Investigator Site File – Table of Contents Document Filing Guideline

Section	Contents *Template Index page*	Document Filing Guideline / Available Templates
1.0	**Participating Site Team**	
1.1	Contact List	**Documents to be filed in this Section include:** • **Site Contact List –** current and superseded *Note: Include all key Site Research Team Staff, i.e. Provide Name, Role, Phone and Email for the PI, Sub-Is/AIs, SC, Research Nurse and other key team staff, e.g. Data Manager, Pharmacist, Laboratory Manager.* *Note: Ensure the first page is stamped with 'Superseded' when filing superseded documents.*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 and signed by all site staff assigned/involved with the study 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** TEMPLATE Investigator Short CV • **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	*This section is deliberately left blank as it is maintained by the Sponsor-Investigator/CPI and not used by sites. This section should not contain any files.*	
2.2	Team Communication • Include meeting minutes, emails, significant correspondence	**Documents to be filed in this Section include:** • **Copies of meeting minutes, emails, etc** • **All other significant correspondence.**
3.0	**Protocol/Protocol Amendments**	
3.1	Site Protocol Version Tracker	**Documents to be filed in this Section include:** • **Site Protocol Version Tracker -** to be completed and maintained by the Site Study Coordinator/Research Nurse to track the history of current approved protocol versions and any 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.
3.2	Current HREC Approved Study Protocol signed by PI	**Documents to be filed in this Section include:** • **Study Protocol –** current HREC/IRB and RGO (or equivalent) approved and signed Final Protocol • **Signed Protocol Signature Pages –** signed by Site Principal Investigator and Sponsor.
3.3	Superseded Study Protocols signed by PI	**Documents to be filed in this Section include:** • **Superseded Protocol versions with signed Signature Pages** *Note: Ensure the first page is stamped with 'Superseded' when filing superseded documents.*

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**
3.5	Non-Compliance Reports - Deviations from GCP or the protocol	**Documents to be filed in this Section include:** • **Non-Compliance Report Forms** – completed and signed by Site Principal Investigator
3.6	Local Serious Breaches and CAPA Documents	**Documents to be filed in this Section include:** • **Site-Specific Corrective and Preventive Action Plans –** to be completed and signed by Site Principal Investigator and submitted to the Sponsor for review, detailing any corrective and preventative action to be taken in addressing the serious breach encountered at 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 encounted at site. • **Site-Specific CAPA Tracking Log** – maintained by site Study 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 Tracker	**Documents to be filed in this Section include:** • **Site-Specific PGICF & PICF Version Trackers -** to be completed and maintained by the Site Study Coordinator/Research Nurse 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 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) *Note: Completed and signed PGICFs and PICFs are to be filed in the participant shadow files.*	**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;**
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	Site PGICF & PICFs - Superseded Site Authorised Version(s)	**Documents to be filed in this Section include:** • **Superseded copies of 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** e.g. advertisements, participant diaries, telephone scripts, GP letters, templates, participant newsletters, cards and questionnaires (eg, QoL), as applicable to study.
4.6	Signed PGICF & PICFs - Both the information sheet and consent form	**Documents to be filed in this Section include:** • **Signed and dated PGICF & PICFs** *Note: 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/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	*This section is deliberately left blank as it is maintained by the Sponsor-Investigator/CPI and not used by sites. This section should not contain any files.*	
6.0	**Ethics Committee (EC)/Human Research Ethics Committee (HREC)/Institutional Review Board (IRB)/Review Ethics Board (REB)**	
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 Documents - 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 ISF relevant to this communication.*
6.4	Interim / Annual / Final Reports to Ethics Committee and Committee Acknowledgements of Receipt *Note: Safety Reports to HREC/RGO are to be filed in Section 14.3*	**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** • **Acknowledgment 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** • **Acknowledgment 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	**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** • **Acknowledgment 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** • **Acknowledgment 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	**Study-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 • **Site-Specific trial related SOPs** – current version.
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: - Site Initiation Booking Confirmation - Agenda - Site Initiation Presentation - Attendance Log	**Documents to be filed in this Section include:** • **Essential Documents Required from Sites Request Letter** • **Site Initiation Booking Confirmation Letter** • **Site Initiation Agenda** • **Site-Specific Site Initiation Presentation slide set –** Site-Specific version of site initiation presentation/slide set. • **Site Initiation Attendance Log** – completed by all who attended the Site Initiation Meeting and signed by the site Principal Investigator**.**
9.2	Site Initiation Follow Up Letter	**Documents to be filed in this Section include:** • **Site Initiation Follow-Up Letter to Site**
9.3	Site Activation Documentation/Letter	**Documents to be filed in this Section include:** • **Official Notification of Site Activation Letter**

10.0	**Site Training**	
10.1	Investigator Meetings	**Documents to be filed in this Section include:** • **Investigator Meeting Presentation slide set, if applicable** • **Investigator Meeting Attendance Log** – completed and signed by all attendees.
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. *Note: SIV presentation should be filed in section 9.1.*
10.3	Site-Specific Training Log	**Documents to be filed in this Section include:** • **Site Staff Training Logs (both individual and study team) -** 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, as 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 by the Sponsor.**
11.0	**Participant Recruitment**	
11.1	Pre-Screening Log	**Documents to be filed in this Section include:** • **Site-Specific Pre-Screening Log –** current and superseded**.**
11.2	Consent, Screening & Enrolment Log Template	**Documents to be filed in this Section include:** • **Site-Specific Consent, Screening & Enrolment Log –** current and superseded.
11.3	Participant ID Log	**Documents to be filed in this Section include:** • **Site-Specific Participant Registration Log –** current and superseded.
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	Randomisation / Registration User Manual, if applicable	**Documents to be filed in this Section include:** • **Copy of trial specific participant Randomisation or Registration user manual –** current and superseded.
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, to and from the Sponsor.**
13.0	**Data Management – Forms & Procedures**	
13.1	Blank Paper CRF – current and superseded (if applicable)	**Documents to be filed in this Section include:** • **Paper CRF (file for printing) –** current version • **Paper CRF (file for printing) –** superseded **version** *Note: Completed CRFs are considered part of the ISF but must be filed separately from the ISF.*
13.2	CRF Completion Guidelines	**Documents to be filed in this Section include:** • **CRF Completion Guidelines** – current version • **CRF Completion Guidelines** – superseded versions.
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	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.

13.5	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to data management to and from the Sponsor.**
14.0	**Safety Monitoring & Reporting** *Note: Non-Australian sites may customise this section*	
14.1	Blank Expedited Safety Report Form - Current and superseded versions	**Documents to be filed in this Section include:** - **Copy of blank Expedited Safety (SAE) Report Form** – current and superseded - **Copy of blank Expedited Safety (SAE) Report Cover Sheet** – current and superseded - **Copy of Expedited Safety (SAE) Report Completion Instructions** – current and superseded - **Expedited Pregnancy Coversheet** – current and superseded *(for drug trials, if applicable)* - **Expedited Pregnancy Report Form** – current and superseded *(for drug trials, if applicable)* - **Expedited Pregnancy Reporting Instructions** – current and superseded *(for drug trials, if applicable)*
14.2	Reference Safety Information i.e. Investigator Brochure, Product Information etc - Current and Superseded	**Documents to be filed in this Section include:** • **Reference Safety Information** – current and superseded. • **IB Version Tracker**
14.3	Copy of Completed Expedited Safety Report Forms and associated correspondence sent to Sponsor-Investigator/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.
14.4	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 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 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	This section is deliberately left blank as it is maintained by the Sponsor-Investigator/CPI and not used by sites. This section should not contain any files.	
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	This section is deliberately left blank as it is maintained by the Sponsor-Investigator/CPI and not used by sites. This section should not contain any files.	
15.4	Monitoring Visit Correspondence including feedback to site including Correspondence	**Documents to be filed in this Section include:** • **Monitoring Visit Confirmation Letters** • **Monitoring Visit Follow Up Letters**
15.5	Trial Close-Out - Including Correspondence	**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 Research Governance - Copy of all Audit Reports - Copy of all Related 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: - Copy of all Reports - Copy of all 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	Research Sample Lab Manual - If applicable	**Documents to be filed in this Section include:** • **Copy of the trial-specific Research Sample Lab Manual** – current and superseded.
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, or equivalent.
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: The Biospecimen Log is updated by the site Study Coordinator/Research Nurse each time a sample is collected, processed and stored as per protocol requirements.*
16.5	Biospecimen Shipment Receipt Tracking	**Documents to be filed in this Section include:** • **Copies of courier shipping documents, invoices, receipts, custom declarations, consignment notes, import permits from site to the Central Laboratory and/or Sponsor.**
16.6	Biospecimen Storage Monitoring Documentation - If applicable	**Documents to be filed in this Section include:** • **Any site-specific documentation relating to the monitoring of biospecimen storage at site** i.e. Freezer Temperature Logs, Liquid Nitrogen Monitoring Logs etc.
16.7	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to the storage of Biospecimen Research aspects of the study, from the site to the Sponsor.**
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); e.g: - Paper CRF - Paper Diaries - Blood Collection Tubes	• **Any receipts of study supplies to 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 –** fully executed.
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 Agreements (DSA)** • **Insurance/Indemnity, as applicable** • **Expressions of Interest (EoI)**
18.3	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to any Agreements pertaining to the study, to and from the Sponsor.**
19.0	**Finance Documentation**	
19.1	Invoices/Receipts	**Documents to be filed in this Section include:** • **Copies of relevant Site-Specific invoices and receipts pertaining to the study, including requests for Per Patient Payments (PPP) made to the Sponsor.**
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 the Sponsor.**
20.0	**Other Communication**	
20.1	Newsletters from Sponsor-Investigator	**Documents to be filed in this Section include:** • **Copies of Newsletters received from the Sponsor to Participating sites.**
20.2	Other General Correspondence	**Documents to be filed in this Section include:** • **Other significant general correspondence received from the Sponsor.**
21.0	**Archiving**	
21.1	Archiving Details	**Documents to be filed in this Section include:**

		• **Investigator Agreement to Archive Trial Documents Form** – completed and signed by Site Investigator and Sponsor.
21.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regarding trial archiving to and from the Sponsor.**
22.0	**Investigational Product *(Drug/Device Trials Only)***	
22.1	Instructions for handling IP and trial related materials - e.g. Pharmacy Manual	**Documents to be filed in this Section include:** • **Pharmacy Manual** – current and superseded • **Drug Order Form** – current and superseded
22.2	Documentation of IP Shipment i.e. Drug Receipt - If applicable	**Documents to be filed in this Section include:** • **Shipping Records of IP to Site –**if applicable *Note: These receipts are generally located within the participating Site Pharmacy folder.* *Note: In the Comments column of the ISF Table of Contents write "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located within the 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: Ensure the first page is stamped with 'Superseded' when filing superseded documents.* *Note: These logs are generally located within the Participating Site Pharmacy.* *Note: In the Comments column of the ISF 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 Maintenance Logs, etc.

		Note: In the Comments column of the ISF Table of Contents write "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located within the 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-specifc reporting of 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 folder. The required forms for completion are generally provided by the Drug Company providing the IP.* *Note: In the Comments column of the ISF Table of Contents write "All IMP related activities have been delegated by Sponsor to Central Pharmacy or Site Pharmacy – documents located within the 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, to and from the Sponsor.**