**Tele-Trial Model Supervision Plan Template**

**Satellite sites with on-site medical specialist without clinical trials experience**

# Background

This document details the supervision plan to enable recruitment of participants to a clinical trial using the Tele-Trial model at satellites sites where there is an on-site medical specialist but the site does not have clinical trials experience. The template reflects the need for supervision of most clinical trial activities conducted at the satellite site. As the satellite site becomes more experienced in the conduct of clinical trials the level of supervision can be adjusted accordingly at the discretion of the Principal Investigator (PI) at the primary site and the Sub-Investigator (SI) at the satellite site.

The Principal Investigator for a clinical trial conducted using the tele-trial model has the same responsibilities under ICH-GCP as required for any clinical trial. The PI will oversee all aspects of the trial, whether the activity is completed at the primary site or satellite sites and has responsibility to ensure the safety of all participants in the trial. Duties may be delegated by the PI, but the PI has accountability for all the clinical trial activity completed at the satellite site and must ensure all personnel working on the trial are adequately trained in all aspects of the clinical trial according to ICH-GCP.

# Complementary documents and processes

This supervision plan is complementary to:

* the feasibility assessment
* the site selection process
* the delegation log
* the Australian ICH GCP (including tele-trials) Standard Operating Procedures which can be accessed at: <https://www.health.qld.gov.au/hiiro/html/regu/for_researcher/gcp,research-ethics-and-governance-standard-operating-procedures-sop/_nocache>
  + 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

Cluster refers to all the sites involved in undertaking the clinical trial using the Tele-Trial Model. The cluster consists of the primary site who assumes overall responsibility for the conduct of the clinical trial and one or more satellite sites, conducting the clinical trial under the direction of the primary site.

Name of cluster this supervision plan applies to:

The primary and satellite sites for the cluster are:

