## Evaluation of a Site as a Satellite Site

This questionnaire can assess whether a site is suitable for conducting a clinical trial as a satellite site under the teletrials model. This is an example only; please consult the relevant state RCCC for any state-specific guidance. This evaluation may be undertaken at the point of site feasibility for new trials (if the protocol is finalised) or as required if considering introducing satellite sites into an already established clinical trial.

This questionnaire may also be submitted to the Sponsor for input and advice once the site has considered its capabilities and seeks approval to be included as a Satellite Site under the Australian Teletrials Model.

Red text is instructional and should be deleted prior to submission.

Please mark sections not applicable to your evaluation as N/A

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| --- | --- | --- |
| Trial Title |  | |
| Sponsor Type | Commercial / Collaborative Group / Institution | |
| Sponsor Name: |  | |
| Sponsor Representative and contact details: | **Name:**  **T:**  **E:**  NB: it is recommended that one primary contact is nominated to reduce burden of information sharing between site/departments | |
| Primary Site Name |  | |
| Principal Investigator |  | |
| Site Contact Person and contact details: | **Name:**  **T:**  **E:** | |
| Satellite Site Name: |  | |
| Associate Investigator: |  | |
| Contact Person at Satellite Site and contact details: | **Name:**  **T:**  **E:** | |
| **Trial Design and Study Visits:** | | |
| Does the trial design allow for some or all visits to be undertaken remotely? | |  |
| Does this Satellite Site have all the support resources and personnel available locally? | | E.g: psychologists, other medical specialists, specific imaging? |
| Are there some procedures for this trial that will be outsourced to a private vendor by this satellite site? | |  |
| If a private vendor will be used, is there a service agreement already in place for the provision of this service? | |  |
| Are there specific timepoint visits or procedures that must be done at the Primary Site? If so, please identify. | |  |
| Will the Sponsor contribute to participant travel costs from this Satellite Site? | | Would travel or accommodation vouchers be provided for assisting with travel, who will manage reimbursements? |
| Are there any procedures or examinations in the trial protocol that cannot be done via Telehealth? | |  |
| Where will clinical trial supplies (including participant folders, protocols etc) be stored at this Satellite Site? | |  |
| Who will perform the Site Initiation Visit at this Satellite Site? | | Sponsor or Primary Site. |
| Will Satellite Site staff be responsible for data entry for their patients? If not, then how will this be managed? | | Is education in answering data queries required? Consider communication strategies for data entry |
| Where will study documents be archived at the completion of the trial? | | Consider archiving requirements regarding time and method of archiving |
| **Satellite Site Research Staff** | | |
| How many staff (FTE) are available at the Satellite Site to work on this trial? | |  |
| How many staff have previous clinical trials / Teletrials experience? | | Specify previous clinical trial experience relevant to this trial. |
| Are intended research staff at the Satellite Site permanent or temporary staff? | | If temporary staff, how long is their contract and when does it expire? |
| What days do the research staff work? | |  |
| Does this Satellite Site have telehealth facilities? | |  |
| Where will clinical trial supplies (including participant folders, protocols etc) be stored at this Satellite Site? | |  |
| Who will perform the Site Initiation Visit at this Satellite Site? | | Sponsor or Primary Site. |
| Will Satellite Site staff be responsible for data entry for their patients? If not, then how will this be managed? | | Is education in answering data queries required? |
| **Satellite Site Pharmacy and Investigational Medicinal Product (IMP)** | | |
| Does the satellite site have dedicated pharmacy staff or do other clinical staff undertake pharmacy duties? | | Has the pharmacist/site staff been consulted about this clinical trial? |
| Does the pharmacy have capacity to store, prepare, dispense and log all IMP, as required by this protocol? | | If not, what alternative are there? Can a private pharmacy in the area do this? |
| How is the IMP administered? | | Delete whichever is not relevant.  Oral / Parenteral / Other (please specify) |
| Is special equipment or training required to administer IMP or other study medication?  Who supplies special equipment? | | Eg specific giving sets  Eg: Sponsor or Site? |
| Does the IMP have specific storage or preparation requirements? | | Eg: shelf life after reconstitution; storage requirements, sterile prep? |
| If IMP requires reconstitution, who can do this? | | Eg: Site staff, Site Pharmacy, External provider |
