# Appendix 5 Supervision Plan

## National Teletrial Supervision Plan: Where a Medical Specialist is an Associate Investigator at the Satellite Site

**Supervision Plan for (xxx) Satellite Site for the Clinical Trial Protocol (xxx)**

### Introduction

A clinical trial that is conducted using the Teletrial Model involves a cluster of sites. The term ‘cluster’ refers to all the sites involved in undertaking the clinical trial using the Teletrial Model. The cluster consists of the Primary Site (PS) which assumes overall responsibility for the conduct of the clinical trial and one or more Satellite Sites (SS), conducting the clinical trial under the direction of the Primary Site. A Principal Investigator (PI) is appointed at the Primary Site to take responsibility for overall supervision of the trial across a cluster in accordance with Good Clinical Practice and other trial regulatory requirements.

The level of supervision should be guided by two main factors:

* Whether there are one or more medical specialists at the Satellite Site. In all cases, the level of clinical oversight would mirror what is appropriate for telehealth.
* The level of clinical trial experience of Satellite Site staff, including whether the Lead Associate Investigator at the Satellite Site has prior experience as a Principal Investigator in their own right. The level of clinical trial oversight may reduce as site staff develop competence in clinical trial conduct.

This Supervision Plan provides a framework for the allocation and delegation of duties and functions. The template reflects the need for supervision of most clinical trial activities conducted at the Satellite Site. The PI should develop procedures for reviewing and documenting the performance of delegated tasks (e.g., observation of the performance of selected assessments) in a timely manner. As the Satellite Site becomes more experienced in the conduct of clinical trials, the level of supervision for certain activities can be adjusted accordingly at the discretion of the PI and by mutual agreement. Investigators may also wish to refer to the TransCelerate Oversight Informational Program, which outlines basic components relevant to PI oversight of clinical trials, and uses scenarios to convey key concepts. Further information is available:

* [Guidance for Use of Principal Investigator Oversight Information Program](https://myscrs.org/wp-content/uploads/2018/11/Guidance-for-Use-of-PI-Oversight-Module-23Jan2015_FINAL.pdf); and
* [TransCelerate Investigator Oversight](https://myscrs.org/tc_sqt/modules/01_TransCelerate_Investigator_Oversight/story_html5.html).

This document is supplementary to the standard suite of documents generated as part of a trial’s set-up (e.g. the Clinical Trial Research Agreement, Delegation Log).

| **This Supervision Plan applies to:** | |
| --- | --- |
| Primary Site | Blank cell |
| Satellite Site | Blank cell |

### Abbreviations

Please refer to [Glossary of Terms](#_Glossary) in the Teletrials Compendium for a full list of definitions.

