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| Primary Site workflow checklist |
| For Victorian Sites regarding the Australian Teletrial Program |
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This checklist is completed by the Primary Site for each Satellite Site joining a Teletrial cluster.

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| Trial Details | |
| Trial title | Enter trial title |
| Sponsor type | Choose an item. |
| Sponsor representative | Enter name |
| Enter phone number |
| Enter email address |
| Primary Site name and contact details | Enter Site name |
| Enter Site contact |
| Enter phone number |
| Enter email address |
| Principal Investigator contact details | Enter name |
| Enter phone number |
| Enter email address |
| Satellite Site name and contact details | Enter Site name |
| Enter Site contact |
| Enter phone number |
| Enter email address |
| Associate Investigator contact details | Enter name |
| Enter phone number |
| Enter email address |
| Date the Associate Investigator was approached to join the Teletrial | Click or tap to enter a date. |

\* This form has been adapted from the Australian Teletrial Program *Primary Site Workflow Check List.*

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| Primary Site Tasks | |
| **Evaluation and Feasibility** | |
| Ascertain the willingness of the Principal Investigator to conduct the trial as a teletrial and accept responsibility for the conduct of the trial within the cluster |  |
| Complete the *Evaluation of a trial as a Teletrial checklist* to determine if a trial is suitable to be conducted under the Australasian Teletrial Model (if not already done) |  |
| Provide the Sponsor with the *Evaluation of a trial as a Teletrial checklist* and obtain written agreement from the Sponsor to conduct the trial as a teletrial |  |
| If Satellite Site(s) with potential participants have been identified, contact the clinicians at the Satellite Site(s) to ascertain their agreement and capacity to conduct a teletrial |  |
| In collaboration with the Satellite Site complete the *Evaluation of a site as a Satellite Site checklist* and provide it to the Sponsor |  |
| In collaboration with the Satellite Site, obtain the Associate Investigator’s CV and evidence of any ICH GCP training and other clinical trials related training from the Satellite Site research team in preparation for submission to the Sponsor |  |
| Once a Satellite Site has been selected, the Sponsor should formally acknowledge the selection in a formal letter to the Primary Site |  |
| **Ethics and Governance** | |
| Notify the Sponsor that amendments of the following document will be required:   * CTRA – Schedule 1 to include Satellite Site(s) and Schedule 2 to include any agreed updates to the study budget for the Primary Site with consideration of inclusion of Satellite Site(s) * Form of Indemnity – Standard for Primary Site and Satellite Site(s) * Form of Indemnity – HREC only to include Satellite Site(s) * CTN/CTA – to include Satellite Site(s) |  |
| Contact the Coordinating Principal Investigator (CPI) to notify and provide the reviewing HREC with the following:   * Written agreement from the Sponsor to run the trial as a teletrial from the outset or to convert an approved clinical trial to a teletrial (if not already approved as such) * Name of proposed Satellite Site(s) * Master PICF with optional teletrial wording for trials intended to be run as teletrials from the outset   **or**  Amended Master PICF with optional teletrial wording when converting an already approved trial to a teletrial and all participating sites agree to be teletrial sites  **or**  The Stand Alone Teletrial PICF when converting an already approved trial to a teletrial and some sites but not all participating sites will be teletrial sites   * Form of Indemnity – HREC only including newly added Satellite Site(s) |  |
| Liaise with the Satellite Site to complete the Supervision Plan |  |
| Agree on study budget with the Sponsor and Satellite Site |  |
| Governance application submission (SSA) to Primary Site RGO should include the following additional documents:   * Cover letter from PI indicating that the trial is to be conducted under the Australian Teletrial Model with Primary Site and Satellite Site(s) details * HREC approval for conducting the trial as a teletrial and amended documents * Sponsor agreement for conducting the trial as a teletrial and proposed Satellite Site(s) * Head agreement between the Sponsor and the Primary Site * Teletrial Subcontract for each Satellite Site * Supervision Plan for each Satellite Site * Approved Master PICF with optional teletrial wording included or the Stand Alone Teletrial PICF and site-specific PICF * Other site-specific documents as required |  |
| Governance application submission (SSA) to Satellite Site RGO should include the following additional documents:   * Cover letter from AI indicating that the trial is to be conducted under the Australian Teletrial Model with Primary Site and Satellite Site(s) details * HREC approval for conducting the trial as a teletrial and amended documents * Sponsor agreement for conducting the trial as a teletrial and proposed Satellite Site(s) * Teletrial Subcontract for each Satellite Site * Supervision Plan for the Satellite Site * Approved Master PICF with optional teletrial wording included or the Stand Alone Teletrial PICF and site-specific PICF * Other site-specific documents as required * Primary Site Authorisation letter/certificate * Primary Site RGO correspondence regarding the establishment of associated Satellite Site(s) * AI CV and evidence of mandatory training e.g. GCP |  |
| Contact the RCCC-Victoria to organise the Teletrial Support Program (TSP) payment. Email RCCC Victoria at [rccc@safercare.vic.gov.au](mailto:rccc@safercare.vic.gov.au). |  |

