**Supervision plan for xxx satellite site for the clinical trial protocol (xxx) via the teletrial model**

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# Background

This document details the supervision plan for the xxx, to enable recruitment and assessment of participants on study using a teletrial model. The Principal Investigator (PI) for a clinical trial using the teletrial model will oversee and conduct the trial according to exactly the same responsibilities outlined by ICH-GCP and regulatory requirements, as any clinical trial, whether the activity is completed at the primary site or satellite sites and ensure the safety of the human participants in the trial. Duties may be delegated by the PI, but the PI remains accountable for all activity completed for the clinical trial and must ensure any personnel working on the trial are adequately trained and supported in all aspects of the trial.

# Complementary documents and processes

This supervision plan is complementary to:

* the feasibility assessment;
* the site selection process;
* site(s) initiation
* training protocol
* the delegation log and
* the Queensland Health adopted (QH) Standard Operating Procedures (SOP) for teletrial model which include:
  + 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

The trial cluster refers to the group of sites involved in the conduct of the study, including 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 of the primary site using the teletrials model.

This supervision plan applies to the all sites participating in the xxx Clinical Trial

The primary and satellite sites for the cluster are:

1. Primary site: xxx
2. Satellite site: xxx

# Document History

|  |  |  |
| --- | --- | --- |
| **Date** | **Activity** | **Responsible parties** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

# Responsibilities Matrix

|  |  |  |  |
| --- | --- | --- | --- |
| Clinical Trial Activity | **Insert initials of PS staff (as per Appendix A)** | **Insert initials of SS staff (as per Appendix A)** | **Comments – insert plan and study logistics** |
| Communication | | | | |
| Coordination of regular study teleconference meetings |  |  |  |
| Liaison between satellite site and sponsor re site visits |  |  |  |
| Education | | | | |
| Ensuring all staff at both primary and satellite sites are trained in appropriate aspects of the trial. |  |  |  |
| Research governance at satellite site – initial application | | | | |
| Creation of local satellite site(s) SSA application |  |  |  |
| Staff coverage at satellite site | | | | |
| Arranging for back up staff as required at satellite site(s) |  |  |  |
| Recruitment and consenting of participants at satellite site | | | | |
| Recruitment and consenting |  |  |  |
| Randomisation of Satellite Site Patients | | | | |
| Randomisation of a patient onto the trial |  |  |  |
| Clinical care decisions | | | | |
| Allocation of responsibility for trial related management decisions and management of hospitalized participants & documenting in delegation logs |  |  |  |
| Safety reporting | | | | |
| Reporting of safety events, including protocol deviations / violations, to sponsor |  |  |  |
| Reporting of safety events, including protocol deviations / violations, to HREC |  |  |  |
| Funds management |  |  |  |
| Payment to satellite sites |  |  |  |

| Clinical Trial Activity | **Responsible party – insert initials of staff**  **(as per Appendix A)** | | | | | | | **Comments – insert plan and study logistics** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |  | |  |  |  |  |  | |
| Obtaining local site HoD 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 |  | |  |  |  |  |  | |
| Receipt of IP |  | |  |  |  |  |  | |
| Dispensing of IP |  | |  |  |  |  |  | |
| Reconciliation of 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 |  | |  |  |  |  |  | |
| Storage of Site documents 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 hospitalized patients at satellites (e.g. progression, need for additional investigations). |  | |  |  |  |  |  | |
| Safety reporting occurring at satellite site | | | | | | | | | |
| Reporting of safety events, including protocol deviations / violations, to CPI |  | |  |  |  |  |  | |
| Reporting of safety events, including protocol deviations / violations, to site RGO |  | |  |  |  |  |  | |
| Research governance at satellite site – amendments | | | | | | | | | |
| Amendment of site specific documentation |  | |  |  |  |  |  | |
| Obtaining local site HoD 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** |
| Primary Site Study Staff | | | | | |
|  |  |  | Coordinating Principal Investigator (CPI) |  |  |
|  |  |  | Research Coordinator (RC) |  |  |
|  |  |  | Pharmacist (Ph) |  |  |
| Satellite Site Study Staff | | | | | |
|  |  |  | Lead Sub-investigator (LSI) |  |  |
|  |  |  | Sub-investigator (SI) |  |  |
|  |  |  | Research Coordinator (RC) |  |  |
|  |  |  | Research Coordinator (RC) |  |  |
|  |  |  | Pharmacist (Ph) |  |  |
|  |  |  | Sub investigator (SI) |  |  |
|  |  |  | Sub investigator (SI) |  |  |
|  |  |  | Sub investigator (SI) |  |  |
|  |  |  | Sub investigator (SI) |  |  |

# 

# Signatures to the agreement of the supervision plan

Primary site PI signature:

Satellite site lead SI signature: