

WA Teletrial Support Program Guidelines for sites external to WA Country Health Service

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 by connecting established clinical trial sites with geographically distant Satellite Sites. This is a decentralised clinical trial known as a Teletrial. This model allows people to access to clinical trial therapy at a local site, closer to home.

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

The WA Regional Clinical Trial Coordinating Centre (WARCCC) has been established to implement the ATP in Western Australia.

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:
	 \$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	Funding of \$700 per RRR participant per year for up to two years to
Participant Funding*	support Satellite Site delivery of Teletrials.

*Eligibility criteria applies 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</u> <u>Monash Model</u> using the <u>Health Workforce Locator Tool</u>. For example, 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 WARCCC 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.

REQUEST FOR FUNDING

Eligibility for funding will be assessed by WARCCC following completion of the **WA Teletrial Support Program Funding Application for Sites External to WACHS**.

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

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

CONDITIONS OF FUNDING

Applicants for funding agree to the following conditions:

- 1. WARCCC will make determinations regarding an applicant's eligibility for TSP funding in its absolute discretion.
- 2. WARCCC may in its discretion cap participation TSP funding payments and all TSP funding payments are subject to budget availability.
- 3. WARCCC 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 WACHS WARCCC Communication Guideline. A WA Country Health Service WARCCC patient media consent form will be provided if relevant for media featuring clinical trial patients.
- 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. WARCCC, 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, WARCCC 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 WARCCC includes an amount to cover any liability for GST, if applicable.
- 10. The payment of any TSP funding by WARCCC 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

TSP funding is available until 4 **October 2026**, unless the grant is exhausted sooner.