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| **Satellite Site Start-up** | |
| Ensure the Satellite Site has the following:   * Copies of relevant trial documents such as Protocol, Laboratory Manual, Pharmacy Manual * Satellite Site Study File with copies of essential documents, including delegation and training logs * List of any trial-specific requirements for the Satellite Site * Worksheets developed by the Primary Site or Sponsor for each study visit * Access to eCRF if applicable * Any other trial-related requirements (e.g. pathology kits) |  |
| Provide the Sponsor with copies of any correspondence between the site and the RGO in relation to regulatory requirements |  |
| Liaise with the Sponsor regarding the Site Initiation Visit for the Satellite Site. The Satellite Site must have site authorisation or assurance of intended authorisation before SIV |  |
| **Prior to first participant visit at the Satellite Site** | |
| Ensure that Satellite Site has all study related materials and completed mandatory training |  |
| Ensure that any required investigations from support services including pathology couriers have been booked |  |
| Ensure the Primary Site PI is notified of the first participant at the Satellite Site |  |
| Follow processes documented in the Supervision Plan |  |
| **Day of consent of first participant at the Satellite Site** | |
| Contact the Satellite Site to ensure the participant is still attending. Follow the consent process documented in the Supervision Plan |  |
| **Day after participant first visit at the Satellite Site** | |
| Liaise with the Satellite Site after the visit to ensure the following:   * Pathology is dealt with in accordance with the Protocol and Pathology Manual * Any screening investigations if required have been booked * Data entry is completed * All required study logs are completed * Study visit is documented in medical notes * Follow processes documented in the Supervision Plan * Next visit is booked and confirmed with participant |  |
| Notify the RCCC-Victoria [rccc@safercare.vic.gov.au](mailto:rccc@safercare.vic.gov.au). Eligibility payments will be assessed for the TSP |  |
| **Midpoint between screening visit and next visit** | |
| Liaise with the Satellite Site to discuss the following if applicable:   * Pathology results and any other screening investigations * Preparation for the randomisation visit * IMP logistics – confirming arrangements on IMP storage and transportation * Follow the process documented in the Supervision Plan |  |
| **Day prior to second visit of first participant at the Satellite Site** | |
| Liaise with the Satellite Site to discuss results, eligibility criteria, randomisation procedures, and any processes documented in the Supervision Plan |  |
| **Day of randomisation visit of first participant at the Satellite Site** | |
| Follow the randomisation process as documented in the Supervision Plan and be available to support the Satellite Site as required |  |
| Liaise with the Satellite Site after the visit to ensure:   * Pathology is dealt with in accordance with the Protocol and Pathology Manual * Data entry is completed * All required logs are completed * Study visit is recorded in medical notes * Next study visit has been booked and confirmed with participants |  |
| **Following randomisation visit** | |
| Continuous oversight and support of the Satellite Site in accordance with the Supervision Plan |  |
| **After final visit of last participant at the Satellite Site** | |
| Confirm study completion activities with Satellite Site including plan for archiving study documentation |  |
| Ensure the RCCC-Victoria has been contacted regarding any updates |  |

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| To receive this document in another format, phone 0499 810 778, using the National Relay Service 13 36 77 if required, or email [Regional Clinical Trial Coordinating Centre (RCCC-VIC)](mailto:rccc@safercare.vic.gov.au) <rccc@safercare.vic.gov.au>.  Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.  © State of Victoria, Australia, Department of Health, April 2024. |