A Quick Guide to establishing a teletrial

General Information and Requirements for establishing a teletrial

(extracted from the *National Standard Operating Procedures for Clinical Trials including teletrials*).

**Definition:** A teletrial uses telehealth technology to communicate between the Primary Site and Satellite Site/s and enable delivery of aspects of a clinical trial as defined in the Supervision Plan. Telehealth technology supports a Principal Investigator to supervise Associate Investigator/s to conduct a clinical trial at a Satellite Site which is geographically remote from the Principal Investigator’s Primary Site. The Principal Investigator remains responsible for the trial.

**Trial activities** are delegated by the Primary Site (clinical trial site) to the Satellite Site, to enable performance of activities associated with the conduct of a clinical trial at the Satellite Site

A detailed **Supervision Plan** is required, in addition to a Delegation Log required by ICH GCP for all Satellite Sites regardless of experience. The Supervision Plan outlines processes for a Principal Investigator in the supervision of any individual or party to whom he/she delegates study-related duties and functions conducted at a Satellite Site, which includes, but is not limited to, details on joint consultations using telehealth, collation and monitoring of documents, frequency of joint trial meetings across a cluster (with minutes of these meetings) and clarification of activities performed by the PI and the AI, other study staff and independent third party i.e. external service providers.

A **Satellite Site** should have appropriately contracted qualified and trained Investigator(s) and delegated staff to undertake delegated trial related activities. Associate Investigators (AIs) at Satellite Site(s) operate under the direction and responsibility of the Principal Investigator (PI) at the Primary Site.

An AI when located at the Satellite Site is the local contact for study related matters at the Satellite Site and will be under the supervision of the PI at the Primary Site.

The South Australia/Northern Territory Regional Clinical Trial Coordinating Centre **(SA/NT RCCC)** will assist Primary and Satellite Sites located in South Australia and the Northern Territory with the processes required to set up and conduct a Teletrial.

E: sarccc@sa.gov.au or nthealth.teletrials@nt.gov.au

**Steps Required to Establish a Teletrial**

1. Evaluate the clinical trial as to its suitability to be conducted as a teletrial
	* Complete *Evaluation of a Clinical Trial as a Teletrial checklist* form
	* Complete *Evaluation of Site as a Satellite Site* if Satellite sites have been identified
2. If trial looks to be suitable to be conducted as a teletrial, liaise with the Sponsor to obtain agreement to conduct the trial as a teletrial
	* Need letter from Sponsor that the Sponsor support this trial being conducted as a teletrial
3. Submit amendment to Human Research Ethics Committee (HREC) to approve trial as teletrial

(Please note: If the trial has not already been approved by the HREC, ensure the HREC is notified of the Sponsor’s agreement to conduct a Teletrial and ensure the Teletrials Specific wording is added to the Master PICF)

* + See HREC application checklist
	+ Include updated PICF documents – Either Master PICF updated with teletrial wording, or standalone teletrial PICF
1. Identify potential Satellite Sites and Primary Site
	* Ensure appropriately qualified clinicians/staff willing to undertake the teletrial
	* Ensure Primary Site is agreeable to take on responsibility for the cluster
	* Complete *Evaluation of a Site as a Satellite Site Checklist* if not done earlier and ensure Sponsor agrees to Satellite Site involvement
2. In collaboration with each Primary Site, a supervision plan must be developed with each Satellite Site, according to the level of clinical trial experience and clinician expertise available at the site
	* Templates on Medicines Australia website
3. Prepare contracts
	* Teletrials subcontract between Primary Site and each Satellite Site
	* Amendments to Sponsor-Primary Site CTRA (Sch 1 to add Satellite Sites and Sch 2 for additional payments)
4. Regulatory:
	* all sites must maintain their own insurances
	* the indemnity provided by the Sponsor to the Primary Site, must be extended to include all Satellite Sites.
	* Where each site is responsible for its own insurances and indemnities, this also applies to Satellite Sites in accordance with local research governance practices.
	* Satellite sites must be included in the CTN only if Investigational Product is being stored at Satellite Site. If updating, the Principal Investigator at the Primary Site is listed as the Principal Investigator at each Satellite Site within the same cluster. (The Associate Investigator at the Satellite Site is not listed as the Principal Investigator for that Satellite Site)
5. Ensure all sites are familiar with National SOPs for clinical trial including teletrials
6. Undertake all required Research Governance Processes
	* First Primary Site RGO submission (Refer to *Primary Site RGO submission checklist*)
		+ Primary Site RGO must approve study being conducted as teletrial at Satellite Site
	* Once approved by Primary Site RGO, Satellite Site RGO submission (Refer to *Satellite Site RGO submission checklist*)