Safer Care Victoria

**May 2025**

# Guide for Setting up Teletrials

## Steps and documents required in Victoria

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**MAY 2025**

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**Australian Teletrial Program**
Access to clinical trials, closer to home

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# Preface

## Introduction

The Australasian Teletrial Model (ATM) was developed in 2016 by the Clinical Oncology Society of Australia (COSA) Regional and Rural Group in consultation with clinical trial Sponsors, clinicians, health administrators and regulatory bodies to enhance access to clinical trials for people with cancer living in rural and remote areas. A pilot implementation project was conducted in 2018 to facilitate the adoption of the model nationally.

Following the success of the pilot, the Australian Teletrial Program (ATP) was funded by the Australian Government under the Medical Research Future Fund (MRFF) infrastructure grant opportunity to improve access to, and participation in, clinical trials for those living in regional, rural and remote areas. ATP is conducted through the establishment of Regional Clinical Trial Coordinating Centres (RCCCs) in Northern Territory, Queensland, South Australia, Tasmania, Victoria and Western Australia. In Victoria, the Regional Clinical Trial Coordinating Centre is located within Safer Care Victoria and is responsible for implementing the ATP in Victoria. ATP-Vic is a centralised service to enable and facilitate Victoria's rural/regional/remote health services to ensure the required support, policy and workforce are available to bring clinical trials and teletrials closer to home.

Originally developed to improve access to clinical trials for cancer patients in rural and remote areas, teletrials have since proven to be effective for all types of clinical trials. Teletrials aim to improve the equity of access for clinical trials for underserved populations and to enhance the diversity of trial participants.

## About this Guide

This Guide provides general information for Sponsors and sites on the additional steps and specific documents required to establish teletrials in Victoria.

The Guide does not cover all the requirements for setting up and conducting clinical trials in Australia. It should be read in conjunction with other publications including the National Teletrials Compendium which consists of the National Principles for Teletrials in Australia and the National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia.

This Guide reflects current thinking and best practice of the Victorian Teletrials Collaborative (VTC) partners. It provides a set of recommendations and does not constitute legal advice, nor should it be cited as such. As the field of teletrials evolves, the Guide will be updated to reflect emerging insights and experiences.

For any questions or feedback, please contact RCCC@safercare.vic.gov.au

## Victorian Teletrial Collaborative

The VTC partners share the goal of implementing widespread use of teletrial methodology to improve timely and efficient access and recruitment to clinical trials. By sharing knowledge and expertise across Victoria, the

VTC fosters collaboration, ensures the sustainability of teletrials, and provides state-wide support while minimising duplication and maximising impact. The VTC consists of:

- TrialHub (Alfred Health) trialhub@alfred.org.au
- Victorian Comprehensive Cancer Centre Alliance (VCCC Alliance) research@vcccalliance.org.au
- Regional Trials Network- Victoria (RTN Vic) research@regionaltrialsnetwork.org
- Regional Clinical Trial Coordinating Centre Victoria: ATP-Vic (Safer Care Victoria) RCCC@safercare.vic.gov.au

# Part I: Background

## Clinical trials

Clinical trials[1] are "*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes*".

Clinical trials include but are not limited to:

- surgical and medical treatments and procedures,
- experimental drugs and diagnostics,
- biological products,
- medical devices,
- health-related service changes,
- health-related preventative strategies,
- health-related educational interventions.

In Australia, clinical trials are conducted under a strict regulatory framework based on the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) principles[2] and ISO 14155:2020 Good Clinical Practice for the design, conduct, recording and reporting of clinical investigations of medical devices.[3]

All clinical trials in Australia are required to have ethical and scientific review conducted by a human research ethics committee (HREC). Guidance on human research ethics is set out in the National Statement on Ethical Conduct in Research 2023 . Additionally, organisations conducting clinical trials must provide authorisation for the project to commence at that site. More information can be found in Research Governance and Site Specific Assessment – Process and Practice document.

The Therapeutic Goods Administration (TGA) oversees clinical trials involving unregistered therapeutic goods through two schemes: the Clinical Trial Notification (CTN) scheme and the Clinical Trial Authorisation (CTA) scheme. More information can be found in the Australian Clinical Trial Handbook (2021).

