Clinical Oncology Society of Australia

Queensland Government

CHECKLIST - Documents for RGO Submission Primary and Satellite Sites

Steps	Primary site submission	Date Complete	Comments
1.	SSA form and documents listed below: • PI signed letter to RGO • SR HREC Amendment application letter – if required • HREC Amendment approval letter • Primary site signed CTRA Teletrial subcontract for each satellite site (number of copies as per RGO requirements • Supervision plan for each satellite site • CTRA Amendment x 3 copies • Teletrial Cluster Specific Patient Informed Consent Forms. Master PICFs as per RGO requirements. Please note: • These are additional documents and accompany all other documents usually submitted to RGO to open a clinical trial. • The supervision plan details all accountability and responsibilities of both primary and satellite site(s) as outlined in the Australian ICH GCP SOPs (including teletrials) and the COSA Australasian Teletrial Model National Implementation Guide. • The primary site RGO will acknowledge all other documents submitted to assist the satellite RGO with their approval if required.		
2.	CTN • CTN to be provided for all sites where the IMP is to be stored • A new CTN is not required if IMP is being shipped not stored. All satellite sites within a cluster are covered under the CTN registered with the TGA.		
3.	A new indemnity per site if provided by sponsor. Please note: Indemnities are added to Schedule 3 of the subcontract. A direct indemnity between the sponsor and the satellite site is preferred.		

Steps	Satellite Site	Date Complete	Comments
1.	Satellite site SSA form.		
2.	Prepare and submit documents for satellite site RGO approval including the documents received from the sponsor and primary site including: • Copy of primary site RGO Teletrial approval and acknowledgment • CTRA Amendment, HREC application and approval letters, CTRA Teletrial Subcontract, Clinical Trial Notification, Fully Signed Supervision Plan, Cluster PICFs, Current approved Protocol, Investigator Brochure (if RGO requests it) • Indemnities, insurance etc plus any other documentation required for RGO submission approval • Radiation safety letter • All patient Diaries, Thank you cards, Quality of life Questionnaires and anything provided to participants must be submitted Please note: These are additional documents and accompany all other documents usually submitted to RGO to open a clinical trial.		