PARTICIPATING SITE INFORMATION FILE (SIF) – Guidance and Template Map

Site Investigator File – Table of Contents Document Filing Guideline

Section	Contents *Template Index page*	Document Filing Guideline / Available Templates
1.0	**Participating Site Trial Team**	
1.1	Contact List	**Documents to be filed in this Section include:** • **Participating Site Contact List –** current and superseded *Note: Include all key Site Research Team Staff, i.e. Provide Name, Role, Phone and Email for the PI, Sub-Is/AIs, SC, Research Nurse and other key team staff, e.g. Data Manager, Pharmacist, Laboratory Manager.* *Note: Ensure the first page is stamped with 'Superseded' when filing superseded documents.*
1.2	Signature and Delegation of Duties Log	**Documents to be filed in this Section include:** • **Signature and Delegation of Duties Log –** Completed including details of all site staff involved with the trial and signed and dated by the site Principal Investigator. *Note: The Signature and Delegation of Duties Log should list all site staff involved with the trial – At a minimum this should include: the site Principal Investigator, Associate Investigators, Study Coordinators/Research Nurses and Clinical Trial Pharmacists (if the trial involves an Investigational Medical Product).*
1.3	CVs - Include copies of Medical Licenses (if applicable)	**Documents to be filed in this Section include:** • **Original Curriculum Vitae – CVs must be signed and dated within the last two years** • **Copies of Medical Licenses, if applicable** *Note: Include CV's from all key research personnel from the participating site. 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.*

1.4	GCP Training Certificates	**Documents to be filed in this Section include:** • **GCP Training Certificates** *Note: Include GCP training certificates from all staff listed in the delegation log at the participating site. GCP training must have been TransCelerate accredited GCP training and completed within the **last three years.***
1.5	EDC (Electronic Data Capture) Training Certifications - if applicable	**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.
2.0	**Project Management**	
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 - Include meeting minutes, emails, significant correspondence	**Documents to be filed in this Section include:** • **Copies of meeting minutes, emails to and from site** • **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 –** maintained by Trial Coordinator.
3.2	Signed Protocol Signature Page / Investigator Agreement Page - Current	**Documents to be filed in this Section include:** • **Signed Current Protocol Signature Page –** signed and dated by Sponsor-Investigator or Sponsor Representative and Site Principal Investigator. *Note: The full protocol does not need to be filed here as it is already filed in section 3.2 the main TMF.*
3.3	Signed Protocol Signature Page - Superseded Versions	**Documents to be filed in this Section include:**