[1] Australian Commission on Safety and Quality in Health Care. (2022). *The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials*. Sydney: ACSQHC.

[2] Integrated Addendum to ICH E6(R1): Guidelines for Good Clinical Practice E6(R2), 2016 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

[3] ISO 14155:2020 – Clinical investigation of medical devices for human subjects — Good clinical practice

## What is a teletrial?

Teletrial is a new methodology for conducting clinical trials bringing trial activities closer to participants' homes, particularly those in regional, rural, or remote areas. It is a robust version of decentralised clinical trials[4].

In a teletrial, a group of clinical trial sites, known as a cluster, work together to conduct a clinical trial. A teletrial cluster consists of (Figure 1: Teletrial cluster):

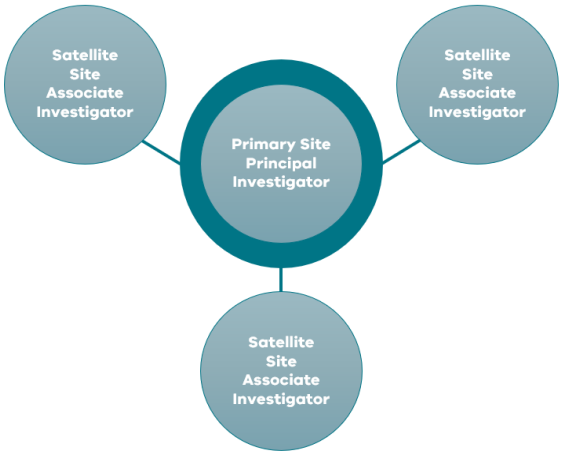


**Figure 1: Teletrial cluster**

- A single Primary Site that coordinates the trial across the entire cluster. The Principal Investigator (PI), located at the Primary Site, has full responsibility for conducting the clinical trial at their site and any Satellite Sites within their cluster.
- One or more Satellite Sites that conducts delegated clinical trial activities under the supervision of the Principal Investigator at the Primary Site, allowing patients to participate in clinical trials closer to home while maintaining the integrity and oversight of the trial. Each Satellite Site has an Associate Investigator (AI) who acts as the local point of contact for study-related matters and conducts the delegated trial activities under the supervision/oversight of the PI at the Primary site.
- Teletrial uses telecommunications technology to allow a Primary Site to work with Satellite Site/s and to deliver aspects of a clinical trial.
- A detailed Supervision Plan, in addition to a Delegation Log, is required for each Satellite Site regardless of its experience under ICH-GCP.
- The conduct of the trial is detailed under the Head Agreement (Clinical Trial Research Agreement/ Clinical Trial Agreement) between the Sponsor and the Primary Site and a Teletrials Subcontract between the Primary Site and the Satellite Site.
- Satellite Site participants can attend all or some of all their trial visits at the Satellite Site as determined by the Protocol and the Supervision Plan.

## Why teletrials?

Teletrials adopt a networked approach, improving access and participation in clinical trials. Benefits may include:

- Increased access to clinical trials by geographically dispersed populations, including First Nations people.
- Increased representation of diverse trial participant populations to enhance the validity and generalisability of trial evidence.
- Improved recruitment and retention of participants into clinical trials.

[4] Underhill, C., Sabesan, S., & Wilson, E. (2024). Decentralised clinical trials: a game changer for improved access to clinical trials. *The Lancet Oncology, 25*(12), E625. DOI: 10.1016/S1470-2045(24)00595-3

- Supporting research on rare diseases and conditions impacting populations with limited mobility and access barriers.
- Fostering collaboration and network development between clinical trial sites.
- Building clinical trial capability and capacity for clinical trial sites.
- Improving health outcomes for patients with care closer to home.

