Electronic Site Investigator File (eSIF) Filing Index for MCRI sponsored clinical trials

General Guidance

- Refer to MCTC070 Site Investigator File (SIF) Essential Document Filing for filing guidance
- The index should be filed at the front of the file.
- Sections can be added as appropriate according to design of the trial and relevant to the site, but ensure the numbering remains in sequential order
- Should a document or section be filed separate from the main file or in another section from what is stipulated in the index, the location of the
- document (e.g. Clinical Trial Pharmacy, participant binder – hard copy) should be entered in the 'Notes' column.
- If a document is not applicable to the trial, please enter 'NA' in the notes column.
- Superseded versions should be clearly indicated e.g. by marking a single line through the front page, noting "Superseded", initialled and dated.
- Some sections should be sub-divided to ease filing.
- Documents relating to an amendment should be filed together. Each amendment should be clearly labelled.
- Correspondence and version-controlled documents must be filed in chronological order with the most recent on top.
- Only copies of site documents are needed in the TMF site File, the original must be kept at site by the local Trial team;
- There should be no transfer of participant identifiable information between the sites unless there is a documented agreement in place;
- Completed participants' CRFs must be filed separately.

For Single-centre trials: the TMF site information documents filed in the SIF may be merged with the TMF.

PI Name:	
Site Name:	
Site Code/Number: *(If applicable)*	

Section	Folder/Sub-Folder Name	Contents	Notes
1.0	**Participating Site Team**		
1.1	Contact List	**Documents to be filed in this section include:** • **Participating Site Contact List**	
1.2	Signature and Delegation of Duties Log	**Documents to be filed in this section include:** • **Signature and Delegation of Duties Log -** Include all site staff involved with the trial.	
1.3	CVs	**Documents to be filed in this section include:** • **CV Site Principal Investigator** • **CV Study Coordinator / Research Nurse** • **Original Curriculum Vitae** • **Copies of Medical Licenses, if applicable**	
1.3.1	Other CVs	**Documents to be filed in this section include:** • **Original Curriculum Vitae** from all Site staff involved in the Trial • **Copies of Medical / AHPRA Licenses, if applicable**	
1.4	GCP Training Certificates	**Documents to be filed in this section include:** • **GCP Cert. Principal Investigator** • **GCP Cert. Study Coordinator**	
1.4.1	Other GCP Training Certificates	**Documents to be filed in this section include:** • **GCP training certificates**	
1.5	EDC Training Certificates	**Documents to be filed in this Section include:** • **Copies of site staff EDC TrainingCertificates/ Certifications, if applicable** • **Copies of site staff completed CRF Exercises/ Knowledge Assessments, if applicable**	

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1.6	Other Training Certificates	**Documents to be filed in this section include:** • **Other training certificates** from all Sitestaff involved in the study.	
1.7	Wet Ink Signatures	**Documents to be filed in this section include:** • **Wet ink signature log**	
2.0	**Project Management**		
2.1	Site Selection Documentation - if applicable	**Documents to be filed in this Section include:** • **Site Feasibility Questionnaire** • **Site Feasibility Assessment** • **Site Selection Letter** • **Any significant correspondence to and from the Site relating to Site-Specific Feasibility Questionnaire and completed Feasibility Assessment**	
2.2	Team Communication	**Documents to be filed in this Section include:** • **Copies of meeting minutes, emails, etc** • **All other significant correspondence.**	
3.0	**Protocol/Protocol Amendments**		
3.1	Site Protocol Version Tracker	**Documents to be filed in this section include:** • **Site Protocol Version Tracker**	
3.2	Signed Protocol Signature and Investigator Agreement Pages	**Documents to be filed in this section include:** • **Signed Protocol Signature Pages** • **Previous protocol versions Signed Protocol Signature Pages**	
3.3	Local Site Non-Compliance Log - Deviations from GCP or the protocol	**Documents to be filed in this section include:** • **Site-Specific Non-Compliance Log** .	

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3.4	Local Site Non-Compliance Reports - Deviations from GCP or the protocol	**Documents to be filed in this Section include:** • **Non-Compliance Report Forms** • **Non-Compliance Review Form**	
3.5	Serious Breaches and CAPA Documents - From Sponsor-Investigator and all other sites	**Documents to be filed in this Section include:** • **Site-Specific Corrective and Preventive Action Plans** • **Site-Specific Corrective and PreventiveAction Plan Reviews** • **Site-Specific CAPA Tracking Log**	
3.6	Copy of all Serious Breach reports to Sponsor and local Research Governance Office or regulatory Authority	**Documents to be filed in this Section include:** • **Copies of Site-Specific Serious Breach Reports submitted to Sponsor-Investigator** • **Copies of Site-Specific Serious Breach Reports submitted to local RGO or RegulatoryAuthorities, if available** • **Copies of all correspondence received from Sponsor-Investigator, local RGO and local Regulatory Authorities relating to submitted Serious Breach Reports.**	
3.7	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to protocol development, protocol amendments, serious breaches and CAPAs.**	
4.0	**Participant Information & Consent Forms**		
4.1	Site Specific PGICF & PICF Version Tracker	**Documents to be filed in this Section include:** • **Site-Specific PGICF & PICF Version Tracker(s)** • **Other PICF Version Tracker(s), as applicable.**	
4.2	Site Specific PGICF & PICFs	**Documents to be filed in this Section include:** • **Current Site-Specific PGICF and/or PICF** • **Copy of any PGICF and/or PICF Translations and Translation Certificates, if applicable**	

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4.3	Other Approved Participant Information	**Documents to be filed in this Section include:** • **Site-Specific authorised copies ofadvertisements, participant diaries, telephone scripts, GP letters, templates, participant newsletters, cards and questionnaires (eg, QoL), as applicable to study)**	
5.0	**Regulatory Documents**		
5.1	Regulatory Authorisation or Acknowledgement	**Documents to be filed in this Section include:** • **CTN/CTX Authorisation/Acknowledgement from the TGA, if applicable** • **Applicable International Regulatory Authorisation/s from other Regulatory Agencies/Competent Authorities;** • **Any significant communication to and from Regulatory Agencies/Competent Authorities, as applicable.**	
5.2	Supplementary Documents: - Form FDA 3454; Financial Disclosure - Form FDA 1572; Statement of Investigator Form	**Documents to be filed in this Section include:** • **Financial Disclosure Form (FDA 3454 Form), if applicable** • **Statement of Investigator Form (FDA 1572 Form), if applicable.**	
5.3	Completed Site Green Light Approval Form	**Documents to be filed in this Section include:** • **Site Green Light Approval Form**	
6.0	**Ethics Committee**		

Section	Folder/Sub-Folder Name	Contents	Notes
6.1	Ethics Committee Approval Letters, Certificates and Acknowledgements	**Documents to be filed in this section include:** • **Initial Ethics Committee Approval Letter** • **Letters/Acknowledgement relating to theoriginal Protocol/PICF/IB etc** • **Subsequent Amendment approvals/acknowledgement from the Ethics Committee** • **Ethics Aproval Letters/Acknowledgements relating to ALL other project submissions.**	
6.2	Ethics Submission Documentation Initial & Amendments Including responses to HREC queries	**Documents to be filed in this section include:** • **Complete Initial Ethics application** • **A copy of the Responses to HREC Queries, if applicable** • **Complete copy of any Protocol Amendments submitted to Ethics, including supporting ERM documentation** • **Copies of all additional Amendments or Project Notifications submitted to Ethics, including supporting ERM documentation.**	
6.3	Ethics Committee Composition, Constitution & Statement of Compliance	**Documents to be filed in this section include:** • **Ethics Committee Composition** • **Statement of Compliance of EC/HREC/IRB, as applicable.**	

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6.4	Annual Project Progress Reports and Final Project Report	**Documents to be filed in this Section include:** • **Copies of all Annual Project Progress Reports submitted to Ethics, including supporting ERM documentation** • **Copy of the Final Project Progress Report submitted to Ethics, including supporting ERM documentation** • **Acknowledgment of Receipt of Annual andFinal Progress Reports by EC/HREC/IRB Committee**	
6.5	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the Ethics Committee regarding initial and subsequent submissions.**	
7.0	**Research Governance Office (RGO), if applicable**		
7.1	Governance Authorisation Letters	**Documents to be filed in this section include:** • **Initial RGO Approval Letter, if applicable** • **Subsequent Amendment approvals from the RGO.**	
7.2	RGO Submission Documentation	**Documents to be filed in this Section include:** • **Copies of all local Research Governance Office (RGO) Submissions and Application documents, if applicable**	
7.3	Annual Project Progress Reports & Final Project Report - Including Acknowledgement of Receipt	**Documents to be filed in this Section include:** • **Evidence of submission of Annual Progress Reports to local Research GovernanceOffice (RGO), or equivalent, if applicable** • **Evidence of submission of Final Project Report to local Research Governance Office (RGO), or equivalent, if applicable** • **Acknowledgment of Receipt of Annual and Final Project Reports by RGO.**	

