Regional Clinical Trial Coordinating Centre Workflow Check List

*This form is completed by the RCCC, in collaboration with the Primary Site, for each Satellite Site being set up in a teletrial cluster.*

|  |  |
| --- | --- |
| **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** |  |
| **Primary Site Contact Details** | **T:** **E:** |
| **Name of Principal Investigator at Primary Site** |  |
| **Contact Details: Principal Investigator at Primary Site:** | **T:** **E:** |
| **Date Satellite Site invited to join the cluster:** | DD/MMM/YYYY |
| **Name of Satellite Site** |  |
| **Name of Associate Investigator at Satellite Site** |  |
| **Contact Person at Satellite Site** |  |
| **Contact details for Satellite Site Contact Person** | **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

ATP Australian Teletrial Program

CPI Coordinating Principal Investigator (HREC applications only)

CRC Clinical Research Coordinator

eCRF electronic Case Report Form

HREC Human Research Ethics Committee

ICH GCP International Conference on Harmonisation Good Clinical Practice.

IMP Investigational Medicinal Product

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)

SUSAR Suspected Unexpected Serious Adverse Reaction

TSP Teletrial Support Program

Regional Clinical Trial Coordinating Centre Workflow Check List

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| **The following RCCC CSS tasks should be commenced as soon as possible and aim for completion within 7-10 days after notification of a possible teletrial Satellite Site**  |
| **RCCC CSS contacts Primary Site to ascertain:** |
| * written agreement from the Sponsor that the trial may be conducted under the teletrial model
* where required, Confidentiality Disclosure Agreement for the RCCC to allow access to the trial protocol and supporting documents.
 |  |
| * Primary Site evaluation of suitability of potential Satellite Site (including a clinical trial specific equipment audit of the Satellite Site)
 |  |
| * details of clinical trial (disease group, phase of trial, type of IMP involved etc)
 |  |
| * specific Protocol requirements (number of visits, type of visits to be conducted via telehealth)
* Obtain copy of current Protocol
 |  |
| * pathology requirements (specific collection / processing / storage / transport requirements)
* Obtain Laboratory Manual for the trial
* Consider if Sponsor will negotiate pathology processing e.g. can specimens be stored at -20oC before being sent on dry ice to Primary Site or sent directly to the Central Laboratory?
 |  |
| * pharmacy requirements (specific transport / storage / compounding / administration requirements)
* Obtain Pharmacy Manual
 |  |
| * any other specific tests or procedures required for the trial
 |  |
| * contact details of the Satellite Site: location and investigator team
 |  |
| * possible opportunity for mentoring of Satellite Site CRC onsite, or via TEAMS at Primary Site, e.g.:
* experienced research coordinator: 1-day training
* inexperienced research coordinator: 1-week training with ongoing support as required, by RCCC and Primary Site
 |  |
| * has the HREC has been notified of the Teletrial and approved the *Optional Teletrials Wording* for the PICF.
* If this has not been done, the RCCC takes the following steps:
* prepares HREC notification about the Satellite Site and ensures Teletrials specific wording has been included in the approved Master PICF and sends same to CPI site
* If teletrials specific wording has not been included in the approved Master PICF, prepares an amendment to the HREC for approval of the amended Master PICF, and forwards same to CPI site for submission to HREC – along with evidence of Sponsor agreement for the teletrial model to be introduced
 |  |
| **RCCC CSS contacts Satellite Site Investigator to:** |
| * introduce themselves and explain the function of the RCCC and concept of teletrials and to organise a longer discussion within the next few days to cover the following topics:
* confirmation of the Associate Investigator/s and research team at the Satellite Site, including their intended length of stay in the regional, rural or remote health care institution
* request copies of any work unit guidelines from the Satellite Site relating to clinical trials work (for inclusion in the Supervision Plan)
* identify any Satellite Site specific guidelines for treating this patient group (for inclusion in the Supervision Plan)
 |  |