## General considerations

- It is recommended that the protocol and/or other study-specific documents include wording that allows for the study to be conducted using teletrial methodology.
- All clinical trials can incorporate teletrial methodology, but several factors must be considered to ensure adherence to ICH-GCP principles using a risk-based approach. These include the type and phase of the trial, protocol complexity, the safety profile of any investigational product, the patient population and the capacity and capabilities of both Primary and Satellite Sites.
- Teletrial methodology can be applied in various scenarios including:
  - Sites with limited capacity and capability to independently conduct clinical trial activities can partner with a Primary Site so that the participants' visits are shared and coordinated across the two sites.
  - Sites with limited trial experience can collaborate with more experienced Primary Site to gain access to guidance and support.
  - Sites can partner with other sites where a Sponsor requires only one site to achieve the required recruitment target, such as in rare disease indications.
- When incorporating teletrial methodology, it is essential to ensure that participants' rights, safety and wellbeing are protected with no added risks. Measures should be implemented to ensure data integrity is maintained across multiple sites.
- A trial that is already open to recruitment can be amended to incorporate teletrial methodology if the Sponsor deems it suitable and the sites forming a cluster are willing and have the required capability and capacity. However, incorporating teletrial methodology during the trial design is considered more efficient.
- Any number of Satellite Sites can be added to a teletrial cluster with the Sponsor's approval. The decision to add sites depends on factors like protocol complexity, site and Sponsor's experience with teletrials, site's capacity and capability, PI capacity to provide adequate supervision and oversight and recruitment potential. Larger clusters may be appropriate for rare disease trials with low recruitment, while smaller clusters may be better suited for more complex trials with higher expected recruitment.
- The Sponsor may use different approaches at different sites for the same trial protocol. While some sites may act as regular independent sites, others may form teletrial clusters with Primary and Satellite Sites (Figure 2: Multisite clinical trial including a teletrial cluster)

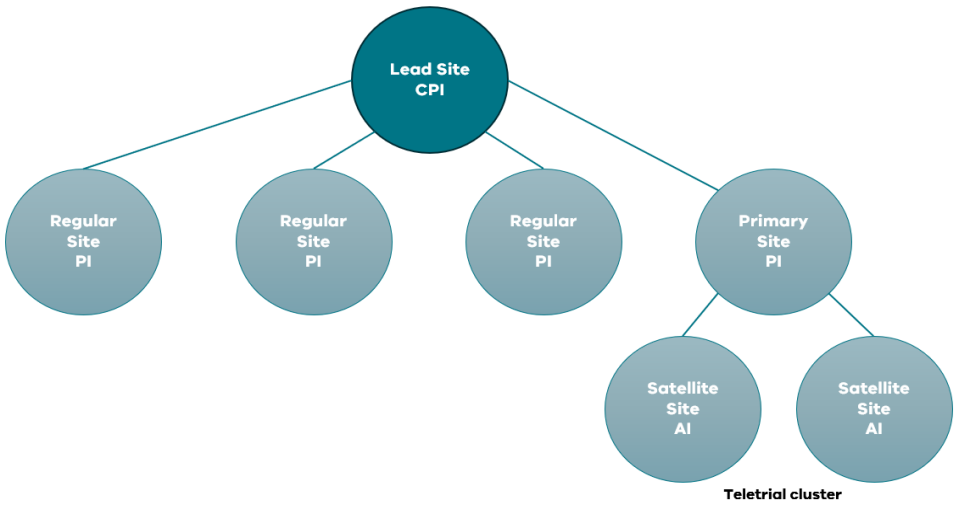


**Figure 2: Multisite clinical trial including a teletrial cluster**

- A site can act as a Satellite Site for one trial and independently run or act as a Primary Site for another trial, as each protocol has different requirements. A primary site can be in either metropolitan or regional areas.
- It is ideal to incorporate participants' input into the design of teletrials to ensure it meets their needs and preferences.
- Teletrials use different forms of telecommunication technologies to connect the Primary Site with Satellite Site(s). This connection facilitates the conduct of trial activities and provides the necessary oversight and supervision. The choice of technology used depends on the specific needs and design for each trial.
- When confidential information is shared between teletrial sites, it should be done using a safe and secure method (e.g. secure cloud-based data transfer) that is established during feasibility and documented in the Supervision Plan.