| Clinical Trial Activity | Responsible Party – insert initials of staff | | | | Comments |
| --- | --- | --- | --- | --- | --- |
| **PS responsible** | **SS with direct supervision from PS** | **SS with support from PS** | **SS responsible** |
| Communication | | | | | |
| Conducting, coordinating and documenting participant visits |  |  |  |  |  |
| **Guidance: Delete from final document**   * Determine whether joint consultations are required based on the whether the SS has a medical specialist Investigator and whether SS staff have prior clinical trial experience (e.g. have demonstrated competencies in the conduct of key trial procedures). * When there is a medical specialist at a SS who has been an Investigator in a prior trial, the PI (in liaison with the sponsor) may deem joint consultations unnecessary and instead, may provide oversight through regular trial meetings. * The person responsible should document the consultation in the medical records, or for Source Data not relevant to a participant’s clinical care, in the participant’s trial file as described in the Source Data Location List\*. The visit number/status, date, delivery mode, persons present, all actions assigned to individuals etc. Is to be included.   \**The location of trial documentation may be dependent on how the trial has been set up (e.g. whether the Sponsor intends to monitor the SS directly, whether the SS Investigator has direct access to the electronic records of the PS, etc.)*  Further information and guidance can be found in appendix 8 examples 1 and 2, and at:   * [Guidance for use of principal investigator oversight information program](https://myscrs.org/wp-content/uploads/2018/11/Guidance-for-Use-of-PI-Oversight-Module-23Jan2015_FINAL.pdf); and * [Transcelerate investigator oversight](https://myscrs.org/tc_sqt/modules/01_TransCelerate_Investigator_Oversight/story_html5.html). | | | | | |
| Coordinating regular trial meetings to discuss participants and trial progress (e.g. using telehealth or videoconference) |  |  |  |  |  |
| **Guidance: Delete from final document**  The frequency and duration of trial meetings will be dependent on the nature and complexity of the trial and the number of participants recruited. The following agenda items are to be discussed, and minutes (with clear allocation of actions) to be produced and filed in both the PS and SS Trial Files. Any minutes relating to the clinical care of individual participants are also to be filed in the participant medical records at both the PS and the SS.   * Overall status of the study * Overall status of the site (staffing etc.) * Overall status of each participant enrolled at the Satellite Site including any safety concerns * New study updates, information or communications from the study Sponsor or CRO   Any issues from the Satellite Site are to be followed up and resolved in timely manner. | | | | | |
| Coordination of Sponsor Monitoring Visits |  |  |  |  |  |
| **Guidance: Delete from final document**  If the Sponsor conducts SS monitoring visits, liaison with the SS Coordinator and Pharmacist will be arranged as appropriate. The PS should be made aware of all visits and PS staff may wish to be present via telehealth as required. | | | | | |
| Arranging sponsor visits to the Satellite Site |  |  |  |  |  |
| Education and Competence | | | | | |
| Ensuring all staff at the Satellite Sites are trained in appropriate aspects of the trial and GCP and are competent to perform their role |  |  |  |  | **See National Teletrial Compendium** [**SOP 03 for further details**](#_SOP_03_Site) |
| Ensuring staff are aware of and understand any relevant SOPs |  |  |  |  |  |
| Ensuring staff are aware of/trained on amendments |  |  |  |  |  |
| Staff Coverage | | | | | |
| Arranging for back up staff as required at the Satellite Site |  |  |  |  |  |
| Clinical Care Decisions | | | | | |
| Allocating responsibility for trial related management decisions and management of hospitalised participants at the Satellite Site (e.g. progression, need for additional investigations) |  |  |  |  |  |
| Funds Management | | | | | |
| Managing payments to Satellite Sites |  |  |  |  |  |
| Research Governance at the Satellite Site: Initial Application | | | | | |
| Creating a Satellite Site SSA application (where applicable) |  |  |  |  |  |
| Creating site-specific documentation |  |  |  |  |  |
| Obtaining local site HoD sign-off |  |  |  |  |  |
| Submitting to the local site RGO |  |  |  |  |  |
| Responding to local site RGO queries |  |  |  |  |  |
| Research Governance at the Satellite Site: Start Up | | | | | |
| Satellite Site start up (General) |  |  |  |  |  |
| Satellite Site start up (Pharmacy) |  |  |  |  |  |
| Satellite Site start up (Pathology) |  |  |  |  |  |
| Satellite Site start up (Medical Imaging) |  |  |  |  |  |
| Providing other trials related equipment |  |  |  |  |  |
| Contracting third party provider/supplier |  |  |  |  |  |
| Investigational Medicinal Product (IMP) for Satellite Site (amend if devices trial) | | | | | |
| Transporting IMP to the Satellite Site |  |  |  |  |  |
| Ordering of IMP |  |  |  |  |  |
| Receiving and storing IMP |  |  |  |  |  |
| Dispensing of IMP |  |  |  |  |  |
| Reconciling IMP |  |  |  |  |  |
| Training pharmacy staff (e.g. in the requirements of the pharmacy manual) |  |  |  |  |  |
| Screening of Potentially Eligible Participants at the Satellite Site | | | | | |
| Screening (inclusion/exclusion criteria) |  |  |  |  |  |
| Consent Process at the Satellite Site | | | | | |
| Consenting either remotely or at the Satellite Site |  |  |  |  |  |
| Documenting consent in participant’s medical records |  |  |  |  |  |
| Essential Document Managements/CRF entry for Participants Recruited at the Satellite Site | | | | | |
| Storing/managing Source Documents |  |  |  |  |  |
| Randomisation | | | | | |
| Randomising a participant onto the trial |  |  |  |  |  |
| Managing paper CRF data entry |  |  |  |  |  |
| Managing e-CRF data entry |  |  |  |  |  |
| Storing Essential Documents at the Satellite Site as per GCP and SOP 08 of Compendium |  |  |  |  |  |
| Participant Study Involvement at the Satellite Site | | | | | |
| Scheduling of next visit |  |  |  |  |  |
| Notifying participant of next visit |  |  |  |  |  |
| Scheduling of study tests/procedures |  |  |  |  |  |
| Booking of study tests/procedures with relevant department(s) |  |  |  |  |  |
| Managing trial visit requirements (e.g. physical exam, tests, processing samples for shipping etc) |  |  |  |  |  |
| Conducting trial consultations and assessments as per Protocol |  |  |  |  |  |
| Safety Reporting occurring at the Satellite Site | | | | | |
| Reporting safety events to Sponsor |  |  |  |  |  |
| Reporting safety events to the Satellite Site RGO |  |  |  |  |  |
| Reporting safety events to the HREC (if required) |  |  |  |  |  |
| Deviations and Serious Breaches at the Satellite Site | | | | | |
| Reporting Protocol deviations to the Sponsor |  |  |  |  |  |
| Managing Serious Breaches occurring at the Satellite Site |  |  |  |  |  |
| Research Governance at the Satellite Site: Amendments | | | | | |
| Managing amendments of site-specific documentation |  |  |  |  |  |
| Obtaining local site HoD sign-off (if required) |  |  |  |  |  |
| Submitting to the local site RGO |  |  |  |  |  |
| Responding to local site RGO queries |  |  |  |  |  |
| Study Close-Out at the Satellite Site | | | | | |
| Satellite Site close-out |  |  |  |  |  |
| Satellite Site close-out (Pharmacy) |  |  |  |  |  |
| Satellite Site close-out (Pathology) |  |  |  |  |  |
| Satellite Site close-out (Medical Imaging) |  |  |  |  |  |
| Managing Satellite Site archiving of trial documentation |  |  |  |  |  |

Signatures to the agreement of the Supervision Plan

| PI Signature:Click or tap here to enter text. | Date: Click or tap to enter a date. | | SS Lead AI Signature: Click or tap here to enter text. | | --- | | Date:Click or tap to enter a date. |
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