



WA Teletrial Support Program Guideline for Sites External to WA Country Health Service

# WA Teletrial Support Program Guidelines for Sites External to WA Country Health Service

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

<sup>\*</sup>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 Satellite Site(s) located in WA.
- 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 for Sites
  external to WA Country Health Service.
- Agree to WA Country Health Service Trial Centre conditions of funding listed below.

## Ineligibility criteria

- Trials that are not conducted under the ATP (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 for Sites External to WA Country Health Service.

Payment will be made following the receipt of the completed **WA Teletrial Support Program**Payment Request Form for Sites External to **WA Country Health Service** with an associated invoice addressed to **WA Country Health Service**.

Please request application forms from, and 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 for Sites external to WA Country Health Service. Recipients warrant they have all necessary permissions to share this data.
- 5. WA Country Health Service Trial Centre, WA Country Health Service and the State of Western Australia (collectively "the Released Parties") are not responsible or liable in any way for the success or otherwise of the Teletrial or for any losses or additional costs suffered by recipients in carrying out the Teletrial. Recipients release the Released Parties from all liability in relation the Teletrial, the TSP funding and any related matter and agree to not make any claims against the Released Parties arising directly or indirectly in relation to these matters. The Recipient agrees this clause may be pleaded by the Released Parties as a bar to any proceedings commenced by the Recipient in relation to the Teletrial, the provision of TSP funding or any related matter.
- 6. 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).
- 7. 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.
- 8. 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.
- 9. The total funding provided by WA Country Health Service Trial Centre includes an amount to cover any liability for GST, if applicable.
- 10. 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 May 4 2025 until October 4 2026**, unless funding is exhausted sooner. Retrospective payment is not available.

## WA Teletrial Support Program Funding Application for Site External to WA Country Health Service 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. The National Teletrials Compendium, 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				
Trial title					
Trial short name					
Sponsor	Organisation name and contact name				
CRO	Organisation name and contact name (if applicable)				
Lead Site	Lead site name and Coordinating Principal Investigator name				
Primary Site	Clinical Trial Site, list one Primary Site per form				
Primary Site Principal Investigator	Located at the Primary Site				
Satellite Site(s)	May be more than one				
Satellite Site Associate Investigator(s)	Located at the Satellite Site, may be more than one per site				
Registry ID number	ANZCTR or Clinicaltrials.gov registration number				

#### 2. Participant recruitment information

Item	Complete this section
Anticipated number of participants at each site listed above	
Anticipated recruitment start date	
Anticipated recruitment end date	





Form

## 3. Initial eligibility criteria

Item	Complete this section		
Trial short name and Primary Site name (for cross check)			
-	ined by the WHO?  y that prospectively assigns human participants  e health-related interventions to evaluate the	□Yes	□ No
Detail (Include name of intervention	and health outcome):		
Are there trial activities that coul	d be performed at a Satellite Site?	□Yes	□ No
Details (list trial activities)			
Is the Satellite Site(s) located in a Perth Metropolitan area?) Online	a MMM2-MMM7 region (i.e. outside of the MMM calculator	□Yes	□ No
Is the Satellite Site(s) located in \	□Yes	□ No	
Details (list locations of Satellite Site	es under this Primary Site):		
Is trial approved by an Australian	Human Research Ethics Committee?	□Yes	□ No
Details (list HREC name and appro	val date)		
	Il participant level data for reporting to the rm titled 'WA Teletrial Support Program external to WA Health)	□Yes	□ No
Details:			
Do you agree to the WA Country Funding?	Health Service Trial Centre Conditions of	□Yes	□ No





Form

## 4. Payment information

Item	Complete this section		
Organisation name			
ABN			
Bank details	Bank Name: BSB:	Account Number:	
Contact details for invoicing	Name: Email: Contact Number:	Position:	

## 5. Contact information

Item	Complete this section
Form completed by	
Date submitted	
Do you expect to submit additional requests for other sites?	□Yes □ No Details:

## WA Teletrial Support Program Payment Request for Sites External to WACHS Form

#### **Instructions**

Include participants who have attended at least one protocol listed trial visit at the Satellite Site.

This may include a screening visit even if the outcome is a screen fail.

MMM category: enter the participants home address [here] and select 'Modified Monash Model' and select 'Modified Monash Model'

PS = Primary Site. This is the established clinical trial site where the Principal Investigator is located.

SS = Satellite Site. This is the geographically distant site under the supervision of the Principal Investigator.

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

#### 1. Trial Information

Item	Complete this section
Department	
Site	
Institution	

#### 2. Study Information

Study ID	Date of Consent	Date & visit name of first trial visit at Satellite Site	Age	Cultural Background (select all that apply)	Home MMM Category (1 – 7)	Distance from home to PS (km)	Distance from home to SS (km)
E.g. 001	13/01/24	13/01/24 Screening	36-55 yrs	Aboriginal	4	501- 1000km	0-20km
			Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.
			Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.
			Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.
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			Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.
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			Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.
			Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.

#### 3. Contact Information

Item	Complete this section		
Form completed by			
Date submitted to WACHS Trial Centre			
Do you expect to submit additional requests for payment in the future?	Yes □	No □	
requests for payment in the fature:	Detail:		