# Decentralised Clinical Trial
# Supervision Plan
## Satellite Sites Management for Protocol NUMBER XXXX
## TRIAL TITLE
## XXXXXX

| This Supervision Plan applies to: | |
|---|---|
| Primary Site | |
| Satellite Site | |

# Background

This document details the supervision plan to enable recruitment of participants to a clinical trial using the Decentralised Clinical Trial (DCT) model at satellite sites (SS).

The supervision plan may change over time as the SS becomes experienced with clinical trial activities. These changes are agreed upon by the Primary Site (PS) and SS and will be documented in Appendix B. Re-submission of the Supervision Plan to the local research governance organisations is at the discretion of the Principal Investigator (PI).

Under the DCT Model, in New Zealand, the Co-ordinating Investigator (CI) is the health professional, who is the Investigator at one of the Primary sites, who is assigned the responsibility for the conduct of the study, and coordination of Investigators at different sites participating in a multicentre trial under the International Committee on Harmonization of Good Clinical Practice (ICH GCP) guidelines. (MEDSAFE uses the term Principal Investigator for the CI role). The Principal Investigator is the Investigator responsible for the conduct, management, monitoring, and reporting of a trial at their own site.

## Complementary documents and processes

This supervision plan is complementary to:

- the feasibility assessment
- the site selection process
- site initiation
- the protocol
- the delegation log
- standard processes according to ICH-GCP
- the NZ national teletrial guidelines and SOPs at PS and SS

## Cluster

Cluster refers to the group of sites involved in undertaking the clinical trial including the primary site (PS) who assumes overall responsibility for the conduct of the clinical trial and one or more SS, which conduct the trial under the direction of the PS using the DCT Model.

The PS and SS for this supervision plan are:

1. The Primary site:

2. Satellite sites:

## General guidance for completing supervision plan

All sections of the supervision must be completed or marked as ‘not applicable’. The column labeled ‘insert plan and trial logistics’ should detail the specific information for each item, including the parties responsible and the level of support being provided to the SS.

## Document History

| Date | Activity | Responsible parties (Primary Site and Sponsor or CRO) |
|---|---|---|
| XX/XX/20XX | Initial Document | PS |
| | | |
| | | |
| | | |

