Investigator Site File (ISF)

	Contents	Notes
1.0	**Site Trial Team**	
1.1	Contact List	
1.2	Delegation and Signature Log	
1.3	CVs including copies of Medical Licenses	
1.4	GCP Training Certificates	
1.5	EDC (Electronic Data Capture) Training Certifications	
1.6	Other Training Certificates	
2.0	**Project Management**	
2.1	This section is deliberately left blank	Site Selection Documentation in SIF
2.2	Internal Team Communication	
3.0	**Protocol/Protocol Amendments**	
3.1	Site Protocol Version Tracker	
3.2	Current HREC Approved Study Protocol signed by PI	
3.3	Superseded Study Protocols signed by PI	
3.4	Local Site Non-Compliance Log	
3.5	Non-Compliance Reports	
3.6	Local Serious Breaches and CAPA Documents	
3.7	Copy of all Serious Breach reports to Sponsor and local Research Governance Office or regulatory Authority	
3.8	Related Correspondence	
4.0	**Participant Information & Consent Forms (Site-Specific)**	
4.1	Site-Specific PGICF & PICF Version Trackers	
4.2	Current Site-Specific PGICF & PICFs	
4.3	Other Authorised Site-Specific Participant Information	
4.4	Superseded Site-Specific PGICF & PICFs	
4.5	Other superseded Authorised Site-Specific Participant Information	
4.6	Signed PGICF & PICFs	*Located in participant shadow files.*
5.0	**Regulatory**	
5.1	Current and superseded regulatory Authorisation or Acknowledgement	
5.2	Supplementary FDA Documents	
5.3	This section is deliberately left blank	Site Green Light Approval in SIF
6.0	**Ethics Committee**	
6.1	Ethics Approval Letters (current and superseded)	
6.2	Ethics Submission Documentation (initial and amendments including queries + responses)	
6.3	Ethics Committee Composition, Constitution & Statement of Compliance	
6.4	Interim/Annual / Final Reports to Ethics Committee and Committee Acknowledgements of Receipt	
6.5	Related Correspondence	
7.0	**Local Research Governance Office (RGO)**	

7.1	Governance Authorisation Letters (current and superseded)	
7.2	RGO Submission Documentation (initial and amendments including queries + responses)	
7.3	Annual Project Progress Reports & Final Project Report with Receipt acknowledgements	
7.4	Related Correspondence (to and from local RGO)	
8.0	**Site-Specific Procedures/SOPs**	
8.1	Current Site-Level Manual of Procedures / trial-related Standard Operating Procedures, if applicable	
8.2	Superseded Site-Level Manual of Procedures / trial-related Standard Operating Procedures, if applicable	
9.0	**Site Initiation**	
9.1	Site Initiation Meeting Documentation; including Agenda, attendance log, and Site Initiation presentation	
9.2	Site Initiation Report and Follow Up Letter	
9.3	Site Activation Documentation/Letter	
10.0	**Site Training**	
10.1	Investigator Meetings	
10.2	Other Presentations	
10.3	Trial Specific Training Log	
10.4	Other Training Resources	
11.0	**Participant Recruitment**	
11.1	Pre-Screening Log	
11.2	Consent, Screening & Enrolment Log Template	
11.3	Participant ID Log	
11.4	Related Correspondence	
12.0	**Participant Randomisation / Registration Procedures**	
12.1	Randomisation / Registration User Manual	
12.2	Records of Unblinding (local participants)	
12.3	Related Correspondence	
13.0	**Data Management – Forms & Procedures**	
13.1	Blank Paper CRF – current and superseded (if applicable)	*Completed CRFs are considered part of the ISF but are filed separately*
13.2	CRF Completion Guidelines	
13.3	Completed Electronic Data Capture (EDC) System Account Application Forms	
13.4	Current and Superseded Site Source Document Plan	
13.5	Related Correspondence	
14.0	**Safety Monitoring & Reporting**	
14.1	Current and Superseded Blank Expedited Safety Report Form	
14.2	Current and Superseded Reference Safety Information	
14.3	Copy of Completed Expedited Safety Report Forms (all SAEs, suspected SUSARs and USMs) sent to Sponsor-Investigator	
14.4	Copy of all Safety Reports sent by PI to local Research Governance Office (RGO) or Regulatory Authority	
14.5	On-Site procedure for unblinding in either the case of medical emergency or for safety reporting purposes	

14.6	Related Correspondence	
15.0	**Study Quality Assurance, Monitoring, Audits & Inspections**	
15.1	This section is deliberately left blank	Pre-trial visit reports in SIF
15.2	Site Monitoring Log	
15.3	This section is deliberately left blank	Site Monitoring reports in SIF
15.4	Monitoring Correspondence including Feedback to Site	
15.5	Trial Close-Out Report & correspondence	
15.6	Local Research Governance audit reports and correspondence	
15.7	Regulatory Inspections reports and correspondence	
16.0	**Local Laboratory Documentation**	
16.1	Research Sample Lab Manual	
16.2	Local Lab Certificates of Accreditation	
16.3	Normal Local Lab Reference Ranges	
16.4	Biospecimen Log	
16.5	Biospecimen Shipment Receipt Tracking	
16.6	Biospecimen Storage Monitoring Documentation	
16.7	Related Correspondence	
17.0	**Supplies/Shipping Records**	
17.1	Documentation relating to provision of Study Supplies (excluding Investigational Product/Medical Devices)	
18.0	**Legal Documentation**	
18.1	Fully Executed Clinical Trial Agreement	
18.2	Other Agreements as applicable	
18.3	Related Correspondence	
19.0	**Finance Documentation**	
19.1	Invoices/Receipts	
19.2	Related Correspondence	
20.0	**Other Communication**	
20.1	Newsletters from Sponsor-Investigator	
20.2	Other General Correspondence	
21.0	**Archiving**	
21.1	Archiving Details	
21.2	Related Correspondence	
22.0	**Investigational Product**	
22.1	Instructions for handling IP and trial related materials	
22.2	Documentation of IP Shipment / Receipt i.e. Drug Receipt	*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	*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	*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, & Destruction	*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	