## Considerations when setting up teletrials

There are typically four additional considerations needed to set up a teletrial, as compared to setting up a conventional clinical trial (Figure 3: Considerations when setting up a teletrial):

| | | | |
|---|---|---|---|
| Teletrial wording in the protocol and/or trial-specific documents | Optional teletrial wording in the Participant Information and Consent Form | Supervision Plan | Teletrial Subcontract (as applicable) |

**Figure 3: Considerations when setting up a teletrial**

- Wording in the protocol and/or or trial-specific documents allowing a risk-based approach to establish trial clusters or similar.
- Additional wording in the Participant Information and Consent Form (PICF) or use of a Stand-alone Teletrial PICF.:
  - For a new trial that is intended to incorporate the teletrial methodology from the outset the Master PICF should include optional teletrial specific wording and additional consent questions related to ATP reporting purposes.
  - For an existing trial with ethical approval that is set to incorporate the teletrial methodology, the Master PICF should be amended to include the optional teletrial specific wording and additional consent questions related to ATP reporting purposes, or the Stand-alone Teletrial PICF can be used in addition to the Study Master PICF. Use of this PICF means that the Master PICF does not require amending to incorporate the teletrial specific wording. (Figure 4: Participant Information and Consent Form in teletrials)
- A Supervision Plan between the Primary Site and each participating Satellite Site in the cluster. The Supervision Plan is a mandatory requirement for teletrials. It outlines the role of a PI at the Primary Site in supervising and overseeing any study-related duties and functions conducted at Satellite Sites within a cluster.
- A Teletrials Subcontract between the Primary Site and each participating Satellite Site in the cluster.

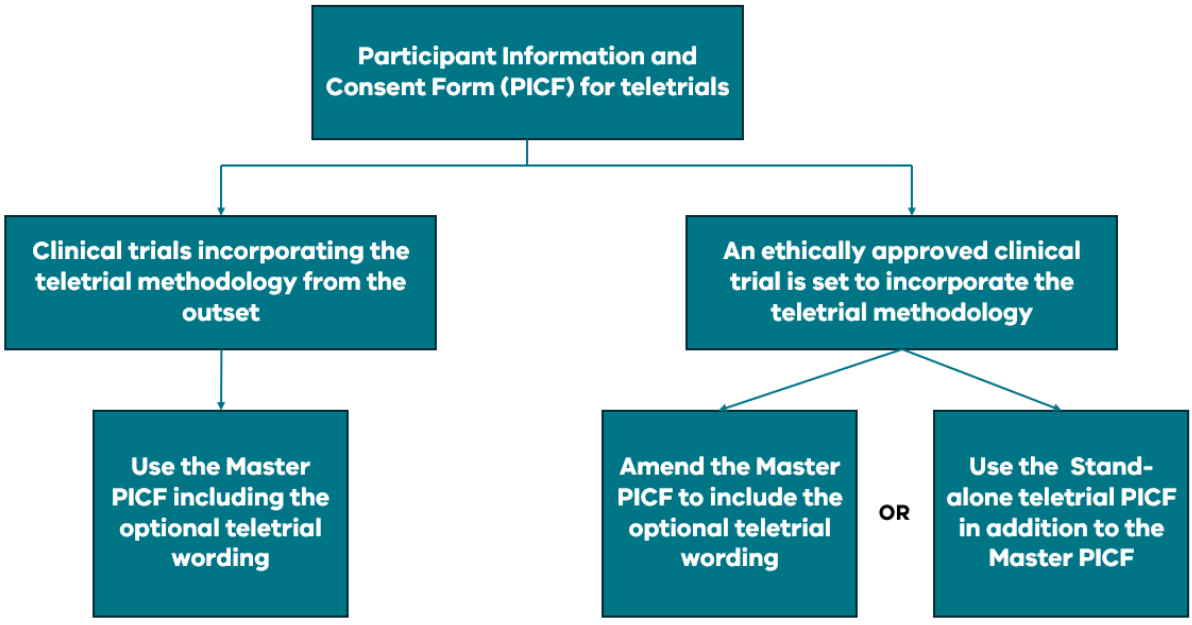


**Figure 4: Participant Information and Consent Form in teletrials**

## Roles and responsibilities

Refer to the National Clinical Trials Governance Framework for the roles and functions of clinical trial staff in Australia and the National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia for Investigator responsibilities.

### Principal Investigator (PI)

The PI is responsible for ensuring that all trial activities, regardless of their location, are conducted in compliance with the study protocol, regulatory requirements, and ethical standards. This includes ensuring the safety and well-being of participants and maintaining data integrity.

In teletrials, the PI of a cluster is always located at the Primary Site and has an appointment/employment arrangement at the Primary Site. The PI at the Primary Site is not required to hold an appointment at the Satellite Site. The PI is responsible for the conduct of the trial at the Primary Site and assumes overall responsibility providing supervision/oversight to each Satellite Site within the cluster. For teletrials, the PI should also:

- Ensure a comprehensive site assessment is conducted for each Satellite Site to evaluate the site's capabilities and determine the extent to which trial related activities can be conducted at the site.
- Develop and complete a Supervision Plan, in collaboration with the AI at each Satellite Site, prior to the start of a teletrial and maintain/update as required throughout the conduct of the trial.
- Ensure study staff, including those at Satellite Site(s), are appropriately qualified and trained to perform the delegated trial tasks.
- The PI may delegate the AI at the Satellite Site to further authorise and delegate their staff members to trial activities
- Implement procedures to ensure the delegated trial duties and functions are performed safely, and that the integrity of all data generated is maintained. This is achieved by standard site monitoring procedures.
- Ensure effective communication and coordination between all sites and personnel within the cluster. A regular supervision meeting should be established to discuss operational issues that arise during conduct of the trial.

### Associate Investigator (AI)

An AI at a Satellite Site is the local contact for trial matters and conducts trial activities under the supervision/oversight of PI at the Primary Site. The AI is delegated to and supervised by the PI at the Primary Site to perform trial procedures and/or to make trial decisions as documented in the Supervision Plan and the Delegation of Duties Log.

# Part II: Steps for setting-up teletrials in Victoria

The following section outlines the additional steps and documents required to set up a trial as a teletrial. It should be followed in conjunction with the standard clinical trial startup and initiation process.


**Figure 5 Steps for setting up teletrials**

## Feasibility assessment

The purpose of this step is to:

- Evaluate whether a trial protocol can be conducted using teletrial methodology (if not already incorporated into the protocol).
- Determine if a site has the capacity and capability to participate in the teletrial cluster as either a Primary Site or a Satellite Site.

> Sponsors and sites are encouraged to reach out to ATP-Vic for support in setting up teletrials in Victoria.

### Evaluation of a trial as a teletrial

- **Purpose:** To determine suitability of running a trial under teletrial methodology.
- **Description:** If the trial protocol or other trial-related documents do not explicitly incorporate teletrial wording, the Sponsor can collaborate with the Primary Site to determine the protocol's suitability to be conducted as a teletrial.
- **Resources:** The Evaluation of a Trial as a Teletrial checklist can be used to guide this assessment.
- **Outcome:** The Sponsor must agree to run the trial as a teletrial.

### Site(s) assessment and selection

- **Purpose:** To determine site(s) suitability to conduct the clinical trial as part of a teletrial cluster.

- **Description:** Trial Sponsors typically require a Confidentiality Disclosure Agreement (CDA) to be signed before sharing the trial protocol. Sites will have institutional policy regarding CDA signatures. In most cases, a separate CDA will be required for Primary and Satellite Sites. The PI is responsible for evaluating any Satellite Site to ensure that the site is willing to participate in the trial, has access to the patient population for recruitment and determine their capacity and capability to conduct some or all the trial activities. The Sponsor can either accept the evaluation and recommendation of the Primary Site PI or choose to undertake an evaluation of the proposed Satellite Site.
- **Resources:** Evaluation of a Site as a Satellite Site checklist can be used to guide this assessment.
- **Outcome:** the Sponsor should formally acknowledge the Primary Site stating their agreement to conduct the clinical trial as a teletrial, naming all participating Satellite Sites. The letter should be directed to the PI at the Primary Site and copies sent to each Satellite Sites' AI.

## Finalising agreements

The purpose of this step is to establish standardised processes for key aspects of the trial and document them in a Supervision Plan, as well as to finalise the budget and contract agreements for the trial's conduct.

### Budget Negotiations

- **Purpose:** To agree on the teletrial budget.
- **Description:** The Sponsor undertakes budget negotiations with the Primary Site in a routine manner. The Primary Site negotiates the budget with each Satellite Site. Various models are in use for sharing budget received from Sponsors for the conduct of a teletrial. Some networks share payments based on amounts assigned to study specific procedures. Other networks use a more pragmatic approach such as assigning a proportion of the payments based on approximate workload. Networks are encouraged to determine how they will approach payment at an early stage of establishing a teletrial.
- **Resources:** Sites established schedule of fees. Sites can also refer to ATP Teletrial Budget and Costing Guideline.
- **Outcome:** Successful agreement on the budget for the teletrial, ensuring adequate funding for all sites.

