Teletrials Supervision Plan

Based on the Generic Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia

Government of South Australia
SA Health

Contents

Acknowledgment

This Teletrials Supervision Plan has been adapted from Queensland Health Standard Operating Procedures to provide this generic version.

Background

According to ICH GCP E6 R(2) the Principal investigator (PI) is responsible for supervising any individual or party to whom the PI delegates trial-related duties and functions conducted at the trial site (e.g., sub/associate investigators, study coordinators, pharmacists, residents, research fellows) and all aspects of the trial, whether the activity is completed at the Primary Site or Satellite Sites. If the PI retains any services of any individual or party to perform trial-related duties or functions, the PI must ensure the individual or party is qualified to perform those duties and functions and must implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

This Supervision Plan template is to assist in the capture of the supervision that occurs between the PI/Primary Site staff and staff at the Satellite Site, any external individual or independent service provider as well as any new staff involved in the clinical trial at the Primary Site.

A Supervision Plan must be created at the outset of a study. A separate plan is made for each Satellite Site the Principal Investigator is responsible for supervising in a trial regardless of their experience. The level of supervision will be determined by the level of experience of the Satellite Site and staff to be supervised.

Aims

- To establish an effective supervisory relationship by recording who from the Primary Site is providing supervision of the study to whom at the Satellite Site.
- To ensure all study team members have knowledge of and adhere to the established policies and procedures which have been ethically and institutionally approved for the study.
- To establish a process to identify any activity/issue to be addressed and manage its resolution and implementation
- To document the supervision process, frequency of contact and manner in which the contact will take place i.e. face to face, phone or via Telehealth and any outcome or action required.
- To inform the team of personnel cover for holidays, unexpected leave, after hours, and periods of absence with a full contact list.
- To provide a place where these activities are recorded as agreed.

Complementary documents

This plan is complementary to:

- the delegation log and
- the Generic Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia:
    - Standard Operating Procedure (SOP) Creation, Implementation and Revision
    - Investigator Responsibilities
    - Site Staff Qualifications, Training Records and Capability
    - Protocol and Investigational Brochure (IB) Requirements
    - Communication with Human Research Ethics Committee (HREC), Research Governance Office (RGO), Sponsor and Institution's Insurer
    - Site Initiation
    - The Study Site Master File and Essential Documents
    - Case Report Forms and Source Documents
    - Participant Informed Consent Process and Documentation
    - Handling and Shipping of Biological Substances and / or Dangerous Goods in Clinical Trials
    - Management of Investigational Product
    - Safety Data Monitoring and Reporting Requirements for Clinical Trials
    - Site Close Out and Archiving

Supervision Plan template – Example 1

Responsibilities Matrix: Primary Site (PS)

The below responsibilities are mandatory for the Primary Site and cannot be delegated to a Satellite Site:

Clinical Trial Activity	Insert initials of PS staff responsible	Comment / Action
Communication		
Coordination of regular study teleconference meetings/consultations		• Timetable regular and consistent meetings. Any issues from Sub-Investigator (SI)/Satellite Site to be followed up and issues resolved in timely manner. • All consults with trial patients will be done using telehealth technology. • The following people should be present: PI (compulsory), SI at Satellite Site (compulsory), main study coordinator (as needed), and nurse at the Satellite Site (as needed). • Medical notes should be documented by the PI into patient Medical Records or *e*Medical Records and into source notes by the Satellite SI, as appropriate
Liaison between Satellite Site and sponsor re site visits		• Consider liaison between the sponsor and the PI for initial visit then once the visit has been established and for future visits, communication could be directly between the Sponsor and the Satellite Site

Clinical Trial Activity	Insert initials of PS staff responsible	Comment / Action
Site Study File and Documentation		
Maintenance of Essential Documents		• Sponsor/Clinical Research Coordinator (CRC) at Primary Site to oversee Satellite Site study file on a regular basis. • The Site Delegation Log must be checked regularly and kept up to date • Training Log must be checked regularly and kept up to date
Education and Training		
Ensure all staff at both Primary and Satellite Sites are trained in: • **GCP** • **protocol and** • **relevant associated procedures e.g. laboratory, IMP and device handling, data transfer including imaging, pathology**		• Sponsor to provide GCP training or sites may also undertake own training e.g. using TransCelerate endorsed providers • Sponsor or PI are responsible for ensuring that all Satellite staff are trained as designated. PI can provide via videoconference at a later date when Satellite Site has a potential participant to screen and enrol • The Site Delegation Log may guide what training is to be given to clinical trial related staff • All training is to be documented. Training Log must be checked regularly and kept up to date • Sponsor or PI to provide all protocol specific training to Satellite Site staff