		• **Superseded Protocol versions signed Signature Pages** *Note: The full superseded protocol(s) do not need to be filed here as it is already filed in section 3.3 the main TMF.*
3.4	Local Site Non-Compliance Log - Deviations from GCP or the Protocol	**Documents to be filed in this Section include:** • **Site Specific Non-Compliance Log** – maintained by Study Coordinator.
3.5	Non-Compliance Reports - Deviations from GCP or the Protocol	**Documents to be filed in this Section include:** • **Non-Compliance Report Form –** completed and submitted by participating sites • **Non-Compliance Review Form** – completed and assessed by Sponsor-Investigator.
3.6	Local Serious Breaches and CAPA Documents	**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 Sponsor-Investigator • **Site-Specific CAPA Tracking Log** – maintained by Trial Coordinator.
3.7	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.**
3.8	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** (Site-Specific)	
4.1	Site-Specific PGICF & PICF Version Trackers	**Documents to be filed in this Section include:** • **Site-Specific PGICF & PICF Version Trackers -** to be completed and maintained by the Trial Coordinator to track the history of the 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 approval dates, as applicable. • **Other PICF Version Trackers, as applicable** i.e. Biobanking Consent PICF Tracker etc *Note: As a general rule, for every PICF developed for your study, an accompanying tracker should also be developed and maintained.*
4.2	Site-Specific PGICF & PICFs - Current Site Authorised Version(s)	**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.**
4.4	Blank Site-Specific PGICF & PICFs - Superseded Site-Authorised Versions	**Documents to be filed in this Section include:** • **Superseded copies of blank site-specific PGICF & PICFs**
4.5	Other Authorised Site-Specific Participant Information - Superseded Versions	**Documents to be filed in this Section include:** • **Superseded copies of other authorised site-specific Participant Information**
4.6	*This folder does not exist in the SIF. Section 4.6 of the ISF is for signed PGICF and PICFs but best practice is to file these in the participant shadow files.*	
5.0	**Regulatory**	
5.1	Regulatory Authorisation or Acknowledgement - Current and superseded	**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;** e.g. FDA IND Authorisation (USA) , MHRA Authorisation (UK), Health Canada Authorisation, MedSafe Authorisation (NZ) etc • **Any significant communication to and from Regulatory Agencies, 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 *Note: FDA Forms 3454 and 1572 only need to be completed by the Principal Investigator at each participating site.* *Note: FDA Form 1572 only needs to be completed for studies which fall under an IND in the USA. Always obtain the most recent version of the form directly from the FDA website; available online.* *The FDA also produce a Set of Instructions to assist Investigators with completion of the 1572 form* as well as a FAQ. *Note: Form 3454 needs to be completed for all studies which have sites bases within the USA, regardless of whether the study falls under an IND or not; i.e.* ***Is clinical investigator financial disclosure information required in IND or IDE applications?*** ***A:*** *No, IND/IDE Sponsors are not required to submit information regarding clinical investigator financial interests or arrangements in IND or IDE applications. They are, however, required to collect this information before a clinical investigator participates in a clinical study and clinical investigators are required to disclose financial information to Sponsors.* *Always obtain the most recent version of the form directly from the FDA website; available online.* *The FDA also produce a Guidance Document to assist Sponsors with Financial Disclosure forms.*
5.3	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 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 Approval Letters Current and superseded	**Documents to be filed in this Section include:** • **EC/HREC/IRB/REB Aproval Letters relating to the original Protocol/PICF/IB etc** • **Subsequent Amendment approvals/acknowledgement from EC/HREC/IRB/REB Committees** • **EC/HREC/IRB/REB 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 copy of the initial institution specific Ethics Committee application relating to the original Protocol/PICF/IB etc, including a copy of the HREA (or equivalent), if available** • **A copy of the Responses to HREC Queries, if available** • **Complete copy of any Protocol Amendments submitted to institution specific Ethics Committee, including supporting documentation, if available** • **Copies of all additional Amendments or Project Notifications submitted to institution specific Ethics Committee, including supporting documentation, if available.**
6.3	Ethics Committee Composition, Constitution & Statement of Compliance	**Documents to be filed in this Section include:** • **EC/HREC/IRB/REB Committee constitution** • **Statement of Compliance of EC/HREC/IRB/REB, as applicable.** *Note: If Ethics Committee Composition is not provided by the HREC, then evidence documenting this decision must be filed in this section of the SIF relevant to this communication.*
6.4	Interim/Annual / Final Reports to Ethics Committee and Committee Acknowledgements of Receipt	**Documents to be filed in this Section include:** • **Evidence of submission of all Annual Project Progress Reports submitted to EC/HREC/IRB/REB Committees, including supporting documentation**

	Note: Safety Reports to HREC/RGO are to be filed in Section 14.4	• **Acknowledgemt of Receipt of Annual Progress Report by EC/HREC/IRB/REB Committee** • **Evidence of submission of the Final Project Progress Report submitted to EC/HREC/IRB/REB Committees, including supporting documentation** • **Acknowledgemt of Receipt of Final Project Report by EC/HREC/IRB/REB Committee.**
6.5	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the EC/HREC/IRB/REB Committee regarding initial and subsequent submissions.**
7.0	**Local Research Governance Office (RGO), if applicable**	
7.1	Governance Authorisation Letters - Current and superseded	**Documents to be filed in this Section include:** • **Local Research Governance Office (RGO) Approval/Authorisation letters, if applicable –** current and superseded
7.2	RGO Submission Documentation - Initial & Amendments - Including responses to Local RGO queries	**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** • **Acknowledgemt of Receipt of Annual Progress Report by RGO** • **Evidence of submission of Final Project Report to local Research Governance Office (RGO), or equivalent, if applicable** • **Acknowledgemt of Receipt of Final Project Report 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.**
8.0	**Site-Specific Procedures/SOPs**	
8.1	Site-Level Manual of Procedures / trial-related Standard Operating Procedures, if applicable - Current version	**Documents to be filed in this Section include:** • **Site-specific Manual of Procedures Document** – current version • **Any site-specific Manual of Procedures associated documents, if applicable** • **Site-specific trial related SOPs** – current version

		• **Any site-specific trial related SOP associated documents, if applicable**
8.2	Site-Level Manual of Procedures / trial-related Standard Operating Procedures, if applicable - Superseded versions	**Documents to be filed in this Section include:** • **Site-specific Manual of Procedures Document** – superseded versions • **Site-specific trial related SOPs –** superseded versions *Note: Ensure the first page is stamped with 'Superseded' when filing superseded documents.*
9.0	**Site Initiation**	
9.1	Site Initiation Meeting Documentation; including: - Agenda - Site Initiation Presentation - Attendance Log	**Documents to be filed in this Section include:** • **Essential Documents Required from Sites Request Letter** – site-specific version • **Site Initiation Booking Letter** – site-specific version • **Site Initiation Agenda** – site-specific version • **Site Initiation Attendance Log** – completed by all who attended the Site Initition Meeting and signed by the site Principal Investigator**.**
9.2	Site Initiation Report and Follow Up Letter	**Documents to be filed in this Section include:** • **Site Initiation Follow-Up Report** – site-specific version • **Site Initiation Follow-Up Letter to Site** - site-specific version *Note: Participaing Sites do not receive a copy of the SIV Follow-Up Report, they only receive a copy of the SIV 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** - site-specific version
10.0	**Site Training**	
10.1	Investigator Meetings	**Documents to be filed in this Section include:** • **Investigator Meeting Presentation slide set** • **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 used for site training purposes here.** For example, presentations for site re-training, training on the study database etc.

