goulburn Valley Health (GVH) Clinical Trial Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the GVH website or Prompt.

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Document Approval

Name:	Dr John Elcock
Position:	Executive Director of Medical Services and Chief Medical Officer
Date:	16 June 2023

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Version	Effective Date	Review Date	Author(s)	Amendment Details
1.0	12 Nov 2020	16 June 2023	Dr Ainsley Robinson Research and Ethics	Reviewed and updated to v2.0

GVHealth	**TITLE:**	**Clinical Trial Standard Operating Procedure 03: Site Staff Qualifications, Training Records and Capability**	
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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 within the auspices of Goulburn Valley Health (GVH) , according to the principles of International Council for Harmonisation of Technical requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice (and requirements of the Integrated Addendum to this Guideline published by the Therapeutics Goods Administration (TGA)) (ICH GCP E6 (R2)), the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007) - Updated 2018, and the requirements of the National Clinical Trials Governance Framework (NCTGF).

ICH GCP E6 (R2) 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.

2. SCOPE:

This SOP applies to all GVH employees, visiting health professionals, contractors, any external researchers, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving GVH patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. PROCEDURE:

3.1. Site Staff Qualifications

3.1.1. The Principal Investigator must:

- Be qualified by education, training, and experience, including in skills, competencies and training requirements articulated in the NCTGF, and assume ultimate responsibility for the proper conduct of the research.
- Submit a current Curriculum Vitae (CV) to the Research Governance Officer (RGO) if not submitted previously and at any time the CV changes including (see Appendix 1: Example CV Template):
  - Current Australian Health Practitioner Regulation Agency (AHPRA) registration details.
  - Evidence of appropriate GCP training (see Section 3.4).
  - Other relevant documentation requested by the Sponsor, the Human Research Ethics Committee (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 are qualified by education, training and experience, including skills, competencies and training requirements articulated in the NCTGF, to assume responsibilities to perform the delegated study-related duties and functions that they have the legal authority to do so. Delegation should be consistent with the Roles and Responsibilities specified in the NCTGF.
- Ensure all Investigational site staff, at both Primary and Satellite Sites, independent third parties, and/or external service providers who has been delegated significant responsibilities, have a current CV submitted to the RGO and in the Study Master File (SMF) for sighting by Sponsor and/or regulatory authority.
- 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.

ICH GCP E6 (R2) requires an Investigator or Institution that retains the services of an individual or party to ensure the individual or party is qualified to perform those trial related activities.

All vendors contracted as third-party suppliers of clinical trial services (e.g., Investigational Product (IP) shipment, eye tests, laboratory or radiology services, participant identification services) should appropriately qualified and have 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/Logs

3.2.1. 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 IP, 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 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 2: Example Training Record).
- Ensure that all required training is completed and the Training Record/Log is kept up to date. A copy is 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

3.3.1. 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 PI specified in the NCTGF.
- Demonstrate a potential for recruiting the required number of suitable participants, either from the Primary Site only or from associated Satellite Sites, within the specified recruitment period.
- 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. The PI is responsible for ensuring the Delegation Log is maintained and current. See Appendix 3: Example 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 supporting departments (e.g. pharmacy, laboratories, radiology) are involved in trial-specific activities (e.g. dispensing Investigational Medicinal Products (IMPs)), 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.

- Where applicable, ensure each Satellite Site maintains their own site Delegation Log separate to the Primary Site. Where the PI has delegated such a task to the Satellite Site Associate Investigator (AI), The AI will delegate duties appropriately, sign and date the log and send a copy to the Primary Site, when requested. See: Appendix 3: Example 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 that documents the manner and frequency of supervision to be undertaken between Primary Site and Satellite Site, and other study staff, especially AIs and other team members new to the role. The Supervision Plan must include cover for planned leave. See: Appendix 4: 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 NCTGF, 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.

3.4.1. Staff with Significant Trial Related Duties (all trials):

- Core trial staff must receive TransCelerate accredited GCP training. Refresher GCP training is available to trial staff, to ensure that staff maintain awareness of current clinical trial standards and legislation.