| How would IMP be transported to the Satellite Site pharmacy?  Can IMP be easily transported to the site? | |  |
| Who meets these costs? | |  |
| How will IMP get to this satellite site during extreme weather events such as floods? | | Eg: Site / Sponsor SOP in place, RFDS agrees to take a box of IP on routine visit, for collection by research staff, or IMP can be dispensed and sent out in advance of the weather event? |
| Does the dose vary throughout the trial or is the same dose given throughout? | |  |
| Where will the IP be stored at this Satellite Site?  How much storage space is required? | | Will Sponsor agree to store IMP at Satellite Sites? (Consider CTN implications).  What are the dimensions of the IMP? Is there sufficient space to store used/returned IMP if required? |
| How will destruction of IMP be managed at this Satellite Site? | | Does site have facilities to destroy IP on-site?  Will used IP be shipped back to primary site for accountability review and subsequent destruction? |
| Is IMP supplied per patient for the entire study at the outset? Or is it sent in batches throughout the study? | |  |
| Is IMP to be assigned via a pharmacy portal? If yes, who will be assigned to do this – primary site or satellite site? | |  |
| If doses vary, what are they based on and is there a sufficient visit window to allow for dispensing of new IMP if dispensing is undertaken at the Primary Site? | |  |
| Does this satellite Site have the capacity to treat known adverse reactions or any suspected unexpected serious adverse reactions? | |  |
| **Pathology:** | | |
| Are specimens processed locally or through a Central Laboratory? | | Delete whichever is not relevant.  All processing locally / Basic processing locally / Central Lab |
| All processing locally / Basic processing locally / Central Lab | |  |
| Are there specific pathology processing requirements? | | Eg specific centrifuge process, time specific processing, -80oC freezer, time sensitive processing |
| Does the Satellite Site have all the lab equipment required for processing specimens (including batch storage) for this clinical trial? | |  |
| Has the local laboratory manager been consulted about this trial, and indicated their support for it? | | Provide reference ranges and lab manager CV as required |
| If dry ice is required, who provides this and pays for the associated cost? | |  |
| Are there specific specimen transport requirements? | | Will specimens be held & sent in batches, or sent on the day of the study visit? |
| Will Sponsor pay costs associated with transporting specimens from Satellite Sites? | |  |
| What couriers are used for the trial? Will they pick up from the Satellite Site? If not, how will specimens from Satellite Sites be transferred? | | Establish a chain of custody document as required, confirm courier constraints |
| **Imaging:** | | |
| Is this site able to undertake all the imaging requirements of the study? | |  |
| If not, where is the closest accredited centre that can provide imaging, and can they provide qualification imaging if required? | |  |
| How frequently does the protocol require imaging? Is travel to the Primary Site a preferred option? | |  |
| Can the site upload data or do data file transfers? | |  |
| **Monitoring and Source Data Verification:** | | |
| Does this site use an integrated Electronic Medical Record or other electronic medical record that can be accessed remotely? | | Consider data access levels for remote monitoring |
| How will source data verification occur for medical records at this site? | |  |
| If this Satellite Site does not use an integrated medical record, who is available at the site to certify copies of the paper medical record that are to be sent to the Primary Site? | |  |
| Will this Satellite Site store its own Investigator Site File (ISF)? | | If Primary Site will store all ISFs, how many ISFs will be needed? How will this impact study archive? |
| **Equipment Required for the Trial:** | | |
| What other equipment is required to conduct this trial at this Satellite Site? | |  |
| Is there a maintenance or calibration record available for this equipment? | |  |
| **Other Comments** | | |
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**Supporting documents to be provided along with Satellite Site Evaluation:**

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| --- | --- |
| CV for Associate Investigator at Satellite Site |  |
| Certificates for clinical trials related training undertaken by any research staff at the Satellite Site. E.g GCP training, license registration with AHPRA |  |
| Any other supporting documents (please specify) |  |

**Please send this completed form to your jurisdictional Regional Clinical Trials Coordinating Centre, along with any supporting documents.**

Can this form be improved? Let us know at [Australian\_Teletrial\_Program@health.qld.gov.au](mailto:RCCCQLD@health.qld.gov.au)