

WA Teletrial Support Program Guideline for WA Country Health Service Teletrials

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Introduction

The Australian Teletrial Program (ATP) is funded by the Commonwealth Government's Medical Research Future Fund – National Critical Infrastructure Initiative – 2019 Rural, Regional, and Remote Clinical Trial Enabling Infrastructure grant. The ATP aims to improve equity of access to clinical trials for people living in rural, regional, and remote (RRR) areas. The ATP is responsible for implementing clinical trial infrastructure at country sites to enable the Australian Teletrial Model (ATM). The WA Country Health Service Trial Centre has been established to implement the ATP in Western Australia.

The ATM connects established clinical trial sites with geographically distant Satellite Sites. This relationship is a shared care clinical trial model known as a Teletrial. This model allows people to attend clinical trial visits at a local site, closer to home.

The Principal Investigator and clinical trial team at the Primary Site support and supervise the Satellite Site clinical trial team. The Primary Site Principal Investigator is responsible for trial conduct at both the Primary Site and connected Satellite Sites.

Teletrial Support Program

The Teletrial Support Program (TSP) provides funding support to both Primary and Satellite Sites conducting Teletrials.

The funding program seeks to:

- Support experienced clinical trial sites in expanding clinical trial activity to RRR sites through implementing Teletrials.
- Support RRR clinicians to offer patients clinical trial participation at their local site through Teletrials.
- Enable RRR patients to access potential new treatments closer to home.

Structure

Two types of funding are available under the TSP:

Primary Site Trial Funding*	Funding of up to \$10,000 per protocol to enable eligible primary sites to initiate Teletrials. Payments are divided as follows: • \$5,000 when an eligible RRR participant has their first protocol listed trial visit at the first Satellite Site • \$5,000 when an eligible RRR participant has their first protocol listed trial visit at a second Satellite Site
Satellite Site Per Participant Funding*	Funding of \$700 per RRR participant per year for up to two years to support Satellite Site delivery of Teletrials.

^{*}Eligibility criteria apply and is subject to budget availability

Eligibility criteria

To be eligible the trial must:

- Be a clinical trial as defined by the World Health Organisation (WHO): "A clinical trial
 is 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."
- Have trial activities that can be performed at a Satellite Site (note: the patient's home is not considered a site).
- Have a Satellite Site located in a MMM2-MMM7 region (as categorised by the <u>Modified Monash Model</u> using the <u>Health Workforce Locator Tool</u> e.g. outside of the Perth Metropolitan area).
- Have a Primary and Satellite Site(s) located in WA Health.
- Be approved by an Australian Human Research Ethics Committee.
- Agree to share statistical data for reporting to the Commonwealth. Data required is included in the form titled **WA Teletrial Support Program Payment Request Form.**
- Agree to WA Country Health Service Trial Centre conditions of funding listed below.

Ineligibility criteria

- Trials that are not conducted under the Teletrial model (e.g. multi-site trials without a Primary Site Satellite Site relationship or trials direct to patients at home).
- Research studies that do not meet the WHO definition of a clinical trial (e.g. registries, observational and retrospective research studies).
- Trial activities funded or supported for the same activity by other recipients under the National Critical Infrastructure Initiative – 2019 Rural, Regional, and Remote Clinical Trial Enabling Infrastructure grant.
- Trials that have received funding through another Teletrial Support Payment Scheme.

Request for funding

Eligibility for funding will be assessed by WA Country Health Service Trial Centre following completion of the **WA Teletrial Support Program Funding Application**.

Payment will be made following the receipt of the completed **WA Teletrial Support Program Payment Request Form.**

Please email completed applications to WACHSTrialCentre@health.wa.gov.au.

Conditions of funding

Applicants for funding agree to the following conditions:

- 1. WA Country Health Service Trial Centre will make determinations regarding an applicant's eligibility for TSP funding in its absolute discretion.
- 2. WA Country Health Service Trial Centre may in its discretion cap participation TSP funding payments and all TSP funding payments are subject to budget availability.
- 3. WA Country Health Service Trial Centre will work with each TSP funding recipient ("Recipient") to develop a good news story for each trial that can be shared from both institutions. Media communications will follow the WA Country Health Service Trial Centre Communication Guideline. A WA Country Health Service Trial Centre patient media consent form will be provided if relevant for media featuring clinical trial patients.
- 4. Recipients agree to share statistical data from their teletrial for reporting to the Commonwealth. The data required is included in the form titled **WA Teletrial Support Program Payment Request Form.** Recipients warrant they have all necessary permissions to share this data.
- 5. Recipients must comply with all local, State and Commonwealth laws applicable to the Teletrial (including but not limited to all applicable privacy laws and codes).
- 6. If a Recipient commits a breach of any of these conditions, WA Country Health Service Trial Centre can terminate any further funding payments at any time and without giving the Recipient any prior notice.
- 7. Recipients must allow the Auditor General for the State of Western Australia, or an authorised representative, to have access to and examine a Recipient's records and information concerning the TSP funding payment(s) upon request.
- 8. The total funding provided by WA Country Health Service Trial Centre includes an amount to cover any liability for GST, if applicable.
- 9. The payment of any TSP funding by WA Country Health Service Trial Centre does not constitute an endorsement by any of the Released Parties of any goods or services provided by a Recipient or the Teletrial. Recipients agree they must not make any representation to this effect.

Effective dates

This funding is available prospectively **from October 4 2021 until October 4 2026**, unless funding is exhausted sooner. Retrospective payment is not available.

WA Teletrial Support Program Funding Application Form

Teletrials involve the allocation of trial activities to a geographically separate Satellite Site. The Principal Investigator is located at the Primary Site and takes responsibility for conducting the clinical trial at their site and at the Satellite Site. This facilitates participation in clinical trial closer to home. <u>The National Teletrials Compendium</u>, 2020

Completed application form to be submitted to: <u>WACHSTrialCentre@health.wa.gov.au</u>

If completing this form manually, please use a pen and write neatly using BLOCK LETTERS

1. General information

Item	Complete this section
Department	
Site	
Institution	

2. First trial planned

Item	Complete this section
Proposed trial title (if known)	
Proposed Principal Investigator (if known)	
Proposed Satellite Site (if known)	
Anticipated Satellite Site Recruitment start date (if known)	

3. Eligibility criteria

Item	Complete this section	
Department meets eligibility criter	□ Yes	
Scheme Guidelines – Eligibility Cr	iteria	□ No
Has this department claimed the T	eletrial Department Establishment Scheme	□ Yes
previously?		□ No
Do you agree to the WA Country H	lealth Service Trial Centre conditions of	□ Yes
funding?		□ No
Department meets eligibility criter	ia as listed in the Department Establishment	□ Yes
Scheme Guidelines – Eligibility Cr	riteria	□ No

4. Contact information

Item	Complete this section
Form completed by	
Date submitted	

WA Teletrial Support Program Payment Request Form

Completed form to be submitted to: <u>WACHSTrialCentre@health.wa.gov.au</u>
If completing this form manually, please use a pen and write neatly using BLOCK LETTERS

Upon approval of this request, payment will be arranged by the WA Country Health Service Trial Centre through inter entity Journal Transfer.

1	General	linfor	mation
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Item	Complete this section
Department	
Site	
Institution	

2. Trial information

Item	Complete this section
Trial title	
Primary Site	
Satellite Site	

3. Satellite Site Research Governance Authorisation

Item	Complete	this section
Satellite site number	□ One	□ Two
RGS number		
Date of letter of authorisation		

4. Trial visit information

Item	Complete this section
Satellite Site number	□ One □ Two
Participant study ID	E.g. 001
Date of consent	
Date of first trial visit at Satellite Site	
Visit name per protocol	E.g. Screening

5. Payment details

Item	Complete this section
Cost centre name	
Cost centre number	
Account code/number (if applicable)	
Cost centre responsible officer/owner name	

6. Contact information

Item	Complete this section
Form completed by	
Date submitted	