1. Primary site:
2. Satellite site:
3. Satellite site:

# Document History

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| --- | --- | --- |
| **Date** | **Activity** | **Responsible parties (Primary Site and Sponsor or CRO)** |
|  |  |  |
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# 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 Primary Site staff (as per Appendix A)** | Insert Plan and Study Logistics | **Comments** |
| --- | --- | --- | --- |
| Communication | | | |
| **Coordination of Regular Clinical Trial Meetings**  Timetable regular and consistent meetings with agenda and minutes for all meetings scheduled.  Any issues from the satellite site are to be followed up and resolved in timely manner.  Telehealth technology shall be employed at the discretion of the Principal and Sub Investigator (SI). The SI working on the trial will be trained in the clinical trial protocol and the PI will delegate the conduct of clinical trial activities as appropriate. Supervision is at the discretion of the PI and SI    The following people should be present: Principal Investigator (PI) (compulsory), Sub- Investigator (SI) at satellite site (compulsory), Primary study coordinator (compulsory), and Clinical Research Coordinator (CRC) at the satellite site (if possible).  Medical notes should be documented by the SI into the Electronic Medical Record (EMR) or the paper Medical Record and into source notes, as appropriate.  For the first 2 months of the first patient’s involvement in the study telehealth/videoconference meetings will occur every 2 weeks between the PI and the SI at the satellite site. Then four weekly while there are patients on active treatment. While patients are in follow up this time frame can be extended upon agreement.  The following Agenda items must be discussed, and minutes documented:  1. Overall status of the study  2. Overall status of the site (staffing etc.)  3. Overall status of each patient enrolled at the satellite site including any safety concerns  4. New study updates, information or communications from the study sponsor or CRO  All meetings with a record of who attended must be documented in Minutes with Action Points identified and documented.  Minutes should be filed in the Study Master File at the primary and satellite sites. Minutes relating to a specific patient can be scanned into EMR or another medical record at both the primary and the satellite site  Prompt resolution of Action Points should be documented in the next meeting’s Minutes. |  |  |  |
| **Liaison between satellite site and sponsor re site visits:**  Sponsor or CRO to inform and liaise with, the Primary Site when planning visits to satellite sites  The sponsor or CRO will liaise with the Satellite Site SI, CRC and Pharmacist to arrange a site visit. Primary site will be present via telehealth as required.  The frequency of site visits will be defined by the sponsor or CRO in collaboration with sites. |  |  |  |
| Education | | | |
| **Ensuring all staff at both primary and satellite sites are trained in appropriate aspects of the trial:**  All staff should provide a current CV prior to enrolling any patients into the clinical trial.  The Site Delegation Log must define each staff members responsibility in the clinical trial at both the primary and satellite sites and will be used to guide provision of training.  The Site Delegation Log must be checked regularly and be kept up to date.  The Site Delegation Log must be provided to the sponsor whenever a change in site personnel or staff responsibilities occurs.  All training is to be documented.  PI is responsible for ensuring that all satellite staff are trained as designated.  Sponsor or CRO to provide all protocol specific training as designated by the PI.  Sponsor to provide all ICH-GCP training (if not already accredited) as designated by the PI.  Sponsor to provide all other training required as designated by the PI. |  |  |  |
| Research governance at satellite site – initial application | | | |
| **Creation of local satellite site(s) SSA application**  Primary site PI or delegate creates satellite sites SSAs and transfers them permanently to satellite site(s) SI. Or as per usual governance processes. |  |  |  |
| Staff coverage at satellite site | | | |
| **Arranging for back up staff as required at satellite site(s)**  Development and maintenance of site delegation logs, including arranging and consulting around cover for satellite site staff, including satellite site Clinical Research Coordinator (CRC) and pharmacist when they are away. |  |  |  |
| Recruitment and consenting of participants at satellite site | | | |
| **Recruitment and consenting**  Pre-Screening for eligibility will be undertaken by the satellite site with supervision from the primary site as required.  The PI is responsible for determining the eligibility of the participant for the clinical trial  The consent interview will be conducted at the satellite site by telehealth consultation with the PI at the primary site. Alternatively, consent can be fully delegated to the sub-investigator by the PI.  The PI, the Satellite Site SI and the Primary Site Study Coordinator must be present. The satellite site CRC to be present if possible.  Once the patient agrees to participate, the patient will sign the Informed Consent document. If the consent is supervised by the PI the Informed Consent document can either be faxed or emailed to the PI in real-time to sign or mailed to the PI to be signed and dated on the day of receipt  Once consent is signed the patient will then be enrolled into the clinical trial as outlined in the clinical trial protocol. |  |  |  |
| Randomisation at satellite site | | | |
| **Randomisation of a patient onto the trial**  The Satellite Site SI or CRC can perform the trial randomization of the patient in the event of issues with randomization at the satellite site, the PI would be contacted to perform the randomization. |  |  |  |
| Clinical care decisions | | | |
| **Allocation of responsibility for trial related management decisions, management of hospitalized participants & documenting in delegation logs**  The SI is responsible for the on-site care management and safety of the trial patients under their care. All trial activity is supervised by the PI. Any issues relating to trial activity are the responsibility of the PI at the primary site  The primary site PI must be notified of any hospital admissions, other serious adverse events and important protocol specific events such as overdose. The PI will provide appropriate advice and assistance if clinically required.  In the event of Telehealth system failure telephone services are to be utilized. |  |  |  |
| **Unblinding procedure**  Unblinding procedures to be performed by the primary site.  Any communication to the participant and satellite site will be undertaken by the PI. |  |  |  |
| Safety reporting | | | |
| **Reporting of safety events, including** **protocol deviations / violations to sponsor**  The same requirements that apply to the Primary site apply to the Satellite site. If the event involves a satellite site patient the satellite site reports directly to the sponsor and the Primary site is copied.  As per NHMRC Safety monitoring and reporting in clinical Trials involving therapeutic goods: <https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf> |  |  |  |
| **Reporting of safety events, including protocol deviations / violations, to HREC**  The Primary site is responsible for all communication with the HREC.  As per NHMRC Safety monitoring and reporting in clinical  Trials involving therapeutic goods: <https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf> |  |  |  |
| Funds management | | | |
| **Payment to satellite sites**  The Primary site is responsible for disbursement of funds to the Satellite site.  The agreed funding between the primary and satellite site is outlined in the tele-trials subcontract. This will be agreed to by the Research Governance Offices of both primary and satellite sites. |  |  |  |
| **Participant reimbursements e.g. travel costs**  The primary Site will be responsible for disbursement of subject travel cost funds to the satellite site.  The Satellite Site will be responsible to deliver the agreed stipend to the participant. |  |  |  |

