ECTU Central Office SOP _TM_18: Creating and Maintaining a Pharmacy site File (PSF)

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	20 Sept 2019	Initial creation
2.0	11 Jul 2022	Moved to new SOP template Section 4.1.1 updated and section 4.2.5 added
3.0	22 Jul 2024	Addition of Pharmacy Site File receipt process (sections 3.2 and 4.1.8) Addition of section 4.1.10 TM-T11 ECTU Pharmacy Manual Template incorporated Minor formatting changes and clarifications throughout

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for creating and maintaining a Pharmacy Site File (PSF) for a Clinical Trials of Investigational Medicinal Products (CTIMP) study.

2.0 SCOPE

This SOP applies to all CTIMP studies that are fully managed by ECTU where a PSF will be required and is not already available at site. If available, study sites may use their own established PSF format if agreed with the Trial Manager/Sponsor.

3.0 RESPONSIBILITIES

3.1 If sites do not have their own established PSF format, the Trial Manager or designee will be responsible for creating the PSF for each site.

3.2 If the PSF is provided by the Trial manager or designee, the Pharmacist or designee at site will be responsible for confirming receipt of the PSF.

3.3 The Pharmacist or designee at site will be responsible for maintaining the PSF and ensuring that it is held in a secure location for the duration of the study.

3.4 Trial Manager or designee will be responsible for ensuring that any updated documents applicable to the PSF are provided to the site as required. The receipt of these should be logged appropriately.

3.5 The Principal Investigator (PI) at site will be responsible for ensuring that the PSF is archived along with the Investigator Site File (ISF) in accordance with the protocol.

3.6 The Pharmacist or designee will ensure that the PSF is complete and has been reviewed prior to archiving.

4.0 PROCEDURE

4.1 Creating a Pharmacy Site File (PSF)

4.1.1 The PSF will be created by the Pharmacist, or designee, prior to the start of the study at their site using their own established PSF format. Alternatively, if the site don't have a PSF format, the Trial manager or designee will be required to create the PSF for the site using the PSF Contents template below (see 4.1.6).

4.1.2 The PSF will be split into six main sections. Additional sections and sub-sections can be added as required and the PSF Contents page updated accordingly.

4.1.3 Where applicable, each section will contain a sub-section for superseded documents.

4.1.4 The PSF Contents Page will be the first page of the PSF and all documents will then be filed in accordance with this.

4.1.5 Documentation will be filed in the PSF in descending date order (most recent document at the front).

4.1.6 The following sections will be included in the PSF:

- **1. Study and Pharmacy Information**
  This section will include the study protocol, management approval documentation, pharmacy procedures and guidelines (e.g. pharmacy manual), study contact list and a copy of the completed delegation log held in the ISF.

- **2. Investigational Medicinal Product (IMP) Information and Management**
  This section will contain all documentation relating to the IMP including the Investigator Brochure and/or Summary of Product Characteristics, Qualified Person Release Certificates and shipment documentation.

- **3. Templates**
  All relevant pharmacy templates will be kept in this section (unless specified elsewhere).

- **4. Completed Documents**
  All completed documents (e.g. completed prescriptions) as applicable should be filed in this section.

- **5. Correspondence**
  Any relevant correspondence should be filed in this section.

- **6. Miscellaneous Documents**
  This section can be used for any other relevant documents (e.g. pharmacy fee documentation, contract/agreement information).

4.1.7 The PSF will be clearly labelled with the study name and site name/number. All sections and sub-sections will be clearly labelled.

4.1.8 The Trial Manager or designee will ensure that the PSF is available at the pharmacy prior to the start of study. If the PSF is provided by the Trial manager or designee, the Pharmacist or designee at site is responsible for confirming receipt of the PSF. A PSF receipt form can be created for this purpose by adapting the ISF receipt template and sent to the site with the PSF. The completed PSF receipt will be filed in the TMF section 7.3 Monitoring Reports, along with other Site Initiation Visit (SIV) documentation.

4.1.9 The Trial Manager or designee will ensure that all current versions of the essential documents listed in the PSF Contents page are included at site set up.

4.1.10 The Trial Manager or designee will ensure that the Pharmacist and PI are aware of their responsibilities as outlined in section 3 prior to the start of the study. This usually forms part of the training provided at site set-up, which is documented in the SIV report and/or site training log.

4.2 Maintaining a Pharmacy site File (PSF)

ECTU's expectation is that, in line with Sponsor SOPs,

4.2.1 The Pharmacist or designee will ensure that any updated versions of PSF documents are filed when they are received.

4.2.2 Superseded documents will be retained in the appropriate sub-section.

4.2.3 The Pharmacist or designee will ensure that all completed documents are filed.

4.2.4 The Pharmacist or designee will be responsible for completing the End of Trial Review of the PSF and completing the appropriate section on the PSF Contents page. The PSF should not be archived until this has been completed.

4.2.5 The PI will ensure that the file is archived in a suitable fashion in accordance with the protocol.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU PSF Templates:

- TM-T11 ECTU Pharmacy Manual Template
- TM-T32 Pharmacy Site File Contents Template
- TM-T29 Master IMP Inventory Log Template
- TM-T30 Participant IMP Accountability Log Template
- TM-T33 Prescription Template
- TM-T35 Treatment Allocation Log
- TM-T34 Temperature Log Template
- TM-T31 Pharmacy Signature Log Template
- TM003 ISF Receipt Template

ACCORD Documents

- ACCORD Delegation Log (CR007-T12)
- ACCORD Study Specific Training Log (CR007-T17)
- ACCORD Deviation Log (CR010-T01)

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