**Stand Alone Teletrial Participant Information Sheet and Consent Form – Person Responsible/Medical treatment decision maker**

***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]* |
| **Name of person signing this consent form** | *[Name of person consenting on behalf of this Participant]* |

This clinical trial is being undertaken using the teletrial model, which means participation in the trial at a site closer to the participant’s 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 the trial visits may be done locally, but the participant might also need to travel to another hospital or clinic for some visits. If this is required, the study team will explain when and where the participant will need to attend their study visits.

Health professionals at *[insert name of Satellite Site]* will communicate with the Primary hospital electronically, to conduct study visits and review the participant’s medical records. Any clinical information about the participant will be sent from their local site/hospital to the Primary (main) clinical trial site using coding matching their Study ID. Their name and contact details will not be included. Telehealth communications between the Primary clinical trials site and the participant’s 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 the participant’s home postcode so that we can work out the remoteness category of where they live; but we will not include their postcode in any reports – we will only report the remoteness category.

With your consent, the research team will also collect the following information about the participant’s involvement in this teletrial, and this will be used for ATP reporting: age, gender, cultural background, location of their study visits, and whether they finished the study. Their name and date of birth will not be recorded.

If you consent to information about the participant’s involvement in teletrials being collected for ATP reporting, their 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 the participant’s involvement in teletrials to be collected and used for ATP reporting, you do not have to agree*.* They may still participate in a teletrial, and only their postcode information will be collected.

Information about their 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 for the participant to take part, they don’t have to. If you consent for them to take part and later change your mind, you are free to withdraw them from the project at any stage. Your decision whether or not to take part, or to take part and then withdraw will not affect their routine treatment, their relationship with those treating them or their relationship with *[Name of Site/s].*

If you agree for the participant 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 their 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 the participant to be collected for ATP reporting purposes, you also need to decide if you want their information removed from the teletrial database.

If you want their information removed, please let their study team know. An automatically generated code was sent to their study team when the participant’s information was first entered into the database. No-one, except their study team, knows which participant the code was generated for. If you don’t want their information included, the study team will organise for their information to be removed from the database, using the code that was sent to them when the participant’s 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 – Person Responsible/Medical treatment decision maker**

*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]* |

**Consent Agreement**

I am the Person Responsible/ Medical treatment decision maker for *[Participant's Name]* (the Participant).

I have read the Teletrial Participant Information Sheet or someone has read it to me in a language that I understand.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that I will be given a signed copy of this document to keep on behalf of the participant.

I give permission for the doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Insert name of Primary site and / or Satellite site]* concerning the participant’s disease and treatment for the purposes of this teletrial. I understand that such information will remain confidential.

I give consent for information about the participant’s 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.*

**Declaration by Person Responsible/Medical treatment and decision maker – for** **Person Responsible/Medical treatment decision maker who has read the information**

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| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name of Person providing consent (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Relationship of Person providing consent to Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Person providing consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_ |

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| **Declaration -** for Person Responsible/Medical treatment decision maker unable to read the information and consent formSee Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness\*.Witness to the informed consent processName (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\*Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

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

I have given a verbal explanation of the implications of participating in the teletrial aspects of the project and I believe that the Person Responsible/Medical treatment decision maker has understood that explanation.

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| Name of Study Doctor/Senior Researcher \*(please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_ |

\* A senior member of the research team must provide the explanation of, and information concerning participating in a teletrial.

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

**Withdrawal of Consent – Person Responsible/Medical treatment decision maker***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** **Person Responsible/Medical treatment and decision maker**

I wish to withdraw my consent for *[Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]* 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 the participant to stop participating at a teletrial Satellite Site and continue all their involvement in the clinical trial at the Primary Site,

**OR*** I do not want them to participate at either the teletrial Satellite Site or the clinical trial Primary Site. I want to withdraw them from the trial altogether.
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| **AND** |
| *Please select one option:** I give permission for the information collected about the participant’s 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 the participant’s involvement in this teletrial to be kept in the database and used for reporting. I want their information to be removed.
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**Person Responsible/Medical treatment decision maker Signature Date**

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| *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:* |

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

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| Name of Study Doctor/Senior Researcher \*(please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_ |

I have given a verbal explanation of the implications of withdrawal from the teletrial aspects of the project and I believe that the Person Responsible/Medical treatment and decision maker has understood that explanation.

\*A senior member of the research team must provide the explanation of, and information concerning the withdrawal from the teletrial aspects of the project.

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