Electronic Site Investigator File (eSIF) – Table of Contents Document Filing Guideline

Key Terms:

Placeholders: In Florence, a Placeholder is just what the name states - a spot that holds a place for a future document. When you are developing a study, you usually know from the outset, the certain 'key documents' that you will require in the future. Creating a Placeholder (also defined as a digital "sticky note") upfront, ensures that you hold a place for an expected Document, guaranteeing that you won't overlook them in the future. Some examples include CVs, GCP training certificates, Master PICFs, ethics approval certificates, etc. These can be used to create tasks and generate reports on binder completeness.

eLogs: An eLog is a digital log which has data continuously added to it to list actions taken, approvals, etc. Florence allows the user to create and maintain eLogs directly within the platform itself, avoiding the need to create a template log outside of Florence and subsequently importing the template log into Florence. The user creates log templates for your team so that everyone has a standardised way of recording and storing the data. With eLogs, you can create entries, edit entries, request signatures and sign both entries and the entire log within the Florence platform. Suggested template eLogs are available within the Florence platform for your use.

Section	Contents	Document Filing Guideline / Comments
1.0	**Participating Site Team**	
1.1	Contact List	**Existing Placeholders:** • **Participating Site Contact List** *The Contact List should include all key Site research team staff, i.e. PI, Sub-Is/AIs, SC, Research Nurse and other key team staff, e.g. Data Manager, Pharmacist, Laboratory Manager.*
1.2	Signature and Delegation of Duties Log	**Existing Placeholders:** • **Signature and Delegation of Duties Log -** Include all site staff involved with the trial. *If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog.* *The Signature and Delegation of Duties Log should list all site staff involved with the trial. At a minimum, this should list the Site Principal Investigator, Associate-Investigators, Study Coordinator, Research Nurses, and Clinical Trial*

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		Pharmacist (if the trial involves an Investigational Medical Product).
1.3	CVs	**Existing Placeholders:** • **CV Site Principal Investigator** • **CV Study Coordinator / Research Nurse** **Documents to be filed in this Section include:** • **Original Curriculum Vitae –** CVs must be signed and dated within the last two years. TEMPLATE Investigator Short CV • **Copies of Medical Licenses, if applicable** *CVs must include details of qualifications, training and previous appointments of all site staff involved in the study. At a minimum this should include: the site Principal Investigator, Sub-Investigators and Clinical Trial Pharmacists (if the trial is blinded/randomised and the Trial Pharmacists are completing participant randomisation). CVs must include details of qualifications, training and previous appointments.* *We recommend that Melbourne Children's Campus staff shortcut to a centrally filed copy of each CV to reduce administrative burden.*
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. TEMPLATE Investigator Short CV • **Copies of Medical / AHPRA Licenses, if applicable** *CVs must include details of qualifications, training and previous appointments of all site staff involved in the study.* *We recommend that Melbourne Children's Campus staff shortcut to a centrally filed copy of each CV to reduce administrative burden.*
1.4	GCP Training Certificates	**Existing Placeholders:** • **GCP Cert. Principal Investigator** • **GCP Cert. Study Coordinator** *Include GCP training certificates from all staff listed in the Signature and Delegation of Authority Log at the participating site.*

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		GCP training must have been TransCelerate accredited GCP training must be completed every three years to remain current. *We recommend that Melbourne Children's Campus staff shortcut to a centrally filed copy of each GCP Certificate to reduce administrative burden.* *Related Link:* You can organise GCP training here.
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 from the participating site. *Include GCP training certificates from all staff listed in the Signature and Delegation of Authority Log at the participating site.* *GCP training must have been TransCelerate accredited GCP training must be completed every three years to remain current.* *We recommend that Melbourne Children's Campus staff shortcut to a centrally filed copy of each GCP Certificate to reduce administrative burden.*
1.5	EDC Training Certificates	**Documents to be filed in this Section include:** • **Copies of site staff EDC Training Certificates/ Certifications, if applicable** • **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 *The wet ink signature log is a paper-based form which must be scanned, certified, and uploaded to Florence at the end of the trial. An original paper copy of wet ink signatures must be kept by the site.* *We recommend Melbourne Children's Campus staff shortcut to a centrally filed copy of their wet ink signature page to reduce administrative burden.*
2.0	**Project Management**	