| * confirm the professional experience of Satellite Site staff including any experience with clinical trials
 |  |
| * confirm that the Institutional executive and RGO are aware and supportive of a teletrial being conducted at the Satellite Site
 |  |
| * consider possibility of 1 week of mentoring of Satellite Site research coordinator at Primary Site (if Primary Site agreeable)
 |  |
| * identify any anticipated 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 (and provide solutions for potential barriers)
 |  |
| * confirm equipment and resources at the Satellite Site, and discuss additional equipment required for the teletrial, or whether the teletrials visits should be conducted at a different, larger location nearby
 |  |
| * inform Satellite Site about mandatory training, TSP and other supports
 |  |
| * sends mandatory training plan to Satellite Site research team
 |  |
| * confirms follow up appointment with Satellite Site within next 2 weeks to check on progress with mandatory training and start up procedures
 |  |
| * contacts Manager of the Pathology Service that supports the institution in which the Satellite Site is located, to discuss pathology requirements as detailed in the Laboratory Manual
 |  |
| * contacts RCCC Educator to initiate required general training for the Satellite Site prior to enrolment of the first participant at the Satellite Site. (N.B. Trial specific training to be provided by the Primary Site). Training to include:
* ICH GCP(mandatory, online)
* Packing and Shipping Dangerous Goods (mandatory, online)
 |  |
| * Introduction to Clinical Trials
 |  |
| * Supervision Plan and What it Means
 |  |
| * How to Read a Protocol
 |  |
| * Consent process
 |  |
| * Protocol Deviation / Violation and documentation of same
 |  |
| * Reporting of SUSARs, SAEs and AEs
 |  |
| * initiates contact with Satellite Site RGO to notify them of the intended clinical trial and to confirm any site-specific requirements
 |  |
| * liaises with Primary Site to duplicate Primary Site SSA Form and transfer duplicated SSA Form to the Satellite Site (share application with RCCC staff)
 |  |
| **The RCCC CSS should aim to complete the following tasks within 3 weeks of being notified of a Satellite Site**  |
| * commences development of the Supervision Plan with Primary Site and Satellite Site via teleconference
 |  |
| * liaises with Primary Site to commence budget development for Satellite Site, in accordance with Primary Site business processes
 |  |
| * ensures Primary Site sends completed Supervision Plan to Sponsor, along with mandatory training certificates from Satellite Site research team
 |  |
| * confirms with the Satellite Site any specific equipment required for the trial - which is not provided by the Sponsor - but which may be provided by the ATP has been provided or is in progress
 |  |
| * confirms with the Satellite Site any procedures which need to be outsourced (cross check with Satellite Site Assessment Checklist)
 |  |
| * provides the Funding Agreement for the TSP if the Primary Site and Satellite Site are potentially eligible to receive payments under the TSP (include invoicing details in the Funding Agreement)
 |  |
| * ensures Primary Site has provided trial worksheets to the Satellite Site
 |  |
| * confirms with Satellite Site staff that training in all aspects of the Protocol including eCRF completion, trial processes and review of trial specific worksheets has been organised / completed, in accordance with the Supervision Plan
 |  |
| * confirms with Primary Site that site initiation for Satellite Site has been organised, if necessary
 |  |
| * ensures the Satellite Site has copies of all approved documentation, filed and stored according to method agreed by Sponsor, including digitally, in accordance with the Supervision Plan
 |  |
| * ensures Post-Approval Amendment has been submitted to the Primary Site RGO along with:
* Supervision Plan for the Satellite Site
 |  |
| * Sponsor agreement for the Satellite Site
 |  |
| * ICH GCP Certificates for all Satellite Site research team members
 |  |
| * CV of Associate Investigator/s at the Satellite Site
 |  |
| * Amended CTRA which names the Satellite Site in Schedule 1, and any budget updates
 |  |
| * Teletrial Subcontract between the Primary Site and the Satellite Site.
 |  |
| * finalises SSA Form for Satellite Site (refer to Guidance for Sponsors and Sites (TT Toolkit) for list of required documents).