3.4.2. 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 all types of adverse events (AEs);
- documenting activities in source notes;
- notifying Protocol deviations and AEs to the core trial team;
- escalating any other issues identified to the core trial team.

3.4.3. Staff provided Abbreviated GCP Training include:

- pharmacy staff involved in general dispensing, under the oversight of a trial pharmacist who is GCP certified.
- laboratory/diagnostic staff undertaking routine tests used in a trial, under the oversight of a lead contact who is GCP certified.
- chemotherapy nurses with only the role of administering IPs 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.

3.4.4. 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 NCTGF, 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).

ABBREVIATIONS AND TERMS:

Please refer to GVH_CT-SOP-Abbreviations and Terms.

KEY ALIGNED DOCUMENTS:

Nil.

REFERENCES:

ICH GCP E6 (R2)

NCTGF and User Guide

APPENDICES:

Contributors to the document

	Name	Position	Department
Document Owner:	Dr Ainsley Robinson	Clinical Trials Coordinator	Research and Ethics
Document Author:	Dr Ainsley Robinson	Clinical Trials Coordinator	Research and Ethics
Contributor:	Dr Md Rafiqul Islam	Director of Research	Research and Ethics
Committee:	Executive Committee – Safety, Quality & Performance		
	Dr John Elcock, Chief Medical Officer/ Executive Director, Medical Services		

Appendix 1: Example CV Template

TransCelerate Abbreviated CV Template

Also available from https://transceleratebiopharmainc.com/assets/site-qualification-and-training/

TransCelerate BIOPHARMA INC.

ABBREVIATED CURRICULUM VITAE

Name & Title

First, Middle, Last Name: _____ Job/Professional Title: _____

Name & Critical Contact Details

Company/Institution Name: _____ Phone: _____
Address1: _____ Fax Number: _____
Address2: _____ Mobile/Cell Phone: _____
Email Address: _____

Facilities Affiliations

Primary Facility	Facility/Department Name	Address

Education

Degree/Certificate	Institution	Specialty	Year Completed

Professional Experience

Job Title	Institution/ Department	Year Started	Year Completed

License Details

Type of License	License Issuer	Professional License Number	State, Province or Region	Country	Issue Date	Expiration Date

Page 1 of 2 TransCelerate BioPharma Abbreviated CV Template Version 4.1, Q3 2019

TransCelerate BIOPHARMA INC.

ABBREVIATED CURRICULUM VITAE

Name & Title

First, Middle, Last Name: _____ Job/Professional Title: _____

Good Clinical Practice (GCP) Training Details

Course Provider	Title of Training	Version	Date Completed

Research Experience

STUDY TYPE

☐ Academic ☐ Government ☐ Industry ☐ Investigator-Initiated

☐ Other / Please Specify:

CLINICAL STUDY PHASES

☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

THERAPEUTIC AREA(S) OF EXPERTISE

Therapeutic Area	Sub-Therapeutic Area

TOTAL CLINICAL RESEACH EXPERIENCE

Therapeutic Areas	Sub-Therapeutic Area	Number of Completed Studies	Number of Ongoing Studies

SIGNATURE (Please follow the direction of the Sponsor in completing this field.)

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: X _____ ***Date:*** _____

Page 2 of 2 **TransCelerate BioPharma Abbreviated CV Template Version 4.1, Q3 2019**

Appendix 2: Example Training Log

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

Trainee Name:	
Trainee Role:	☐ Principal Investigator (PI) ☐ Study Coordinator (SC) ☐ Associate-Investigator (AI) ☐ Pharmacist ☐ Other (Specify role e.g. Study Nurse)
PI Name:	
Protocol Name/Number:	
Site: ☐ Primary ☐ Satellite	
Training Method:	☐ Classroom face to face ☐ Video/teleconference ☐ eLearning ☐ Self-directed ☐ Other (see below)
Other:	