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7.4	Related Correspondence - To and from local RGO	**Documents to be filed in this Section include:** • **All significant correspondence to and from the RGO regarding initial and subsequent submissions.**	
8.0	**Study-Specific Procedures/SOPs**		
8.1	MoP and SoP's	**Documents to be filed in this Section include:** • **Site-Specific Manual of Procedures Document, if applicable** • **Site-Specific trial related SOPs** • **Any Study Specific SOP associated documents, if applicable**	
9.0	**Site Initiation**		
9.1	Site Initiation Meeting Documentation	**Documents to be filed in this Section include:** • **Essential Documents Required from Sites Request Letter** • **Site Initiation Booking Confirmation Letter** • **Site Initiation Agenda** • **Site-Specific Site Initiation Presentation slide set– site-Specific version of site initiation presentation/slide set.** • **Site Initiation Attendance Log**	
9.2	Site Initiation Follow Up Letter	**Documents to be filed in this Section include:** • **Site Initiation Follow-Up Letter to Site**	
9.3	Site Activation Documentation/Letter	**Documents to be filed in this section include:** • **Official Notification of Site Activation Letter**	
10.0	**Site Training**		

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10.1	Investigator Meetings	**Documents to be filed in this Section include:** • **Investigator Meeting Presentation slide set, if applicable** • **Investigator Meeting Attendance Log – completed and signed by all attendees.**	
10.2	Other Presentations	**Documents to be filed in this Section include:** • **File presentations other than the Site-Specific Site Initiation Visit presentation delivered here.**	
10.3	Site-Specific Training Logs	**Documents to be filed in this section include:** • **Site-Specific Training Log** • **Other Training Attestation Forms, as applicable**	
11.0	**Participant Recruitment**		
11.1	Consent, Screening & Enrolment Log	**Documents to be filed in this section include:** • **Site Consent, Screening & Enrolment Log**	
11.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to participant recruitment.**	
12.0	**Participant Randomisation and Registration Procedures**		
12.1	Records of Unblinding - Site Participants	**Documents to be filed in this Section include:** • **Copies of all local participant records of unblinding during study conduct and reasons for unblinding.**	
12.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to participant randomisation and unblinding procedures, to and from the Sponsor.**	
13.0	**Data Management – Forms & Procedures**		

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13.1	Completed Electronic Data Capture (EDC) System Application Forms	**Documents to be filed in this Section include:** • **Electronic Data Capture (EDC) System Account Application Form**	
13.2	Source Document Plan	**Documents to be filed in this section include:** • **Site-Specific Source Document Plan – completed, signed and dated by the Site Principal Investigator.**	
13.3	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to data management.**	
14.0	**Safety Monitoring & Reporting**		
14.1	Copy of Completed Site Expedited Safety Report Forms and associated correspondence sent to Sponsor - All SAEs, suspected SUSARs and USMs	**Documents to be filed in this Section include:** • **Copies of completed initial Expedited Safety(SAE) Report Forms** • **Copies of completed follow-up Expedited Safety (SAE) Report Forms**	
14.2	Copy of all Safety Reports sent to the local Research Governance Office (RGO) or regulatory Authority - If applicable	**Documents to be filed in this Section include:** • **Copies of Site-Specific safety reports/notifications submitted to local RGO or Regulatory Authorities, if available.** • **Copies of all correspondence received from local RGO or Regulatory Authorities relating to submitted safety reports/notifications.**	
14.3	On-Site Procedure for Unblinding in either: - The case of a medical emergency - For safety reporting purposes	**Documents to be filed in this Section include:** • **Site-Specific Emergency Procedures for Unblinding Manual, if applicable**	

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14.4	Other related correspondence	**Documents to be filed in this Section include:** • **Copies of "Dear Investigator Letters (DIL)", Safety Memo's, Safety Notifications, SUSAR 6-Monthly line listings received from pharmaceutical companies, with or without acknowledgement of receipts, and sent to local RGO or Regulatory Authorities, as applicable.** • **All other significant correspondence relating to safety monitoring and reporting requirements.**	
15.0	**Study Quality Assurance, Monitoring, Audits & Inspections**		
15.1	Pre-Trial Visit Reports, Attendance and Correspondence - If applicable	**Documents to be filed in this Section include:** • **Pre-Trial Site Visit Checklist** • **Pre-Trial Site Visit Report** • **Pre-Trial Site Visit Attendance Log** • **All significant correspondence**	
15.2	Site Monitoring and Visit Log	**Documents to be filed in this section include:** • **Site Monitoring and Visit Log**	
15.3	Monitoring Visit Reports and Remote Monitoring Reports	**Documents to be filed in this Section include:** • **Monitoring Visit Reports (on site and remote)**	
15.4	Monitoring Visit Correspondence - Including Feedback to site	**Documents to be filed in this Section include:** • **Monitoring Visit Confirmation Letters** • **Monitoring Visit Follow Up Letters**	
15.5	Trial Close-Out	**Documents to be filed in this Section include:** • **Trial Close-Out Report, if applicable** • **Trial Close-Out Letter** • **Investigator Agreement to Archive Letter** • **All significant correspondence relating to trial close-out activities to and from the Sponsor.**	

