Australian Teletrial Program – Victoria (ATP-VIC)
REDCap and Teletrial Support Program (TSP) payment Guidance

TSP payment eligibility and structure

Teletrial Support Program

The Teletrial Support Program (TSP) provides funding support to sites conducting Teletrials, if eligibility criteria are met, to support cluster management and site development for clinical trials.

The funding program seeks to:

- support experienced clinical trials sites in expanding clinical trial activity to rural, regional and remote sites through implementing Teletrials
- support clinicians in rural, regional and remote areas to offer clinical trial participation locally through Teletrials
- enable patients in rural, regional and remote areas access to potential new treatments closer to home.

Eligibility Criteria

An eligible Teletrial must:

- be a clinical trial as defined by WHO - a 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
- be conducted in accordance with the Australasian Teletrial Model (ATM)as defined by the *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia* (i.e. have a Primary Site with linked Satellite Sites operating under a Supervision Plan)
- have a Primary or Satellite site located in the Northern Territory, Queensland, South Australia, Tasmania, Victoria or Western Australia
- have Satellite Sites with at least one participant enrolled whose home postcode is classed as an MM2 – MM7 category**
- have ethics and governance approval
- be aligned with the purpose, aims and scope of the Commonwealth Standard Grant Agreement MRFRR000005
- not be funded or supported for the same activity by other recipients under this MRFF grant round (see definition on page 3).

***MM2 – MM7 categories are classified at: https://www.health.gov.au/health-topics/health-workforce/health-workforce-classifications/modified-monash-model using the Health Workforce Locator tool at https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator*

Structure

Two levels of funding are available under the TSP:

- Primary Site Teletrial Cluster Management grant*: funding of up to $10,000 (GST exclusive) per protocol to enable eligible Primary Sites to re-invest in Teletrials and clinical trials support.

  Payments will be made as follows:

  - $5,000 when an eligible participant is enrolled at one Satellite Site
  - $5,000 when an eligible participant is enrolled at another Satellite Site.
- Satellite Site Per Participant grant*: funding of $700 per participant per year for up to 2 years (GST exclusive) to enable ongoing Satellite Site participation in the Teletrial model.

**Eligibility criteria applies.*

Glossary

ATP – *Australian Teletrial Program*

MMM – *Modified Monash Model.* Defines whether a location is a city, rural, remote or very remote.

MRFF – *Medical Research Future Fund*

PI – *Principal Investigator*

Primary site – Under the Teletrials Model, the Primary Site coordinates the trial across a cluster to enhance participant reach, recruitment and management. The Principal Investigator located at the Primary Site has full responsibility for conducting the clinical trial at their site and any Satellite Site within their cluster under ICH GCP

RCCC – *Regional Clinical trials Coordinating Centre*

REDCap – *data collection database*

Satellite site – Satellite Site is in a healthcare facility geographically separate from the Primary Site. Trial activities are delegated by the Primary Site to the Satellite Site clinical team, in which the Associate Investigator will instruct and implement trial activities under supervision by the Primary Site PI.

Teletrial – Teletrials uses telehealth to connect clinical trials to regional and rural areas by setting up Satellite Sites and connecting these to a Primary Site clinical trial. This has potential to extend clinical trials into rural and regional Victoria through funding from the Commonwealth Government. A Principal Investigator, at the Primary Site, is responsible for the trial and supervises the Associate Investigator/s at the Satellite Site/s. There may be multiple Satellite Sites associated with a Primary Site, referred to as a 'cluster' of Satellite Sites.

TSP – *Teletrial Support Program.* It is supported by funding from the Australian Government under the Medical Research Future Fund. The Program has been funded $75.2 million over five years to bring clinical trials closer to home for patients in Queensland, Victoria, Tasmania, South Australia, Western Australia and the Northern Territory.