### Clinical Trial Research Agreements

- **Purpose:** To reach agreements between the Sponsor, Primary Site, and Satellite Sites within a cluster regarding the terms and conditions for the teletrial, ensuring clarity in responsibilities, budget, and contractual obligations.
- **Description:**
  - Head Agreement between the Primary Site and the Sponsor (Clinical Trial Research Agreement/ Clinical Trial Agreement). If using the Clinical Trial Research Agreement – Medicines Australia Standard Form as the Head Agreement between the Sponsor and the Primary Site., the following teletrial-specific changes should be incorporated by the Sponsor into the relevant sections:
    Schedule 1 – details of the Primary Site and Satellite Site(s).
    Schedule 2 - additional teletrial-related budget items. Payments and invoicing, and terms and conditions for the Satellite Site(s).

If additional Satellite Sites join a cluster, the Sponsor should amend Schedules 1 and 2 of the CTRA, as above. This agreement must be executed in full prior to executing the Teletrials Subcontract.

- The Clinical Trial Research Agreement – Teletrials Subcontract (Primary and Satellite Sites) formalises the relationship between the Primary Site and each Satellite Site in a cluster.
- The Clinical Trial Research Agreement (CTRA) for Investigator-Initiated Teletrials can be used where the Primary Site Institution is acting as the Sponsor and the other institution acting through Satellite Sites.

- **Resources:**
  - Medicines Australia CTRA.
  - Medicines Australia Teletrials Subcontract.
  - Clinical Trial Research Agreement (CTRA) for Investigator-Initiated Teletrials
- **Outcome:** Fully executed agreements between the Sponsor, Primary Site, and Satellite Sites, including any amendments to the CTRA and Teletrials Subcontract (if required), ensuring all contractual obligations are clearly defined and agreed.

## Indemnity

- Where indemnity is provided, there are two options for indemnity:
  1. Direct indemnity to both the Primary Site and Satellite Site(s).
  2. A single indemnity to the Primary Site that also covers the Satellite Site(s).
- For non-commercial clinical trials, where indemnity is not provided by the Sponsor, each participating site (Primary or Satellite) must hold valid insurance to conduct the trial. In Victoria, state-wide insurance is provided through the Victorian Managed Insurance Authority (VMIA) for public hospitals and clinicians.
- Resources: Medicines Australia Form of Indemnity

## Supervision Plan

- **Purpose:** To develop a Supervision Plan for each Satellite Site within a cluster.
- **Description:** The Supervision Plan is developed in collaboration between the PI at the Primary Site and the AI at participating Satellite Site/s in a cluster. The Supervision Plan is a site-specific document for research governance review. The HREC assesses the scientific merit and ethical acceptability of the research protocol but does not require approval of this plan.
- **Resources:** The Supervision Plan template is available on the Australian Teletrial Program webpage. Guidance videos and resources on completing the Supervision Plan are also accessible on the ATP website.
- **Outcome:** Fully executed Supervision Plan for each Satellite Site, endorsed by the PI at the Primary Site and the AI at the Satellite Site.

## Approvals and authorisations

### Ethics Submission and Approval

There is no change to the ethics submission process for HREC review when an application for a trial is intended to incorporate teletrial methodology. However, it is recommended that relevant sections of the Human Research Ethics Application (HREA) include a description of the use of the teletrial methodology including Sponsor agreed process by which consent will be obtained at participating Satellite Sites (if applicable) and information about how the participant data will be securely shared between sites within a cluster.

- **Purpose:** To obtain ethics approval to run a new trial as a teletrial from the outset or to submit an ethics amendment request to the reviewing HREC requesting approval of adding a teletrial component to a trial.
- **Description:** It is the responsibility of the Primary Site to notify the Coordinating Principal Investigator (CPI) of the Sponsor's agreement to run the trial as a teletrial from the outset or to incorporate teletrial methodology in an already approved trial.
- **Resources:** Refer to the ATP Ethics Teletrial Checklist to guide submission requirements for the ethical review of a clinical trial incorporating teletrial methodology.
- **Outcome:** HREC approval letter listing each participating Satellite Site supervised by a (named) Primary Site.

