ECTU Central Office SOP_TM_20: Provision of ISFs to Study Sites

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Authorship and Approval			
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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.

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 document 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. All documents included in the ISF initially sent to a site will be listed in the table of contents.

4.1.4 The Trial Manager, or delegate, will prepare a table of contents for any other files sent to a site, e.g. pharmacy file, lab file, imaging file.

4.1.5 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.

4.1.6 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.

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

4.1.8 If there are any updates to the ISF table of contents during the study the trial manager, or delegate, will send the site the updated table of contents along with any other amended documentation.

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

4.2 Provision of ISF in paper format

4.2.1 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 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 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 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 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 After the initial ISF has been provided the site will acknowledge receipt of documents sent subsequently by completing and returning a document or amendment receipt, 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 SOP CR001 Establishing and Maintaining Investigator Site Files, Trial Master Files and Sponsor Files

ECTU_SOP_TM_18 Creating and Maintaining a Pharmacy Site File

TM001 - non-CTIMP ISF Table of Contents Template

TM002 - CTIMP ISF Table of Contents Template

TM003 - ISF Receipt Template

TM004 - Document/Amendment Receipt Template