Investigator Site File Contents Template

Present	File Section	Documentation
☐	Contact List	Contact list table for the Sponsor and Associates Contact List of Clinical Trial Staff
☐	Correspondence	General correspondence with Sponsor, Newsletters, CRO/CRA, teleconference and meeting notes
☐	Agreements	Clinical trial research agreement, site indemnities, confidential disclosure agreement(s) Insurance Certificate
☐	Finance	Invoice requests Payments to third party (if applicable)
☐	Human Research Ethics Committee (HREC) and Research Governance Office Ethics committee approvals and/or acknowledgements	All HREC submissions, acknowledgements and approvals Including protocol amendments and updated Investigator Brochures and master PIS/CF All submitted and approved advertising materials and /or other information provided to the participants such as diaries or questionaries All reports to ethics committee.eg. Annual, safety and close out reports
☐	Research and Ethics office/ Research Governance Office approval and/or acknowledgements	All site specific submissions such as; Site Specific Assessment (SSA) Site specific PIS/CF All approval and acknowledgement letters Correspondence as required such as adding Investigators or change of Contact person
☐	Investigator's Brochure and safety reports	All versions as provided to ethics, safety updates/reports from sponsor/site

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☐	Protocol	All versions as approved by the HREC A signed protocol signatory page should also be in this section
☐	Regulatory documents	CTX or CTN receipt from the Sponsor
☐	Sample CRF/ eCRF Instruction manual	Approved version of sample CRF or eCRF and/or instruction manual Any correspondence, presentations and/or CRF/eCRF completion guidelines provided by the Sponsor
☐	Serious Adverse Events	Documented Submission by the Principal investigator and/or delegate, and acknowledgement by HREC and Local Governance Office of a Safety Event Documented evidence of Sponsor/Investigator acknowledgement
☐	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
☐	Audit	Audit or correspondence, audit reports (if available) and auditor follow-up letters
☐	Laboratory	Clinical laboratory certification (NATA), current laboratory normal values for medical/laboratory/technical procedures and/or tests included in the protocol, all laboratory related correspondence
☐	Curriculum Vitae	Signed and dated copies of a current curriculum vitae for all medical staff, principal investigator, sub-investigators and other study staff. A two page CV should be present for all those listed on the delegations log.
☐	Delegation Log	Site personnel signature sheet with a list of signatures and initials of all persons authorised to

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		make entries and/or corrections on the CRF/eCRFs and certain delegated tasks.
☐	Training Log	Evidence of Delegated Clinical Trial Staff having the appropriate study training Updated with each protocol amendment Applicable to all study related training e.g. Protocol and eCRF
☐	Pathology shipping records	Shipment records, date of shipment, batch numbers, method, shipment receipt records, certificate of analysis for investigational product, storage conditions. Shipping details of other study related documentation or materials should also be recorded.
☐	Drug accountability records	Investigational product accountability correspondence and/or records – Generally kept with the Clinical trials pharmacist in the Pharmacy Folder until archiving
☐	Randomisation and Unblinding Procedures	Specific instructions on the randomisation process Specific instructions on how to unblind a participant in case of emergency. All Study staff need to be aware of this procedure.
☐	Subject 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 subjects. Sites can store this electronically at site via a secure server.
☐	Subject identification code list	A confidential list of names of all subjects allocated to trial numbers on enrolment in the trial. Allows investigator/institution to reveal subject identity
☐	Subject enrolment logs	Chronological enrolment of subjects by subject number Many sites keep this electronically using Microsoft Excel

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☐	Visit log	Records for all site visits, monitoring visits, sponsor visits, auditor visits, Internal audits
☐	Data query tracking	Data query tracking, monitors site queries and correspondence (this can be electronic)
☐	Clinical study report	Final clinical study report
☐	Signed Informed Consent Forms	Informed Consent forms should be fully signed with all signatories dating their own signature. The original document is kept either within the Site File or Study Participant File. A copy is given to the participant and a copy is kept in the participants medical records.
☐	Other-study specific	Other documents not included in the previous sections