Clinical Trial Activity	Insert initials of PS staff responsible	Comment / Action
Research governance at Satellite Site – initial application		
Creation of site SSA application		• Primary Site Principal Investigator (PI) creates site SSA and transfers/assigns access to Satellite Site Sub/Associate Investigator or CRC
CTRA sub-contract		• PI or Primary Site CRC to initiate and Satellite Site to complete
Staff coverage at Satellite Site		
Ensure back up staff are available as required at both Primary Site and Satellite Site		• Develop cover plan for study staff at both Primary and Satellite Site to identify back up personnel when on leave, after hours or otherwise unavailable • PI back up should be at the Primary Site as the CTRA is between the sponsor and the Primary Site • Ensure Delegation Log and training logs are completed if relevant
Pre-screening, Consenting and Enrolment of participants at Satellite Site		
Pre-screening of a potential participant		• Pre-screening for eligibility will have been undertaken by Satellite Site, however for the first few potential participants, the PI should consider some contact with the Satellite Site to scroll through eligibility criteria addressing challenging criteria

Clinical Trial Activity	Insert initials of PS staff responsible	Comment / Action
Pre-screening, Consenting and Enrolment of participants at Satellite Site		

Consenting		• Identify how consent process will be conducted and documented. What roles will PI and SI have?
		• If the SI has not consented to a clinical trial before, PI could consider observing 1 or 2 consent processes prior to full delegation to SI.
		  o The consent interview will be conducted by Telehealth conference.
		  o The PI and the SI must both be present. The Primary Site study coordinator and the Satellite Site nurse are present if possible.
		  o Once the participant agrees to participate, they and the SI will sign the Informed Consent.
		• The PI can delegate consent processes to the SI if the SI is appropriately qualified, has a comprehensive understanding of the trial and has completed appropriate protocol training
		• Complete and file documentation as per SOP 09 Participant Informed Consent Process and Documentation *(please refer to main SOPs document)*

Enrolment		• Once consent signed by all parties, trial related procedures may begin, and participant should be given the trial wallet card • Remind them to present this card in a situation when the trial team must be notified • Screening log may need to be completed and sent to sponsor/PI/Primary Site CRC on a regular basis as defined in the plan • Participant Identification Log must be completed and filed in the Satellite Site study folder as per SOP 07 The Study Master File *(please refer to main SOPs document)*

Clinical Trial Activity	Insert initials of PS staff responsible	Comment / Action
Randomisation at Satellite Site		
Randomisation of a participant		• The Primary Site remains responsible for the randomisation of the participant and notifies the result of randomisation to the Satellite Site. However, if the Satellite Site has the experience and ability to randomise, the PI could consider delegating this activity to the Satellite Site. In this case relevant notification channels to be discussed and documented and documentation filed as per plan
Recruitment of participants to the trial		
Recruitment consideration via multi-media methods		• Methods such as social media, posters, flyers, radio and TV advertisements may be considered in the advertising campaign to attract potential participants to the trial • Local Satellite Site strategies to be included e.g. Satellite Site responsible for recruiting in local geographical area • Any advertisement MUST have HREC and sponsor approval prior to use

Clinical Trial Activity	Insert initials of PS staff responsible	Comment / Action
Data Management		
• **From Source Document to *e*CRF/database** • **Query Management**		• Specify who will enter the SS participant data into the *e*CRF/database, answer queries, action corrections • If Satellite Site Nurse/SI not familiar with data entry requirements, Primary Site PI/CRC to consider assisting with first data entry attempts then delegate as appropriate • Train up Satellite Site staff and seek access for Satellite Site to *e*CRF from sponsor • Document on Delegation and training log
Clinical care decisions		
Allocation of responsibility for trial related management of hospitalised participants		• If a trial participant is admitted to any hospital, the on-call physician will triage and manage the participant • The Primary Site PI must be notified of the admission (via use of the wallet card), who will then provide appropriate advice and arrange transfer if clinically required • Satellite Site notified as per plan if relevant
Unblinding procedure		• The PI via videoconference with Satellite Site will make all trial related decisions re unblinding

