AUSTRALIAN ICH GCP (Including Teletrials) SOP 30 Appendix 4 Example Supervision Plan Template

Title of Study: _____

Principal Site name: _____

Principal Investigator Name: _____

Signed:_____Date:_____

Satellite Site name: _____

Satellite Site Investigator Name: _____

Signed:_____Date:_____

Cluster Name:_____

Sponsor Company Name: _____

Sponsor Representative Name:_____

Signed:_____Date:_____

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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 has been developed 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 the same clinical trial.

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 confidentiality and ethics, knowledge of policies and procedures is equal across all study team members
- 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 took 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 and processes

This plan is complementary to:

- the delegation log and
- the AUSTRALIAN ICH GCP (Including Teletrials) (SOP) Compendium:
    - Documentation of Investigational Site Staff Qualifications, Training Records and Adequacy of Resources
    - The Study Site Master File and Essential Documents
    - Communication with Human Research Ethics Committee (HREC), Research Governance Office (RGO), Sponsor and Insurer

- Protocol and Investigational Brochure (IB) Development
- Management of Investigational Product
- Participant Informed Consent Process and Documentation
- Case Report Forms, Source Documents, Record Keeping and Archiving
- Site Initiation and Close Out
- Safety Data Monitoring and Reporting Requirements for Clinical Trials
- Investigator Responsibilities
- Handling and Shipping of Biological Substances in Clinical Trials
- Standard Operating Procedure (SOP) Creation, Implementation and Revision

Cluster

A cluster is a group of sites involved in undertaking the study using the teletrial model, consisting of the primary site who assumes overall responsibility for the conduct of the study and one or more satellite sites, which conduct the study under the direction and supervision of the primary site.

Document History

Date	Activity	Responsible parties
Feb 2018	Draft Version 1 developed	Townsville Hospital and Health Service
April 2018	Adaptation to Australian ICH GCP (including Teletrials) SOP 3	HIIRO

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		Timetable-regular and consistent meetings. Any issues from 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), Sub I 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 Mosaiq and/or ieMR and into source notes by the Satellite Sub I, 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
Documentation		
Maintenance of Essential Documents		Sponsor / Clinical Research Coordinator 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

Education & Training		
Ensure all staff at both primary and satellite site are GCP trained		Sponsor to provide GCP training or sites may also undertake own training e.g. using Transcelerate endorsed providers
Ensure all staff at both primary and satellite site are trained in the protocol and relevant associated procedures eg laboratory, IMP and device handling, data transfer including imaging, pathology		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 enroll 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 to provide all protocol specific training
Research governance at satellite site – initial application		
Creation of local satellite site(s) SSA application		Primary site Principal Investigator (PI) creates satellite site SSA and transfers them permanently 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
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. The consent interview will be conducted by telehealth conference. The PI and the SI must both be present. The primary site study coordinator and the satellite site nurse are present if possible. Once the participant agrees to participate, they and the SI will sign the Informed Consent. Complete and file documentation as per SOP 6
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 satellite site study folder as per SOPs

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
Recruitment of participants to the trial		
Recruitment considerations via multi-media methods		Recruitment is the advertising campaign to attract potential people to the trial. Methods such as social media, posters, flyers, radio and TV advertisements may be considered. Any advertisement MUST have HREC approval prior to use
Clinical care decisions		
Allocation of responsibility for trial related management decisions and 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.
Unblinding procedure		The PI via videoconference with satellite site will make all trial related decisions re unblinding
Safety reporting		
Reporting of safety events, including protocol deviations / violations, to sponsor, HREC, Sponsor and TGA		Refer to SOP 9 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

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)		The government incentive program has a finite end. Up to that time, when a consultation occurs via telehealth for an admitted participant, not applicable for an outpatient), each site must follow procedure in the teletrial user guide to obtain the respective fee: Provider receives $200 and receiver receives $137.

Responsibilities Matrix for satellite sites

Clinical Trial Activity	Responsible party – insert initials of staff (as per Appendix A)					Comment, Action
	Primary Site (PS) responsibility	Satellite site with direct supervision from PS	Satellite site with support from PS	Satellite site	NA	
Research governance at satellite site – initial application						
Completion of local SSA application						
Creation of site specific documentation, including sub-contract						
Obtaining local site HoD sign off						
Submission to local site RGO						
Responding to local site RGO queries						
Start up at satellite site						
Satellite site start up - general						
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.
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 IP						Define responsibilities and manner
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						
Data/eCRF Entry for participants recruited at satellite site						
Storage of source documents						
Data entry (not eCRF)						
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						

Scheduling of study tests / procedures						
Booking of study tests / procedures with relevant department(s)						
Study visit(s) requirements e.g. physical exam; 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 PI whilst on the videoconference will either make all trial related decisions or delegate to SI
Safety reporting occurring at satellite site						
Reporting of safety events, including protocol deviations / violations to PI, HREC sponsor						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/sites/default/files/images/NHMRC-guidance-safety-monitoring-and-reporting.pdf and SOP 9
Research governance at satellite site – amendments						
Amendment of site specific documentation						
Obtaining local site HoD sign off if required						
Submission to local site RGO						
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						