INVESTIGATOR SITE FILE – TABLE OF CONTENTS

Protocol No :

Protocol Title :

Principal Investigator :

Site Name :

SECTION	CONTENTS	Present in ISF (Tick Box)	Record NA or if not filed in ISF, state alternative location
1	**Contact Details**		
1.1	Contact details of site staff	☐	
1.2	Contact details of external vendors	☐	
2	**Investigator's Brochure/ Package Insert**		
2.1	Current Version	☐	
2.2	All Previous Submitted Versions and Updates	☐	
3	**Study Protocol and Amendment**		
3.1	Current Approved Version	☐	
3.2	All Previous Approved Versions	☐	
3.3	Protocol Signature Page(s)	☐	
4	**Informed Consent Form**		
4.1	Current Approved Version (including all applicable translations)	☐	
4.2	All Previous Approved Versions (including all applicable translations)	☐	
4.3	Translation Certificates (if applicable)	☐	
4.4	Signed Informed Consent Forms	☐	
4.5	Signed Informed Consent Tracking Log	☐	

SECTION	CONTENTS	Present in ISF (Tick Box)	Record NA or if not filed in ISF, state alternative location
5	**Any Other Written Information Provided to Subjects**		
5.1	***Patient Card/ Patient Diary/ Questionnaires (if applicable)***	☐	
5.1.1	Current Approved Version (including all applicable translations)	☐	
5.1.2	All Previous Approved Versions (including all applicable translations)	☐	
5.1.3	Translation Certificates (if applicable)	☐	
6	**Advertisement for Subject Recruitment**		
6.1	Current Approved Version (including all applicable translations)	☐	
6.2	All Previous Approved Versions (including all applicable translations)	☐	
6.3	Translation Certificates (if applicable)	☐	
7	**Case Report Form (CRF)**		
7.1	Current CRF Version (Blank Sample)	☐	
7.2	Previous CRF Version (Blank Sample)	☐	
7.3	CRF Completion Guidelines	☐	
7.4	Signed, dated and completed CRFs	☐	
7.5	Documentation of CRF Corrections	☐	
8	**Source Documents**	☐	
9	**Institutional Review Board (IRB)**		
9.1	All Submission and Approval Documents e.g. - Investigator's Brochure and updates - Protocol and subsequent amendments - ICF and subsequent amendments	☐	

SECTION	CONTENTS	Present in ISF (Tick Box)	Record NA or if not filed in ISF, state alternative location
	- Any Other Written Information Provided to Subjects - Advertisement - CRF (if applicable)		
9.2	Progress Reports to the IRB	☐	
9.3	IRB Composition	☐	
9.4	Notification of Safety Reports to IRB	☐	
9.5	Notification of Non-compliance to IRB	☐	
9.6	Correspondences with IRB	☐	
10	**Health Sciences Authority (HSA)**		
10.1	All Submission and Approval Documents e.g. - Investigator's Brochure and updates - Protocol and subsequent amendments - ICF and subsequent amendments	☐	
10.2	Trial Status Reports to HSA	☐	
10.3	Clinical Trial Material (CTM) Import Permit (for medicinal products and devices)	☐	
10.4	Notification of Expedited Safety Reports to HSA	☐	
10.5	Notification of Serious Breaches to protocol and/or SGGCP to HSA	☐	
10.6	Correspondences with HSA	☐	
11	**Study Personnel**		
11.1	Signature Sheet	☐	
11.2	Curriculum Vitae of All Study Personnel (including CITI / GCP / Medical Licensure, where applicable)	☐	
11.3	Training Log/ Documentation	☐	
12	**Financial Matters**		
12.1	Signed Confidentiality Agreement	☐	

SECTION	CONTENTS	Present in ISF (Tick Box)	Record NA or if not filed in ISF, state alternative location
12.2	Signed Clinical Trial Agreement	☐	
12.3	Any Other Relevant Agreement/ Contracts	☐	
12.4	Insurance Certificate	☐	
13	**Subject Logs**		
13.1	Subject Screening Log	☐	
13.2	Subject Enrolment Log	☐	
13.3	Subject Identification Log	☐	
13.4	Subject Visit Tracking Log	☐	
14	**Investigational Product (IP)**		
14.1	Instructions for Handling of IP (if not included in protocol or IB)	☐	
14.2	IP Shipping and Receipt Records (including Certificate (s) of Analysis of IP shipped)	☐	
14.3	IP Dispensing and Accountability Logs	☐	
14.4	IP Destruction Documentation	☐	
14.5	IP Storage Temperature Logs	☐	
15	**Randomization**		
15.1	Decoding Procedures for blinded	☐	
16	**Monitoring**		
16.1	Site Visit Log	☐	
16.2	Visit Correspondences (e.g. visit confirmation/ follow up letters)	☐	
17	**Laboratory**		
17.1	Normal values / ranges for Medical / Laboratory / Technical	☐	

SECTION	CONTENTS	Present in ISF (Tick Box)	Record NA or if not filed in ISF, state alternative location
	procedures and/or Tests included in the protocol		
17.2	Certification / Accreditation / Established Quality Control / External Quality Assessment / Other Validation for Medical / Laboratory / Technical Procedures / Tests	☐	
18	**Biological Samples**		
18.1	Biological Sample Handling Log	☐	
18.2	Biological Sample Handling Manual	☐	
18.3	Biological Samples Shipping Records	☐	
18.4	Biological Samples Destruction/ Return Records	☐	
19	**Safety Reports**		
19.1	Serious Adverse Event (SAE) Tracking Log	☐	
19.2	SAE Reports Submitted to Sponsor	☐	
19.3	Expedited Safety Reports (e.g. CIOMS Reports)	☐	
20	**Study Reports/ Publications**		
20.1	Interim Report/ DSMB Reports	☐	
20.2	Final Clinical Study Report	☐	
20.3	Relevant Study Publications/ References	☐	
21	**Study Meetings**		
21.1	Investigator Meeting (e.g. Agenda, Presentations, Attendance List)	☐	
21.2	Site Initiation Visit (e.g. Agenda, Presentations, Attendance List, Report)	☐	
21.3	Other Relevant Meeting Documentation	☐	
22	**Correspondences**		
22.1	Relevant Correspondences with Sponsor	☐	

SECTION	CONTENTS	Present in ISF (Tick Box)	Record NA or if not filed in ISF, state alternative location
22.2	Relevant Correspondences with Site Staff	☐	
22.3	Relevant Correspondences with Central Lab/ Vendors	☐	
22.4	Any Other Relevant Correspondences	☐	
23	**Miscellaneous**	☐	