10.3	Site-Specific Training Log	**Documents to be filed in this Section include:** • **Site Staff Training Log -** completed and signed by all site personnel assigned to the study. The training log should be updated every time new or additional site personnel completes training for the study. • **Other Training Attestation Forms, if applicable –** completed and signed by individual site personnel, as required.
10.4	Other Training Resources	**Documents to be filed in this Section include:** • **Copies of other site-specific training resources/ materials provided to sites.**
11.0	**Participant Recruitment**	
11.1	*This section is deliberately left blank as it is used by the sites for filing the Pre-Screening Log. As such it contains personal information that should not be accessed by the Sponsor-Investigator and the Central Coordinating Team.*	
11.2	Consent, Screening & Enrolment Log Template	**Documents to be filed in this Section include:** • **Site-Specific Consent, Screening & Enrolment Log –** current and superseded *Note: At the end of accrual the completed and anonymised Consent, Screening & Enrolment logs must be moved to TMF Section 11.2.*
11.3	*This section is deliberately left blank as it is used by the sites for filing the Participant ID Log. As such it contains personal information that should not be accessed by the Sponsor-Investigator and the Central Coordinating Team.*	
11.4	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to participant recruitment.**
12.0	**Participant Randomisation / Registration Procedures**	
12.1	This section is not used in the SIF. It is used in the ISF to file the Randomisation / Registration User Manual, if applicable. The Sponsor-Investigator already has this essential document in section 11.1 of the TMF.	
12.2	Records of Unblinding - Local Participants	**Documents to be filed in this Section include:** • **Copies of all local participant records of unblinding during study conduct and reasons for unblinding**
12.3	Related Correspondence	**Documents to be filed in this Section include:** - **All significant correspondence relating to participant randomisation and unblinding procedures.**

13.0	**Data Management – Forms & Procedures**	
13.1	*This section is not used in the SIF. It is used in the ISF to file the current and superseded Blank Paper CRF.*	
13.2	*This section is not used in the SIF. It is used in the ISF to file the CRF Completion Guidelines.*	
13.3	Completed Electronic Data Capture (EDC) System Account Application Forms - Applicable Members of Study Team	**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. *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, if applicable.*
13.4	Site Source Document Plan - Current and superseded versions	**Documents to be filed in this Section include:** • **Site-Specific Source Document Plan** – completed, signed and dated by the Site Principal Investigator. Source Document Plan: Guidance & Template
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	*This section is not used in the SIF. It is used in the ISF to file Blank Expedited Safety Report Form.*	
14.2	*This section is not used in the SIF. It is used in the ISF to file the Reference Safety Information. The Sponsor-Investigator already has the RSI filed in section 24.1 the TMF.*	
14.3	Copy of Completed Site Expedited Safety Report Forms (all SAEs, suspected SUSARs and USMs) sent to Sponsor-Investigator	**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. • **Copies of completed follow-up Expedited Safety (SAE) Report Forms** – completed, signed and dated by the Site Principal Investigator. *Note: In the Comments section of the SIF Table of Contents note that all submitted Expedited Safety (SAE) Report forms received from Participating Sites will be filed in a separate SAE Folder throughout study conduct and all reports filed in Section 13.2 of TMF at the end of the study.*

14.4	Copy of all Safety Reports sent by PI to 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 applicable.** • **Copies of all correspondence received from local Regulatory Authorities relating to submitted safety reports/notifications.**
14.5	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** • – current and superseded
14.6	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 to and from the Sponsor.**
15.0	**Study Quality Assurance, Monitoring, Audits & Inspections**	
15.1	Pre-Trial Visit Reports, Attendance and Correspondence	**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 Log	**Documents to be filed in this Section include:** • **Site-specific Site Monitoring and Visit Log** *Note: Record all site visits completed, whether Site Monitoring or Site Audit visits are performed, on this 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)** Template: Site Monitoring Vist Report
15.4	Monitoring 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:**

