TEMPLATE & GUIDANCE

Pages 1-4 contain instructions pertaining to the use of this filing index.

Delete pages 1-4 when filing this index.

FORM & GUIDANCE

Title: Combined Trial Master File (TMF) and Investigator Site File (ISF) Filing Index for MCRI sponsored clinical trials

Document ID: MCTC237

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Applicability: Clinical Trials

Author

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The author is signing to confirm the technical content of this document

Institution/Department name: [Melbourne Children's/MCTC]

Reviewed and Approval

The following signature confirms that this document has been reviewed and approved for use.

NAME and TITLE: Kate Scarff, MCTC Quality Assurance Lead

This document is effective two weeks from the date of the last approval signature and will be reviewed in three years, or earlier if required.

Document History:

Version	Author	Effective Date [DD/MMM/YYYY]	Description of Change
1.0	Grace Whitehouse & Laura Galletta	17/08/2026	Initial version

PURPOSE

This Filing Index supports:

- Compliance with ICH Good Clinical Practice (ICH E6) and applicable regulatory requirements
- Maintenance of a complete, accurate and contemporaneous record of trial conduct
- Inspection readiness, including rapid identification and retrieval of essential documents
- Maintenance of a record of where essential records are located, including source data and source records, in accordance with ICH E6(R3) C.2.4

SCOPE

This Filing Index applies to:

- Single-centre MCRI-sponsored trials carried out at Melbourne Children's campus only. In this case, it is preferable to have a merged TMF and ISF index to reduce duplication of documentation.
- Electronic and paper Combined Trial Master File (TMFs) and Investigator Site Files (ISFs)
- All phases of the trial lifecycle (start-up, conduct, close-out, and archiving)

- All essential records required by ICH GCP E6(R3) and trial-specific records

This Filing Index does not apply to MCRI-sponsored trials that are multi-centre. In this case, the TMF and Melbourne Children's campus ISF will need to be managed separately in accordance with MCTC173 and MCTC177

RELATED DOCUMENTS

- MCTC006 SOP | Management of Essential Records
- MCTC173 Form | eISF Filing Index for IITs
- MCTC177 Form | eTMF Filing Index for IITs

USE OF THIS FILING INDEX AND GENERAL GUIDANCE

This Filing Index is a controlled template and must be used as a live tracking tool throughout the trial lifecycle.

The Filing Index must be maintained as a document and stored in one of the following:

- eTMF/ISF in Florence eBinders or other application, e.g. SharePoint or Microsoft Teams
- Paper-based TMF/ISF binder

The Filing Index must be actively updated throughout the study to reflect the location of essential records.

The Filing Index should be:

- Initiated during the site start-up phase and maintained throughout study conduct, close-out and archiving.
- Completed and maintained by a designated study team member (e.g. Site Principal Investigator or Research Nurse/Study Coordinator), with overall responsibility retained by the Site Principal Investigator. Clinical Trial Managers may support site staff in the completion of the filing index.

- Used to ensure that all essential records are accounted for, organised, and readily accessible.

Filing and Maintenance Principles:

- Documents should be filed in the relevant system (e.g. Florence, SharePoint or other approved system) in chronological order, with the most recent version filed first
- Superseded documents must be clearly marked as "Superseded", where applicable. In Florence eBinders, this may be completed via the 'stacking' function when uploading new documents
- Sections within this Filing Index may be added or adapted to reflect study-specific requirements, provided numbering remains sequential
- Enter the location of the document if filed outside the TMF/ISF. The "Location field" must specify the exact system and folder/path sufficient for an independent reviewer (e.g. monitor/auditor/inspector) to locate the document without additional guidance (e.g. "Pharmacy Binder located with Pharmacy Team until the end of the recruitment period, Investigational Product Shipment records filed within Pharmacy Binder" or "Hospital EMR (Epic) for documents/data appearing in the medical record")
- If a document is not applicable, record "Not Applicable"; e.g. if biological sample collection is not applicable to your trial, enter "Not Applicable" for Lab Manual
- You may also choose to document missing records or documents that are not applicable via a Note to File (NTF)
- The Filing Index must be maintained such that all documents can be located and retrieved within a short timeframe (generally within 5–10 minutes under normal conditions)

How to use this Form:

- Pages 1-4 form part of the guidance associated with this Form and do not need to be filed in the ISF.
- Delete pages 1-4 and continue with completing the Form.

- Upload completed Filing Indices as the very first document within each TMF/ISF in Florence eBinders/SharePoint or file as the first document in each paper TMF/ISF.