(can’t be submitted until acknowledgment from Sponsor, HREC and Primary Site RGO has been obtained) |  |
| * liaises with Satellite Site to offer to conduct a practice *initial visit* with the research coordinator at the Satellite Site prior to the first participant’s first visit – if required or requested by Satellite Site
 |  |
| ***Optional:* Date of *Practice Visit* prior to first visit of first participant at Satellite Site: (if required or requested) (dd/mmm/yyyy)** |
| **Before the first visit of the first participant in a trial, the RCCC CSS ensures:** |
| * Sponsor, HREC and Primary Site RGO acknowledgements are filed as agreed at both the Primary and Satellite Sites
 |  |
| * Satellite Site RGO Authorisation has been granted, filed and a copy sent to the Primary Site
 |  |
| * Satellite Site has copies of all approved current documents including visit worksheets from the Primary Site
 |  |
| * Site Delegation Log and other Logs are provided to the Satellite Site and have been completed
 |  |
| * first participant at Satellite Site has been provided with PICF ahead of the visit and their appointment has been booked and confirmed with the Primary Site
 |  |
| * screening visit pathology kits have been sent to the Satellite Site and are at the site
 |  |
| * IMP has been sent to the Satellite Site and has arrived
 |  |
| **Date of the first visit of the first participant at the Satellite Site: (dd/mmm/yyyy)** |
| **Day that first participant at the Satellite Site is consented, the RCCC CSS:** |
| * is available via phone or teleconference to support staff at Satellite Site if needed
 |  |
| * ensures the Satellite Site completes the Satellite Site Participant Registration form in the ATP database.
 |  |
| * ensures Funding Agreements under the TSP have been signed by relevant delegates at the Primary and Satellite Sites and returned to the RCCC for processing
 |  |
| * forwards signed Funding Agreements and confirmation of enrolment of participant at the Satellite Site to ATP for processing of TSP grant
 |  |
| * confirms teleconference with research coordinator at Satellite Site for day PRIOR to next study visit for this participant
 |  |
| * contacts Primary Site CRC following first participant visit at Satellite Site to check on the visit and any additional support required at either site
 |  |
| * confirms teleconference with Primary Site the day PRIOR to the next visit for the first participant at the Satellite Site to ensure the first participant is suitable to continue and the Satellite Site is prepared for the visit
 |  |
| **Date of the second visit of the first participant at the Satellite Site: (dd/mmm/yyyy)** |
| **Day prior to second visit for first participant at the Satellite Site, the RCCC CSS:** |
| * undertakes teleconference with CRC at Primary Site to discuss the upcoming visit for the first participant at the Satellite Site, and to confirm that all required trial materials including IMP are at the Satellite Site
 |  |
| * undertakes teleconference with research coordinator at Satellite Site to ensure they are comfortable with the upcoming visit and tasks involved
 |  |
| * organises to contact the Satellite Site research coordinator the day after the visit to check on progress
 |  |
| **Thereafter, the RCCC CSS:** |
| * repeats Step 6 for the duration of the study or until the Satellite Site staff are comfortable with their roles and involvement
 |  |
| * confirms date of final study visit for the first participant at the Satellite Site and organises teleconference with Satellite Site research coordinator the day following the final visit
 |  |
| **Date of the final visit of the first participant at the Satellite Site: (dd/mmm/yyyy)** |
| **Within 1 week of study completion by the first participant, the RCCC CSS:** |
| * contacts the Satellite Site to confirm:
	+ participant completion activities including responding to data queries
 |  |
| * + ? new participants enrolled (if so, check that the ATP data collection sheet for each participant has been completed, if consent was provided)
 |  |
| * + ongoing training
 |  |
| * + update the ATP Database
 |  |
| * + feedback survey on the teletrials process
 |  |
| * + Satellite Site interest in ongoing involvement in clinical trials
 |  |
| * if this visit is also the final visit for the study overall, the RCCC CSS also discusses study archiving requirements
 |  |
| * organises teleconference with Primary Site to discuss teletrial process and performance of the Satellite Site
 |  |
| * Primary Site discussion to include:
	+ number and type of Protocol deviations or violations from Satellite Site
 |  |
| * + number and type of data queries from Satellite Site
 |  |
| * + ongoing educational requirements at Satellite Site
 |  |
| * + any other matters involving the Satellite Site
 |  |