Guideline number	**57.011A**	Version	**2.0**
Title	**Investigator Site File (ISF)**		

The maintenance of an Investigator Site File (ISF) is necessary for effective management of research studies during start-up, throughout the conduct and after the study is complete, demonstrating compliance with protocol, Good Clinical Practice (GCP) and regulations.

The Principal Investigator (PI) is responsible for set-up, maintenance, storage and archive of the ISF. This duty may be delegated to another member of the study team and recorded in the Delegation Log.

It is important to maintain essential documents for each research study for quality check, monitoring, audit and regulatory inspection purposes. Sponsor may provide an ISF, if not provided use index detailed in Appendix 1 of this guide.

Procedure

1. The ISF should be set-up following the relevant index, filing all documents in corresponding dividers.
2. All documents should be filed promptly and in descending order of version or date.
3. ISF should be reviewed regularly by the study team to ensure the contents are up-to-date.
4. The ISF may be subject to regular monitoring and audit by Sponsor and GCRF Internal Audit Pool.
5. The ISF should be stored in a securely although easily accessed by the study team.
6. If any documents are filed separately from the ISF, this should be recorded by a file note detailing where such documents are filed (pharmacy, laboratory and participant research record).
7. There may be several volumes of an ISF; each file must be labelled numerically indicating the total number of files i.e. 1 of 5.
8. All relevant study correspondence should be retained, however this may be stored electronically and a File Note will detail the location.
9. R&I Permission must be granted before a new version of a document can be implemented, follow GUI 57.011B Study Amendments when new version of document received. Superseded documents must be maintained and stored within the ISF; the document must be clearly marked superseded with the implementation date of the new version.
10. GUI 57.005B GCRF Archiving Process must be followed once the study is complete.

Appendix 1 – Investigator Site File Index

Study Title			
R&D Number		**PI**	

1	**Protocol**	**Yes**	**N/A**
1.1	Current Signed Approved Protocol		
2	**Approved Supporting Documents**	**Yes**	**N/A**
2.1	Current Approved Participant Information Sheet (PIS)		
2.2	Current Approved Consent Form (CF)		
2.3	Current Approved GP Letter		
2.4	Questionnaires		
3	**Original Approvals**	**Yes**	**N/A**
3.1	REC Application & Approval Letters		
3.2	CTA Application & Regulatory Authorisation Letters (MHRA etc.)		
3.3	R&I Application (OID and Appendix) & Local R&I Approval Letter		
3.4	Site Initiation Report		
3.5	Regulatory Green Light Letters		
4	**Amendments**	**Yes**	**N/A**
4.1	Amendments listed by number with most recent at front		
5	**Pharmacy Documents**		
5.1	Investigators Brochure (IB)		
5.2	Summary of Product Characteristics (SmPC)		
5.3	Prescription		
5.4	Pharmacy working documents		
6	**Safety Reporting (File note relevant for documents stored in separate Safety File)**	**Yes**	**N/A**
6.1	Procedures for adverse event management and reporting		
6.2	Procedures for 24 hours medical cover and unblinding/code break		
6.3	Adverse Event Log		
6.4	Serious Adverse Event Reports		
6.5	Adverse Events Reports		
6.6	SUSAR Reports		
6.7	Urgent Safety Measures		
6.8	Notification of Safety Information		
7	**Working Documents**	**Yes**	**N/A**
7.1	Final Version of Case Report Form (CRF)		
7.2	Instructions for Completion of CRF		
7.3	Source Document Agreement		
7.5	Data Queries		
7.6	Any other working documents		
8	**Study Team**	**Yes**	**N/A**
8.1	Delegation Log		
8.2	Study Team Signed CVs		
8.3	Study Team GCP Certificates		
8.4	Study Team Training Log		
9	**Monitoring, Audit, Inspection**	**Yes**	**N/A**

9.1	Monitoring Plan		
9.2	Monitoring Visit Log		
9.3	Monitoring, Audit, Inspection Reports		
10	**Contracts/ Finance**	**Yes**	**N/A**
10.1	Signed Clinical Trial Agreement		
10.2	Insurance and Indemnity documents		
10.3	Costing templates		
11	**Laboratory and Equipment**	**Yes**	**N/A**
11.1	Sample Handling and Storage Instructions		
11.2	Local and Central Lab Services		
11.3	Local Lab Reference Ranges		
11.4	Local Lab Accreditation Certificate		
11.5	Sample Shipment Records		
11.6	Log of Retained Samples		
11.7	Temperature Logs		
12	**File Notes**	**Yes**	**N/A**

Guideline signatories

Prepared by Signature	Eilidh Wright Date
Approved by Signature	Lynn Prentice Date

Document history

Version	Date	Description
1.0	22/06/2018	First release
2.0	24/11/2023	Update to GCTU Guideline template v1.0 Minor changes to ISF index