Trial Name and Acronym:	
Sponsor- Investigator Name:	
Site Name:	
Site Code/Number: *(If applicable)*	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
1.0	**Central Trial Coordination Team**		
1.1	Contact List	• Site Contact List	
1.2	Signature and Delegation of Duties Log	• Signature and Delegation of Duties Log - Include all site staff involved with the trial.	
1.3	CVs	• CV Site Principal Investigator CV Study Coordinator | Research Nurse. Original CVs must be signed and dated within the last two years. • Copies of Medical Licenses, if applicable	
1.3.1	Other CVs	• 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	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
1.4	GCP Training Certificates	• GCP Training Certificate from Site Principal Investigator • GCP Training Certificate from Site Study Coordinator | Research Nurse	
1.5	Other Training Certificates	• Other relevant training certificates from all Site staff involved in the study.	
1.6	Wet Ink Signatures	• 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	Trial Start Up Checklist	• Completed Trial Start-Up Checklist	
2.2	Administration	• Completed Roles and Responsibilities Matrix • Any significant correspondence	
2.3	Trial Meeting Agenda, Minutes and Notes	• Trial meeting agendas and minutes of every • meeting with the Sponsor-Investigator and/or • research team i.e. internal team meetings	
2.4	Correspondence and Communication	• Copies of meeting minutes, emails, etc • All other significant correspondence.	
3.0	**Protocol/Protocol Amendments**		
3.1	Site Protocol Version Tracker	• Site Protocol Version Tracker	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
3.2	Current HREC Approved Study Protocol signed by the PI	• Study Protocol – current HREC approved and signed Final Protocol • Signed Protocol Signature Pages – signed by the Site PI • Previous protocol versions Signed Protocol Signature Pages	
3.3	Evidence of Peer Review	• Evidence of Protocol Peer Review	
3.4	Non-Compliance Report templates	• Master Non-Compliance Report form • Master Non-Compliance Review form	
3.5	Non-Compliance Reports to Sponsor	• Copies of completed Non-Compliance Report Forms and corresponding Review Forms • Non-Compliance log	
3.6	Serious Breaches and CAPA Documents	• Corrective and Preventive Action Plan (Master) • Corrective and Preventive Action Plan (CAPA) Reviews • CAPA Tracking Log	
3.7	Copy of all Serious Breach reports to Sponsor-Investigator, HREC or Regulatory Authorities	• Copies of all Serious Breach Reports submitted to Ethics Committees, including supporting ERM documentation and any return acknowledgment • Copies of all Serious Breach Reports submitted to Regulatory Authorities any return acknowledgment	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
3.8	Related Correspondence	• All significant correspondence relating to protocol development, protocol amendments, serious breaches and CAPAs.	
4.0	**Participant Information & Consent Forms**		
4.1	PGICF & PICF Version Tracker	• PGICF & PICF Version Tracker(s) • Other PICF Version Tracker(s), as applicable	
4.2	HREC Approved PGICF and PICF	• Approved Site-Specific Parent/Guardian ICF and Participant ICF	
4.3	Other Approved Participant Information	• Site-Specific authorised copies of advertisements, participant diaries, telephone scripts, GP letters, templates, participant newsletters, cards and questionnaires (e.g., QoL), as applicable to study.	
4.4	PGICF and PICF Review and Approval	• PGICF / PICF Review Checklist – Clinical Trial Manager | Study Coordinator • PGICF / PICF Approval and Sign-Off Form	
5.0	**Regulatory Documents**		
5.1	Green Light Approval Form	• Green Light Approval Form – Master Template • Completed site-specific Green Light Approval Form	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
5.2	Regulatory Authorisation or Acknowledgement	• Copy of the CTN/CTA/CTX Acknowledgement from the TGA, if applicable	
5.3	Regulatory Submissions	• Copy of the electronic CTN Submission to the TGA listing participating sites • Copy of the eBS Submission Document from the TGA, if available • Copy of the TGA CTN Invoice, if available • Proof of CTN Payment, if available	
5.4	Insurance	• Insurance/Indemnity documentation (as applicable)	
5.5	Correspondence	• Any significant communication to and from Regulatory Agencies/Competent Authorities, as applicable.	
6.0	**Sponsorship**		
6.1	Sponsor Authorisation Letter	• Sponsorship Committee Authorisation Letter	
6.2	Completed Risk Assessment and Management Tool	• Completed Risk Assessment and Management Tool	
6.3	Related Correspondence and Meeting Minutes	• All significant correspondence to and from the Sponsor regarding initial and subsequent submissions.	
7.0	**Ethics Committee**		

