Primary Site Workflow Check List

*This checklist is* ***completed by the Primary Site for each Satellite Site******joining a Teletrial Cluster****.
The Primary Site should complete this checklist in collaboration with both the RCCC that is assisting the Satellite Site, and the relevant Satellite Site.*

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

**Acronyms used in this Check List:**

|  |  |  |  |
| --- | --- | --- | --- |
| AE | Adverse Event | ICH GCP | International Conference on Harmonisation, Good Clinical Practice |
| AI | Associate Investigator | IMP | Investigational Medicinal Product |
| ATP | Australian Teletrial Program | PICF | Participant Information Sheet and Consent form |
| CPI | Coordinating Principal Investigator | RCCC  | Regional Clinical Trial Coordinating Centre |
| CRA | Clinical Research Associate | RCCC CSS | Regional Clinical Trial Coordinating Centre Cluster Start-up Specialist |
| CRC | Clinical Research Coordinator | RGO  | Research Governance Office/r |
| CTRA  | Clinical Trials Research Agreement | SAE | Serious Adverse Event |
| eCRF | electronic Case Report Form | SIV | Site Initiation Visit |
| CTN  | Clinical Trial Notification | SSA | Site Specific Assessment |
| HREC  | Human Research Ethics Committee | TSP | Teletrial Support Program |

