Teletrials Clinical Consultation User Guide

Government of South Australia

SA Health

Contents

Introduction

Purpose

The purpose of this user guide is to provide clinical trial staff with:

- a course of action to book, provide and receive a clinical consultation when performing participant visits for a clinical trial, employing telehealth communication
- a guide regarding the flow of documentation between a Primary Site and one or more Satellite Site/s.

Teletrials consultations may occur for inpatients or outpatients.

Glossary

For a list of all acronyms and terms used in this document refer to the Generic Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia.

Background

The concept of using Teletrials will enhance participant reach throughout States and Territories and enable rural and remote patients to participate in and aid recruitment to clinical trials, as well as enable them to access new therapies and interventions as do their metropolitan counterparts. When there is more than one Satellite Site under the supervision of the same Primary Site, this group will be termed a cluster. There are also the added advantages of the opportunity to upskill both regional and metropolitan staff and to facilitate growth of trials in the region.

The overall cost savings for running clinical trials are significant. A large portion of the costs savings are due to not having to regularly transport and house patients from the region to a metropolitan Primary Site. Even if more sites are set up there will be significantly less transportation for the patients and their carers, meaning that patients can stay at home, which is a substantial benefit to the patients.

In order to meet any concerns of the effectiveness of and compliance to Telehealth procedures, the service is monitored annually and measured against the Key Performance Indicators for 100 % compliance for the following parameters:

- Date of consultation
- Delivery mode
- Time consultation commenced and finished
- Whether verbal consent has been obtained to conduct the teletrial consultation via Telehealth
- The names of people in attendance during the teletrial consultation (i.e. patient, nurse, allied health personnel and/or clinician at both the receiver and provider end)
- Patient observations (if required)
- Names of health care facilities involved
- Name and designation of the clinician providing advice

The level of risk has been identified as low but in certain circumstances may be identified as higher than low risk. Source documentation for the teletrial consultation can be found in the patient health record accessible from the Primary Site.

Environment and Set-up

Prior to considering teletrials as a means for enhancing recruitment into clinical trials, the relevant health care providers must decide whether teletrial consultation is suitable for the participant. As per standard patient care all reasonable efforts must be made to maintain patient confidentiality during a teletrials consultation by setting up the consultation room to ensure visual and auditory privacy. Audio and visual recording of patient teletrials consultation on any device should comply with local policy. Written evidence of the consultation is to be documented in the patient's medical record.

Clinical

The Principal Investigator will be based at the Primary Site which is where the Study Master File (SMF) is kept. Satellite Sites are selected by the Primary Site and this is where the Satellite Site Study File (SSSF) is located. Records of the telehealth consultation are filed in the SMF where source documents are held: See *Generic Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia* (SOP 07 The Study Master File).

As a minimum requirement for clinical support, the health professional or trial staff member as per the delegation log and supervision plan, should always accompany patients during the teletrial consultation at the Satellite Site.

The health professional or trial staff member is responsible for completing the relevant documentation in the patient medical record, and later entering this data into the clinical trial eCRF as well as other duties that may be delegated by the providing end specialist (Primary Site and Investigator) such as observations and emotional support.

Specific protocol requirements must be taken into consideration and completed or results to be available before participant consultation occurs at the Satellite Site (e.g. blood test results or observations).

Administration

Administration support will be required at both Primary (provider) and Satellite (recipient) Sites. Duties will include appointment booking, chart preparation, completion of the eCRF and filing after the consultation.

- A note in the participant's health record (current UR) shall be made or a new health record (new UR) made on all teletrial patients at both provider (Primary Site) and recipient site (Satellite Site) and written documentation must be added to the participant's medical record. This provides source documentation of the telehealth trial visit.
- If a health record needs to be created contact the relevant administration officer in this area. This can be done after the consultation.
- Teletrials documentation in the participant health record will clearly state:
    - Delivery mode of consultation;
    - Date / Start and finish time;

- Clinical trial and Visit status;
- Particulars of the call including persons present, facility locations, including delegation and any assessments performed as well as outcomes or information given to the participant.

> If the *e*CRF is unable to be completed at the Satellite Site, the Satellite Site will notify the Study Coordinator at the Primary Site of the core information to be documented in the *e*CRF.

> Follow up care and instructions will be communicated as appropriate, with provider site emailing recipient site letter/ notes of consultation and filed in participant's health record.

> The participant's health record (Primary and Satellite site) will be managed as per local policy.

> If a participant fails to attend for a consultation, the Principal Investigator will be notified, and the study coordinator will work with the Satellite Site to rebook the participant's trial visit and follow up procedures in the protocol.

For Inpatient Telehealth activity it is the responsibility of the study coordinator at the Primary Site to enter teletrials data into the participant's health record as instructed by clinical staff and sponsor e.g. Clinical Research Associate (CRA).

Prior to commencing consultation

A local site Telehealth Coordinator if available can assist with the set up and booking processes. Videoconferencing for the purposes of making an appointment or when a site to site supervision or training session is to be undertaken is excluded.

Principal Investigator (PI)

If unable to meet face to face, the PI can provide teletrials consultation with a named patient for a clinical trial situated at a Satellite Site accompanied by an appropriate health practitioner and will assess suitability for the patient's inclusion to the study.
Appointments can be made from the Satellite Site to the Primary Site study coordinator via Telehealth.

Appointments outside of the hospital or health service

Where an appointment is required outside of the hospital or health service in a private clinic or GP rooms via Telehealth, the Satellite Site will need to contact the Primary Site to authorise the direct clinical dial-in for the Principal Investigator via email. The following details must be included:

> Name and Date of Birth of patient

> The clinical trial for scheduling and Principal Investigator name

> Proposed appointment date and time.

> Additional requirements / special requests for the videoconference consult.

Satellite Site

On email confirmation from the Primary Site, the site staff at the Satellite Site should ensure room and Videoconference equipment are also available at proposed date and time

- All equipment used for a teletrial consultation will be cleaned according to the National Health and Medical Research Council (NHMRC) Infection Control Guidelines https://www.safetyandquality.gov.au/our-work/healthcare-associated-infection/national-infection-control-guidelines/ pre and post use.
- A user test is performed by the study coordinator at the Primary Site and admin officer at Satellite Site to check Videoconferencing equipment used for the teletrial consultation prior to clinical consultation.

Process

a) Check the assigned room contains the following:

- Facilitates a private and confidential consultation
- Has suitable seating available for all participants
- Has a suitable desk or flat surface for microphone, patient notes and provides a space for documenting notes in the patient chart etc.
- Has all study equipment, investigational product, documentation available as needed

b) Check the video conference equipment is set up correctly ensuring:

- Camera and monitor are turned on with the microphone and remote control placed in a suitable / accessible position
- Test call has been made by dialing “111”
- Furniture arranged to ensure, where possible, camera view shows all consultation participants
- Focus camera (using the remote control only) to facilitate good eye contact
- Where possible, show all participants, noting that ‘Self view’ can be turned off if requested by the patient once the camera has been focused
- Place a sign on all entrances to the room indicating that a Telehealth videoconference consultation is in progress
- Satellite Site to electronically book appointment for own facility
- Satellite Site generates patient letter of appointment
- 1 day before clinic date (or other time frame where mutually agreed) Satellite Site confirms the following with the Primary Site study coordinator contact via email:
    - Appointment date and time of patient
    - Videoconference name (or number) for provider site to dial into

Process for patient arrival

When the patient arrives at the Satellite facility:

- Record the patient arrival
- Ensure patient medical record is available for the consultation
- Escort all participants to the assigned room in preparation for the consultation

- Start the telehealth consultation by dialling in. Wait until both Satellite Site staff, patient and Primary Site staff are present before proceeding to next step
- Signed consent must be obtained for the clinical trial prior to trial procedures taking place. To ensure this, the patient should receive and have read the Participant Information and Consent Form and a Telehealth leaflet prior to the video conference at the Satellite Site by the local health professional, ready for discussion whilst the Principal Investigator is present on the video conference.

During the consultation

When both sites are connected:

- Un-mute the microphone for the duration of the consultation to facilitate spontaneous interaction between participants i.e. environment is more consistent with a face to face consultation encouraging questions and avoiding the need for these to be repeated
- Confirm, at both ends, that the auditory and visual quality is appropriate for the consultation being undertaken. The consultation should not proceed if issues related to transmission quality cannot be resolved
- If technical issues are experienced contact the Telehealth provider advising them of problems with a clinical consultation
- Introduce all participants (visually as well as verbally) and if anyone joins the consultation after this initial introduction they are to be introduced and participants must consent to their participation before continuing the consultation. Consent noted in patient's medical record
- If the patient is deemed eligible for the trial and the patient is willing to participate, the Primary Site Principal Investigator acknowledges this consent verbally via teletrials consultation and the accompanying health professional acts as witness. The result is documented in the patient's health record progress notes at both provider (Primary Site) and recipient site (Satellite Site) and the consent completed as per Generic Standard Operating Procedures for Clinical Trials SOP 09 Participant Informed Consent Process and Documentation.
- During the videoconference avoid drumming fingers, tapping pens, shuffling papers, etc. near the microphone
- Be aware of the short delay in transmission and allow a pause for others to comment
- Ask the participants if they have any further questions / concerns and address these.
- Ensure the following have been documented in the patient health record as per example below:
    - Delivery mode of consultation, date time start/end
    - Name and Date of Birth of patient
    - Clinical trial to be booked into and Principal Investigator name and name of site
    - Proposed next appointment date and time
    - Additional requirements / special requests for the videoconference consult

- Patient consent obtained as per Generic Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia SOP 09 Participant Informed Consent Process and Documentation
- Brief summary of consultation, including follow up instructions

Example:

"Telehealth consultation 01/01/2014 0900 - 0945 Dr. Jones/ Paediatric Consultant, Excel Hospital. Clinical trial: Title _____: Patient consent signed. Present in consultation room is – Tom Smith (patient), Mrs. Smith (Patients mother), Registered Nurse. No observations required. Brief discussion regarding recent clinical trial process and study. To continue with current medication regime. Consultation notes to follow from providing site. Follow up appointment requested in 1 months' time (signature) RN CITIZEN.

Inpatient teletrial consultation

All Inpatient Telehealth events should meet the following requirements:

- The patient was an admitted patient at the facility
- The patient is eligible for the clinical trial
- The service delivered was a substitute for face-to-face activity
- Clinical notes were recorded in the admitted patient's medical record
- The patient or patient representative must be present during a ward round, clinical consultation or consultation with a Retrieval Service.

A teletrial event may occur more than once during the clinical study.

Capture of Inpatient teletrials data

Inpatient teletrial activity must be documented in the patient's medical record at the Satellite Site.

Closing the consultation

Satellite Site:

- Ensure the call is disconnected (Press Hang Up button **twice**)
- Ask patient if they have any further questions relating to the consultation
- Escort the patient to the clinic reception area and end the visit
- Send notes of administration relevant to clinical study to Primary Site

Primary Site:

Investigator must ensure consultation documentation for the clinical trial is recorded in the patient notes and eCRF and notes are filed in the patient health record.

- Clinical notes are filed at both the Satellite and Primary Site facilities. It is important to note that the patient will have a different UR number for their health record at each site. For ease of reconciliation it is good practice to note the two (or more if more than two sites are involved in the telehealth consultation) UR numbers for the patient on the trial specific Participant Identification Log.
- This summary of the telehealth consultation may also be sent to the patient's GP if the patient has consented to this.

Trouble shooting

If a connection is not possible, another secondary unit should be utilised. If this option is not possible, contact the provider site/ specialist to determine the appropriate course of action for the patient.

Appendix 1 Budgetary considerations for teletrial consultations

1. Unplanned disconnection

To claim teletrial inpatient activity, there must be a successful connection between videoconference systems. This is when real-time audio and visual information is transmitted and received by videoconference systems involved in a teletrial session and interactive real-time activity commences.

In cases of unplanned disconnection between videoconference systems and successful reconnection of the systems occurs, the Telehealth session is considered to be continuous. If reconnection is not successful, the time of unplanned disconnection should be allocated as the end time of a Telehealth session.

2. Funding / Budgetary clarification

Rebates may be available for outpatient consultations for both the Primary and Satellite Sites and in some states for inpatient consultations.

A nominal administrative fee from the clinical trials budget would need to be negotiated upfront for the Satellite Site for collaboration with the study coordinator at the Primary Site.

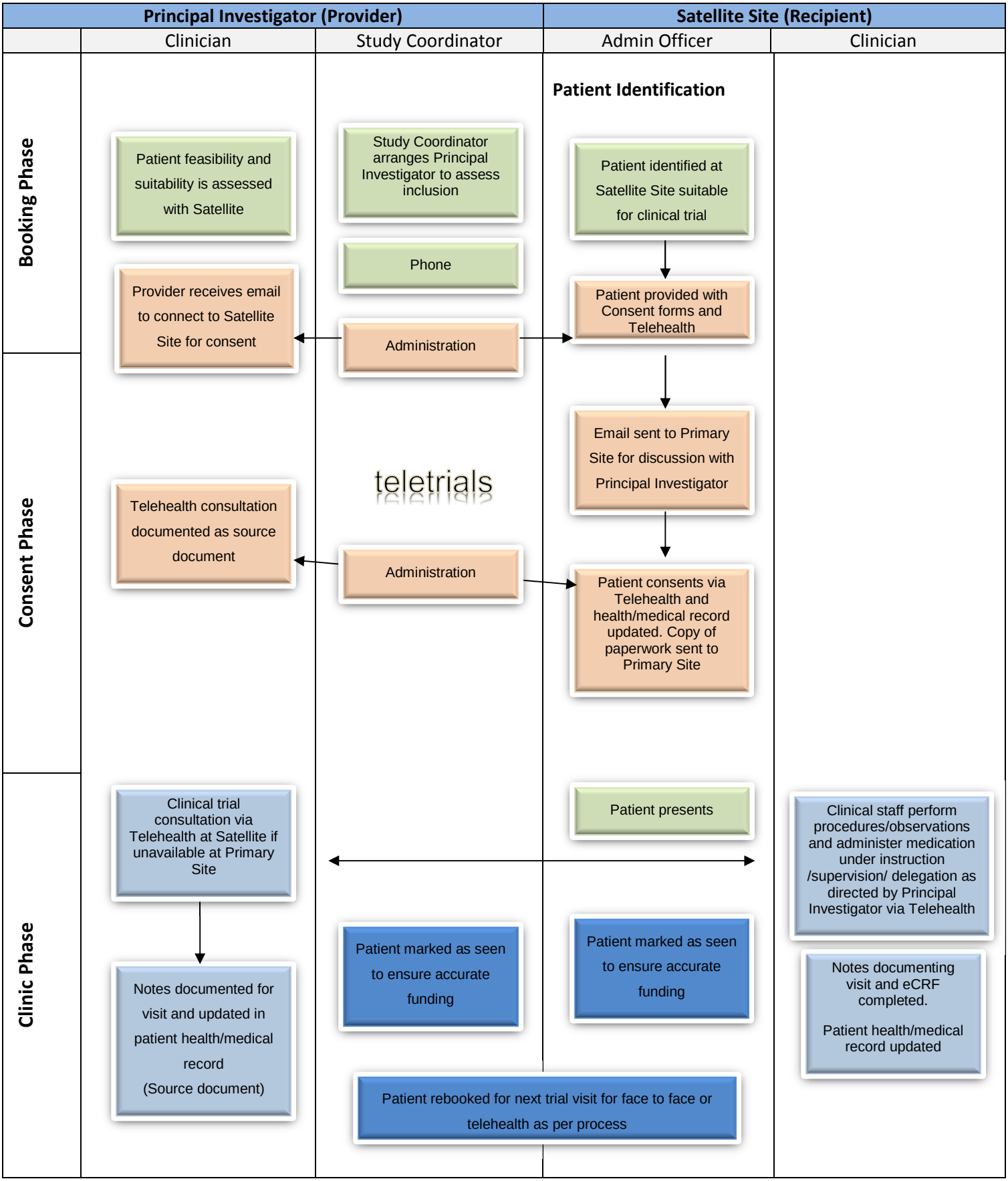
Retrieval Services

On the occasion of an adverse/serious adverse event, the standard care would be to retrieve to the nearest tertiary hospital, even if they are not the Primary Site. Payment for retrievals is always from the ascending site and not be part of the clinical study costs.

Accompanying patient notes to the retrieval site must include details that the patient is participating in a clinical trial.

It is imperative that the Primary Site is notified as per the SAE process outlined in the *Generic Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia* (SOP 12 Safety Data Monitoring and Reporting Requirements for Clinical Trials).

Appendix 2 Teletrials booking process for Satellite to Primary



Appendix 3 Outpatients Teletrial Clinic Form

	Providing Site Principal Investigator (Primary Site)	**Recipient Site** (Satellite Site)
Clinical Trial Name/Clinical Trial Code:		
Clinic Name/Clinic Code:		
Principal Investigator Name:		
Providing Site Name:		
Recipient Site Name:		
Provider Location Town:		
Recipient Location Town:		
Date of Consultation: DD/MM/YYYY		
Contact Numbers		
Administration Officer Name:		
Consultant /Clinician Name:		
Email address:		
Recipient Telehealth Unit Name/number		
Recipient Staff requirement (List)		
Pre clinic Instructions		
Post consult instructions		
Post clinic Instructions		

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