Guidance for the use of optional Teletrial Wording in the
[Participant Information Sheet and Consent form templates](https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources)

published on the NHMRC website.

**Optional Teletrial wording to be inserted into Participant Information Sheet**

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| **Teletrials (see placement in the PICF guidance on page 4. Delete this highlighted instruction text prior to use)**This clinical trial is being undertaken using the teletrial model, and you may participate in the trial at a site closer to your home using telehealth technology such as telephone, video, or computer (telehealth) conferencing to connect clinicians at one location to clinicians and patients in other locations. Some of your visits may be done locally, but you might also need to travel to another hospital or clinic for some visits. If this is required, your study team will explain when and where you will need to attend your study visits. Health professionals at *[insert name of Satellite Site]* will communicate with the Primary hospital electronically, to conduct study visits and review your medical records. Any clinical information about you will be sent from your local site/hospital to the Primary (main) clinical trial site using coding matching your Study ID. Your name and contact details will not be included. Telehealth communications between the Primary clinical trials site and your local site/hospital will be subject to the same confidentiality provisions as are in place for all telehealth consultations.  |

**Withdrawing your consent (see placement in the PICF guidance on page 4 Delete this highlighted instruction text prior to use)**

Participation in a clinical trial or a teletrial is voluntary. If you don’t wish to take part, you don’t have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether or not to take part, or to take part and then withdraw will not affect your routine treatment, your relationship with those treating you or your relationship with *[Name of Site/s].*

If you agree to participate in a clinical trial that is being conducted as a teletrial, and then change your mind, you have two choices:

1. to stop participating at a teletrial Satellite site and continue your involvement in the clinical trial at the Primary site
2. withdraw from the trial altogether.

In either case, if you have provided consent for additional information about you to be collected for ATP reporting purposes, you will need to decide if you want your information removed from the ATP database *(if applicable)*.

If you want your information removed, please let your study team know. An automatically generated code was sent to your study team when your information was first entered into the database. No-one, except your study team, knows which participant the code was generated for. If you don’t want your information included, your study team will organise for your information to be removed from the database, using the code that was sent to them when your information was added *(if applicable).*

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| Do not include the section below unless conducting the Teletrial under the Australian Teletrial Program i.e with the assistance of a regional clinical trials coordinating centre (RCCC) or other coordinator.  **Delete this red text prior to use.****Required reporting about teletrials in the Australian Teletrial Program. (see placement in PICF guidance on page 4 Delete this highlighted instruction text prior to use)** **)** The Australian Government Department of Health is sponsoring the expansion of a teletrial model across Australia though the Australian Teletrial Program (ATP), which means that across Australia, people may participate in clinical trials closer to home. This Program is coordinated by Queensland Health.The ATP is required to report back to the Australian Government Department of Health about the difference teletrials make – especially to people from regional, rural or remote areas. Research teams from James Cook University and Queensland University of Technology will be assisting in evaluating the model and ATP reporting. We will record your home postcode so that we can work out the remoteness category of where you live; but we will not include your postcode in any reports – we will only report the remoteness category.With your consent, the research team will also collect the following information about your participation in this teletrial, and this will be used for ATP reporting: age, gender, cultural background, location of your study visits, and whether you finished the study. Your name and date of birth will not be recorded. If you consent to information about your participation in teletrials being collected for ATP reporting, your information will be merged with information from all other Teletrial participants who have consented to this data collection for ATP reporting. Individual data will not be reported. If you do not want information about your participation in teletrials to be collected and used for ATP reporting, you do not have to agree*.* You may still participate in a teletrial, and only your postcode information will be collected.Information about your participation in teletrials will be stored on a server located within Queensland Health and will be protected in accordance with the *Hospital and Health Boards Act 2011* (Qld), the *Information Privacy Act 2009* (Qld) and the Australian Privacy Principles.  |

**Consent Form.**

**Trial and Site details table:**

**Add the following additional row to the Trial and Site details table at the start of the Consent Form:**

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| --- | --- |
| Satellite Site details (if applicable) | *[Name of Satellite Site]**[Name of Associate Investigator]* |

**Additional dot points to be added to the Consent text:**

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| *[If conducting a Teletrial, insert this clause]* I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Insert name of primary site]* concerning my disease and treatment for the purposes of this Teletrial. I understand that such information will remain confidential.*[If conducting a Teletrial under the Australia Teletrial Program, insert this clause]* I give consent for information about my participation in this teletrial to be collected and used by researchers at James Cook University and Queensland University of Technology for reporting about the Australian Teletrial Program. **Yes / No****(Delete this red text prior to use.)** |

**Withdrawal of Consent**

I, (print name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ wish to withdraw my consent to participate in this teletrial, as indicated in my choices below:

Indicate your preferences in the boxes below

Remove this red text before use. If your site wishes to use tick boxes to indicate preferences, please make the change prior to HREC review.

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| *Please select one option:*1. I want to stop participating at a teletrial Satellite Site and continue all my involvement in the clinical trial at the Primary Site,

OR1. I do not want to participate at either the teletrial Satellite Site or the clinical trial Primary Site. I want to withdraw from the trial altogether
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| *Please select one option:*(1) I give permission for the information collected about my involvement in this teletrial to be kept in the database and used for reporting, OR(2) I do not give permission for the information collected about my involvement in this teletrial to be kept in the database and used for reporting. I want my information to be removed. |

**Suggested placement of wording in the NHMRC PICF Templates:**

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| **Which PICF Template?** | **Optional Teletrial Wording for Insertion in PICF template** |
| **Teletrials** | **Withdrawal of Consent** and **Form for Withdrawal of Participation**  | **Required reporting about teletrials in the Australian Teletrial Program.** |
| **Where to place the wording:** |
| PICF Interventional - Self | **Section 3:** What does participation in this research involve? | **Section 13:** What if I withdraw from this research project?**And** Form for Withdrawal of Participation | **Section 16:** What will happen to information about me? |
| PICF Interventional – Parent / Guardian |
| PICF Interventional – Person Responsible  |

If a clinical trial has already commenced, rather than amending the approved Master PICF, considering using the Stand-Alone Teletrial PICF, as an adjunct to the Master PICF.