# Responsibilities Matrix for satellite sites

| Clinical Trial Activity | **Responsible party – insert initials of staff**  **(as per Appendix A)** | | | | | Insert Plan and Study Logistics | Comments |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Primary Site (PS) responsible** | **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** |  |  |  |  |  |  |  |
| **Obtaining local site Head of Dept sign offs** |  |  |  |  |  |  |  |
| **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 product (IP) for satellite site | | | | | | |  |
| **Ordering of IP**  Identify what triggers both initial and resupply shipment of IMP, by whom and when*.* |  |  |  |  |  |  |  |
| **Receipt of IP**  Record whether satellite sites receive IP directly from sponsor or primary site. IP is stored as per Trial requirements at the satellite site. |  |  |  |  |  |  |  |
| **Dispensing of IP**  Identify who dispenses IP |  |  |  |  |  |  |  |
| **Reconciliation of IP**  Identify who reconciles IP |  |  |  |  |  |  |  |
| Screening of potentially eligible participants at satellite site | | | | | | |  |
| **Screening (Inclusion / exclusion criteria)** |  |  |  |  |  |  |  |
| Data/eCRF Entry for patients recruited at satellite site | | | | | | |  |
| **Recruitment process documented in participant’s medical file** |  |  |  |  |  |  |  |
| **Storage of source documents** |  |  |  |  |  |  |  |
| **Data entry (not eCRF)** |  |  |  |  |  |  |  |
| **eCRF Entry**  Data is entered into the eCRF at theprimary site for each visit conducted at the satellite site as required.  Source data for all visits to be collated at the primary site in the patient file and in a shadow file at the satellite site. |  |  |  |  |  |  |  |
| **Storage of data at satellite site as per GCP**  Any source documents not available in the hospitals’ eMR systems will also be stored in a patient shadow file at the satellite site. |  |  |  |  |  |  |  |
| 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 hospitalized patients at satellites (e.g. progression, need for additional investigations).**  The PI is responsible for all trial related decisions. Primary site PI to make all treatment related decisions in consultation with the Satellite Site SI. |  |  |  |  |  |  |  |
| Safety reporting occurring at satellite site | | | | | | |  |
| **Reporting of safety events, including protocol deviations / violations, to CPI**  The same requirements that apply to the Primary site apply to the Satellite site. Reporting should be made directly to the sponsor and the Primary site copied.  All Serious Adverse events (SAE) should be reported as per ICH-GCP to the sponsor within 24hrs and to the PI.  As per NHMRC Safety monitoring and reporting in clinical Trials involving therapeutic goods: <https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf> and sponsor requirements. |  |  |  |  |  |  |  |
| **Reporting of safety events, including protocol deviations / violations, to site RGO**  As per NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods: <https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf> and sponsor requirements. |  |  |  |  |  |  |  |
| Research governance at satellite site – amendments | | | | | | |  |
| **Amendment of site-specific documentation** |  |  |  |  |  |  |  |
| **Obtaining local site Head of Department sign offs 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** |  |  |  |  |  |  |  |

# 

# Appendix A – Study staff

(To be used in conjunction with delegation log)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title** | **First name** | **Surname** | **Role in study** | **Initials** | **Comments** |
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**Appendix B - Log of changes to Supervision Plan post submission to research governance**

Appendix B is to be used when site specific changes are required to the Supervision Plan. If the changes apply to all sites in the cluster then these changes should be incorporated into a new version of the Supervision Plan.

| **Change to Clinical Trial Activity** | | | **Insert initials of Primary Site staff (as per Appendix A)** | | **New Plan and Study Logistics** | | | | **Comments** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Example:* Recruitment and consenting**  Pre-Screening for eligibility will be undertaken jointly by the primary site and the satellite site. | | |  | | Pre-Screening for eligibility will be undertaken by satellite site. | | | | Satellite site now familiar with pre-screening and will undertake the activity unsupervised | |
|  | | |  | |  | | | |  | |
|  | | |  | |  | | | |  | |
|  | | | | | | | | | | |
| **Clinical Trial Activity** | **Change to Responsible party – insert initials of staff**  **(as per Appendix A)** | | | | | | | **Change to Plan and Study Logistics** | | **Comments** |
| **Primary Site (PS) responsible** | **Satellite site with direct supervision from PS** | | **Satellite site with support from PS** | | **Satellite site** | **NA** |  | |  |
|  |  |  | |  | |  |  |  | |  |
|  |  |  | |  | |  |  |  | |  |

# Signatures to the agreement of the supervision plan:

Primary site Principal Investigator PI signature:

Primary site Clinical Research Coordinator CRC signature:

Satellite site Sub-Investigator:

Satellite site Clinical Research Coordinator CRC or Nurse signature:

**Additional Signatures if required:**

Primary Site Pharmacist:

Satellite Site Pharmacist: