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| Evaluation of a site as a Satellite Site checklist |
| Use this checklist to guide the decision making about whether a site is suitable to conduct a clinical trial as a Satellite Site under the Australian Teletrial Model. |
| OFFICIAL |



This evaluation form should accompany the site feasibility for new trials proposing a teletrial or if considering introducing Satellite Sites into an already approved clinical trial.

This form should be submitted to the Sponsor when seeking approval to have the site included as a Satellite Site under the Teletrials model.

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

\* This form has been adapted from the Australian Teletrial Program *Evaluation of a Site as a Satellite Site Checklist.*

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| **Satellite Site Research Staff** | |
| How many staff are available at the Satellite Site to work on this trial? | Enter number of staff |
| How many staff have previous clinical trials experience? | Enter number of staff |
| **Satellite Site Pharmacy and Investigational Medicinal Product (IMP)** | |
| Does the Satellite Site have dedicated pharmacy staff or do other clinical staff undertake pharmacy duties? | Provide details |
| Does the pharmacy have capacity to store, prepare, dispense and log all IMP as required?  If not, what alternatives are there?  e.g local private pharmacy | Provide details |
| How would IMP be transported to the Satellite Site pharmacy? | Provide details |
| How is the IMP administered? | Choose an item. |
| Is special equipment required to administer IMP or other study medication?  e.g specific giving sets | Provide details |
| If special equipment is required to administer IMP, who supplies the equipment? | Choose an item. |
| Is special training required for Site Staff to administer IMP? | Choose an item. |
| Does the IMP have specific storage or preparation requirements? | Provide details |
| If IMP requires reconstitution, who can do this? | Provide details |
| Who will meet these costs? | Provide details |
| Does the dose vary throughout the trial or is the same dose given throughout? | Provide details |
| Is IMP to be assigned via a pharmacy portal? If yes, who will be assigned to do this – Primary Site or Satellite Site? | Choose an item. |
| Where will the IMP be stored and who is responsible for the accountability log?  Who will dispense IMP? | Provide details |
| Is IMP supplied per participant for the entire study at the outset?  Or is it sent in batches throughout the study? | Provide details |
| If doses vary, what are they based on and is there a sufficient visit window to allow for dispensing of new IP? | Provide details |
| What are the requirements or instructions for destruction of the IMP? | Provide details |
| What are the identified adverse events and suspected unexpected serious adverse reactions for the IMP? | Provide details |
| **Pathology** | |
| Are specimens processed locally or through a Central Laboratory? | Provide details |
| Are there specific pathology processing requirements?  e.g centrifuge process, -80 C freezer | Provide details |
| Does the Satellite Site have all the lab equipment required for processing specimens including batch storage, for this clinical trial? | Provide details |
| Has the local laboratory manager been consulted about this trial, and indicated their support for it? | Provide details |
| If additional training for processing specimens is required, who provides this training? | Provide details |
| Are there specific specimen transport requirements?  e.g in batches or on day of study visit | Provide details |
| If dry ice is required, who provides this? | Provide details |
| Will Sponsor pay costs associated with transporting specimens from Satellite Sites? | Provide details |
| What couriers are used for the trial?  Will couriers pick up from the Satellite Site?  If not, how will specimens from Satellite Sites be transferred? | Provide details |
| **Imaging** | |
| Is this site able to undertake all the imaging requirements of the study? | Choose an item. |
| If not, where is the closest centre that can provide the required imaging? | Provide details |
| Is travel to the Primary Site for imaging requirements a preferred option? | Provide details |
| Can the site upload data or do data file transfers? | Provide details |
| **Equipment required for the trial** | |
| What other equipment is required to conduct this trial at this Satellite Site? | Provide details |
| Is there a maintenance or calibration record available for this equipment? | Provide details |
| **Trial Design and Study Visits** | |
| Does the trial design allow for some or all visits to be undertaken at the Satellite Site? | Provide details |
| Does this Satellite Site have all the support resources and personnel available locally?  e.g. Medical specialists | Choose an item. |
| Are there some procedures for this trial that will be outsourced to a private vendor by this Satellite Site? | Choose an item. |
| If a private vendor will be used, is there a service agreement already in place for the provision of this service? | Provide details |
| Are there specific time points or procedures that must be done at the Primary Site? | Provide details |
| Will the Sponsor contribute to participant travel costs from this Satellite Site? | Choose an item. |
| Where will clinical trial supplies be stored at this Satellite Site?  e.g. participant and study folders | Provide details |
| Where will the Site Initiation Visit for this Satellite Site be conducted? | Choose an item. |
| Who will perform the Site Initiation Visit at this Satellite Site? | Provide details |
| Will Satellite Site staff be responsible for data entry for their participants?  If not, then how will this be managed? | Provide details |
| Where will study documents be archived at the completion of the trial? | Provide details |
| **Monitoring and Source Data Verification** | |
| How will source data verification occur for medical records at this site? | Provide details |
| **Other comments** | |
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**If the site Trial Coordinator or Sponsor is uncertain about any of the processes detailed in this form, further assistance is available from the Study Start-up Specialist (SSS)**.

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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. |