National Principles for Satellite Site Authorisation in Clinical Trials

Purpose

This document provides principles regarding best practices to support efficient cluster start-up and approvals when satellite sites are included using the Australasian Teletrial model (ATM) for all relevant stakeholders, including teletrial site staff members, principal and associate investigators, and research governance officers. The principles ensure equity of access to clinical trials for regional, remote, and rural people, including Aboriginal and Torres Strait Islander peoples, in a timely and patient-focused manner. These principles may also benefit underrepresented and vulnerable populations, such as culturally and linguistically diverse people/communities, even within metropolitan settings.

Note: These principles are not mandated policy, and their application is at the discretion of each jurisdiction, subject to their individual regulatory requirements.

Rationale

Limited access to clinical trials and poorer survival outcomes faced by people from regional, rural, and remote Australian communities are well established. The Teletrial model of care was created to foster partnerships between primary and satellite sites, allowing satellite locations to offer clinical trials locally through trial clusters. However, the current satellite site authorisation processes have been identified as barriers to patient-centred care and workforce well-being. Timelines for satellite site authorisation can be lengthy and duplicative, creating a barrier to equitable access to clinical trial therapy. These principles are developed to address these delays nationally and ensure timely access to clinical trials at satellite sites.

Scope

These principles leverage the ATM's numerous benefits, emphasising human-centeredness and stakeholder collaboration. They build on the existing National Mutual Acceptance processes for ethics approvals and aim to provide Australians with more timely access to clinical trials in their local areas. Additionally, these principles support all stakeholders involved in satellite site authorisation at health services, including hospital executives, research governance officers, principal investigators, associate investigators, clinical trial coordinators, research nurses and regional clinical trial coordinating centre staff.

Health Equity

For Aboriginal and Torres Strait Islander people

These principles support health equity among Aboriginal and Torres Strait Islander peoples so they can maintain their connection to the country whenever possible. This is an integral part of Indigenous peoples' right to self-determination and helps them maintain a sense of belonging in their community. Keeping cultural identity and connection while providing access to treatment could help provide more equitable access to clinical trials for underserved or underrepresented populations.

Principles

Cluster Approval

In the teletrials model, all relevant stakeholders will be patient-focused and provide timely approvals.

Governance Authorisation and Acceptance

i. **Collaborative Partnerships:** Principal Investigators, Associate Investigators, Research Governance Officers, and other relevant stakeholders must collaborate effectively. By doing so, they can ensure timely approvals and prevent patient disadvantages.
ii. **Supervision Plan as Evidence of Cluster Collaboration and Satellite Site Capabilities:** A completed supervision plan covering the satellite sites' capabilities and feasibility components of the trial protocol should be accepted as evidence of satellite site (and cluster) capabilities.
iii. **Standardised Contractual Agreements:** Appropriate selection of contractual agreements, using standardised approaches such as Clinical Trial Research Agreements (CTRAs) and cluster sub-contracts, is required.
iv. **Timely Reviews:** Satellite sites should streamline the review process for governance documents by reducing redundant efforts and expediting authorisation procedures. This ensures patients have equitable access to clinical trials closer to their homes.
v. **Focused Governance Assessment:** Satellite sites are not required to conduct a complete governance assessment of the project. They should focus only on governance elements relevant to their activities, considering their capacity to deliver the trial (already evidenced in completed supervision plans as listed in point ii)
vi. **Acceptance of Primary Site Contracts and Budgets:** Satellite sites will accept the contract and budget negotiated and approved at the primary site, minimising additional steps required for approval.
vii. **Waiving Fees for Teletrials:** The research governance office of satellite sites should consider waiving the review/processing fees for all teletrials and any HREC amendment fees.

viii. **Ethics Notification Scheme for Site Activation:** Lead HRECs should adopt a notification scheme rather than requiring an amendment for satellite site activation.

ix. **Clinical Trial Notification in a cluster:** In a teletrial cluster, including each satellite site on the primary CTN is possible. It is advisable to do this to avoid additional fees, as adding sites is viewed as an amendment. Sites can be activated at any time after CTN submission.

x. **Annual reports:** Teletrial cluster management, under the oversight of the Primary Site, removes the need for the Satellite Site to submit an annual report to its Research Governance Office (RGO).

a. Flow Diagram for cluster activation

Other opportunities

Application of these principles enables site-related discussions to occur early among stakeholders. This paves the way for adopting pre-approval methodologies and concepts to expedite approval processes.

Acknowledgement

The ATP has created this document to simplify the activation process for Teletrial Satellite Sites as part of its Harmonisation initiative. We appreciate the contributions of the following members:

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Natasha Savvides, Barwon Health, Victoria
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Clare McKay, Australian Teletrial Program-Northern Territory
Sonia Hancock, Metro South Health, Queensland Health
Kaye Hewson, Australian Teletrial Program, National Office
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