## Teletrial Ethical Review Checklist

Use this checklist to guide submission requirements for the ethical review of a clinical trial to be conducted as a teletrial. This is an example only; please consult the relevant state RCCC for any state-specific guidance. An ethical review of the teletrial model may be undertaken at the commencement point of the clinical trial regulatory review process or as an amendment to an existing approved clinical trial if the introduction of satellite sites (with identified potential participants) is considered to broaden recruitment.

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

Part A: Approved Studies (if your study has not received ethical approval, please proceed to part B):

Where a clinical trial has received ethical approval and you are seeking approval of an amendment to introduce the Teletrial methodology, please consider addressing the following in your submission:

# Red text is instructional only

|  |  |
| --- | --- |
| Updated study protocol with addition of overview / definition of Teletrial model. Please see [definition guide](https://australianteletrialprogram.gov.au/definition-guide/) available for use.  Updated protocol must be available in both tracked and clean versions, including version control, for consideration |  |
| Consenting process updated to include [ATP Teletrial Consent](https://australianteletrialprogram.gov.au/resources/) for collection of evaluation data  Consider most appropriate mechanism of consent (verbal, written standalone, written inclusion in master main PICF)  Updated PICFs must be available in both tracked and clean versions for consideration |  |
| Submission of a notification of addition of satellite sites via preferred submission platform, including CV and evidence of GCP training for the Satellite Site Associate Investigator.  [Notification to Reviewing HREC – Addition of Satellite Site Checklist](https://australianteletrialprogram.gov.au/resources/)  This may be able to be reviewed in parallel to the amendment documents, please confirm with your reviewing HREC. Submission requirements may vary. Please confirm submission requirements with your reviewing HREC. |  |
| Updated HREC only Indemnity  Ensure both Primary and Satellite Sites are named. Please confirm submission requirements with your reviewing HREC. |  |

*Part B: New studies:*

*Where it is intended that a clinical trial be conducted via the Teletrials model from the outset, please consider addressing the following in your submission:*

|  |  |
| --- | --- |
| Study protocol inclusive of overview / definition of Teletrial model. Please see [definition guide](https://australianteletrialprogram.gov.au/definition-guide/) available for use. |  |
| Consenting process inclusive of [ATP Teletrial Consent](https://australianteletrialprogram.gov.au/resources/) for collection of evaluation data  Consider most appropriate mechanism of consent (verbal, written standalone, written inclusion in master main PICF) |  |
| Updated HREC only Indemnity  Ensure both Primary and Satellite Sites are named. Please confirm submission requirements with your reviewing HREC. |  |
| List of sites\* to be included in review, including evidence of endorsement to proceed with study activity as requested by reviewing HREC\*\*  \*Please identify which sites are Satellite Sites and which are Primary  \*\*Please confirm submission requirements with the reviewing HREC. |  |

Do you think there are opportunities for improvement in this form? Please let us know!  
E: [Australian\_Teletrial\_Program@health.qld.gov.au](mailto:RCCCQLD@health.qld.gov.au)