Australian Teletrial Program
Access to clinical trials, closer to home

Teletrial Supervision Plan

Information for Human Research Ethics Committees

What is a teletrial?

The Australian Teletrial Model is a new way for patients to participate in a clinical trial closer to home, using tele-communications to connect a nearby health facility with the primary clinical trial site. Technologies such as telehealth and/or remote monitoring are utilised to allow aspects of a clinical trial to be safely conducted and supervised at geographically remote Satellite Sites which partner with an experienced clinical trial site.

This document provides the Human Research Ethics Committee (HREC) with a summary of a Supervision Plan. Individual site-specific Supervision Plans are developed and submitted to relevant Research Governance Offices for each Satellite Site application. The use of this document is optional and may be edited according to jurisdictional preferences.

What is a supervision plan?

The supervision plan outlines how the Primary Site will conduct the trial across its partner Satellite Sites (teletrial cluster), describes the oversight to be provided by the Primary Site and specifies which trial activities have been allocated by the Primary Site to the individual Satellite Site. These decisions are influenced by factors such as the Satellite Site team's clinical trial experience and their facility's service capability.

The Primary Site and Satellite Site collaborate on the development of the supervision plan specific to that Satellite Site and may also seek assistance from the Regional Clinical Trial Coordinating Centre in their jurisdiction.

Further information about Teletrials is available in the National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia (2020) at the Australian Government *Department of Health and Aged Care's* **website**.

What does a supervision plan include?

Protocol Specific Activities	This is based on the Schedule of Activities in the Protocol. Options for protocol activities to be conducted at the Satellite Site are selected. All duties will be reflected in the delegation log.
Recruitment and Consent	This is highly specific for each Satellite Site, taking into consideration the type of trial, the qualifications and clinical trials experience of trial staff at Satellite Site and resources required for screening potential participants.

Randomisation	Depending on the randomisation method used by the Sponsor, this may be restricted to the Primary Site only, or may be delegated to a Satellite Site depending on the type of trial, Investigation Product being tested, and facilities at the Satellite Site.
Clinical Care	Describes which clinicians will take responsibility for the clinical care decisions and documentation.
Investigational Medicinal Product	Provides information on handling and tracking of Investigational Medicinal Product (IMP) across a cluster. Governance of all activities in relation to IMP management will be in accordance with best practice, the protocol, Investigator Brochure, relevant pharmacy manuals and site workflows.
Biospecimens	Describes where trial specific pathology tests and specimen collection is to be undertaken, and results are shared with the Primary Site.
Imaging	Many trials require highly specific imaging, that may or may not need to be performed using the same equipment. This section describes how and where trial specific imaging is to be undertaken, and the method by which images are transferred to the Primary Site or Sponsor.
Medical Devices	Provides information on handling and management of Investigational Medicinal Device across a cluster.
Other Intervention	Provides information if the trial involves an intervention that is not a drug or device.
Training	Details any relevant training required to conduct the clinical trial at the Satellite Site. This section also links to the training and delegation log required by the Trial Sponsor.
Communication	Outlines the communication strategy between all sites within a teletrial cluster.
Reporting and Safety Management	Details the process for managing and reporting safety events to the Primary Site. It can also include other reporting requirements relevant to the trial.
Data and Documentation	Describes how information will be collected at a Satellite Site, transfer of source data including de-identified participant information to the Primary Site, and data entry responsibilities for the electronic Case Report Form. It also covers management of Investigator Site Files, and other trial specific requirements such as direct data entry into a portal.