Evaluation of a Site as a Satellite Site Checklist

Insert subtitle

*Use this form to guide the decision making about whether a Satellite Site is suitable to conduct a clinical trial under the teletrials model. This evaluation may be undertaken with the site feasibility for new trials (if protocol is finalised), or as needed, if considering introducing Satellite Sites into an already running clinical trial.*

*This form may also 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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| **Clinical Trial Title** |  |
| **Sponsor Type** | Delete whichever is not relevant.Commercial / Collaborative Group / Institution |
| **Sponsor Name** |  |
| **Sponsor Representative** |  |
| **Contact details for Sponsor Representative** | **T:****E:** |
| **Primary Site Name** |  |
| **Principal Investigator** |  |
| **Primary Site contact person** |  |
| **Primary Site contact details** | **T:****E:** |
| **Satellite Site Name** |  |
| **Satellite Site contact person**  |  |
| **Satellite Site contact details** | **T:****E:** |

| **Satellite Site Research Staff**  |
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| How many staff are available at the Satellite Site to work on this trial? |  |
| How many staff have previous clinical trials experience? |  |
| 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? Are these accessible for use in clinical trials? | e.g. Healthdirect |
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| **Satellite Site Pharmacy and Investigational Medicinal Product (IMP)** |
| Is IMP supplied per patient for the entire study at the outset? Or is it sent in batches throughout the study? |  |
| How would IMP be transported to the Satellite Site pharmacy? |  |
| Is IMP to be assigned via a pharmacy portal? If yes, who will be assigned to do this – primary site or satellite site?  |  |
| 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? | e.g. 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? |
| Where will the IMP be stored at this Satellite Site?  | Will Sponsor agree to store IMP at Satellite Sites? (CTN implications). |
| What are the dimensions of the IMP? How much storage space is required? |  |
| Does the IMP have specific storage or preparation requirements?  | e.g. Shelf life after reconstitution, storage requirements, sterile prep?  |
| Does the satellite site have dedicated pharmacy staff or do other clinical staff undertake pharmacy duties? | Has the pharmacist 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? |
| If IMP requires reconstitution, who can do this?  | e.g. Site staff, Site Pharmacy, External provider |
| How is the IMP administered? | Delete whichever is not relevant.Oral / Parenteral / Other |
| Is special equipment or training required to administer IMP or other study medication? | e.g. Specific giving sets |
| If special equipment is required for administering the IMP, who supplies the equipment? Sponsor or site? |  |
| Does the dose vary throughout the trial or is the same dose given throughout? |  |
| 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? |  |
| What are the requirements for destruction for IMP and who is responsible? |  |
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| **Pathology** |
| Are specimens processed locally or through a Central Laboratory? | All processing locally / Basic processing locally / Central Lab |
| Are there specific pathology processing requirements? | e.g. specific centrifuge process, time specific processing, -80oC freezer |
| Does the Satellite Site have all the lab equipment required for processing specimens (including batch storage) for this clinical trial?  |  |
| Are there trained staff who can process samples according to the protocol? |  |
| Has the local laboratory manager been consulted about this trial, and indicated their support for it? |  |
| If dry ice is required, who provides this? |  |
| 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? |  |
| Who will be responsible for handling/shipping? (includes dry ice)If research team is responsible, is the shipper certified appropriately? | Local lab / Research teamYes / (No: Please contact SA/NT RCCC team) |
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| **Imaging** |
| Is this site able to undertake all the imaging requirements of the study? |  |
| If not, where is the closest centre that can provide imaging, and can they provide qualification imaging if required? | Is the closest centre private or public and are they agreeable to being involved? |
| Who will pay the costs of travel to other centres for the participants? |  |
| 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?  | Also what platforms are used |
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| **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? |  |
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| **Monitoring and Source Data Verification** |
| Does this site use electronic medical records that can be accessed remotely from the Primary Site? |  |
| 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? |  |
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| **Trial Design and Study Visits** |
| Does the trial design allow for some or all visits to be undertaken remotely? |  |
| What telehealth technologies/facilities are available at site? | e.g. Healthdirect |
| Are there any procedures or examinations in the trial protocol that cannot be done via Telehealth? |  |
| Are there specific time points or procedures that must be done at the Primary Site? |  |
| 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? |  |
| Will the Sponsor contribute to participant travel costs from this Satellite Site? |  |
| Where will clinical trial supplies (including participant folders, protocols etc) be stored at this Satellite Site? |  |
| Are there appropriate storage facilities for clinical supplies? | e.g. locked cabinets in secure area |
| 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? | Who will provide any required training e.g. education in answering data queries required |
| Where will study documents be archived at the completion of the trial and who is responsible? |  |
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| **Other Comments** |
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| **Date of completion of checklist** |
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Documents to be attached to this Satellite Site Evaluation:

* CV for Associate Investigator at Satellite Site
* Certificates for clinical trials related training undertaken by any research staff at the Satellite Site.

If there are items that you consider should be included in this document, please let us know.
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