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15.6	Local RGO Audits	**Documents to be filed in this Section include:** • **Copies of all reports resulting from any Audits occurring at site, if available** • **Any correspondence related to Audits occurring at site, if available.**	
15.7	Regulatory Inspection Reports	**Documents to be filed in this Section include:** • **Copies of all reports resulting from Regulatory Inspection occurring at site, if available** • **Any correspondence related to Regulatory Inspections occurring at site, if available.**	
16.0	**Local Laboratory**		
16.1	Local Lab Certificates of Accreditation - If applicable	**Documents to be filed in this Section include:** • **Copy of the Local Site Lab Accreditation**	
16.2	Local Lab Reference Ranges - If applicable	**Documents to be filed in this Section include:** • **Copy of the Local Site Lab Reference Ranges**	
16.3	Biospecimen Collection Log - If applicable	**Documents to be filed in this Section include:** • **Biospecimen Collection Log**	
16.4	Biospecimen Shipment Receipt Tracking	**Documents to be filed in this Section include:** • **Copies of courier shipping documents, invoices, receipts, custom declarations, consignment notes, import permits from site to the Central Laboratory and/or Sponsor.**	
16.5	Biospecimen Storage Monitoring Documentation - If applicable	**Documents to be filed in this Section include:** • **Any Site-Specific documentation relating to the monitoring of biospecimen storage at site**	
16.6	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence**	

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17.0	**Supplies/Shipping Records**		
17.1	Documentation relating to provision of Study Supplies	**Documents to be filed in this Section include:** • **Copies of any correspondence or documentation regarding the provision of study supplies to site** • **Any receipts of study supplies to site, if applicable.**	
18.0	**Legal Documentation**		
18.1	Fully Executed Clinical Trial Research Agreement (CTRA)	**Documents to be filed in this section include:** • **Clinical Trial Agreement – fully executed between Site and Sponsor.**	
18.2	Other Agreements as applicable	**Documents to be filed in this Section include:** • **Copy of other agreements as applicable:** • **Material Transfer Agreements (MTA)** • **Data Sharing Agreements (DSA)** • **Insurance/Indemnity, as applicable** • **Expressions of Interest (EoI), if applicable.**	
18.3	Relevant Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to any Agreements pertaining to the study.**	
19.0	**Finance Documentation**		
19.1	Invoices and Receipts	**Documents to be filed in this Section include:** • **Copies of relevant Site-Specific invoices and receipts pertaining to the study, including per patient payments.**	

Section	Folder/Sub-Folder Name	Contents	Notes
19.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regarding the study budget, invoice tracking, per patient payments, etc.**	
20.0	**Other Communication**		
20.1	Newsletters from Sponsor-Investigator	**Documents to be filed in this Section include:** • **Copies of Newsletters from the sponsor to Participating Sites**	
20.2	Other General Correspondence	**Documents to be filed in this Section include:** • **Other significant general correspondence**	
21.0	**Archiving**		
21.1	Archiving Details	**Documents to be filed in this Section include:** • **Investigator Agreement to Archive Trial Documents Form**	
21.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regarding trial archiving to and from the Participating Site.**	

FOR DRUG & DEVICE TRIALS ONLY			
22.0	**Investigational Product**		
22.1	Documentation of IP Shipment - If available	**Documents to be filed in this Section include:** • **Shipping Records of IP to the Site – if available**	
22.2	Documentation of IP Dispensing, Accountability and Inventory	**Documents to be filed in this Section include:** • **Site-Specific Bulk Drug Accountability Log** • **Site-Specific Individual Drug Accountability Log**	
22.3	Documentation of IP Storage Monitoring	**Documents to be filed in this Section include:** • **Any Site-Specific documentation relating to the monitoring of IP Storage and IP Storage Facilities at participating sites**	
22.4	Documentation of Central IP: - Quarantines - Returns - Destructions/Drug Destruction Form	**Documents to be filed in this Section include:** • **Site-Specific Drug Destruction Forms, as completed by the site** • **AnySite-Specific IP Deviations (i.e. temperature excursions, IP complaints, IP quarantines) and associated forms, as completed by the site** • **Any IP Returns and/or Drug Destruction Forms relating to any unused IP at the end of the study, as completed by the site**	
22.5	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to the Investigational Product/s.**	