murdoch children's research institute

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

General Guidance

- Refer to MCTC071 Investigator Site File (ISF) Filing Guidance
- Sections can be added as appropriate according to design of the trial, but ensure the numbering remains in sequential order
- Should a document or section be filed separate from the main ISF 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- Superseded versions should be clearly indicated e.g. by marking a single line through the front page, noting "Superseded", initialled and dated.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.
- Completed participants' CRFs are considered part of the ISF but must be filed separately from the ISF.

For Single-centre trials carried out at Royal Children's Hospital only

- It is acceptable to only have TMF set up without the need of a separate site file; local essential documents will be included for conducting the trial. In this case, the ISF index should be merged with the TMF index to ensure all documentation is retained correctly with minimal duplication.

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

Section	Folder/Sub-Folder Name	Contents	Notes
1.0	**Site Coordination Team**		
1.1	Contact List	**Documents to be filed in this section include:** • **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 –** CVs must be signed and dated within the last two years. • **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 **–** CVs must be signed and dated within the last two years. • **Copies of Medical / AHPRA Licenses, if applicable**	
1.4	GCP Training Certificates	**Documents to be filed in this section include:** • **GCP Training Certificate from Site Principal Investigator** • **GCP Training Certificate from Site Study Coordinator**	
1.4.1	Other GCP Training Certificates	**Documents to be filed in this section include:** • **GCP Training Certificates** from all other key research team personnel at the participating site.	
1.5	EDC Training Certificates	**Documents to be filed in this Section include:** • **Copies of site staff EDC Training Certificates/ Certifications, if applicable**	

Section	Folder/Sub-Folder Name	Contents	Notes
		• **Copies of site staff completed CRF Exercises/ Knowledge Assessments, if applicable**	
1.6	Other Training Certificates	**Documents to be filed in this section include:** • **Other training certificates from all Site staff involved in the study.**	
1.7	Wet Ink Signatures	**Documents to be filed in this section include:** • **Wet ink signature log** OR • **Wet ink signature page from all site staff involved with the trial who digitally sign documents using Florence**	
2.0	**Project Management**		
2.1	Internal 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	Current HREC Approved Study Protocol signed by the PI	**Documents to be filed in this section include::** • **Study Protocol –** current HREC approved and signed Final Protocol • **Signed Protocol Signature Pages –** signed by the Site Principal Investigator • **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:** • **Local Site Non-Compliance Log**	

Section	Folder/Sub-Folder Name	Contents	Notes
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** – completed and signed by Site Principal Investigator	
3.5	Local 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 Preventive Action Plan Reviews** • **Site-Specific CAPA Tracking Log**	
3.6	Copy of all Serious Breach reports to Sponsor and local Research Governance Office (RGO) 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 Regulatory Authorities, 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**	

Section	Folder/Sub-Folder Name	Contents	Notes
		• **Copy of any PGICF and/or PICF Translations and Translation Certificates, if applicable.**	
4.3	Other Approved Participant Information	**Documents to be filed in this Section include:** • **Site-Specific authorised copies of advertisements, 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	Insurance	**Documents to be filed in this Section include:** • **Copy of Insurance Policy and/or Certificate of Currency (CoC)**	
6.0	**Ethics Committee**		
6.1	Ethics Committee Approval Letters, Certificates and Acknowledgements	**Documents to be filed in this Section include::** • **Initial Ethics Committee Approval Letter**	

Section	Folder/Sub-Folder Name	Contents	Notes
		Other Documents to be filed in this Section include: • **Letters/Acknowledgement relating to the original Protocol/PICF/IB etc** • **Subsequent Amendment approvals/acknowledgement from the Ethics Committee** • **Ethics Approval 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 relating to the original Protocol/PICF/IB etc, including a copy of the HREA** **Other Documents to be filed in this Section include:** • **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.**	
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**	

Section	Folder/Sub-Folder Name	Contents	Notes
		• **Acknowledgment of Receipt of Annual and Final 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** • **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 i.e. for Australian sites only, and including any responses to local RGO questions/queries.**	
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 Governance Office (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.**	
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.**	

Section	Folder/Sub-Folder Name	Contents	Notes
8.0	**Study-Specific Procedures/SOPs**		
8.1	Site-Specific Manual of Procedure	**Documents to be filed in this Section include:** • **Site-specific Manual of Procedures Document**	
8.2	Other Study Standard Operating Procedures (SOPs)	**Documents to be filed in this Section include:** • **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 – completed by all who attended the Site Initiation Meeting and signed by the site Principal Investigator.**	
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**		
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.**	

Section	Folder/Sub-Folder Name	Contents	Notes
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.** For example, presentations for site re-training, any training delivered on the study database etc.	
10.3	Site-Specific Training Logs	**Documents to be filed in this section include:** • **Site Staff Training Logs** • **Other Training Attestation Forms, as applicable**	
10.4	Other Training Resources	**Documents to be filed in this Section include:** • **Copies of other site-specific training resources/ materials provided by the Sponsor**	
11.0	**Participant Recruitment**		
11.1	Pre-Screening Log	**Documents to be filed in this section include:** • **Site Pre-Screening Log**	
11.2	Consent, Screening & Enrolment Log	**Documents to be filed in this section include:** • **Site Consent, Screening & Enrolment Log**	
11.3	Participant ID Log	**Documents to be filed in this section include:** • **Site Participant ID Log**	
11.4	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	Trial Specific Randomisation and Registration User Manual	**Documents to be filed in this Section include:** • **Trial specific participant Randomisation or Registration User Manual**	

