Teletrial Support Program (TSP) funding

PURPOSE

This guideline provides a step-by-step process on how the funding grant for Teletrials is managed from Australian Teletrial Program (ATP) Office to Metro South Health (MSH) Clinical Trial Units currently running a Teletrial study as per Queensland Regional Clinical Trial Coordinating Centre (QRCCC).

OUTCOME

This guideline aims to:

- Outline how payment to the principal site as part of the ATP Teletrial funding will be granted to the Clinical Trials Unit running a Teletrial study.
- Enhance access to clinical trials closer to home for Queenslanders in regional, rural, or remote locations by using telehealth technology to enable clinical trials to be conducted as Teletrials.

SCOPE

This guideline applies to all MSH employees conducting research and specifically to MSH clinical trial teams involved in a Teletrial study.

GUIDELINE

1. WHAT IS A TELETRIAL

- A Teletrial is a group of clinical trial sites that work together as a cluster.
- Within each cluster there is one principal site and one or more geographically remote satellite sites.
- The Principal Investigator is based at the principal site and provides supervision of the trial which is conducted by Associate Investigators at satellite sites within the cluster.

1.1 Teletrial Support Program

- The Teletrial Support Program (TSP) aims to support clinical research teams to participate in the ATP and provides funding (up to $10,000 (GST exclusive) per protocol to enable eligible principal sites and funding of $700 (GST exclusive) per participant to eligible satellite sites to:
    - enable participation in the Teletrial model
    - to accelerate expansion of clinical trials to rural, regional and remote patients through the teletrial model.
- Principal Investigators, located at the principal site, could be eligible for two $5,000 payments if there are two satellite sites with eligible recruitment. This payment is capped (maximum of $10,000) even if more satellite sites have patients with a postcode of MMM2 or above.

1.2 Conditions of funding

- Payments will be made to support the principal site or satellite site for eligible teletrials.
- Funded sites must provide teletrial details to the QRCCC as part of the data collection and reporting for the ATP.
- Information about teletrials funded through the TSP under the ATP may be made available publicly including the trial name, trial site, therapeutic area, and contact details.

2. PROCESS

- Once advised by QRCCC that the principal site is eligible the research team must undertake the following process:
    - Following ethics approval and Site Specific Assessment (SSA) authorisation the Principal Investigator/ principal site notifies QRCCC via email (qrccc@health.qld.gov.au) of the teletrial and provides relevant trial information.
    - The principal site staff/QRCCC enters trial information into REDCAP Data System (QRCCC monitored)
    - REDCAP will auto generate a report to notify QRCCC that a principal site is eligible for TSP.
    - The Finance Report informs QRCCC of money owed to the principal site in the next amendment windows (usually February and October)
    - QRCCC raises a memo which is firstly signed by the Australian Teletrial Project Director
    - QRCCC sends signed memo to the Health Service Chief Executive (cc to Metro South Health Teletrial Coordinator and Metro South Research) for approval
    - A fully executed copy of the memo must be returned to QRCCC by the requested due date to enable release of funds under the amendment window
    - MSH Finance Management team which provides business support the principal site clinical trial unit department/division will liaise with the Department of Health to receive funding
    - MSH Finance Management team must journal down to project cost centre
    - The clinical trial unit/research project receives funding support payment.
- Researchers are encouraged to contact the Metro South Health Teletrial Coordinator to discuss this process.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Metro South Research	Undertake ethical review and SSA authorisation.	N/A

Queensland Regional Clinical Trial Coordinating Centre (QRCCC)	Coordinates the Australian Teletrial Program on behalf of Queensland and Queensland Health.	N/A
Principal Investigators	Responsible for the conduct of the trial located at the principal site and for liaison with the Associate Investigators.	N/A
Associate Investigators	Responsible for the conduct of the trial located at the satellite site.	N/A
QRCCC Cluster Start-Up Specialist	Provides operational support to ensure rural, regional and remote satellite sites and have the capacity and capability to participate in clinical trials. Also ensures that the teletrial cluster is established prior commencing clinical trial as teletrial.	N/A
Teletrial Coordinator	Provides administrative assistance in obtaining necessary approvals from trial Sponsors, HREC and RGO for Teletrial conversion or start-up.	N/A

DEFINITIONS

Term	Definition
Teletrial	A teletrial is a group of clinical trial sites that work together as a cluster. Within each cluster there is one principal site and one or more geographically remote satellite sites. The Principal Investigator is based at the principal site and provides supervision of the trial which is conducted by Associate Investigators at satellite sites within the cluster.
Principal site	The main health facility that coordinates the trial across a cluster to enhance participant reach, recruitment and management.
Satellite site	A satellite site is located in a geographically separate health facility and trial activities are delegated by the principal site (clinical trial site) to the satellite site, to enable performance of activities associated with the conduct of a clinical trial at the satellite site and to support trial accessibility of remote participants to a clinical trial.
Teletrial cluster	A group of sites involved in undertaking the same study, consisting of a principal site who assumes overall responsibility for the conduct of the same study and one or more satellite sites, which conduct the study under the direction of the principal site using telehealth.
REDCAP Data System	A secure web application used to manage and store data used in clinical trial/study.

Funding window	The allocated months (amendment windows usually are February and October) each year to execute memos to the Hospital and Health Services for eligible funding.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated from time to time)** • *Financial Accountability Act 2009* (Qld) • *Financial and Performance Management Standard 2019* (Qld) • *Hospital and Health Boards Act 2011* (Qld) • *Hospital and Health Boards Regulation 2012* (Qld) • *Human Rights Act 2019* (Qld)

Standards	• National Clinical Trials Governance Framework
	• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.
	  ○ Standard 1 – Clinical Governance
	  ○ Standard 2 – Partnering with Consumers

Supporting documents	• WI2023-299 Ethical and scientific review of research • WI2023-301 Site specific assessment of research

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, to give proper consideration to human rights. When making a decision about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: https://www.forgov.qld.gov.au/humanrights.

GUIDELINE DETAILS

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