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
7.1	Ethics Approval Letters	• Initial Ethics Committee Approval Letter • 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.	
7.2	Ethics Submission Documentation • Initial submission & Amendments • Including responses to HREC queries	• Complete Initial Ethics application relating to the original Protocol/PICF/IB etc, including a copy of the HREA • A copy of the Responses to HREC Queries, if applicable • Complete copy of any Protocol Amendments submitted to Ethics Committees, including supporting ERM documentation • Copies of all additional Amendments or Project Notifications submitted to Ethics Committees, including supporting ERM documentation.	
7.3	Ethics Committee Composition, Constitution & Statement of Compliance	• Ethics Committee Composition • Statement of Compliance of EC/HREC/IRB as applicable.	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
7.4	Annual Project Progress Reports and Final Project Report	• Copies of all Annual Project Progress Reports submitted to ethics, including supporting ERM documentation • Copies of all Annual Safety 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, Safety and Final Progress Reports	
7.5	Related Correspondence	• All significant correspondence to and from the Ethics Committee regarding initial and subsequent submissions	
8.0	**Research Governance Office (RGO), if applicable**		
8.1	Governance Authorisation Letters	• Initial RGO Approval Letter • Subsequent Amendment approvals from RGO.	
8.2	Annual Project Progress Reports & Final Project Report - Including Acknowledgement of Receipt	• Evidence of submission of Annual Progress Reports and Annual Safety 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.	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
8.3	Related Correspondence	• All significant correspondence to and from the RGO regarding initial and subsequent submissions.	
9.0	**Study-Specific Procedures/SOPs**		
9.1	Manual of Procedure	• Manual of Procedures Document • Other trial related SOPs, to support the conduct of the trial at the site (if applicable)	
9.2	Other Study Standard Operating Procedures (SOPs)	• Other Study Specific SOPs and associated documents, if applicable.	
10.0	**Site Training**		
10.1	Investigator Meetings	• Investigator Meeting Presentation slide set, if applicable • Investigator Meeting Attendance Log – completed and signed by all attendees	
10.2	Site Initiation	• Copy of Site Initiation Visit presentation • Site Initiation Agenda • Site Initiation Booking Letter • Site Initiation Attendance Log • Site Initiation Follow Up letter • Notification of Site Activation Letter	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
10.3	Training Logs	• Training Logs - completed and signed by all applicable site staff. • Other Training Attestation Forms, as applicable	
10.4	Other Training Resources	• Copies of other training resources and/or materials	
11.0	**Participant Recruitment**		
11.1	Site Pre-Screening Log	• Site Pre-Screening Log	
11.2	Site Consent, Screening & Enrolment Log	• Site Consent, Screening & Enrolment Log	
11.3	Site Participant Registration or Randomisation Log	• Site Participant registration or randomisation Log	
11.4	Related Correspondence	• All significant correspondence relating to participant recruitment	
13.0	**Participant Randomisation and Registration Procedures**		
12.1	Randomisation and Registration User Manual	• Trial specific participant Randomisation or Registration User Manual	
12.2	Records of Unblinding	• All local participant records of unblinding during study conduct and reasons for unblinding • Unblinding Log	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
12.3	Related Correspondence	• 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	• For eCRFs; annotated CRFs, if applicable • For Paper CRFs; blank CRFs, if applicable	
13.2	CRF Completion Guidelines	• CRF Completion Guidelines	
13.3	Trial specific Data Management Plan	• Data Management Plan Data Validation Plan • Data Sharing Plan • Source Document Plan • Medical Review Plan and associated Review Forms • Other Data Review Committees and/or Plans	
13.4	Database Management Documentation	• Database Specifications documentation • Database User Acceptance Testing and UAT Log • Database Amendment documentation and Change Control Log • Data Export / Transfer of Data Forms (if applicable)	
13.5	Trial Database Design Approval Form	• Evidence of Database Approval by Sponsor-Investigator	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
13.6	Electronic Data Capture (EDC) System Application Form	• Master Electronic Data Capture (EDC) System Account Application Form, if applicable	
13.7	Completed Electronic Data Capture (EDC) System Application Forms	• Completed Electronic Data Capture (EDC) System Account Application Form, if applicable, from central trial team members	
13.8	Source Records and Source Data	• Copies of all applicable source records and/or source documents	
13.9	Related Correspondence	• All significant correspondence relating to Data Management.	
14.0	**Safety Monitoring & Reporting**		
14.1	Expedited Safety Report Form and Safety Reporting Guidelines	• Safety Monitoring Plan (if applicable) • 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)* • Safety Event (SAE) Review Form Template	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
14.2	Reference Safety Information	• Reference Safety Information I.e. Investigator Brochure, Product Information, Material Safety Data Sheets (MSDS) etc.	
14.3	Completed Site Expedited Safety Report Forms and associated correspondence sent to Sponsor • all SAEs, suspected SUSARs and USMs	• Copies of completed initial Expedited Safety (SAE) Report Forms • Copies of completed follow-up Expedited Safety (SAE) Report Forms • Copies of completed Safety Event (SAE) Review Forms	
14.4	Safety Reports sent to RGO, HREC, TGA, Regulatory Authorities and Participating Sites.	• Copies of safety reports and/or 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	On Site procedure for unblinding for a medical emergency or safety reporting	• On site Emergency Procedures for Unblinding Manual, if applicable	
14.6	Other Related Correspondence	• All significant correspondence relating to safety monitoring and reporting requirements.	
15.0	**Study Quality Assurance, Monitoring, Audits & Inspections**		