Protocol and Non-protocol-specific training topics	Trainer(s) Name & Role (if applicable)	Training method	Training Completed DDMMMYYYY
Protocol (version/date)			
Investigator Responsibilities (version/date)			
Informed Consent (version/date)			
Interactive Web response System (IWRS/IVRS) (version/date)			
ICH GCP E6 R2 (version/date)			
CRF completion (version/date)			
EDC system (version/date)			
Serious Adverse Event (SAE) Reporting (version/date)			
Safety Monitoring Plan (version/date)			

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, NHMRC 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 of Trainee Date (dd-mmm-yyyy)

Appendix 3: Example Delegation Log

TransCelerate/SCRS Site Signature and Delegation of Responsibility Log Also available from https://myscrs.org/learning-campus/site-management-modules/ (Scroll down to the Forms section)

Site Signature and Delegation of Responsibilities Log

TransCelerate BIOPHARMA INC.

Study Sponsor:		Principal Investigator:	
Protocol Study Number:		Study Site Number:	
Country:			

PLEASE REFER TO THE GUIDANCE DOCUMENT FOR DETAILED INSTRUCTIONS ON THE COMPLETION OF THIS FORM.

THIS FORM IS TO BE COMPLETED FOR SITE PERSONNEL INVOLVED IN THE STUDY TO WHOM THE INVESTIGATOR HAS DELEGATED SIGNIFICANT STUDY-RELATED DUTIES. THE FORM IS TO BE COMPLETED PRIOR TO CONDUCTING STUDY RELATED TASKS.

THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE FOR ALL TASKS CONDUCTED AT THE STUDY SITE, THEREFORE THE PI COMPLETES THE SECTIONS INDICATED BUT THE PI IS NOT DELEGATED SPECIFIC TASKS IN THE TASK SECTION OF THE LOG.

THE PRINCIPAL INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL.

THE STUDY SITE IS REQUIRED TO MAINTAIN AN UP TO DATE VERSION OF THIS FORM IN ACCORDANCE WITH SPONSOR REQUIREMENTS.

IN THE EVENT THAT THE PI CHANGES REFER TO THE GUIDANCE DOCUMENT.

START OF STUDY DECLARATION: (to be completed at the start of the study)

Name of Principal Investigator	Principal Investigator's Signature*	Principal Investigator's Initials	Date (dd/mmm/yyyy)

***My signature confirms/acknowledges that the information contained here is accurate and that:**

- **I will remain responsible for the overall study conduct and reported data.**
- **I will ensure study oversight.**
- **I will authorize the delegation of study-related tasks to each individual as listed.**
- **The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.**
- **I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated study-related tasks prior to appropriate delegation and completion of study training appropriate to the role.**
- **I will ensure that site staff receives, in a timely manner, the appropriate information and training for delegated tasks.**
- **I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.**

END OF STUDY DECLARATION: I confirm that the information contained in this document is accurate and complete.

Name of Principal Investigator:	Signature:	Date:

Site Signature and Delegation of Responsibilities Log

TransCelerate BIOPHARMA INC.

Study Sponsor:	Click or tap here to enter text.	**Principal Investigator:**	Click or tap here to enter text.
Protocol Study Number:	Click or tap here to enter text.	**Study Site Number:**	Click or tap here to enter text.
Country:	Click or tap here to enter text.		

STUDY TASKS:

Medically Qualified/Trained/Licensed Staff	*Trained/Qualified Staff*	*Trained/Qualified Staff Continued*
1. Determine eligibility criteria (inclusion/exclusion)	14. Manage IRB/EC communications & submissions	28. Report SAEs
2. Perform Physical Exam	15. Maintain essential documents	29. Other
3. Make study-related medical decisions	16. Collect/process biological samples	30. Other
4. Evaluate study related test results	17. Ship biological samples	31. Other
5. Assess AE/SAE causality	18. Make (e)CRF entries, corrections and queries	32. Other
6. Assess Safety notifications	19. Recruit study subjects	
7. Sign off on (e)CRF visit data	20. Use IWRS/IVRS/IRT	
8. Unblind/Unmask	21. Manage SI receipt/storage/temperature monitor	
9. Discuss medical content of Informed Consent	22. Prepare Study Intervention (SI)	
10. Other	23. Dispense Study Intervention (SI)	
11. Other	24. Perform SI accountability	
12. Other	25. Administer SI	
13. Other	26. Obtain/Conduct Informed Consent	
	27. Obtain medical/medication history	

Site Signature and Delegation of Responsibilities Log

TransCelerate BIOPHARMA INC.