	- Include Correspondence	• **Trial Close-Out Report** • **Trial Close-Out Letter** • **Investigator Agreement to Archive letter** • **All significant correspondence relating to trial close-out activities to and from the site.**
15.6	Local Research Governance - Copy of all Audit Reports - Copy of all Correspondence	**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 Inspections: - Reports - Related Correspondence	**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 Documentation**	
16.1	This section is not used in the SIF. It is used in the ISF to file the Research Sample Lab Manual, if applicable. The Sponsor-Investigator already has this essential document in section 16.1 of the TMF.	
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	Normal Local Lab Reference Ranges - If applicable	**Documents to be filed in this Section include:** • **Copy of the Local Site Lab Reference Ranges** – current and superseded
16.4	Biospecimen Collection Log - If applicable	**Documents to be filed in this Section include:** • **Biospecimen Collection Log** – current and superseded *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.*
16.5	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.**
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**

		participating sites 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 site relating to the storage of Biospecimens/Translational Research aspect of the study, if applicable.**
17.0	**Supplies/Shipping Records**	
17.1	Documentation relating to provision of Study Supplies (excluding Investigational Product/Medical Devices); e.g: - Paper Diaries - Blood Collection Tubes	**Documents to be filed in this Section include:** • **Copies of any correspondence or documentation regarding the provision of study supplies to participating site** • **Any receipts of study supplies to participating site, if applicable**
18.0	**Legal Documentation**	
18.1	Fully Executed Clinical Trial Agreement	**Documents to be filed in this Section include:** • **Clinical Trial Agreement with Site –** signed by Sponsor and Site Principal Investigator
18.2	Other Agreements as applicable: e.g. - Material Transfer Agreement (MTA) - Confidentiality Agreement (CDA) - Data Sharing Agreements - Insurance/Indemnity	**Documents to be filed in this Section include:** **Copy of other site agreements as applicable:** • **Material Transfer Agreements (MTA)** • **Data Sharing/Transfer Agreements** • **Insurance/Indemnity (as applicable)** • **Expressions of Interest (EoI)** *Note: only copies of fully executed agreements should be filed in the SIF. Original wet-ink signed copies are filed with MCRI Legal Team (if applicable)*
18.3	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the MCRI Legal Team or 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,** • **Copies of relevant invoices received from participating sites relating to study-related Per Patient Payments (PPP)**
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. to and from participating sites.**
20.0	**Other Communication**	
20.1	Newsletters from Sponsor-Investigator	**Documents to be filed in this Section include:** • **Copies of Newsletters sent from Sponsor-Investigator 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-Investigator.
21.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regarding trial archiving to and from the Participating Site.**
22.0	**Investigational Product** *Note these essential documents may be located at site Pharmacy during the study but must be archived with the TMF at the end of the study.*	
22.1	This section is not used in the SIF. It is used in the ISF to file the Instructions for handling IP and trial related materials e.g. Pharmacy Manual . The Sponsor-Investigator already has these essential document in section 25.4 of the TMF.	
22.2	Documentation of IP Shipment / Receipt i.e. Drug Receipt *If available*	**Documents to be filed in this Section include:** • **Shipping Records of IP to Site –** *If available* *Note: These receipts are generally located within the participating Site Pharmacy folder.* *Note: In the Comments column of the SIF Table of Contents write "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located in Central or Site Pharmacy folder."*
22.3	Documentation of IP Dispensing, Accountability and Inventory i.e. - Drug Accountability Logs	**Documents to be filed in this Section include:** • **Site-Specific Bulk Drug Accountability Log –** current and superseded • **Site-Specific Individual Drug Accountability Log –** current and superseded *Note: This task is generally located within the Participating Site Pharmacy folder.*

		Note: In the Comments column of the SIF Table of Contents write "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located in Central or Site Pharmacy folder."
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 MaintenanceLogs, etc. *Note: This documentation is generally located within the Participating Site Pharmacy folder.* *Note: In the Comments column of the SIF Table of Contents write "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located in Central or Site Pharmacy folder."*
22.5	Documentation of IP: - Quarantines - Returns - Destructions/Drug Destruction Form	**Documents to be filed in this Section include:** • **Any site-specific IP Deviations at Site (i.e. temperature excursions, IP complaints, IP quarantines) and associated forms** – completed and signed by the site • **Copy of the Drug Company's Assessment on the affected IP and their continued usage decision, if available** • **Any IP Returns, Drug destruction forms and/or other associated forms relating to any unused IP at the end of the study–** completed and signed by the site *Note: This documentation is generally located within the Participating Site Pharmacy Forms. The required forms for completion are generally provided by the Drug Company providing the IP.* *Note: In the Comments column of the SIF Table of Contents write "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located in Central or Site Pharmacy folder."*
22.6	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to the Investigational Product/s.**