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

Primary Site Workflow Check List

| **Satellite Site Name:** | **Trial Title:**  |
| --- | --- |
| **Prior to commencing Satellite Site Start Up** |
| Ascertain willingness of Principal Investigator to conduct the trial as a teletrial (with Sponsor agreement) and accept responsibility for the conduct of the trial within the cluster. |  |
| Complete *Trial Evaluation Checklist* to determine if trial is suitable to be conducted under the teletrial model (if not already done). |  |
| Seek permission from Sponsor to conduct the trial as a teletrial and provide Sponsor with *Trial Evaluation Checklist* and any *Satellite Site Evaluation* checklists.Additionally, notify Sponsor that amendments to the following documents will be required: * CTRA – Schedule 1, to include Satellite Sites
* CTN – to include Satellite Sites if IMP or other unregistered therapeutic goods will be stored at Satellite Sites
* Form of Indemnity – HREC Only, (to include Satellite Sites)
* Form of Indemnity – Standard, to include Satellite Sites
* Confidentiality Disclosure Agreement for the RCCC, to allow access to the trial protocol and supporting documents
 |  |
| If Satellite Sites with potential participants have been identified, contact the clinician at the Satellite Site to ascertain their capacity and agreement to conduct a teletrial. |  |
| Contact the RCCC to notify them of the teletrial and any agreed Satellite Sites. |  |
| **Satellite Site Start Up** |
| If potential participants have been identified from possible Satellite Sites, complete the *Satellite Site Evaluation* checklist (if not done earlier, as above). |  |
| Obtain AI’s CV and evidence of any ICH GCP training and other clinical trials related training from the Satellite Site research team in preparation for submission to the Sponsor |  |
| Seek permission from Sponsor to conduct the trial as a teletrial and provide Sponsor with *Trial Evaluation Checklist* and any/all *Satellite Site Evaluation* checklists (if not already done). |  |
| Provide RCCC and Satellite Site with the following:* 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 and undertake the role of AI.
* copies of relevant trials documents such as Protocol, Laboratory Manual, Pharmacy Manual
* list of any trial specific requirements for the Satellite Site
* worksheets developed by the Primary Site (or Sponsor) for each study visit
 |  |
| Contact CPI to send notification to the Reviewing HREC about:* conversion of clinical trial to a teletrial (if not already approved as such)
* name of proposed Satellite Site/s
* amended Master PICF if teletrials specific wording was not included in the approved Master PICF
* amended consent process to accommodate consent at a remote site using telehealth technology
 |  |
| Send copy of correspondence to proposed Satellite Site/s and RCCC |  |
| Prepare RGO notification for Primary Site RGO and include:* HREC acknowledgment of teletrial model and amended documents and processes
* the agreed Satellite Site/s
* Sponsor agreement for teletrial model and proposed Satellite Site/s
* cluster specific PICF based on approved Master PICF with optional teletrial wording included (or stand-alone teletrial PICF)
* subcontract for each Satellite Site
 |  |
| Send copy of correspondence to proposed Satellite Site/s and RCCC |  |
| When requested, liaise with RCCC and relevant Satellite Site to complete Supervision Plan |  |
| Send the following Satellite Site specific documents to Sponsor for review:* completed Supervision Plan
* mandatory training certificates
 |  |
| Request Sponsor to send Satellite Site a Satellite Site Study File with copies of essential documents, including delegation, training and other logs and other required documentation  |  |
| Agree on study budget and reimbursement plan with Satellite Site |  |
| Duplicate SSA Form for Satellite Site, and transfer ownership of SSA Form to Satellite Site CRC Share Satellite Site SSA Form with RCCC coordinator |  |
| Confirm date with Satellite Site for training in all aspects of the Protocol including eCRF completion, trial processes and review of trial specific worksheets in accordance with the Supervision Plan |  |
| Provide Sponsor / CRA with copies of HREC and RGO correspondence, and remind them to update: * CTRA – Schedule 1, to include Satellite Sites
* CTN – to include Satellite Sites if IMP or other unregistered therapeutic goods will be stored at Satellite Sites
* Form of Indemnity – HREC Only, (to include Satellite Sites)
* Form of Indemnity – Standard, to include Satellite Sites
 |  |
| Provide the following documents to each Satellite Site for their SSA submission:* HREC acknowledgement of teletrial, proposed Satellite Site/s, and any changes to consent process and PICF
* Authorisation Letter for Primary Site
* Primary Site RGO correspondence regarding establishment of the cluster and proposed Satellite Sites, approved cluster PICFs and relevant signed Teletrials Subcontracts
 |  |
| Liaise with Sponsor / CRA regarding Site Initiation for Satellite Site - either join the SIV for the Primary Site (via TEAMS) or organise for training materials to be sent to the Primary Site to undertake training with the Satellite Site when a suitable participant has been identified (Satellite Site must have site authorisation or assurance of intended site authorisation before attending SIV). |  |
| **Prior to First Participant Visit at Satellite Site** |
| Liaise with RCCC to organise teleconference with clinical research coordinator at Satellite Site to ensure all required study materials are at the site, that the clinical research coordinator has completed all mandatory training e.g. ICH GCP, Dangerous Goods, eCRF completion and to confirm times and details for telehealth appointment |  |
| Ensure that any required investigations from support services have been booked (including pathology couriers if required) |  |
| Ensure PI from Primary Site is aware of first participant at Satellite Site and has been booked in to attend or oversee the consent and screening examination of the first participant |  |
| **Day that First Participant at the Satellite Site is Consented** |
| Contact clinical research coordinator at Satellite Site to ensure the participant is still attending and to confirm the time of the telehealth consultation. Confirm appointment time with PI and link into Satellite Site when consultation starts. |  |
| Be available for the duration of the first visit of the first participant at the Satellite Site to answer any queries that arise |  |
| **Day after the First Visit of the First Participant at the Satellite Site** |
| Liaise with the Satellite Site after the visit to ensure:* pathology is dealt with in accordance with the Protocol and Pathology Manual
* any screening investigations required after the screening visit have been booked
* data entry is completed
* all required logs are completed
* study visit is recorded in medical notes and medical notes are made available to the Primary Site in accordance with the Supervision Plan
* next visit for the participant has been booked and the participant is aware
 |  |
| Primary Site updates finance records to show that a Satellite Site has recruited a participant |  |
| Primary Site updates the ATP data collection form |  |
| **Midpoint between Screening Visit and Next Visit** |
| Liaise with Satellite Site to discuss:* pathology results and any other screening investigations
* preparations for randomisation visit
* check that IMP is at Satellite Site or confirm agreed arrangements for sending IMP to Satellite Site when required
 |  |
| **Day Prior to Second Visit for First Participant** |
| Liaise with Satellite Site to check all results and Inclusion / Exclusion Criteria, randomisation procedures |  |
| Confirm appointment time for second visit and notify PI |  |
| **Day of Second Visit (Randomisation Visit) for First Participant** |
| Link into Satellite Site when consultation starts and be available to support Satellite Site as needed during the visit |  |
| Liaise with the Satellite Site after the visit to ensure:* pathology is dealt with in accordance with the Protocol and Pathology Manual
* data entry is completed
* all required logs are completed
* study visit is recorded in medical notes and medical notes are made available to the Primary Site in accordance with the Supervision Plan
* next visit for the participant has been booked and the participant is aware
 |  |
| **Thereafter** |
| In collaboration with the RCCC, continue supervision and support of Satellite Site in accordance with Supervision Plan |  |
| **After Final Visit of the Final Participant at the Satellite Site** |
| Confirm study completion activities with Satellite Site, including archiving plan for study documentation |  |
| Ensures the ATP database has been updated. |  |