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2.1	Site Selection Documentation - if applicable	**Documents to be filed in this Section include:** • **Site Feasibility Questionnaire –** completed by Site • **Site Feasibility Assessment** – completed by Trial Coordinator • **Site Selection Letter –** completed by Trial Coordinator, signed by Sponsor-Investigator. • **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	**Existing Placeholder:** • **Site Protocol Version Tracker** - to be completed and maintained by the Trial Coordinator *If you wish to use the Florence eLog as your version tracker you will need to delete this placeholder and import the relevant template eLog.*
3.2	Signed Protocol Signature and Investigator Agreement Pages	**Existing Placeholders:** • **Signed Protocol Signature Pages –** signed by the Site Principal Investigator **Other Documents to be filed in this Section:** • **Previous protocol versions Signed Protocol Signature Pages** *Note: The full protocol does not need to be filed here as it is already filed in the main TMF.*
3.3	Local Site Non-Compliance Log - Deviations from GCP or the protocol	**Existing Placeholder:** • **Site-Specific Non-Compliance Log** - Maintained by the Study Coordinator *If you wish to use the Florence eLog as your non-compliance log you will need to delete this placeholder and import the relevant template eLog.*
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 submitted by the participating sites. • **Non-Compliance Review Form** – completed and assessed by Sponsor-Investigator.

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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 –** completed and submitted by participating site • **Site-Specific Corrective and Preventive Action Plan Reviews –** completed and assessed by the Sponsor-Investigator and/or Sponsor detailing any corrective and preventative action to be taken in addressing serious breaches encountered at site. • **Site-Specific CAPA Tracking Log** – maintained by Trial Coordinator. *If you wish to use the Florence eLog as CAPA tracking log you will need to delete this placeholder and import the relevant template eLog.*
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 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)** to be completed and maintained by the Trial Coordinator to track the history of Site-Specific PICFs and subsequent amendments. Ensure the tracker document is appropriately labelled with the correct version numbers and the HREC/IRB, Regulatory and RGO (or equivalent) approval dates, as applicable • **Other PICF Version Tracker(s), as applicable.** *A template Florence PICF / PGICF Version tracker eLog is available to import to this section. As a general rule, for every PICF developed for your study, an accompanying tracker should also be developed and maintained.*

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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** *Note: Completed and signed PGICFs and PICFs are to be filed in the participant shadow files.*
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;** e.g. FDA IND Authorisation (USA), MHRA Authorisation (UK), Health Canada Authorisation, MedSafe Authorisation (NZ) etc • **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** – completed and signed by Site Principal Investigator • **Statement of Investigator Form (FDA 1572 Form), if applicable** – completed and signed by Site Principal Investigator.
5.3	Completed Site Green Light Approval Form	**Documents to be filed in this Section include:** • **Site Green Light Approval Form** – completed by Trial Coordinator prior to Site Activation. *Note: This is a **mandatory** requirement for all participating sites and must be completed prior to officially activating a site to recruitment/ randomisation. Prior to authorising the start of a clinical trial and the initiation of research sites, the sponsor must ensure that all approvals, contracts and necessary documentation are in place. Records must be available to verify that all necessary essential documents have been received by the sponsor prior to the authorisation to start the clinical trial at each site. This*

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		should include confirmation that they have been reviewed by an appropriately delegated representative of the sponsor. Once this check is complete, trial activities at site can commence. This process is referred to as the ***'regulatory green light'.***
6.0	**Ethics Committee**	
6.1	Ethics Committee Approval Letters, Certificates and Acknowledgements	**Existing Placeholder(s):** • **Initial Ethics Committee Approval Letter** **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 Aproval Letters/Acknowledgements relating to ALL other project submissions.**
6.2	Ethics Submission Documentation Initial & Amendments Including responses to HREC queries	**Existing Placeholder(s):** • **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.** *Note: Download submissions from the submissions tab in ERM. This will generate a PDF of the completed HREA form and list of submitted documents. The document will have a date generated field (in the footer), indicating the date of submission.* *Related Links:* *Ethics submission resources and information*
6.3	Ethics Committee Composition, Constitution & Statement of Compliance	**Existing Placeholder(s):** • **Ethics Committee Composition** **Other Documents to be filed in this Section include:** • **Statement of Compliance of EC/HREC/IRB, as applicable.**

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		Note: If Ethics Committee Composition is not provided,then evidence documenting this decision must be filed in this section of the ISF relevant to this communication.
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	**Existing Placeholder(s):** • **Initial RGO Approval Letter, if applicable** **Other Documents to be filed in this Section include:** • **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:**

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		• **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** *A template Florence MOP Version tracker eLog is available to import to this section.*
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	**Existing Placeholder(s):** • **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.**
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.

