ECTU Central Office SOP_TM_20: Provision of Investigator Site Files (ISF) to Study Sites

Version No:	3.0
Issue Date:	03 Dec 2024
Effective Date:	18 Dec 2024

Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval/ Authorisation	Date	Signature
Morag MacLean, Senior Trial Manager	Author	03-Dec-2024	Morag MacLean
Raza Hayat, Trial Management Support Officer	Reviewer	03-Dec-2024	Raza Hayat Raza Hayat (Dec 3, 2024 11:26 GMT)
Gina Cranswick, Trial Management Team Lead	Approver	02-Dec-2024	Gina Cranswick Gina Cranswick (Dec 2, 2024 15:49 GMT)
Tanya Tharakan, QA Manager	QA Authorisation	03-Dec-2024	Tanya Tharakan Tanya Tharakan (Dec 3, 2024 12:18 GMT)

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	16 Dec 2020	Initial creation
2.0	22 Nov 2022	SOP has been transferred to current SOP template. Reviewer has been updated to require only one reviewer. Responsibilities section has now been included.
3.0	18 Dec 2024	Updated sections 4.1.3, 4.1.5, 4.4.4 (moved from section 4.1), 4.4.5 Other minor amendments throughout

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for creating and sending Investigator Site Files (ISFs) to sites and confirmation of their receipt.

2.0 SCOPE

This SOP applies to all studies for which the ECTU trial management team are responsible for provision of ISFs to sites. This is relevant for all parts of the ISF, including where applicable files held by Pharmacy, Labs, Imaging and other support services at sites.

3.0 RESPONSIBILITIES

3.1 The Trial Manager or designee will be responsible for

- setting up the initial ISF, including a table of contents, when delegated this task in the co-sponsorship/site agreement
- ensuring an ISF is provided to the site before the SIV, and documenting when the site receives the files
- informing the sponsor of any sites not maintaining a printed version of the ISF

3.2 The PI is responsible for ensuring an ISF is maintained at the site and archived at the end of the study.

3.3 The site staff are responsible for confirming receipt of the ISF and documenting the updates received.

4.0 PROCEDURE

4.1 General Guidelines

4.1.1 The Principal Investigator (PI) is responsible for ensuring an ISF is established prior to the start of a study at their site and updating the file with relevant and applicable documents as the study progresses. The PI is also responsible for archiving the ISF at the end of the study, unless specified otherwise in the site agreement.

4.1.2 The ECTU Trial Manager, or delegate, will set up the initial ISF when delegated this task in the co-sponsorship/site agreement.

4.1.3 The Trial Manager, or delegate, will prepare a table of contents by customising the appropriate ISF Table of Contents Template word document. The Table of Contents provides the structure of the ISF and details which types of documents are to be filed in each section. At the time of ISF provision, some sections of the ISF may be empty but will be included in the Table of Contents to inform the sites where to file future documentation. See section 5.0 for the different types of templates that are available based on non-CTIMP(TM001) and CTIMP(TM002) studies.

4.1.4 The Trial Manager, or delegate, will prepare a customised Table of Contents for any other files sent to a site, e.g. pharmacy file, lab file, imaging file, working folders.

4.1.5 The Table of Contents does not list every document filed or include versions or dates. This level of detailed information is documented in the Excel TM-T2 TMF ISF Index, from which the Trial Manager, or delegate, can extract a site-specific list of all documents that are filed, or should be filed, in an ISF. The Trial Manager, or delegate, will provide sites with detailed ISF indices as appropriate. All documents included in the ISF initially sent to a site will be listed in the ISF receipt.

4.1.6 For trials that will be monitored by the sponsor: the Trial Manager, or delegate, will agree the ISF content and any risk adaption for filing with the monitor.

4.1.7 Prior to opening a site the Trial Manager, or delegate, will provide the site with the ISF, the table of contents and, if applicable, files for supporting services.

4.1.8 The SIV report will document when a site has been sent an ISF electronically, rather than in paper format.

4.1.9 The site will be responsible for maintaining the ISF and filing new documents as the study progresses.

4.2 Provision of ISF in paper format

4.2.1 For sites which will be provided with a paper ISF, a ring binder(s) containing the ISF in paper format will be reviewed by the Trial Manager, or delegate.

4.2.2 The initial table of contents (TM001 or TM002) will be printed and filed at the front of the ISF.

4.2.3 The ISF will be posted to the site ahead of the SIV, if possible. Alternatively, if an SIV is being conducted in person the ISF can be delivered to the site during the visit.

4.3 Provision of ISF in electronic format

4.3.1 For sites who will print their own ISF, the Trial Manager, or delegate, will create an electronic folder structure copying the ISF table of contents. All the initial ISF documents will be filed electronically in these folders.

4.3.2 The initial table of contents (TM001 or TM002) will be filed electronically in section 0.1.

4.3.3 The Trial Manager, or delegate, will send the electronic ISF to the site either by email or with an electronic file sharing platform (e.g. SharePoint). The date the files were sent will be documented in the SIV report.

4.3.4 The site will be asked to print out the electronic files and confirm on the ISF receipt when this has been done. The Trial Manager, or delegate, will inform the sponsor if any site confirms they are not maintaining a printed version of the ISF.

4.4 Receipt of ISF

4.4.1 The Trial Manager, or delegate, will customise the TM003 ISF Receipt template and send to the site with the ISF. The date and version of the documents will be listed in the ISF receipt form.

4.4.2 The site will confirm that the ISF has been received and checked by completing and returning the ISF receipt to ECTU.

4.4.3 The completed ISF receipt will be filed in the TMF section 7.3 Monitoring Reports, along with other SIV documentation.

4.4.4 If there are any updates to the ISF during the study the trial manager, or delegate, will send the site the new or amended documentation. The initial table of contents (TM001/TM002) is not updated. The TM-T2 TMF ISF Index is updated when a new document(s) is sent to a site.

4.4.5 The site will acknowledge receipt of documents sent subsequently by completing and returning a document or amendment receipt (TM004 - Document/Amendment Receipt Template), or by confirming by email which documents have been received. The document or amendment receipt or the confirmatory email will be filed in the appropriate section of the TMF.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ACCORD Website

- ACCORD SOP CR001 Establishing and Maintaining Investigator Site Files, Trial Master Files and Sponsor Files

ECTU Website

- ECTU_SOP_TM_18 Creating and Maintaining a Pharmacy Site File

ECTU Shared Drive

- TM001 - non-CTIMP ISF Table of Contents Template
- TM002 - CTIMP ISF Table of Contents Template
- TM003 - ISF Receipt Template
- TM004 - Document/Amendment Receipt Template
- TM-T2 - TMF ISF Index Template

ECTU_SOP_TM_20 Provision of ISFs to Study Sites v3.0 and associated documents

Final Audit Report 2024-12-03

Created:	2024-12-02 (Greenwich Mean Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAATeXvCXF8bbQz-5U8VhhK4PcF5mPeOs58

"ECTU_SOP_TM_20 Provision of ISFs to Study Sites v3.0 and associated documents" History

Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-12-02 - 15:27:05 GMT- IP address: 192.41.114.230

Document emailed to morag.maclean@ed.ac.uk for signature
2024-12-02 - 15:31:51 GMT

Document emailed to Raza Hayat (raza.hayat@ed.ac.uk) for signature
2024-12-02 - 15:31:51 GMT

Document emailed to Gina Cranswick (gina.cranswick@ed.ac.uk) for signature
2024-12-02 - 15:31:51 GMT

Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2024-12-02 - 15:31:52 GMT

Email viewed by Gina Cranswick (gina.cranswick@ed.ac.uk)
2024-12-02 - 15:49:22 GMT- IP address: 104.47.11.62

Document e-signed by Gina Cranswick (gina.cranswick@ed.ac.uk)
Signature Date: 2024-12-02 - 15:49:33 GMT - Time Source: server- IP address: 192.41.114.224

Email viewed by morag.maclean@ed.ac.uk
2024-12-03 - 09:45:18 GMT- IP address: 192.41.114.226

Signer morag.maclean@ed.ac.uk entered name at signing as Morag MacLean
2024-12-03 - 09:45:56 GMT- IP address: 192.41.114.226

Document e-signed by Morag MacLean (morag.maclean@ed.ac.uk)
Signature Date: 2024-12-03 - 09:45:58 GMT - Time Source: server- IP address: 192.41.114.226

Email viewed by Raza Hayat (raza.hayat@ed.ac.uk)

2024-12-03 - 11:26:25 GMT- IP address: 104.47.11.254

Document e-signed by Raza Hayat (raza.hayat@ed.ac.uk)

Signature Date: 2024-12-03 - 11:26:40 GMT - Time Source: server- IP address: 192.41.114.228

Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Signature Date: 2024-12-03 - 12:18:21 GMT - Time Source: server- IP address: 192.41.114.226

Agreement completed.

2024-12-03 - 12:18:21 GMT