## Satellite Site Workflow Checklist

### Post-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.*

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| --- | --- |
| 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))

|  |  |
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| **After Authorisation at the Satellite Site** | |
| Satellite Site to notify Primary Site and RCCC that authorisation at the Satellite Site has been granted |  |
| Liaise with Primary Site and RCCC to organise Site Initiation (if not already booked) and notify AI of proposed Site Initiation date and time.  Book Telehealth facilities for Site Initiation meeting |  |
| Organise Satellite Site Master File when received, including relevant system accesses for study staff, and check with RCCC or Primary Site that all required documentation has been filed and stored according to the method agreed by the Sponsor and in accordance with the Supervision Plan |  |
| **After Site Initiation** | |
| In collaboration with the RCCC and Primary Site, ensure that all required study documentation, IMP, pathology kits and other study resources have been received and are in date |  |
| Ensure site is activated. Written site activation paperwork must be received from the sponsor/CRO for retention on the study file. |  |
| In collaboration with the RCCC (if required), contact the first identified potential participant to provide them with the PICF for review, to discuss the trial and to organise a time to follow up with them |  |
| If potential participant agrees to be involved, organise an appointment for the Screening Visit and books any required investigations e.g. imaging |  |
| If required, liaise with RCCC to conduct a practice visit and seek feedback on readiness several days prior to the first visit of the first participant at the Satellite Site |  |
| **Day Prior to First Participant Visit at Satellite Site** | |
| Ring participant to confirm their attendance. Reschedule if participant can no longer attend and notify AI, Primary Site and RCCC. |  |
| Collect all required study materials (ICF, lab kit preparation/transport, participant paperwork etc.) required for the visit. Do not complete pathology kit labels or documentation until participant has arrived for their visit. |  |
| **Day that First Participant at the Satellite Site is Consented** | |
| Notify the AI and Primary Site when participant arrives at the Satellite Site |  |
| No study procedures to be performed until after the consent is signed |  |
| Start Telehealth appointment when PI from Primary Site and AI from the Satellite Site are present to start the consent and screening discussion |  |
| Photocopy the signed consent form and process in accordance with the Supervision Plan and ICH-GCP |  |
| Study visit completed as detailed in the Protocol |  |
| Ensure all study procedures have been completed prior to participant leaving the premises, all relevant patient materials have been provided and that the participant is aware of procedure times for any additional investigations to be performed after this visit and before the next visit |  |
| Confirm next appointment day, time and date with participant, and notify Primary Site CRC of same |  |
| Ensure pathology specimens have been couriered or stored at the site, in accordance with the Protocol, Pathology Manual and Supervision Plan |  |
| Complete all required logs and undertake data entry in the eCRF in accordance with the Supervision Plan |  |
| Write the visit up in the medical notes. If Satellite Site does not use an eMR, photocopy, de-identify, certify and scan medical notes and email to Primary Site in accordance with the Supervision Plan. |  |
| Complete the ATP data collection sheet and return to the RCCC |  |
| **Midpoint between Screening Visit and the Next Visit** | |
| Liaise with Primary Site regarding results of screening investigations to date |  |
| Ensure IMP is available at site if potential participant is eligible |  |
| Ensure appropriate documentation of participant ID is recorded in screening and enrolment log |  |
| **Day Prior to Second Visit for First Participant** | |
| Liaise with Primary Site to check all results and Inclusion / Exclusion Criteria |  |
| Ring participant to ensure they are attending their scheduled visit |  |
| Notify Pharmacy that a possible randomisation and dispensing will occur the following day |  |
| Collect all required study materials required for the visit. Do not complete pathology kit labels or documentation until participant has arrived for their visit. |  |
| **Day of Second Visit (Randomisation Visit) for First Participant** | |
| Notify the AI and Primary Site when participant arrives at the Satellite Site |  |
| Undertake relevant study procedures in accordance with the Protocol and Supervision Plan |  |
| Complete post visit administrative requirements, for example, randomisation log, eCRF completion, and entry in medical notes. Undertake cluster specific copying of medical notes as per the Supervision Plan. |  |
| **Thereafter** | |
| Satellite Site maintains ongoing relationship with Primary Site and RCCC and completes all study processes in accordance with the Protocol and Supervision Plan |  |
| Satellite Site confirms date of final study visit for the first participant at the Satellite Site and organises teleconference with RCCC CSS the day following the final visit to discuss:   * participant completion activities * completion of the ATP data collection sheet for that participant |  |
| **After Final Visit of the Final Participant at the Satellite Site** | |
| Liaises with RCCC to confirm:   * study completion activities, including future archiving arrangements in accordance with the Supervision Plan and Sponsor requests * ongoing interest in future participation in clinical trials. |  |
| Checks that the ATP data collection sheet has been completed for each participant. |  |

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)