Study Sponsor:	Click or tap here to enter text.	**Principal Investigator:**	Click or tap here to enter text.
Protocol Study Number:	Click or tap here to enter text.	**Study Site Number:**	Click or tap here to enter text.
Country:	Click or tap here to enter text.		

Complete upon assignment of site staff						Complete when staff exit during the study	
Name	**Signature** My signature below indicates that I accept the study task.	**Initials**	**Study Role**	**Study Task(s)** (Select from key)	**PI initials and date** (dd/mmm/yyyy)	**End of task(s)** (dd/mmm/yyyy)	**PI initials and date** (dd/mmm/yyyy)
Example: *Katarina Koordinator*	*Katarina Koordinator*	*KMK*	Study Coordinator	17, 18, 20	*DMG 31/MAY/2017*	30/JUN/2018	*DMG 30/JUN/2018*

INVESTIGATOR SITE COMMENTS (optional): *(all Comments must be signed and dated)*

Site Signature and Delegation of Responsibilities Log
October 2022_V3

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Site Signature and Delegation of Responsibilities Log

TransCelerate BIOPHARMA INC.

Study Sponsor:	Click or tap here to enter text.	**Principal Investigator:**	Click or tap here to enter text.
Protocol Study Number:	Click or tap here to enter text.	**Study Site Number:**	Click or tap here to enter text.
Country:	Click or tap here to enter text.		

Complete upon assignment of site staff						Complete when staff exit during the study	
Name	**Signature** My signature below indicates that I accept the study task.	**Initials**	**Study Role**	**Study Task(s)** (Select from key)	**PI initials and date** (dd/mmm/yyyy)	**End of task(s)** (dd/mmm/yyyy)	**PI initials and date** (dd/mmm/yyyy)

INVESTIGATOR SITE COMMENTS (optional): *(all Comments must be signed and dated)*

Site Signature and Delegation of Responsibilities Log
October 2022_V3

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Site Signature and Delegation of Responsibilities Log

TransCelerate BIOPHARMA INC.

Study Sponsor:	Click or tap here to enter text.	**Principal Investigator:**	Click or tap here to enter text.
Protocol Study Number:	Click or tap here to enter text.	**Study Site Number:**	Click or tap here to enter text.
Country:	Click or tap here to enter text.		

Complete upon assignment of site staff						Complete when staff exit during the study	
Name	**Signature** My signature below indicates that I accept the study task.	**Initials**	**Study Role**	**Study Task(s)** (Select from key)	**PI initials and date** (dd/mmm/yyyy)	**End of task(s)** (dd/mmm/yyyy)	**PI initials and date** (dd/mmm/yyyy)

INVESTIGATOR SITE COMMENTS (optional): *(all Comments must be signed and dated)*

Site Signature and Delegation of Responsibilities Log
October 2022_V3

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Appendix 4: Supervision Plan

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

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

This Supervision Plan for Clinical Trial Protocol (xxx) applies to:	
Primary Site	Blank cell
Satellite Site	Blank cell

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 **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).** **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.** **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.** *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.) Further information and guidance can be found in appendix 8 examples 1 and 2, and at: **GUIDANCE FOR USE OF PRINCIPAL INVESTIGATOR OVERSIGHT INFORMATION PROGRAM; AND** **TRANSCELERATE INVESTIGATOR OVERSIGHT.**					
Coordinating regular trial meetings to discuss participants 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.					
Arranging sponsor visits to the Satellite Site					

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	
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 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					
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					
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)					
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					
Managing Serious Breaches occurring at the Satellite Site					

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	
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)					
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.