### Research Governance

It is recommended that HREC approval and research governance/Site Specific Assessment (SSA) processes run in parallel across a cluster where possible. While research governance/SSA authorisation is granted after ethics approval, starting the governance process early helps minimise delays, allowing authorisation to be granted quickly after ethics approval. Once SSA authorisation is given at the Primary Site, the trial can begin at that site, subsequent SSA authorisation will be required at the Satellite Site before trial activity can begin at that site. Satellite Site can only receive authorisation after the Primary Site receives authorisation.

- **Purpose:** To ensure that both the Primary and Satellite Sites gain research governance/SSA authorisation for trials conducted under the teletrial methodology.
- **Description:** The PI at the Primary Site completes and submits the SSA application for the Primary Site. The RGO at a Primary Site undertakes an assessment of the application. The AI at the Satellite Site completes and submits the SSA application for the Satellite Site. The RGO or delegate at a Satellite Site undertakes an assessment of the application. Ideally this will be in collaboration with the RGO at the Primary Site, particularly in situations where the Satellite site does not have the relevant local expertise.
- **Resources:** Refer to ATP Teletrial Governance Checklist to guide submission requirements for research governance review of a clinical trial incorporating teletrial methodology.
- **Outcome:** An authorisation letter/certificate should list all documents reviewed by the RGO for accuracy/completeness and in line with the site's resources. Primary Site receives authorisation first, followed by Satellite Site(s).

## Regulatory Requirements

It is the responsibility of the Sponsor to complete and submit the CTN via the TGA online portal. The CTN should be updated as Satellite Sites are on-boarded in a cluster. If the trial is to be under the CTA scheme, refer to the TGA webpage for further guidance. The TGA acknowledgement should be provided to all sites in a cluster for inclusion in their governance application. The TGA advises that any site and facility that is undertaking trial activities should be named on the CTN form.

Please refer to the TGA Clinical Trials Handbook for further information on the CTN and CTA schemes and how they may apply to your trial.

## Initiation and activation

The Principal Investigator:

- Mutually agree with the Sponsor a scheduled date, time and location for the Site Initiation Visit to ensure the site is prepared to commence the study. In the case of a teletrial, this may be at the Primary Site only or could include (in person or remotely) any Satellite Site/s within the cluster.
- Ensure that all relevant staff involved with the study have been advised of the meeting and are able to attend either in person or remotely.
- Be in possession of all required approvals and authorisations to conduct the trial. For teletrials, ensure a Supervision Plan is in place between the Primary Site and each Satellite Site in the cluster.

The Sponsor is responsible for:

- Conducting the Site Initiation Visit at the Primary Site. If Satellite Site(s) within the cluster are known at the time of Site Initiation, they should participate in the Site Initiation Visit in person or remotely.
- Providing additional training required by the protocol or other trial processes to the Primary Site and known Satellite Site trial team members where possible at the same time.
- Provide the Primary Site with necessary training resources to use when on-boarding new Satellite Sites in a cluster.
- Provide all trial team members with data entry access in the cluster, in accordance with the responsibilities specified in the Delegation Log.
- Ensures the Trial Master File has been provided to the Primary Site and it is current and collated adequately – either electronically or in hard copy depending on the Sponsor's and Primary site's agreed preference. If the Sponsor has agreed to provide the Site Study File to a Satellite Site, this must occur before any participant is enrolled at that site.
- Ensure that that all staff conducting trial activities within the cluster, are listed as required on respective delegation and training logs.

