**Stand Alone Teletrial Participant Information Sheet and Consent Form**

***This Stand Alone Teletrial PICF does not replace the clinical trial PICF.
Use this Stand Alone Teletrial PICF when converting an approved clinical trial to a teletrial, so that an amendment to the approved clinical trial PICF is not required for the inclusion of details for the Australian Teletrial Program (ATP) (or other teletrials).***

***Do not use this form if:***

1. ***a trial is not yet approved and is intended to be conducted, from the outset, as a teletrial at some or all participating sites***
2. ***a trial is already under-way and every participating site agrees to convert the trial to a teletrial.***

***In these cases, the optional teletrial Specific wording should be included in the Master PICF, as per the guidance in blue below.***

***Please delete all text in blue prior to printing the form.***

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| --- |
| *Complete the details in the table below. For the Satellite Site name and Associate Investigator, please only insert details that are relevant for this participant. Do not list all Satellite Sites and all Associate Investigators in the cluster.* ***Delete this text & row prior to use*** |
| **Title** | *[Full Study Title]* |
| **Study Sponsor** | *[Sponsor]* |
| **Principal Investigator** | *[Principal Investigator]* |
| **Primary Site Name** | *[Name of Primary Site]* |
| **Satellite Site Name** | *[Name of Satellite Site]* |
| **Associate Investigator** | *[Associate Investigator at Satellite Site]* |
| **Participant Name** | *[Name of Teletrial Participant]* |

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.

*Do not include the section below unless conducting the teletrial under the Australian Teletrial Program.* ***Delete this blue text prior to use.***

**Required reporting about teletrials** **in the Australian Teletrial Program.**

The Australian Government Department of Health is sponsoring the expansion of a teletrial model across Australia through 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.

**Withdrawing your consent**

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 also need to decide if you want your information removed from the teletrial database.

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 this Satellite Site is in a different health service from the Primary Site, please insert relevant contact details for the Satellite Site here.* ***Delete this blue text prior to use.***

**Teletrial Participant Consent Form**

*Please complete this table below in the same way as on page 1, and* ***ensure this blue text is deleted prior to use.***

|  |  |
| --- | --- |
| **Title** | *[Full Study Title]* |
| **Study Sponsor** | *[Sponsor]* |
| **Principal Investigator** | *[Principal Investigator]* |
| **Primary Site Name** | *[Name of Primary Site]* |
| **Satellite Site Name** | *[Name of Satellite Site]* |
| **Associate Investigator** | *[Associate Investigator at Satellite Site]* |

**Declaration by Participant**

1. I have read the Teletrial Information Sheet, or someone has read it to me in a language that I understand.
2. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
3. I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Insert name of Primary Site and / or Satellite Site]* concerning my disease and treatment for the purposes of this clinical trial. I understand that such information will remain confidential.
4. 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**

*Do not include this last dot point if* ***not*** *conducting the teletrial under the Australian Teletrial Program.*

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  Date |  |  |
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**Declaration by Study Clinician\***

I have given a verbal explanation of the implications of participating in a teletrial and I believe that the participant has understood that explanation.

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|  |
|  | Name of Study Clinician (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

**Note: All parties signing the consent section must date their own signature.**

**Witness to the Consent**(GCP 4.8.9, and National Statement sections 3.1.25 & 4.5.8)

**Declaration – for participants unable to read the information and consent form**

I confirm that the information in the consent form was accurately explained to, and apparently understood by, the participant and that consent was freely given by the participant.

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|  | Name of Witness\* to Participant’s |  |  |
|  | Signature (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

\* The witness cannot be the Study Clinician, a member of the study team or their delegate and must be over 18 years of age.
**Please note:** In the event that an interpreter is used, the interpreter cannot be a witness to the consent process.

**Note: All parties signing the consent section must date their own signature.**

**Withdrawal of Consent***Please complete this table below in the same way as on page 1, and* ***ensure this blue text is deleted prior to use****.*

|  |  |
| --- | --- |
| **Title** | *[Full Study Title]* |
| **Study Sponsor** | *[Sponsor]* |
| **Principal Investigator** | *[Principal Investigator]* |
| **Primary Site Name** | *[Name of Primary Site]* |
| **Satellite Site Name** | *[Name of Satellite Site]* |
| **Associate Investigator** | *[Associate Investigator at Satellite Site]* |

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.

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

**OR*** 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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| **AND** |
| *Please select one option:** I give permission for the information collected about my involvement in this teletrial to be kept in the database and used for reporting,

**OR*** 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.
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**Participant’s Signature**  **Date**

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher must provide a description of the circumstances:*

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**Declaration by Study Doctor/Senior Researcher†**

Name of Study Doctor
/ Senior Researcher† (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

† A senior member of the research team must provide the explanation of, and information concerning the withdrawal from the research project.

**Note: All parties signing the consent section must date their own signature.**