Data collection guidance using REDCap

1. Victorian RCCC is notified of new trial by Primary Site

Any primary site can be registered on REDCap (ATP database) and managed for eligibility and payments when criteria is met

Primary site to complete the **Teletrial Registration Form*** and return to the RCCC, rccc@safercare .vic.gov.au

2. 'Trial and Primary Site Registration Form' is completed by Victorian RCCC

Site payments will be made to Primary Site PI entered in this form (primary site payment and Satellite site payment). The PI will arrange for payment to go to the Satellite site/s

3. Primary site will submit the 'Primary Site Start Up' form

An automated email with a link and instructions to complete and submit the 'Primary Site Start Up' form is sent. It is sent to the primary site contact person that was entered in the 'Trial and Primary Site Registration Form'.

'Primary Site Start up 2' will need to be submitted for technical processing in REDCap

4. Form is returned to the RCCC to complete the 'Office Use Only' section

Office Use Only section includes:

Information about participants from MM2-7 locations.

Records information about Teletrial Support Program Payments

5. 'Primary Site Participant Registration' form is ready to be completed by the Primary Site

Automated email alert is sent to the primary site contact person when the 'Primary Site Start Up' form has been submitted.

Provides link to survey queue and asks Primary Site to register participants

Reminder email sent to Primary Site after 6 weeks if no participants have been registered

6. 'Satellite Site: Registration Form' is ready to be completed by the Primary Site

When the satellite has recruited a participant at their site, the Primary Site will need to complete the 'Satellite Site: Registration Form'. This can be found in the survey queue.

Victorian RCCC will receive an automated email to complete the 'Office Only Use' section of the 'Satellite Site: Registration Form'

7. Satellite Site: Registration Form 2A and 2B are submitted by the Victorian RCCC

An automated email is sent to the Victorian RCCC to complete the Satellite Site: Registration Form 2A and 2B. These are submitted for technical processing in REDCap

8. 'Satellite Site: Site Commencement Form' is completed by the Satellite Site

'Satellite Site: Registration Form' 'Office Use Only' section completion will trigger the automated email to the Satellite Site to submit the 'Satellite Site Commencement Form'. This will go the contact person that was entered in the 'Satellite Site: Registration Form' by the Primary Site

9. 'Satellite Site Commencement Form 2A' is submitted by the Victorian RCCC

An automated email is sent to the Victorian RCCC to complete the Satellite Site Commencement Form 2A. This is submitted for technical processing in REDCap

10. 'Satellite Site Participant Registration' form is submitted by the Satellite Site

An automated email with a link and instructions to submit the 'Satellite Site Participant Registration' form is sent. It is sent to the primary site contact person that was entered in the 'Satellite Site Commencement Form'

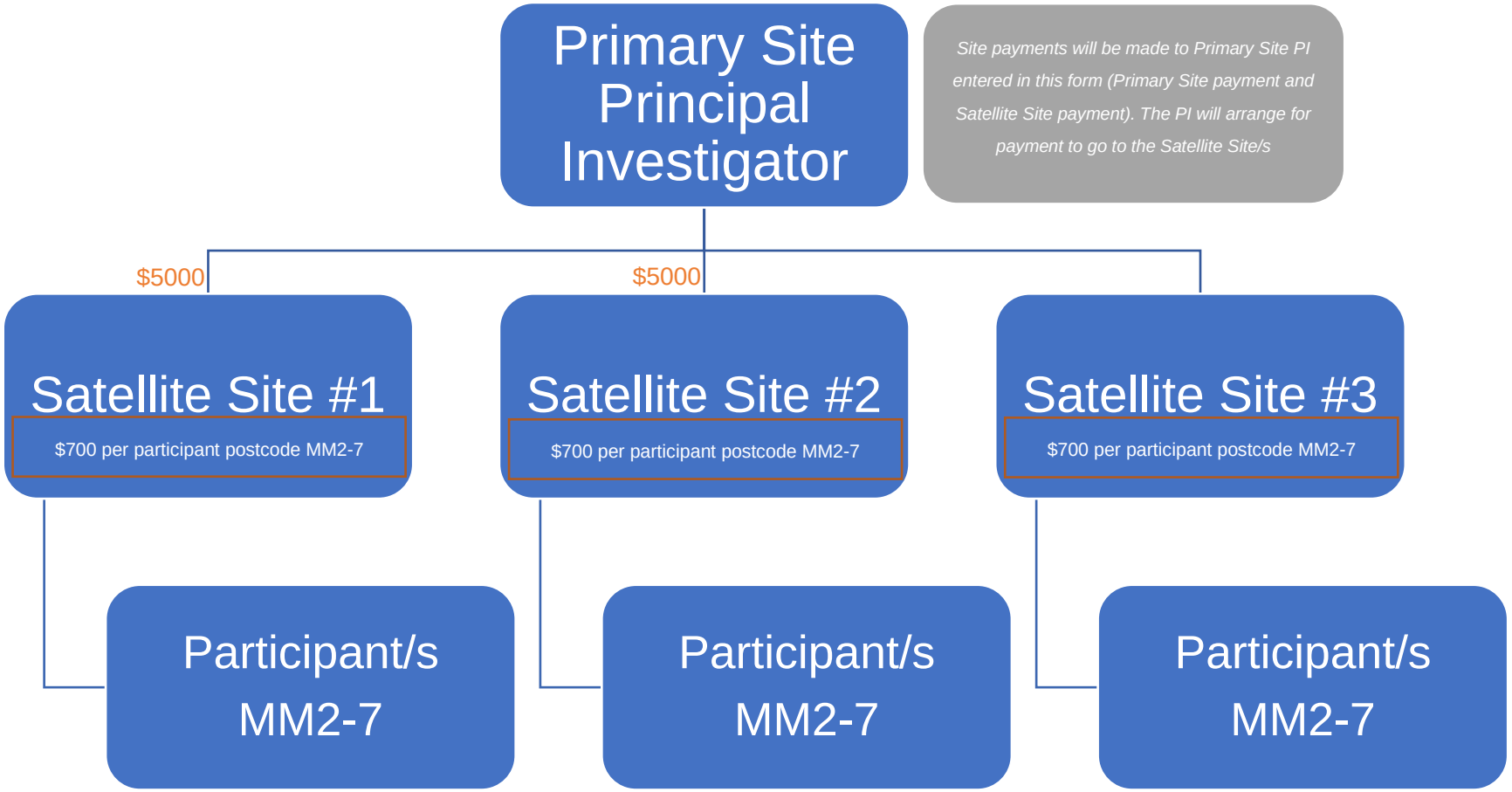
Victorian RCCC will receive an automated email to complete the 'Office Only Use' section of the 'Satellite Site Participation Registration' form once submitted by the site

11. 'Satellite Site Participant Registration Form 2A' is submitted by the Victorian RCCC

An automated email is sent to the Victorian RCCC to complete the Satellite Site Registration Form 2A. This is submitted for technical processing in REDCap

*Teletrial Registration Form can be found under the Teletrial Support Program section in the Clinical Trials and Research Teletrials tile.

Example: TSP payment structure for a Principal Investigator (primary site) with 3 satellite sites



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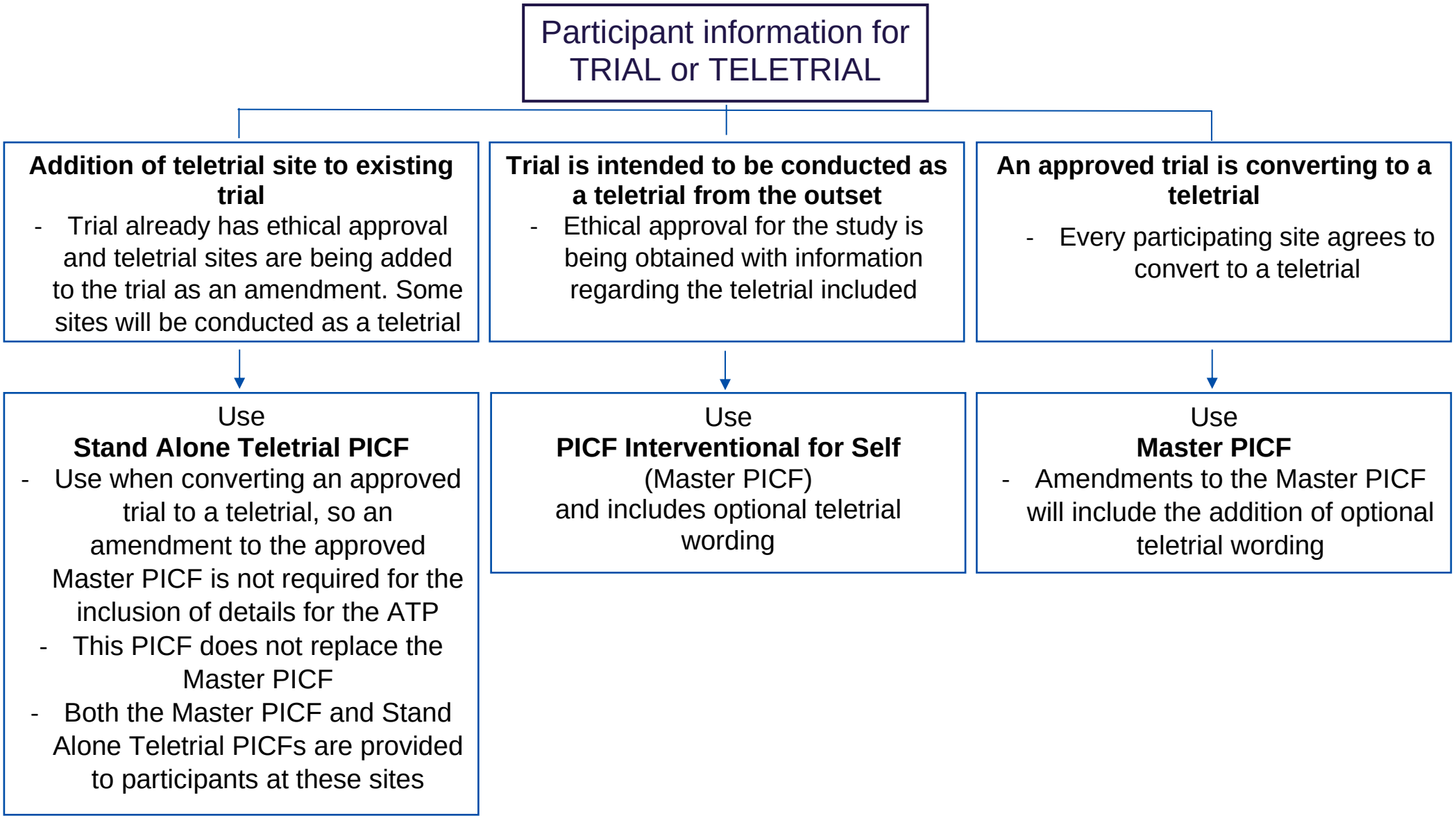
**Eligibility criteria applies*


Participant information for TRIAL or TELETRIAL
Addition of teletrial site to existing trial
- Trial already has ethical approval and teletrial sites are being added to the trial as an amendment. Some sites will be conducted as a teletrial
Trial is intended to be conducted as a teletrial from the outset
- Ethical approval for the study is being obtained with information regarding the teletrial included
An approved trial is converting to a teletrial
- Every participating site agrees to convert to a teletrial
Use
Stand Alone Teletrial PICF
- Use when converting an approved trial to a teletrial, so an amendment to the approved Master PICF is not required for the inclusion of details for the ATP
- This PICF does not replace the Master PICF
- Both the Master PICF and Stand Alone Teletrial PICFs are provided to participants at these sites
Use
PICF Interventional for Self
(Master PICF)
and includes optional teletrial wording
Use
Master PICF
- Amendments to the Master PICF will include the addition of optional teletrial wording

To receive this document in another format, phone 0499 810 778, using the National Relay Service 13 36 77 if required, or email the Regional Clinical trial Coordinating Centre <rccc@safercare.vic.gov.au>.

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