Clinical Trial Activity	Insert initials of PS staff responsible	Comment / Action
Safety reporting		
Reporting of safety events, including protocol deviations / violations, to sponsor, HREC, Sponsor and TGA		• Refer to SOP 12 Safety Data Monitoring and Reporting Requirements for Clinical Trials • As per NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods: **https://www.nhmrc.gov.au/sites/default/files/images/NHMRC-guidance-safety-monitoring-and-reporting.pdf** • Ensure Satellite Site knows the approving HREC reporting requirements • Specify flow of documentation
Funds management		
Payment to Satellite Sites		• To be discussed between Primary and Satellite Site. Agreement to be documented in the sub-contract
Participant reimbursements e.g. travel costs		• As per sponsor agreement which will be documented in the CTRA and carried over to the Satellite Site participants via the sub-contract
Telehealth fee when consultation via telehealth occurs (for admitted participants)		• As per local policy

Responsibilities Matrix: Satellite Site (SS)

Clinical Trial Activity	Responsible party - Insert initials of staff responsible					Comment / Action
	Primary Site (PS) responsibility	Satellite Site with direct supervision from PS	Satellite Site with support from PS	Satellite Site	N/A	
Research governance at Satellite Site – initial application						
Completion of SSA application						
Creation of site specific documentation, including sub-contract						
Obtaining local site Head of Department sign off						
Submission to local site RGO						
Responding to local site RGO queries						
Start up at Satellite Site						
Satellite Site start-up - general						

Clinical Trial Activity	Responsible party - Insert initials of staff responsible					Comment / Action
	Primary Site (PS) responsibility	Satellite Site with direct supervision from PS	Satellite Site with support from PS	Satellite Site	N/A	
Satellite Site start-up – Pharmacy						
Satellite Site start-up - Pathology						
Satellite Site start-up – Medical Imaging						
Provision of other trial related equipment						
Investigational Medicinal Product (IMP) handling for Satellite Site						
Ordering of IMP						• Identify what triggers both initial and resupply shipments of IMP, by whom and when
Receipt of IMP						• Identify who receives IMP e.g. Primary Site Pharmacist receives the IMP and transfers by courier to Satellite Site or Satellite Site receives IMP directly from sponsor

Clinical Trial Activity	Responsible party - Insert initials of staff responsible					Comment / Action
	Primary Site (PS) responsibility	Satellite Site with direct supervision from PS	Satellite Site with support from PS	Satellite Site	N/A	
Dispensing of IMP						• Identify who dispenses IMP e.g. Primary Site Pharmacist receives the IMP and transfers by courier to Satellite Site for dispensing to participant or Satellite Site receives IMP directly from sponsor and dispenses
Reconciliation of IMP						• Define responsibilities and manner • Define on accountability records
Destruction of IMP						• Define responsibilities and manner • Define on accountability records
Pre-screening, consenting, enrolment of potentially eligible participants at Satellite Site						
Pre-screening (inclusion / exclusion criteria), consenting and enrolment documented in participant's medical file						

Clinical Trial Activity	Responsible party - Insert initials of staff responsible					Comment / Action
	Primary Site (PS) responsibility	Satellite Site with direct supervision from PS	Satellite Site with support from PS	Satellite Site	N/A	
Data/eCRF entry for participants recruited at Satellite Site						
Storage of source documents						
Data entry						
eCRF entry						• Data is entered into the eCRF at the Primary Site for each visit conducted at the Primary Site • Data is entered into the eCRF at the Satellite Site for each visit conducted at the Satellite site • Source data for all visits will be filed as per SOPs
Storage of data at Satellite Site as per GCP						
Participant study involvement at Satellite Site						
Scheduling of next visit						
Notification of participant of next visit						

Clinical Trial Activity	Responsible party - Insert initials of staff responsible					Comment / Action
	Primary Site (PS) responsibility	Satellite Site with direct supervision from PS	Satellite Site with support from PS	Satellite Site	N/A	
Scheduling of study tests / procedures						
Booking of study tests / procedures with relevant department(s)						
Study visit(s) requirements e.g. physical examination, tests etc.						
Clinical care decisions						
Trial related treatment decisions and management of hospitalised participants at Satellites e.g. progression, need for additional investigations						• The Primary Site whilst on the videoconference will either make all trial related decisions or delegate to SI

Clinical Trial Activity	Responsible party - Insert initials of staff responsible					Comment / Action
	Primary Site (PS) responsibility	Satellite Site with direct supervision from PS	Satellite Site with support from PS	Satellite Site	N/A	
Safety reporting occurring at Satellite Site						
Reporting of safety events, including protocol deviations / violations to PI, sponsor and HREC						• All safety events should be reported by the SI to the PI as per: • NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods • SOP 12 Safety Data Monitoring and Reporting Requirements for Clinical Trials *(please refer to main SOPs document)*
Research governance at Satellite Site - amendments						
Amendment of site specific documentation						
Obtaining local site Head of Department sign off if required						
Submission to local site RGO						

