## Satellite Site Workflow Checklist

### Pre-Approval Activities

***This form should be completed by the Satellite Site for each new Teletrial****. It should be completed in collaboration with the RCCC and the relevant Primary Site for the trial.*

|  |  |
| --- | --- |
| Trial Title |  |
| Sponsor Type | Commercial / Collaborative Group / Institution |
| Sponsor Representative and contact details: | **Name:**  **T:**  **E:** |
| Name of Primary Site |  |
| Contact Person and details for Primary Site | **Name:**  **T:**  **E:** |
| Name of Principal Investigator and contact details at Primary Site | **Name:**  **T:**  **E:** |
| Date invitation received to be a Satellite Site | DD/MMM/YYYY |
| Name of RCCC Coordinator and contact details: | **Name:**  **T:**  **E:** |
| Satellite Site RGO Name and Contact Details | **Name:**  **T:**  **E:** |

If the Satellite Site Teletrial Coordinator or Sponsor is uncertain about any of the processes detailed in this form, assistance is available from the following sources:

* Primary Site CRC
* RCCC Cluster Start Up Specialist
* Teletrial Liaison Officer in the Department of Health  
  (E: [Australian\_Teletrial\_Program@health.qld.gov.au](mailto:Australian_Teletrial_Program@health.qld.gov.aun))

|  |  |
| --- | --- |
| **Satellite Site Start Up** | |
| Confirm with the Primary Site and the RCCC that the Satellite Site has capacity to start a teletrial at the proposed start date. |  |
| In collaboration with the Primary Site, assist with the completion of the [Satellite Site evaluation](https://australianteletrialprogram.gov.au/resources/) for the site (may include discussions with Pathology, Pharmacy and Imaging and will inform the completion of the Supervision Plan) |  |
| In collaboration with the Primary Site and RCCC, commence development of the [Supervision Plan](https://australianteletrialprogram.gov.au/resources/)  as soon as practicable post ethical approval and site identification. |  |
| When contacted by the RCCC, and in collaboration with the RCCC:   * identify any anticipated general barriers or obstructions to the smooth running of the clinical trial, including environmental factors that may impact delivery of IMP or ability of participants to attend any required visits at the Primary Site |  |
| * develop or review generic clinical trials specific work unit guidelines including any site-specific requirements for treating this patient group |  |
| * confirm the Research Team at the site, including their clinical trials experience, any mandatory training previously completed (e.g. ICH GCP, Dangerous Goods Handling) and provide CV of the Satellite Site AI for submission to the Sponsor |  |
| * identify training required by all members of the research team to conduct clinical trials at the Satellite Site, including training in any local Standard Operating Procedures, software or equipment, and the possibility for the Satellite Site CRC to spend time at the Primary Site, if necessary, for mentoring |  |
| Notify the Chief Executive of the HHS/LHN (via the RGO) of the intention to undertake a teletrial – if required externally to RGO authorisation process. |  |
| Notify the Satellite Site RGO of the intention to undertake a teletrial |  |
| Establish a folder for filing documentation prior to receipt of project specific documents, for example:   * written agreement from the Sponsor that the trial is suitable to be conducted under the teletrial model * confirmation that the Satellite Site clinician has agreed to undertake a clinical trial under the teletrial model * draft Supervision Plan for the trial * when received, confirmation that the Sponsor has agreed to this site as a Satellite Site * written agreement from supporting departments that they have capacity to provide services for the trial * trial specific worksheets used by the Primary Site for the trial |  |
| **On Receipt of Approval from the Sponsor to be a Satellite Site** | |
| Notify all research team members at the Satellite Site of acceptance by the Sponsor and identifies days and times that suit the AI to see trial participants. Confirm RCCC’s availability to support First Patient, First Visit. Notify Primary Site of preferred consultation times. |  |
| Start “desktop” identification of potential participants (based on inclusion and exclusion criteria) in preparation for future contact |  |
| Liaise with Primary Site and RCCC to duplicate Primary Site SSA Form and transfer duplicated SSA Form to the Satellite Site (share application with RCCC staff) |  |
| Liaise with Primary Site regarding budget development for the Satellite Site, including:   * establishment of a cost centre and/or Internal Order Number (ION) for the trial * obtaining formal agreement from supporting departments that they can provide services for the trial, and if not, identify how those services can be provided * development of internal invoices for transferring payments to supporting departments |  |
| Liaise with Primary Site and RCCC to commence trial specific training e.g. Protocol, trial processes, eCRF completion, and use of trial specific worksheets, in accordance with the Supervision Plan |  |
| Submit completed Satellite Site SSA Form to RGO along with required accompanying documents (refer to *Guidance for Sponsors and Sites* in the ATP Teletrial Toolkit for list of accompanying documents). |  |

Do you think there are opportunities for improvement in this form? Please let us know!  
E: [Australian\_Teletrial\_Program@health.qld.gov.au](mailto:RCCCQLD@health.qld.gov.au)