## Responsibilities Matrix

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF (As per Appendix A) | | INSERT PLAN AND TRIAL LOGISTICS |
|---|---|---|---|
| | PRIMARY SITE | SATELLITE SITE | |
| **Communication** | | | |
| **Coordination of regular meetings to discuss participant care and trial progress** | | | |
| ***Guidance: to be deleted from final document***<br>*Responsibility usually resides with PS. The frequency and duration of meetings will depend on the complexity of the trial, and accrual of participants. The required PS and SS at these meetings should be defined and documented. The following agenda items should be considered and documented in the column 'insert plan and trial logistics': Trial status, Site status, Participant status at SS, Study updates* | | | |
| **Coordination of sponsor visits to SS** | | | |
| ***Guidance: to be deleted from final document***<br>*Consider detailing the following information as appropriate. If the sponsor or CRO will monitor or visit the SS, they can liaise directly with the SS. The PS should be aware of all planned visits prior to them occurring, and may wish to be present via telehealth.* | | | |
| **Training** | | | |
| **Ensure all staff at PS and SS are appropriately trained.** | | | |
| ***Guidance: to be deleted from final document***<br>*Consider detailing the following information as appropriate. Responsibility of ensuring SS are trained in appropriate aspects of: The trial and protocol, ICH-GCP, SOPs, Amendments. Responsibility of ensuring delegation logs are up to date and accurate.* | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF (As per Appendix A) | | INSERT PLAN AND TRIAL LOGISTICS | |
|---|---|---|---|---|
| | PRIMARY SITE | SATELLITE SITE | | |
| **Funds Management** | | | | |
| **Management of payments to SS** | | | | |
| ***Guidance: to be deleted from final document***<br>*The process for agreed funding will vary between sites. The funding agreement between the PS and SS will be outlined in the tele-trials subcontract and over-all sign-off will be agreed upon by the authorised representative at both PS and SS and is separate to this supervision plan.*<br>*Consider detailing who will manage the payment process at both PS and SS, and other details as appropriate.* | | | | |
| **Research governance at SS - initial application and amendments** | | | | |
| **Completion of local Site-Specific Application (SSA) form** | | | | |
| **Creation of site-specific documentation** | | | | |
| **Obtaining local site Head of Dept. sign offs as required by region** | | | | |
| **Obtaining local research office sign offs as required by region** | | | | |
| **Obtaining local Māori research review as required by region** | | | | |
| **Amendment management** | | | | |
| **Research governance at SS – start up** | | | | |
| **Satellite site start up – General** | | | | |
| **Satellite site start up – Pharmacy** | | | | |
| **Satellite site start up – Pathology** | | | | |
| **Satellite site start up – Medical Imaging** | | | | |
| **Satellite site start up – Laboratory** | | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF (As per Appendix A) | | INSERT PLAN AND TRIAL LOGISTICS |
|---|---|---|---|
| | PRIMARY SITE | SATELLITE SITE | |
| **Research governance at SS – start up-continued** | | | |
| **Provision of other trial related equipment** | | | |
| **Other third party provider / supplier** | | | |
| **Investigational Product (IP) for Satellite Site** | | | |
| **Ordering of IP**<br>Identify what triggers both initial and resupply shipment of IP, by whom and when. | | | |
| **Transport and Delivery of IP**<br>Identify who is responsible for the delivery of IP | | | |
| **Receipt of IP**<br>Record whether SS receive IP directly from sponsor or PS. IP is stored as per Trial requirements at the SS. | | | |
| **Ordering of IP**<br>Identify what triggers both initial and resupply shipment of IP, by whom and when. | | | |
| **Dispensing of IP**<br>Identify who dispenses IP | | | |
| **Return and Reconciliation of IP**<br>Identify who reconciles IP | | | |
| **Screening of Potentially Eligible Participants at Satellite Site** | | | |
| **Screening (Inclusion / exclusion criteria)** | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF (As per Appendix A) | | INSERT PLAN AND TRIAL LOGISTICS |
|---|---|---|---|
| | PRIMARY SITE | SATELLITE SITE | |
| **Consent and Randomisation of Participants at SS** | | | |
| **Consent**<br>Identify if consent will occur at SS or remotely via telehealth with PS and with what supports | | | |
| **Reconsent** | | | |
| **Documentation of consent and recruitment process in medical records** | | | |
| **Randomisation** | | | |
| **Data / eCRF management for Participants at SS** | | | |
| **Storage and management of source documents** | | | |
| **Managing data entry (not eCRF)** | | | |
| **Managing eCRF entry** | | | |
| **Storage of site documents at SS** | | | |
| **Participant Trial Involvement at SS** | | | |
| **Scheduling of next visit** | | | |
| **Notification of participant of next visit** | | | |
| **Scheduling of trial tests / procedures** | | | |
| **Booking of trial tests / procedures with relevant department(s)** | | | |
| **Notification of participant of trial tests** | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF (As per Appendix A) | | INSERT PLAN AND TRIAL LOGISTICS |
|---|---|---|---|
| | PRIMARY SITE | SATELLITE SITE | |
| **Participant Trial Involvement at SS -continued** | | | |
| **Management of trial visit(s) requirements e.g., physical exam, tests etc.** Need for telehealth technology visits will be documented | | | |
| **Trial consultation and assessments** | | | |
| **Clinical Care Decisions** | | | |
| **Trial Related Treatment Decisions and Management of Hospitalised Participants at SS** (e.g., determination of progression, treatment discontinuation, consideration of additional investigations and out of hours management) | | | |
| **Emergency Unblinding procedures** | | | |
| **Staff Cover at SS** | | | |
| **Arrangement of back up staff for SS, as required** | | | |
| **Safety Reporting and Safety Management at SS** | | | |
| **Reporting of safety events to sponsor and CI** | | | |
| **Reporting of protocol deviations and violations to sponsor and CI** | | | |

| CLINICAL TRIAL ACTIVITY | RESPONSIBLE PARTY – INSERT INITIALS OF STAFF (As per Appendix A) | | INSERT PLAN AND TRIAL LOGISTICS |
|---|---|---|---|
| | PRIMARY SITE | SATELLITE SITE | |
| **Safety Reporting and Safety Management at SS -continued** | | | |
| **Reporting of safety events, including protocol deviations/violations, to SS Research Governance Group** | | | |
| **Reporting of safety events, including protocol deviations/violations, to HDEC** | | | |
| **Management of protocol violations, and other serious concerns at SS** | | | |
| **Satellite site close out** | | | |
| **SS close out** | | | |
| **SS close out – Pharmacy** | | | |
| **SS close out – Pathology** | | | |
| **SS close out – Medical imaging** | | | |
| **SS archiving** | | | |

## Appendix A –Trial Staff

*Example: Supplying Pharmacy End-to-End Process*

(To be used in conjunction with delegation log)

| Title | First name | Surname | Role in Trial | Initials | Comments |
|---|---|---|---|---|---|
| | | | | | |
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## Appendix B - Log of Changes to Supervision Plan Post Submission to Research Governance Office

| CHANGE TO CLINICAL TRIAL ACTIVITY | PS RESPONSIBLE INSERT INITIALS OF STAFF | NEW PLAN AND TRIAL LOGISTICS | COMMENTS |
|---|---|---|---|
| ***Example:***<br>**Recruitment and consenting**<br>Pre-Screening for eligibility will be undertaken jointly by the PS 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 TRIAL LOGISTICS | COMMENTS |
|---|---|---|---|---|
| | PRIMARY SITE (PS) | SATELLITE SITE | | |
| | | | | |
| | | | | |

## Signatures to the Agreement of the Supervision Plan:

Primary site Principal Investigator PI signature:

Primary site Clinical Research Coordinator CRC signature:

Satellite Site Sub I:

Satellite site Clinical Research Coordinator CRC or Nurse signature:

**Additional Signatures if required:**

Primary Site Pharmacist:

Satellite Site Pharmacist: