Conducting a teletrial at Mater

The Australian Teletrial Program (ATP) provides support to bring clinical trials closer to home for patients in rural and remote communities. For more details, refer to the *Evaluation of a Clinical Trial as a Teletrial Checklist* on the ATP website. Funding opportunities and support may be available. For enquiries, contact QRCC@health.qld.gov.au or visit ATP website.

What are the additional requirements for teletrials?

- **A Supervision Plan**
    - A document outlining the Primary Site Principal Investigator's responsibilities for oversight of the Satellite Site, and the trial activities at the Satellite Site. Site-specific supervision plans are submitted to both the Primary Site and relevant Satellite Site Research Governance Offices. A Teletrial Supervision Plan template is available on ATP website.
- **Delegation log**
    - Required by ICH GCP for both the Primary and Satellite sites
- **Evidence of Sponsor agreement to conduct the trial as a teletrial**
    - If Mater is the Sponsor, please complete the Teletrial sponsor agreement letter (located on the Research Compliance internal SharePoint) and provide it to the Research Agreements team who will arrange for signing. In situations where new satellite sites are added after site authorisation, this letter can be updated and resubmitted
    - If your trial is externally sponsored, your sponsor will provide you with written confirmation
- **Agreements**
    - Head Agreement between the Sponsor and the Primary Site (if Mater is not the Sponsor)
    - Teletrial Sub-contract between the Primary Site and the Satellite Site/s
- **Participant Information and Consent Form (PICF)**
    - Option 1: PICF includes teletrial specific wording:
        - Teletrial specific wording is available on the ATP website
    - Option 2: Separate PICFs for satellite sites vs non-satellite sites:
        - A standalone Teletrial template is available on the ATP website

What to do with this information?

- **If commencing a new teletrial**
    - Submit with your HREA/SSA
- **If changing to a teletrial**
    - Include in amendment submission

FAQs

Q: What is the different between multi-site trials and teletrials?

A:

	Multi-site trials	Tele-trials
Nature of site	Trials are conducted at multiple independent sites	Trials are conducted within clusters
Relationship between sites	Sites have no relationship with each other	Primary and satellite sites work in collaboration and are connected by telehealth for some or all aspects of the clinical trial
Trial coordination	At each site, trial coordination is managed by the Principal Investigator (PI), while overall coordination across all sites is overseen by the sponsors, Contract Research Organisations (CROs), and Coordinating Principal Investigator (CPI)	Within a cluster, trial coordination is primarily the responsibility of the PI at the primary site, with contributions from satellite sites, sponsors, and CROs
Site of Primary Investigator (PI)	PI's are appointed at each site	PI at primary site and associate-investigators at satellite sites work in collaboration
Regulatory process	Governance and other regulatory approvals are performed separately by each site	This model facilitates the streamlining of approval processes and minimises duplication through the collaborative efforts of research governance officers within clusters

Q: Can any clinical trial be run as a teletrial?

A: Not all trials are suitable. Phase I trials which require specialised equipment and intense monitoring of participant may not be suitable. Management and transport of Investigational Product (IP) at satellite sites is an important consideration when selecting a suitable trial.

Q: Are satellite sites required to be listed on the Clinical Trial Notification Scheme (CTN)?

A: The CTN only includes sites where Investigational Product (IP) is stored. Satellite sites do not need to be listed if they do not store the IP. However, if the sponsor stores (rather than ships) the IMP at a satellite site, that site must be included on the CTN.

Q: How is patient consent managed for a teletrial?

A: Consent is obtained during a telehealth clinic visit when required and must be documented in the supervision plan.

- If the Associate Investigator (AI) is present during the clinic visit with the patient, they will sign the declaration on the same Participant Information and Consent Form (PICF) as the patient.
- If the PI or AI from the primary site is signing the PICF declaration via telehealth, an exchange of PICFs is required once completed.

The informed consent process is documented in real time at both the primary and satellite sites within the patients' medical record. The PI or AI writes the declaration, and the version and date of the PICF are entered. The PICF is then uploaded to the medical record.

- The patient will receive a copy of the PICF.
- Satellite sites can either fax or scan the signed PICF to the primary site immediately to ensure completion. Alternatively, the PICF can be mailed to the primary site via registered post.

Important Note: If the patient consent is mailed, the PI will sign the PICF on the date it is received, not the date on which consent was obtained from the patient.

Research Governance: research.governance@mater.uq.edu.au
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