Satellite Site Workflow Check List

Ver July 2022

***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:** |  |
| **Contact details for Sponsor Representative** | **T:** **E:** |
| **Name of Primary Site** |  |
| **Contact Person at Primary Site** |  |
| **Contact Details for Contact Person, Primary Site** | **T:** **E:** |
| **Name of Principal Investigator at Primary Site** |  |
| **Contact Details: Primary Site Principal Investigator**  | **T:** **E:** |
| **Date invitation received to be a Satellite Site** | DD/MMM/YYYY |
| **Name of RCCC Coordinator**  |  |
| **Contact details for RCCC Coordinator** | **T:** **E:** |
| **Satellite Site RGO name and phone number** | **RGO 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)

If you have any suggestions for improving this form, please let us know:
E: Australian\_Teletrial\_Program@health.qld.gov.au

W: australianteletrialprogram@health.qld.gov.au

**Acronyms used in this Check List:**

AE Adverse Event

AI Associate Investigator (clinician responsible for the study at a Satellite Site)

ATP Australian Teletrial Program

CRC Clinical Research Coordinator

eCRF electronic Case Report Form (participant specific data capture form)

eMR Electronic Medical Record

HHS Hospital and Health Service

HREC Human Research Ethics Committee

ICH GCP International Conference on Harmonisation Good Clinical Practice

IMP Investigational Medicinal Product

PI Principal Investigator

PICF Participant Information Sheet and Consent form

RCCC Regional Clinical Trial Coordinating Centre

RCCC CSS Regional Clinical Trial Coordinating Centre Cluster Start-up Specialist

RGO Research Governance Office/r

SAE Serious Adverse Event

SSA Site Specific Assessment Form (research governance application form)

TSP Teletrial Support Program

Satellite Site Workflow Check List

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| **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 for the site (may include discussions with Pathology, Pharmacy and Imaging) |  |
| When contacted by the RCCC, and in collaboration with the RCCC: * identifies any anticipated general barriers or obstructions to the smooth running of a clinical trial, including environmental factors that may impact delivery of IMP or ability of participants to attend any required visits at the Primary Site
 |  |
| * develops or reviews generic clinical trials specific work unit guidelines including any site-specific requirements for treating this patient group
 |  |
| * confirms the Research Team at the site, including their clinical trials experience, any mandatory training previously completed (e.g. ICH GCP, Dangerous Goods Handling) and provides CV of the AI at the Satellite Site for submission to the Sponsor
 |  |
| * identifies training required by all members of the research team to conduct clinical trials at the Satellite Site, including training in any local 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 (via the RGO) of the intention to undertake a teletrial – if relevant |  |
| Notify the Satellite Site RGO of the intention to undertake a teletrial – if relevant |  |
| Set up a folder for filing documentation prior to receipt of project specific documents, for example:* written agreement from the Sponsor that the trial may 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
 |  |
| In collaboration with the Primary Site and RCCC, commences development of the Supervision Plan |  |
| **On Receipt of Approval from the Sponsor to be a Satellite Site** |
| Notifies 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. Notifies Primary Site of preferred consultation times. |  |
| Starts “desktop” identification of potential participants (based on inclusion and exclusion criteria) in preparation for future contact |  |
| Liaises 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) |  |
| Liaises 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, identification of how those services can be provided
* development of internal invoices for transferring payments to supporting departments
 |  |
| Liaises 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 |  |
| Submits 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). |  |
| **After Authorisation at the Satellite Site** |
| Satellite Site notifies Primary Site and RCCC that authorisation at the Satellite Site has been granted |  |
| Liaises with Primary Site and RCCC to organise Site Initiation (if not already booked) and notifies AI of proposed Site Initiation date and time.Books Telehealth facilities for Site Initiation meeting  |  |
| Organises Satellite Site Master File when received and checks 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, ensures that all required study documentation, IMP, pathology kits and other study resources have been received and are in date |  |
| In collaboration with the RCCC (if required), contacts 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, organises an appointment for the Screening Visit and books any required investigations e.g. imaging |  |
| If required, liaises with RCCC to conduct a practice visit 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 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 |  |
| Study visit completed as detailed in the Protocol |  |
| Ensure all study procedures have been completed prior to participant leaving the premises, 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 |  |
| **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. |  |