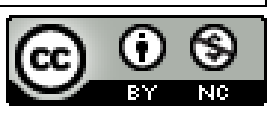
Site Information File (SIF)

	Contents	Notes
1.0	**Site Trial Team**	
1.1	Contact List	
1.2	Delegation and Signature Log	
1.3	CVs & 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	Site Selection Documentation	
2.2	Internal Team Communication	
3.0	**Protocol/Protocol Amendments**	
3.1	Site Protocol Version Tracker	
3.2	Signed Protocol Signature Page / Investigator Agreement Page - Current	*The full protocol is not filed here - in section 3.2 of the TMF.*
3.3	Superseded Signed Protocol Signature Page	*The full superseded protocol(s) is not filed here - in section 3.3 of the TMF.*
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4.4	Superseded Site-Specific PGICF & PICFs	
4.5	Other superseded Authorised Site-Specific Participant Information	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	This section is deliberately left blank	Signed PGICF & PICF in ISF
5.0	**Regulatory**	
5.1	Current and superseded regulatory Authorisation or Acknowledgement	
5.2	Supplementary FDA Documents	
5.3	Site Green Light Approval Form	
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6.1	Ethics Approval Letters (current and superseded)	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7.1	Governance Authorisation Letters (current and superseded)	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	This section is deliberately left blank	Pre-Screening Log in ISF
11.2	Consent, Screening & Enrolment Log Template	*At the end of accrual, completed and anonymised Consent, Screening & Enrolment logs will be moved to Section 10.2 of the TMF.*
11.3	This section is deliberately left blank	Participant ID Log in ISF
11.4	Related Correspondence	
12.0	**Participant Randomisation / Registration Procedures**	
12.1	This section is deliberately left blank	Randomisation / Registration user manual in ISF
12.2	Records of Unblinding (local participants)	
12.3	Related Correspondence	
13.0	**Data Management – Forms & Procedures**	
13.1	This section is deliberately left blank	Blank Paper CRF in TMF
13.2	This section is deliberately left blank	CRF completion guidelines in TMF
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	This section is deliberately left blank	Expedited Safety Report Form in TMF
14.2	This section is deliberately left blank	Reference Safety Information in TMF
14.3	Copy of Completed Expedited Safety Report Forms (all SAEs, suspected SUSARs and USMs) sent to Sponsor-Investigator	*All Expedited Safety (SAE) Report forms received from Participating Sites will be filed separately throughout study conduct and moved to 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	
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	Pre-Trial Visit Reports, Attendance and Correspondence	
15.2	Site Monitoring Log	
15.3	Monitoring Visit Reports and Remote Monitoring Reports	
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	This section is deliberately left blank	Research Sample Lab Manual in TMF
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	This section is deliberately left blank	Instructions for handling IP and Trial related material in TMF
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	