Clinical Trial Activity	Responsible party - Insert initials of staff responsible					Comment / Action
	Primary Site (PS) responsibility	Satellite Site with direct supervision from PS	Satellite Site with support from PS	Satellite Site	N/A	
Responding to local site RGO queries						
Study close out – Satellite Site						
Satellite Site close out						
Satellite Site archiving						
Satellite Site close out - Pharmacy						
Satellite Site close out - Pathology						
Satellite Site close out - Medical imaging						

Supervision Plan template – Example 2

Supervision Plan – Activities **(repeat of activity contact is noted by inserting a line under the repeated activity)**				**Manner of contact can be skype, teleconsultation, videoconference, phone, face-to-face visit**	**This column is to record any action, outcome or resolution to the activity discussed. If follow up is required, this will be recorded on a separate line with the date and manner of that interaction**
#	**Planned Activity**	**Primary Site staff member**	**Satellite Site staff member**	**Date and manner of contact**	**Action / Outcome / Resolution**
1	**Ensure ICH GCP E6 R(2) is undertaken by all Satellite Site staff involved in the trial. Document accordingly on training log**				
2	**Telehealth consultation set-up**				
3	**Delegation log completion for all study staff at Satellite Site including third party**				

Supervision Plan – Activities (repeat of activity contact is noted by inserting a line under the repeated activity)				Manner of contact can be skype, teleconsultation, videoconference, phone, face-to-face visit	This column is to record any action, outcome or resolution to the activity discussed. If follow up is required, this will be recorded on a separate line with the date and manner of that interaction
#	Planned Activity	Primary Site staff member	Satellite Site staff member	Date and manner of contact	Action / Outcome / Resolution
4	Protocol specific training and discussion				
5	Eligibility screening and recruitment				
6	Consenting process remotely or on site				
7	Study consultations/ assessments as outlined in the research protocol				

Supervision Plan – Activities (repeat of activity contact is noted by inserting a line under the repeated activity)				Manner of contact can be skype, teleconsultation, videoconference, phone, face-to-face visit	This column is to record any action, outcome or resolution to the activity discussed. If follow up is required, this will be recorded on a separate line with the date and manner of that interaction
#	Planned Activity	Primary Site staff member	Satellite Site staff member	Date and manner of contact	Action / Outcome / Resolution
8	Serious Adverse Events (SAE) management: source documents, reporting and process				
9	General Communication				
10	Protocol amendments regarding protocol revisions and document on training log				

Supervision Plan – Activities (repeat of activity contact is noted by inserting a line under the repeated activity)				Manner of contact can be skype, teleconsultation, videoconference, phone, face-to-face visit	This column is to record any action, outcome or resolution to the activity discussed. If follow up is required, this will be recorded on a separate line with the date and manner of that interaction
#	Planned Activity	Primary Site staff member	Satellite Site staff member	Date and manner of contact	Action / Outcome / Resolution
11	Pharmacy and IMP/device handling training/discussion (Pharmacy manual) including details of transportation between Primary and Satellite Site, document completion and retention				
12	Pathology and sample handling training/discussion (Lab manual) including details of sample processing, transportation between Primary and Satellite Site, document completion and retention				

Supervision Plan – Activities (repeat of activity contact is noted by inserting a line under the repeated activity)				Manner of contact can be skype, teleconsultation, videoconference, phone, face-to-face visit	This column is to record any action, outcome or resolution to the activity discussed. If follow up is required, this will be recorded on a separate line with the date and manner of that interaction
#	Planned Activity	Primary Site staff member	Satellite Site staff member	Date and manner of contact	Action / Outcome / Resolution
13	Imaging training/discussion				
14	Source documents/Documentation management				
15	CRF completion, eCRF data entry, data handling, query resolution, storage				

Supervision Plan – Activities (repeat of activity contact is noted by inserting a line under the repeated activity)				Manner of contact can be skype, teleconsultation, videoconference, phone, face-to-face visit	This column is to record any action, outcome or resolution to the activity discussed. If follow up is required, this will be recorded on a separate line with the date and manner of that interaction
#	Planned Activity	Primary Site staff member	Satellite Site staff member	Date and manner of contact	Action / Outcome / Resolution
16	Address and document leave for Primary and Satellite study staff including period of leave, back up nominee. Back-up PI must be from the Primary Site as the CTRA is between the sponsor and the Primary Site				
17	Discuss visits by sponsor, Primary Site staff or regulatory bodies				
18	Discuss audit procedures				
19	Study close out and archiving				

For more information

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