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
15.1	Clinical Monitoring Plan	• Clinical Monitoring Plan • Risk Assessment and Risk Management Tool for Clinical Trials • Any other monitoring associated documents	
15.2	Review and Approval of Clinical Monitoring Plan by Sponsor Investigator	• Clinical Monitoring Plan Approval from Sponsor-Investigator	
15.3	Monitoring Log	• Site Monitoring and Visit Log	
15.4	Monitoring Visit Reports	• Site Monitoring Confirmation Booking Letter • Site Monitoring Visit Report • Site Monitoring Follow-Up Letter	
15.5	Monitoring Correspondence and Feedback	• Monitoring Visit Confirmation Letters from Sponsor • Monitoring Visit Follow Up Letters from Sponsor	
15.6 Data Safety Monitoring Board (DSMB)			
15.6.1	DSMB Charter	• DSMC Charter	
15.6.2	DSMB charter review & approval	• DSMB Charter Approval and Sign-Off Form	
15.6.3	DSMB meeting reports and minutes	• All Reports prepared for DSMB meetings • All minutes from DSMB meetings held throughout trial conduct	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
15.6.4	Related correspondence	• All significant correspondence to and from the DSMB • All other DSMB related correspondence	
15.7 Trial Steering, Management, or other Committee(s)			
15.7.1	Committee Charter(s)	• Trial Steering Committee Charter • Trial Management Group Charter • Other Committee Charters	
15.7.2	Documentation of approval by Sponsor Investigator	• Charter Approval and Sign-Off Form	
15.7.3	Committee Meeting Reports and Minutes	• All Reports prepared for all Committee meetings • All minutes from Committee meetings held throughout trial conduct	
15.8	Local Research Governance Audits	• Copies of all Audit Reports sent to Local Research Governance Offices	
15.9	Regulatory Inspection reports	• Copies of all Regulatory Inspection Reports • Any correspondence related to Regulatory Inspections	
16.0	**Statistics**		
16.1	Statistical Analysis Plan (SAP)	• Statistical Analysis Plan (SAP) • Superseded versions of the SAP	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
16.2	Statistical Analysis Plan review and approval	• Statistical Analysis Plan (SAP) Approval and Sign-Off Form	
16.3	Statistical Reports, including reports to DSMB and other analyses	• Copy of reports for DSMB • Copy of any Interim Analysis statistical reports • Copy of Final Analysis statistical reports • Copy of any Other Protocol-Defined Analysis	
16.4	Related Correspondence	• All significant correspondence relating to statistics or the statistical plan for the study	
17.0	**Local Laboratory**		
17.1	Research Sample Lab Manual • If applicable	• Research Sample Lab Manual • Research Sample Lab Manual Approval and Sign- Off • Biospecimen Collection Forms Template • Biospecimen Sample Labels • Other Research Sample related manuals	
17.2	Certificates of Accreditation • If applicable	• Copies of the Lab Accreditation – i.e. NATA Accreditation Certificate	
17.3	Lab Reference Ranges • If applicable	• Copy of the Lab Reference Ranges	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
17.4	Biospecimen Collection Log • If applicable	• Biospecimen Collection Log	
17.5	Biospecimen Shipment Receipt Tracking • If applicable	• Copies of courier shipping documents, invoices, receipts, custom declarations, consignment notes, import permits from site to the Central Laboratory and/or Sponsor.	
17.6	Biospecimen Storage Monitoring Documentation • If applicable	• Any site-specific documentation relating to the monitoring of biospecimen storage at site i.e. Freezer Temperature Logs, Liquid Nitrogen Monitoring Logs etc.	
17.7	Related Correspondence	• All significant correspondence to and from the Central Lab or Sponsor or relating to the Biospecimen Research aspects of the study.	
18.0	**Supplies/Shipping Records**		
18.1	Documentation relating to provision of Study Supplies	• Copies of any correspondence or documentation regarding the provision of study supplies to site (excluding Investigational Product/Medical Devices) • Any receipts of study supplies to site, if applicable.	
19.0	**Legal Documentation**		