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10.3	Site-Specific Training Logs	**Existing Placeholder(s):** • **Site-Specific Training Log -** completed and signed by all site personnel assigned to the study. *Note: The training log should be updated every time new or additional site personnel completes training for the study.* **Other documents to be filed in this Section include:** • **Other Training Attestation Forms, as applicable** – completed and signed by individual site personnel, as required. *A template Florence Training eLog is available to import to this section. If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog.*
11.0	**Participant Recruitment**	
11.1	Consent, Screening & Enrolment Log	**Existing Placeholder(s):** • **Site Consent, Screening & Enrolment Log** *A template Florence Consent, Screening and Enrollment eLog is available to import to this section. If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog.*
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**	
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** – completed and signed forms

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		from key research personnel requiring database access from the participating site. *Note: It is **mandatory** that all site PIs have access to the study database in order to maintain oversight of their participant data, assist with responding to data queries (if required to) and confirm data accuracy by routinely signing-off on their participant data.*
13.2	Source Document Plan	**Existing Placeholder(s):** • **Site-Specific Source Document Plan – completed, signed and dated by the Site Principal Investigator.** *Related Links:* Source Document Plan: Guidance & Template
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** – completed, signed and dated by the Site Principal Investigator and sent to Sponsor. • **Copies of completed follow-up Expedited Safety (SAE) Report Forms** – completed, signed and dated by the Site Principal Investigator and sent to Sponsor.
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**
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**

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		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 –** completed by Trial Coordinator • **Pre-Trial Site Visit Report –** completed by Trial Coordinator • **Pre-Trial Site Visit Attendance Log –** completed by Trial Coordinator • **All significant correspondence** relating to pre-trial site visits to and from the site.
15.2	Site Monitoring and Visit Log	**Existing Placeholder(s)** • **Site Monitoring and Visit Log** – Record all site visits completed, whether Site Monitoring or Site Audit visits are performed, on this Log. *A template Florence Site Monitoring eLog is available to import to this section. If you wish to use the Florence eLog, you will need to delete this placeholder and import the relevant template eLog.*
15.3	Monitoring Visit Reports and Remote Monitoring Reports	**Documents to be filed in this Section include:** • **Monitoring Visit Reports (on site and remote)** Template: Site Monitoring Vist Report
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.**
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:**

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		• **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** – i.e. NATA Accreditation Certificate
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** *Note: Biospecimen Log is maintained by site each time a sample is collected, processed and stored as per protocol requirements. The Trial Coordinator should request Logs from sites on a quarterly basis and reconcile biospecimens against the Protocol and/or Database for compliance.*
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** i.e. Freezer Temperature Logs, Liquid Nitrogen Monitoring Logs etc.
16.6	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** (excluding Investigational Product/Medical Devices)

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		• **Any receipts of study supplies to site, if applicable.**
18.0	**Legal Documentation**	
18.1	Fully Executed Clinical Trial Research Agreement (CTRA)	**Existing Placeholders:** • **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.**
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** – 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 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** *Note: These receipts are generally located within the Participating Site Pharmacy Folder.* *If applicable, file a 'Note to File' indicating "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located in Central or Participating Site Pharmacy folder."*
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** *Note: These logs are generally located within the Participating Site Pharmacy Folder.* *If applicable, file a 'Note to File' indicating "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located within the Central or Participating Site Pharmacy folder."*
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** i.e. Freezer and Fridge Temperature Logs, Freezer and Fridge Monitoring and Maintenance Logs, etc. *Note: This documentation is generally located within the Participating Site Pharmacy Folder.* *If applicable, file a 'Note to File' indicating "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located in Central or Participating Site Pharmacy folder."*
22.4	Documentation of Central IP: - Quarantines - Returns	**Documents to be filed in this Section include:** • **Site-Specific Drug Destruction Forms, as completed by the site**

	- Destructions/Drug Destruction Form	• **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** *Note: This documentation is generally located within the Participating Site Pharmacy Folder.* *If applicable, file a 'Note to File' indicating "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located in Central or Participating Site Pharmacy folder."*
22.5	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to the Investigational Product/s.**