AUSTRALIAN ICH GCP (Including Teletrials) SOP 70 Appendix 1 Example Study Master File Index and Contents

File Section	Documentation	Location	Responsible	
			Primary	Satellite
Contact List	Contact list table for study related personnel at Primary and Satellite sites, including the cluster contact details to all sites		Holds for all sites	Site only. Copy to 1º. Request full list if needed
Correspondence	General correspondence with sponsor, CRO, teleconference and meeting notes		All sites	Copy from 1º
Agreements	Clinical trial agreement location, site indemnities, confidentiality agreement(s) location, letters of intent, Health Service Directive for clinical trial regulatory process for satellite sites		Held at 1º	Copy from 1º
Finance	Financial disclosure forms for any person listed on the FDA Form 1572 (IND study only)		Held at 1º	Copy from 1º

Ethics committee Ethics Committee Approvals/ Acknowledgements Ethics Committee Composition Ethics Committee Correspondence	All ethics correspondence and documentation including all versions of the informed consent form, ethics committee composition, statement of committee compliance to NH&MRC National Statement, approval letters, reports to ethics committee, correspondence as applicable to commercial sponsorship, submission package(s), sample informed consent form, approved advertising materials/wording, other information provided to study participants and approved by ethics, tracked changes to protocol and summary tables, insurance certificate		Held at 1º	Copy from 1º
Investigator's Brochure and safety updates	All versions as provided to ethics, safety updates from sponsor		Held at 1º	Copy from 1º
Protocol	All versions as provided to and as approved by ethics, signed protocol signatory page should also be in this		Signed by 1º	Copy from 1º
Regulatory documents	Australian CTX or CTN form (fully executed), IND form 1572, other regulatory agency forms, all correspondence to the regulatory agencies		Held at 1º	Copy from 1º
Sample CRF	Approved version of sample CRF (a blank set that can be duplicated)		Held at 1º	Copy from 1º

Serious Adverse Events	Documentation tracking the incidence and reporting of SAEs, reports to ethics, reports to the applicable agency (interim and final)		Site Specific 1º notified of any SAEs at same time as sponsor	Site Specific 1º notified of any SAEs at same time as sponsor
Monitoring	All general monitoring correspondence unless specifically belonging in another file section, pre-trial monitoring report, feasibility assessments, monitoring visit reports and follow-up letters, monitor-site correspondence, close-out visit reports		Sponsor visit face to face	Via telehealth or face to face
Audit	Auditor correspondence, audit reports (if available) and auditor follow-up letters		At Primary site	Only if requested
Laboratory	Clinical laboratory certification (NATA, CLIA), laboratory normal values for medical/laboratory/technical procedures and/or tests included in the protocol, all		From Primary site	Only if used
Curricula vitae	Signed and dated copies of CVs for all medical staff, (principal investigator, sub-investigators) and other staff delegated significant duties as listed on the delegation log for the duration of the research project		All investigators and staff with significant duties from all sites	Site specific staff and key 1o
Signature log	Site personnel signature sheet with a list of signatures and initials of all persons authorised to make entries and/or corrections on the CRFs and e-CRFs and certain delegated tasks		All staff from all sites	Site only

CRF completion guidelines	Any correspondence, presentations and/or CRF completion guidelines provided by the Sponsor		Sent to 1º	Copy to 2º
Shipping records for IMP and other study related materials	Shipment records, date of shipment, batch numbers, method, shipment receipt records, certificate of analysis for investigational product, storage conditions		Site specific and on ward to Satellite	Site specific receipt, use and return
Accountability and destruction records	Investigational product accountability and destruction correspondence and records		Site specific and on ward to Satellite	Site specific receipt, use and return
Decoding and Unbinding	Any correspondence relating to decoding and unbinding. Documents how identity of blinded investigational product can be revealed in case of emergency.		Site specific and satellite info stored	Site specific
Participant Screening Logs	Screening logs including participant identification logs (site only for identification in case of emergency), participant registration/screening logs containing a chronological listing of screening/enrolment of participants.		Site specific (1º has copy of satellite site for emergency)	Site specific
Participant identification code list	A confidential list of names of all participants allocated to trial numbers upon enrolment in the trial. Allows investigator/institution to reveal participant identity in the case of emergency or for reasons of safety		1º has all details	Site specific only

Participant enrolment logs	Chronological enrolment of participants by participant number		Site specific only	Site specific only
Visit log	Records for all site visits, monitoring visits, sponsor visits, auditor visits, agency audits		Sponsor visit	Only if sponsor visits
Data query tracking	Data query tracking, monitors site queries and correspondence		Sponsor visit	Remotely accessed
Clinical study report	Final clinical study report (signed copy) if provided		Sent to 1º	Copy from 1º
Signed Informed Consent Forms	Informed Consent forms should be fully signed with all signatories dating their own signature. In addition, time of consent should be recorded in order to establish that consent was obtained prior to any trial procedures. Where informed consent is placed in the medical record, a file note stating this must be added to this section of the file		All Sites	Held at Site, witnessed and processed by telehealth if required.
Other-study specific	Other documents not included in the previous sections		All	Copy from 1º where relevant
Supervision Plan	A plan recording the oversight for the project and staff involved in the study and the role of the Primary Site overseeing the Satellite sites and reporting structure for the study.		Held at site	Explained to all site staff.

Monitoring Plan			At Primary site	Copy from 1º
Safety Monitoring Plan			At Primary site	Copy from 1º