Electronic Investigator Site File (eISF) Filing Index for Commercially Sponsored Trials

General Guidance

- Sections can be added as appropriate according to design of the trial, but ensure the numbering remains in sequential order
- Should a document or section be filed separate from the main ISF or in another section from what is stipulated in the index, the location of the document (e.g. Clinical Trial Pharmacy, participant binder – hard copy) should be entered in the 'Content/Comments' column.
- If a document is not applicable to the trial, please enter 'NA' in the "Content/Comments" column.
- Some sections should be sub-divided to ease filing.
- Documents relating to an amendment should be filed together. Each amendment should be clearly labelled.
- Correspondence and version-controlled documents must be filed in chronological order with the most recent on top.
- Completed participants' CRFs are considered part of the ISF but must be filed separately from the ISF.

Study Name:	
PI Name:	
Site Code/Number: *(If applicable)*	

Section	Folder/Sub-Folder Name	Content/Comments
00.	**To be Filed**	
1.0	**Contacts**	
1.1	Sponsor, CRO and Vendor contact details	
2.0	**Investigators Brochure**	
2.1	Approved IB	
2.2	IB Signature Pages	
2.3	IB Version Tracker	
3.0	**Protocol and Amendments**	
3.1	Approved Protocol	**Documents to be filed in this section include:** • **Protocol administrative change letters**
3.2	Protocol Signature Pages	
3.3	Protocol Version Tracker	
3.4	Protocol Deviation Log	
4.0	**Informed Consent Forms and Patient Materials**	
4.1	Approved Master ICFs	
4.2	Approved Site ICFs	
4.3	ICF Version Tracker	

Section	Folder/Sub-Folder Name	Content/Comments
4.4	Approved Patient Materials	
5.0	**Agreements**	
5.1	Clinical Trial Research Agreements	
5.2	Indemnity and Insurance Certificates	
5.3	Confidentiality Agreements	
5.4	CTRA Version Tracker	
5.5	Investigator Agreement	**Include FDA 1572**
6.0	**HREC and Governance**	
6.1	Submission Documents	
6.2	Approval Letters	
6.3	Correspondence	
6.4	Breaches and Waivers	
6.5	HREC Membership list	
6.6	Annual & interim Reports	
6.7	Final Report & Publication	
7.0	**TGA Documentation**	
7.1	CTN or CTX forms	

Section	Folder/Sub-Folder Name	Content/Comments
7.2	TGA Acknowledgement and correspondence	
8.0	**Site Personnel Documentation**	
8.1	Delegation of Responsibilities Log	
8.2	Wet Ink Signature Pages/Wet Ink Signature Log	
8.3	CV, GCP, Medical Licence	**Documents to be filed in this section include:** • **APHRA Registration**
8.4	Site Personnel Training Records & Certificates	**Documents to be filed in this section include:** • **IATA/CAAA Certificates**
8.5	Financial Disclosure & Data Privacy Forms	
8.6	Training Materials	**Documents to be filed in this section include:** • **IM materials** • **SIV slides** • **Protocol amendment training materials**
9.0	**Laboratory**	
9.1	Normal Values & Reference Ranges	**Documents to be filed in this section include:** • **Local reference ranges** • **Central reference ranges**
9.2	Laboratory Accreditation	
9.3	Laboratory Manual of Procedures	

Section	Folder/Sub-Folder Name	Content/Comments
9.4	Temperature Logs & Service Reports	**Documents to be filed in this section include:** • **MCRU (& MCRI backup assets)**
10.0	**Pharmacy**	
10.1	Pharmacy Manual	
10.2	Other	
11.0	**Supporting Departments and Vendors**	
11.1	Supporting Department Declarations	**Documents to be filed in this section include:** • **Agreements with external vendors** • **SD performs –** e.g. RCH cardiology
11.2	Vendor Manuals	**Documents to be filed in this section include:** • **DTP**
11.3	Calibration Certificates & Service Reports	
12.0	**Monitoring**	
12.1	Site Initiation & Closure Documentation	**Documents to be filed in this section include:** • **Site activation letter** • **Site closure**
12.2	Monitor Visit Log	
12.3	Monitor Visit Letters and Reports	
12.4	Monitor Training & Certification	**For example Florence HC training**

Section	Folder/Sub-Folder Name	Content/Comments
13.0	**Case Reports Forms (CRFs)**	
13.1	Completed CRFs and EDC	
13.2	Blank CRF	
13.3	CRF Guidelines	
13.4	Source Data Location Form	
14.0	**Serious Adverse Event (SAE) and Safety Reports**	
14.1	SAE Reporting Guidelines	
14.2	Blank SAE Report Forms	
14.3	Safety Reports	**Documents to be filed in this section include:** • **DSMB** • **SUSARs**
15.0	**Quality Assurance**	
15.1	Audit/Inspection Documents	**Documents to be filed in this section include:** • **Auditor/Inspector visit Logs** • **Auditor/Inspector visit reports**
15.2	Corrective and Preventative Action plans (CAPAs)	
16.0	**Participant Logs**	

Section	Folder/Sub-Folder Name	Content/Comments
16.1	Pre-screening Log	
16.2	Screening Log	
16.3	Enrolment log	
16.4	Identification Log	* Remains at site level in paper ISF/Archived in sealed envelope. SC will need a NTF to explain.
16.5	Subject Level Informed Consent Log	**Details captured by this log should maintain consent/reconsent versions and dates.**
17.0	**Correspondence**	
17.1	Sponsor & CRO Correspondence	
17.2	Vendor Correspondence	**Documents to be filed in this section include:** • **Central lab** • **EDC** • **IWRS** • **ePRO providers**
17.3	Newsletters	**Documents to be filed in this section include:** • **Memo**
17.4	Site Correspondence	**Documents to be filed in this section include:** • **Supporting departments** • **Study team**
17.5	Audit Correspondence	
18.0	**Finance**	

Section	Folder/Sub-Folder Name	Content/Comments
18.1	Invoices	