Section	Folder/Sub-Folder Name	Contents	Notes
12.2	Records of Unblinding	**Documents to be filed in this Section include:** • **All local participant records of unblinding during study conduct and reasons for unblinding**	
12.3	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**		
13.1	Blank Sample CRF	**Documents to be filed in this Section include:** • **For eCRFs; annotated CRFs**, if applicable • **For Paper CRFs; blank CRFs,** if applicable	
13.2	CRF Completion Guidelines	**Documents to be filed in this Section include:** • **CRF Completion Guidelines**	
13.3	Completed Electronic Data Capture (EDC) System Application Forms	**Documents to be filed in this Section include:** • **Electronic Data Capture (EDC) System Account Application Form – completed and signed forms from key research personnel requiring database access from the participating site.**	
13.4	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.**	
13.5	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to Data Management.**	
14.0	**Safety Monitoring & Reporting**		
14.1	Blank Expedited Safety Report Form	**Documents to be filed in this section include:**	

Section	Folder/Sub-Folder Name	Contents	Notes
		• **Copy of blank Expedited Safety (SAE) Report Form** • **Copy of blank Expedited Safety (SAE) Report Cover Sheet** • **Copy of Expedited Safety (SAE) Report Completion Instructions** • **Copy of blank Expedited Pregnancy Coversheet** *(for drug trials, if applicable)* • **Copy of blank Expedited Pregnancy Report Form** (*for drug trials, if applicable)* • **Copy of Expedited Pregnancy Reporting Instructions** – *(for drug trials, if applicable)*	
14.2	Reference Safety Information	**Documents to be filed in this Section include:** • **Reference Safety Information i.e.** Investigator Brochure, Product Information etc.	
14.3	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**	
14.4	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.**	
14.5	Written 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**	

Section	Folder/Sub-Folder Name	Contents	Notes
14.6	Other Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to safety monitoring and reporting requirements.**	
15.0	**Study Quality Assurance, Monitoring, Audits & Inspections**		
15.1	Site Monitoring and Visit Log	**Documents to be filed in this section include:** • **Site Monitoring and Visit Log – Record all site visits completed, whether Site Monitoring or Site Audit visits are performed, on this Log.**	
15.2	Monitoring Correspondence and Feedback	**Documents to be filed in this Section include:** • **Monitoring Visit Confirmation Letters** • **Monitoring Visit Follow Up Letters**	
15.3	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.**	
15.4	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.**	
15.5	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	Research Sample Lab Manual	**Documents to be filed in this Section include:**	

Section	Folder/Sub-Folder Name	Contents	Notes
	- If applicable	• **Copy of the trial-specific Research Sample Lab Manual**	
16.2	Local Lab Certificates of Accreditation - If applicable	**Documents to be filed in this Section include:** • **Copy of the Local Site Lab Accreditation – i.e. NATA Accreditation Certificate**	
16.3	Local Lab Reference Ranges - If applicable	**Documents to be filed in this Section include:** • **Copy of the Local Site Lab Reference Ranges**	
16.4	Biospecimen Collection Log - If applicable	**Documents to be filed in this Section include:** • **Biospecimen Collection Log**	
16.5	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.**	
16.6	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 i.e. Freezer Temperature Logs, Liquid Nitrogen Monitoring Logs etc.**	
16.7	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the Central Lab or relating to the Biospecimen Research aspects of the study.**	
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**	

Section	Folder/Sub-Folder Name	Contents	Notes
		(excluding Investigational Product/Medical Devices) • **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)** • **Expressions of Interest (EoI), if applicable**	
18.3	Related 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/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**	
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	**Documents to be filed in this Section include:** • **Copies of Newsletters from the Sponsor to Participating sites**	

Section	Folder/Sub-Folder Name	Contents	Notes
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 – completed and signed by Site Investigator and Sponsor.**	
21.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regarding trial archiving to and from the Sponsor.**	

FOR DRUG & DEVICE TRIALS ONLY			
22.0	**Investigational Product**		
22.1	Instructions for Handling IP and Trial Related Materials - Pharmacy Manual	**Documents to be filed in this section include::** • **Pharmacy Manual** **Other Documents to be filed in this Section include:** • **Any Other IMP Handling Instructions, if applicable**	
22.2	Documentation of IP Shipment and Receipt - If available	**Documents to be filed in this Section include:** • **Shipping Records of IP to Site – if available**	

22.3	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**	
22.4	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** i.e. Freezer and Fridge Temperature Logs, Freezer and Fridge Monitoring and Maintenance Logs, etc.	
22.5	Documentation of Central IP: - Quarantines - Returns - Destructions/Drug Destruction Form	**Documents to be filed in this Section include:** • **Site-Specific Drug Destruction Form** • **Any site-specific IP Deviation reports (i.e. temperature excursions, IP complaints, IP quarantines) and associated forms** • **Any IP Returns and/or Destruction forms relating to any unused IP at the end of the study.**	
22.6	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to the Investigational Product/s.**	