**Tele-Trial Supervision Plan: Where a Medical Specialist is a Sub-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 a tele-trials model involves a cluster of sites. The term ‘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 **(SS),** conducting the clinical trial under the direction of the Primary Site. A Principal Investigator 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 Sub-Investigator at the Satellite Site has prior experience as a Principal Investigator in his/her 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 Principal Investigator.

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).

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

**Abbreviations**

|  |  |  |
| --- | --- | --- |
| Primary Site (PS) | Clinical Research Organisation (CRO) | Head of Department (HoD) |
| Satellite Site (SS) | Good Clinical Practice (GCP) | Research Governance Office (RGO) |
| Principal Investigator (PI) | Standard Operating Procedures (SOPs | Investigational Medicinal Product (IMP) |
| Sub-Investigator (SI) | Site Specific Assessment (SSA) | Electronic/Case Report Form (e/CRF) |

\* Refer to Glossary of Terms (XXX) for a full list of definitions.

**Document History**

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

| ***Clinical Trial Activity*** | ***Responsible party – insert initials of staff***  ***(as per Appendix A)*** | | | | | | | ***Comments*** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *PS responsible* | *SS with direct supervision from PS* | *SS with support from PS* | *SS responsible* | | | |
| **Communication** |  |  |  |  |  |  | | |
| **Conducting, coordinating and documenting patient 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 that 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 patient’s clinical care, in the patient’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. should 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 the National Mutual Acceptance: Tele-trials clinical consultation user guide. | | | | | | | | |
| **Coordinating regular trial meetings to discuss patients and trial progress (e.g. using telehealth or videoconference)** |  |  |  |  | | |  | |
| The frequency and duration of trial meetings will be dependent on the nature and complexity of the trial and the number of patients recruited. The following agenda items should be discussed, and minutes (with clear allocation of actions) should be produced and filed in both the PS and SS Trial Files. Any minutes relating to the clinical care of individual patients should also be filed in the patient’s 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 patient 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** |  |  |  |  | | |  | |
| 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. | | | | | | | | |

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| Arranging sponsor/CRO visits to the SS |  |  | | | |  |
| **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 Tele-trial SOP XX for further detail |
| 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 SS |  |  | | | |  |
| **Clinical care decisions** | | | | | | |
| Allocating responsibility for trial related management decisions and management of hospitalised participants at the SS (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-offs |  |  | | | |  |
| 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 trial related equipment |  |  |  |  |  |  |
| Contracting third party provider/supplier |  |  |  |  |  |  |
| **Investigational medicinal product (IMP) for the 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 SS |  |  |  |  |  |  |
| Documenting consent in participant’s medical records |  |  |  |  |  |  |
| **Essential document managements/CRF entry for patients recruited at the satellite site** | | | | | | |
| Storing/managing source documents |  |  |  |  |  |  |
| **Randomisation** | | | | | | |
| Randomising a patient onto the trial |  |  |  |  |  |  |
| Managing paper CRF data entry |  |  |  |  |  |  |
| Managing e-CRF data entry |  |  |  |  |  |  |
| Storing essential documents at SS as per GCP |  |  |  |  |  |  |
| **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 of safety events to sponsor |  |  |  |  |  |  |
| Reporting safety events to the SS RGO |  |  |  |  |  |  |
| **Deviations and serious breaches at the satellite site** | | |  |  |  |  |
| Reporting protocol deviations to the sponsor |  |  |  |  |  |  |
| Managing serious breaches occurring at the SS |  |  |  |  |  |  |
| **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 SS archiving of trial documentation |  |  |  |  |  |  |

**Appendix A – Study staff**

(To be used in conjunction with delegation log which must be completed by the Principal Investigator only)

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| --- | --- | --- | --- | --- | --- |
| **Title** | **First name** | **Surname** | **Role in study** | **Initials** | **Comments** |
| Primary Site Study Staff | | | | | |
|  |  |  | Principal Investigator (PI)\* |  |  |
|  |  |  | Sub-investigator (SI) |  | Indicate whether a medical specialist |
|  |  |  | Research Coordinator (RC) |  |  |
|  |  |  | Pharmacist (Ph) |  |  |
| Satellite Site Study Staff | | | | | |
|  |  |  | Lead Sub-investigator (LSI) |  | Medical specialist |
|  |  |  | Sub-investigator (SI) |  | Indicate whether a medical specialist |
|  |  |  | Research Coordinator (RC) |  |  |
|  |  |  | Pharmacist (Ph) |  |  |

\* The PI may or may not also be the Coordinating Principal Investigator for the study.

**Signatures to the agreement of the supervision plan**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PI Signature:** | **Date:** | |  | | --- | | **SS Lead SI Signature:** | | **Date:** |
|  |  |  |  |