

National Principles for Teletrials in Australia

Based on the International Council for
Harmonisation Guideline for Good Clinical
Practice

ICH E6 (R2)



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Introduction

These National Principles for Teletrials have been developed to assist organisations engaged in conducting clinical trials in Australia to, wherever possible, standardise their procedures for key operations related to clinical trials and specifically teletrials. They have been developed for the National Mutual Acceptance (NMA) Scheme in Australia and to support a consistent approach to national implementation more broadly. They have been endorsed by all states and territories, together with the Therapeutic Goods Administration (TGA) and the National Health and Medical Research Council (NHMRC) through the Clinical Trials Project Reference Group (CTPRG).

The National Principles for Teletrials form part of a Teletrials Compendium, developed to support a consistent national approach to implementation of teletrials in Australia, which includes:

- the National Principles for Teletrials in Australia, and
- the National Standard Operating Procedures for Clinical Trials, including Teletrials.

The documents within the Teletrials Compendium are consistent with the minimum standard imposed by the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) [Guideline for Good Clinical Practice ICH E6 \(R2\)](#) - an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that involve participation of humans - and comply with the Integrated Addendum to this Guideline published by the TGA.

Compliance with the Teletrials Compendium provides public assurance that the rights, safety and well-being of trial participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data generated from the clinical trials are credible. These guidelines are also intended to conform with the Universal Declaration on Bioethics and Human Rights, which seeks to address ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions, and to provide guidance to decisions or practices of individuals, groups, communities, Institutions and corporations, public and private.

The Teletrials Compendium is consistent with the *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*, and also aligns with the Clinical Trials Governance Framework which has been designed to support the delivery and integration of high-quality clinical trials service provision into routine hospital care for improved patient outcomes. These National Principles for Teletrials are also consistent with recommendations from the Clinical Oncology Society of Australia's (COSA) Australasian Teletrial Model – A National Guide to Implementation, September 2016.

These National Principles for Teletrials as described in this document apply to all health service employees including, but not limited to, visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants, facilities and or staff. It is understood that all study personnel involved in the clinical study must operate within their scope of practice.

NMA is a national initiative for mutual acceptance of ethical and scientific review in public hospitals for multi-centre clinical trials and research.

The CTPRG, formerly the Clinical Trials Jurisdictional Working Group (CTJWG), was established in July 2014 and involves senior officials from Commonwealth, State and Territory health departments, and the NHMRC. The CTPRG seeks to identify and implement actions and system redesign that will enable a streamlined and consistent national approach to clinical trials within Australia with the intention of enhancing health outcomes and building Australia's ability to attract national and international clinical trials. Delivery of a framework to support national implementation of the Teletrials Model is a key deliverable identified on the CTPRG Implementation Plan.

The National Principles for Teletrials in Australia

1. In implementing teletrials, jurisdictions will follow National Principles that are consistent with the Clinical Oncology Society of Australia's (COSA) Australasian Teletrial Model – A National Guide to Implementation, September 2016.
2. Teletrials are defined as follows: A teletrial uses Telehealth technology to communicate between the Primary Site and Satellite Site/s for some or all aspects of a clinical trial. This supports a Principal Investigator (PI) to supervise Associate Investigators who conduct a clinical trial at a Satellite Site, geographically remote from the PI's Primary Site. The PI, who is always at the Primary Site and never at the Satellite Site, remains responsible for the trial across the cluster. A detailed Supervision Plan is required, in addition to a Delegation Log required by ICH GCP. Trial participants may have trial visits at both the Primary and Satellite Sites, as determined by the Protocol and as outlined in the Participant Information and Consent Form. The conduct of the trial is detailed under a 'head agreement', using a Clinical Trial Research Agreement/Clinical Trial Agreement between the Sponsor and the PI's Institution; and a Sub-Agreement between the Primary Site and the Satellite Site Institutions (see Terms in the National Standard Operating Procedures for Clinical Trials, including Teletrials).
3. Jurisdictions agree that "traditionally" multicentre clinical trials assume one PI per geographic site, differing from teletrials as defined above. However, for the purposes of teletrials, multicentre trials may include some sites that have Satellite Sites supervised under the Teletrials Model.
4. It is not intended that this model be employed as a means to bypass normal approvals processes. Sites should adopt a Primary Site role when feasibility assessments indicate that sufficient participants can be recruited to a trial through that site alone and a multi-centre model is warranted. If however a site cannot recruit sufficient participants through its own site it can utilise the Teletrials Model to achieve the required recruitment targets i.e. Primary Site can partner with a Satellite Site and Satellite Site can partner with a Primary Site, where the Primary Site will recruit the major share of participants. The sites who partner with a Primary Site are known as Satellite Sites. It is also possible that metropolitan sites partner with other metropolitan sites where a Sponsor requires only one site to achieve the required recruitment target, such as in rare disease indications. In all cases, there is only one PI.
5. National agreed terminology will be used (see Terms in the [National Standard Operating Procedures for Clinical Trials, including Teletrials](#)).
6. Jurisdictional policy and/or procedures (as relevant) will include a Supervision Plan to be developed between the Primary Site and each individual Satellite Site. A template for a Teletrials Supervision Plan is provided as part of the National Standard Operating Procedures for Clinical Trials, including Teletrials (refer to Appendix 5).
7. Jurisdictions agree that a Site-Specific Assessment for each teletrial Satellite Site is required.
8. Jurisdictions agree to implement and use these National Principles, and other key documents in the Teletrials Compendium including the National Standard Operating Procedures and the Supervision Plan.