# More information

Australian Teletrial Program

Clinical Trials and Research Victoria

Medicines Australia

The National Teletrials Compendium

VCCC Alliance Teletrial Toolkit

# Appendix 1: Abbreviations and Terms

## Abbreviations

| Term | Description |
|---|---|
| **AI** | Associate Investigator |
| **ATM** | Australasian Teletrial Model |
| **ATP** | Australian Teletrial Program |
| **ATP-Vic** | Australian Teletrial Program-Victoria |
| **CDA** | Confidentiality Disclosure Agreement |
| **COSA** | Clinical Oncology Society of Australia |
| **CPI** | Coordinating Principal Investigator |
| **CTA** | Clinical Trial Approval |
| **CTN** | Clinical Trial Notification |
| **CTRA** | Clinical Trial Research Agreement |
| **ERM** | Ethical Review Manager |
| **HREA** | Human Research Ethics Application |
| **HREC** | Human Research Ethics Committee |
| **ICH GCP** | International Council for Harmonisation of Good Clinical Practice |
| **IMP** | Investigational Medicinal Product |
| **MRFF** | Medical Research Future Fund |
| **NHMRC** | National Health and Medical Research Council |
| **PI** | Principal Investigator |
| **PICF** | Participant Information and Consent Form |
| **RCCC** | Regional Clinical Trial Coordinating Centre |
| **RGO** | Research Governance Officer |
| **RTN** | Regional Trials Network |
| **SSS** | Study Startup Specialist |
| **TGA** | Therapeutic Goods Administration |
| **VCCC** | Victorian Comprehensive Cancer Centre |
| **VMIA** | Victorian Managed Insurance Authority |

| | |
|---|---|
| **VTC** | Victorian Teletrial Collaborative |

## Terms

A comprehensive list of associated terms can be found in the National Standard Operating Procedures for Clinical Trials and ATP Definition Guide.

# Appendix 2 References and resources

| Reference | Website |
|---|---|
| Australian Clinical Trial Handbook | https://www.tga.gov.au/resources/guidance/australian-clinical-trial-handbook |
| Australian Teletrial Program Website | https://australianteletrialprogram.gov.au/ |
| Clinical Oncology Society of Australia (COSA) | https://www.cosa.org.au/media/332325/cosa-teletrial-model-final-19sep16.pdf |
| International Conference on Harmonisation Good Clinical Practice (ICH GCP) | https://www.tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice |
| Medical Technology Association of Australia CIRA (MTAA CIRA) | https://www.mtaa.org.au/clinical-investigation-research agreements |
| Medicines Australia CTRAs | https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/ |
| Medicines Australia Teletrials Subcontract | https://www.medicinesaustralia.com.au/policy/clinical-trials/tele-trials/ |
| Medicines Australia Forms of Indemnity | https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/ |
| National Principles for Teletrials in Australia | https://www.health.gov.au/resources/publications/national-principles-for-teletrials-in-australia?language=en |
| National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia | https://www.health.gov.au/resources/publications/national-standard-operating-procedures-for-clinical-trials?language=en |
| NHMRC: The National Statement on Ethical Conduct in Human Research | https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023 |
| Therapeutic Goods Administration | https://www.tga.gov.au/clinical-trials#clinical-trials-guidance |
| Victorian Clinical Trials and Research website | https://www.clinicaltrialsandresearch.vic.gov.au/<br>https://www.clinicaltrialsandresearch.vic.gov.au/teletrials |
| VCCC Alliance Teletrial Toolkit | https://vcccalliance.org.au/research/clinical-trial-innovations/teletrial-toolkit |

# Appendix 3 Acknowledgements

Safer Care Victoria (SCV) would like to acknowledge those who have supported the development of this resource. SCV houses the Coordinating Centre for Clinical Trials Research and is the jurisdictional lead for the Australian Teletrials Program in Victoria. It is through this team working in collaboration with other Victorian based entities that this resource was developed.

1. The Australian Teletrial Program (ATP) is funded by the Australian Government under the Medical Research Future Fund Rural, Regional and Remote Clinical Trial Enabling Infrastructure Fund from 2021-2026.
2. The Regional Victoria Trials Alliance: Linkages, Innovation, Special populations, Equity (ReViTALISE) project 2021-2026 was funded by a 5-year Medical Research Future Fund (MRFF). Regional Trials Network-Victoria (RTN-Vic) 2024-2026 was funded by the Department of Health Victoria.
3. The Victorian Comprehensive Cancer Centre (VCCC) Alliance Strategic Program Plan 2021-24 funded by the Victorian Government through the Department of Health.
4. TrialHub is a federally funded pilot program established to support regional, rural and outer metro hospitals with building sustainable clinical trial units

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Safer Care Victoria