## Teletrial Research Governance Review Checklist

Use this checklist to guide submission requirements for research governance review of a clinical trial to be conducted via the Teletrial model at your site. This is an example; please consult the relevant state RCCC for state-specific guidance and requirements.

This checklist assumes standard submission requirements for research governance review of human research in Australia are applied and only provides advice on considerations relevant to submission requirements for RGO review of the Teletrial model.

Red text is instructional only. Purple text indicates a collaboration opportunity.

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| **Submission requirement:** | **PS** | **SS** |
| Usual site required RGO submission requirements  This can be completed collaboratively between Sponsor, Primary Site (PS) and Satellite Site/s (SS) to streamline. Speak to the relevant site to determine submission requirements. | Yes  N/A | Yes  N/A |
| Primary Site RGO authorisation  Evidence of PS RGO authorisation must be provided to the SS. Please note, SS cannot provide RGO authorisation without this. | Yes  N/A | Yes  N/A |
| [Teletrial Supervision Plan](https://australianteletrialprogram.gov.au/resources/)  This must be completed collaboratively between PS and SS. As this is a site-specific document, this should be commenced as soon as practicable post ethical approval being provided and sites being identified | Yes  N/A | Yes  N/A |
| [Clinical Trials Research Agreement (CTRA)/Head Agreement](https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/)  Between the sponsor and PS. Negotiations should consider budgeting and equipment for all sites in the cluster and can be informed by the Teletrial Supervision Plan. This agreement must be executed in full prior to the subcontract. | Yes  N/A | Yes  N/A |
| [CTRA Teletrial Subcontract/Subcontract](https://www.medicinesaustralia.com.au/policy/clinical-trials/tele-trials/)  Between the PS and SS. This agreement formalises cluster responsibilities and obligations. The Head Agreement is to be provided as an appendix at schedule 3 for parties. This agreement cannot be executed in any part until the head agreement is executed in full. | Yes  N/A | Yes  N/A |
| [Indemnity](https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/)  Between Sponsor and each individual site. To be arranged as per standard processes, using standard templates.  Can be completed simultaneously | Yes  N/A | Yes  N/A |
| Consenting process inclusive of [ATP Teletrial Consent](https://australianteletrialprogram.gov.au/resources/) for collection of evaluation data  Consider most appropriate mechanism of consent for the trial type (verbal, written standalone, written inclusion in master main PICF).  Can be completed simultaneously | Yes  N/A | Yes  N/A |