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
19.1	Fully Executed Clinical Trial Research Agreement (CTRA)	• Clinical Trial Agreement– fully executed between Site and Sponsor	Not applicable for single-site IITs
19.2	Other Agreements as applicable	• Copy of other agreements as applicable: • Non-Disclosure Agreements (NDA) • Material Transfer Agreements (MTA) • Data Transfer Agreements (DTA) • Expressions of Interest (EoI), if applicable	
19.3	Related Correspondence	• All significant correspondence relating to any Agreements pertaining to the study.	
20.0	**Finance Documentation**		
20.1	Budget Tracking (Forecasts and Actuals)	• A copy of the trial budget, forecast and actuals	
20.2	Invoices/Receipts	• Copies of relevant invoices and receipts pertaining to the study	
20.3	Related Correspondence	• All significant correspondence regarding the study budget, invoice tracking, per patient payments, etc.	
21.0	**Other Communication**		
21.1	General Correspondence	• Other significant general correspondence	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
22.0	**Publication and Abstracts**		
22.1	Publications	• Copies of accepted publications arising from the study	
22.2	Abstracts	• Copies of any accepted abstracts arising from the study	
23.0	**Clinical Study Report**		
23.1	Clinical Study Report	• Copy of the Final Clinical Study Report, if applicable	
23.2	Statistical Report	• Copy of the Statistical Report • Copy of the Final Statistical Presentation, if applicable	
24.0	**Study Registration and Results Posting**		
24.1	Initial Registration with a Trial Registry	• Copy of the registration release/receipt of the entry from the Registry	
24.2	Updates to Trial Registry	• Copy of any update to the registration record documenting annual updates, updates following change in recruitment status and posting results • Copy of results posted to the registration record	
24.3	Related Correspondence	• All significant correspondence regarding trial archiving	
25.0	**Archiving**		

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
25.1	Archiving Details	• Investigator Agreement to Archive Trial Documents Form – completed and signed by Site Investigator and Sponsor.	
25.2	Related Correspondence	• All significant correspondence regarding trial archiving to and from the Sponsor.	
26.0	**Reference Safety Information for each Investigational Product**		
26.1	Reference Safety Information (IB or PI)	• Full copy of the Investigator Brochure (IB); or • Full copy of the Product Information (PI) • Copies of any Associated Documents e.g. IB Addendums etc • Superseded copies of the Investigator Brochure (IB) • Superseded copies of the Product Information (PI) • Superseded Copies of any Associated Documents e.g. IB Addendums etc	
26.2	IB Version Tracker	• IB Version Tracker	
26.3	IB Signature Pages (if applicable)	• IB Signature Page signed by Sponsor-Investigator/Site Investigator	
27.0	**Investigational Product**		
27.1	Pharmacy Manual	• Copy of current Pharmacy Manual • Copies of superseded Pharmacy Manuals	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
27.2	Unregistered Product Manufacturing Records	• Any correspondence with Drug Company relating to IP manufacturing or importation, if applicable • IP Quality Control Release Documentation relating to the batch of IP supplied for the trial	
27.3	IP Ordering Information and Drug Order Form	• Instructions and Process for ordering IP (e.g. via IWRS), if applicable • Drug Order form	
27.4	IP Packaging and Labelling	• Copy of the Primary Label, if applicable • Copy of the Secondary Label • Secondary Label Approval form – signed by the Sponsor-Investigator	
27.5	Documentation of IP Shipment and Receipt	• Import Permits e.g. AQIS Import Permit, if applicable • IP Shipping Records • Import Letter – study specific and signed by Sponsor-Investigator	
27.6	Documentation of IP Storage Monitoring	• 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.	

Section	Folder/Sub-Folder Name	Contents *(Documents to be filed in this Section)*	Location *(Enter the location of the document if filed outside of ISF. If a document is not applicable, record "Not Applicable")*
27.7	Documentation of IP Quarantines, Returns, and Destruction	• Drug Destruction Form (Master) • Process for Reporting IP Deviations • Process for the Return or Destruction of unused IP	
27.8	Documentation of IP Dispensing, Accountability and Inventory	• Bulk Drug Accountability Log • Individual Drug Accountability Log	
27.9	Copies of Material Safety Data Sheets (MSDS)	• Copy of the Material Safety Data Sheet (MSDS) for each drug/IP used in the study	
27.10	Related Correspondence	• All significant correspondence relating to the Investigational Product/s.	