ECTU Central Office SOP_ QA _01: QA Management of ECTU Controlled Standard Operating Procedures (SOPs), Working Practice Documents (WPDs) and Policies and their Periodic Review

Version No:	3.0
Issue Date:	20 Mar 2025
Effective Date:	09 Apr 2025

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Tanya Tharakan, QA Manager	Author	20-Mar-2025	Tanya Tharakan (Mar 20, 2025 11:39 GMT)
Julia Boyd, Senior Trial Manager	Reviewer	19-Mar-2025	
Joyce Thomson, Chief Operating Officer	Approver	20-Mar-2025	Joyce Thomson (Mar 20, 2025 11:30 GMT)
Tanya Tharakan, QA Manager	Approval	20-Mar-2025	Tanya Tharakan (Mar 20, 2025 11:39 GMT)

Document Revision History		
Version No	Effective Date	Summary of Revisions
1.0	18 Nov 2021	Initial creation
2.0	14 Mar 2024	Periodic review process has been amended. Changes to reflect current processes. Author and QA Manager name has been changed. Minor formatting changes.
3.0	09 Apr 2025	Extensive changes made throughout the document to include archiving procedures for templates, internal audit schedules and training needs analysis, and to reflect current processes.

1.0 PURPOSE

As per ICH GCP and MHRA guidelines, Edinburgh Clinical Trials Unit (ECTU) has written Standard Operating Procedures (SOPs), Working Practice Documents (WPDs) and Policies to ensure that trials are conducted and data generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements. To maintain Quality Assurance, electronic and where applicable, paper copies of SOPs and WPDs are managed, administered and reviewed according to a defined process.

This procedure describes the responsibilities and procedures by which QA controlled SOPs, WPDs and Policies are processed, issued, distributed, reviewed and archived by ECTU QA.

2.0 SCOPE

This procedure pertains to the management and review of ECTU QA controlled SOPs, WPDs and Policies, both paper (where applicable) and electronic documents, following approval and authorisation of the final document. It pertains to SOPs, WPDs and Policies belonging to all areas of ECTU.

Throughout this document where SOP is referenced this can be read as WPD and Policy unless directed otherwise.

3.0 RESPONSIBILITIES

It is the responsibility of QA or delegate to,

- Ensure that this procedure is performed as described, that it is reviewed and updated as necessary, and that relevant support documentation is maintained.
- Process, manage, distribute and archive QA controlled SOPs according to this procedure.
- Timely notify the owning Author/Team Manager that their SOP is due for periodic review.

The Author/Team Manager is responsible for,

- ensuring that the periodic review of each of their departmental SOPs is performed appropriately.
- the content and layout of the SOPs. This includes making sure that the document is in the correct template.
- determining training requirements before the SOP is issued. If SOP specific training is required, this shall be facilitated by the author prior to the effective date, where possible. Such training will be recorded on the REDCap e-training record
- ensuring that the content of the SOPs is consistent with the current regulatory guidelines, along with QA.

Managers and appropriate senior staff members within ECTU have the responsibility to approve SOPs. The list of individuals with this responsibility will be maintained by QA.

4.0 PROCEDURE

Policy	A high-level concise document that specifies accountability and defines the desired outcome – it sets out the position, intent or action of the organisation. Policy documents can be supported by Standard Operating Procedures (SOPs) and Working Practice Documents (WPDs) which detail the activities pertaining to the policy.
Standard Operating Procedure (SOP)	A document containing instructions, generally in the form of text and flowcharts, used to instruct the user on the steps to be carried out when performing a specific activity. This document is designed to describe in sufficient detail how to perform an activity with the aim of ensuring that the activity can be carried out in a consistent and reproducible way. The SOP needs to provide sufficient detail so as to minimise the risk of misinterpretation.
Working Practice Document (WPD)	A document that forms part of a 2-tiered SOP framework. An SOP describes at a high level how to perform an activity, the WPD where required, is designed to provide a more detailed instruction on how to perform an activity in a consistent and reproducible way
Master Document	A unique, QA controlled document, approved and signed and administered by QA.
Issue Date	The date that QA has completed the approval process of the final document and it is ready for distribution through the ECTU.
Effective Date	The date from which a document becomes valid and is allowed for use in the ECTU.
Periodic Review Date (PRD)	The date before which the document should be reviewed (typically 2 years from the effective date or previous PRD).

4.1 Creation of SOP Master Document

4.1.1 Preparation, approval and authorisation of ECTU SOPs is performed according to SOP_ECTU_OP_01: Development and Management of Standard Operating Procedures (SOP), Working Practice Documents (WPD) and Policies.

4.1.2 QA will generate a SOP Master Document of the new version for signing and dating by authorised signatories as described below.

4.1.3 The numbering system and indexing of SOPs will be managed centrally by QA. Approved new SOPs will be categorised and assigned the next available number within the appropriate section. The document number and title will be displayed on the front page of the SOP. Numbers for obsolete SOPs will not be re-allocated.

4.1.4 QA will assign the issue and effective dates for the SOP, and will list these on the front page. The effective date should allow sufficient time from the date of issue for relevant staff to read and sign off the SOP (typically 2 weeks). If there are no changes

to the document the Issue Date remains the same, and the Effective Date will be extended by 2 years from the date and documented in the "Document Revision History" by the author.

4.1.5 QA will manage the version number of the document. The version number will be displayed on the front page of the SOP. Updates to the SOP will result in an increase in version number, this will increase by one whole number when being changed (e.g. v1.0, v2.0). If there are no changes to the document, the version number remains the same.

4.1.6 The effective date, SOP Identifier and version will be printed in the header section throughout the SOP. The footer must also contain a statement regarding users' responsibility to use the most recent version.

4.1.7 The electronic Master Document will be sent for signing and dating by the Author, Reviewer and Approver via Adobe sign. When returned, QA will sign and date to authorise the SOP. There is no requirement for QA to authorise Policies, these will require an Author, Reviewer/s and Approver signature only, QA will then make the document effective as detailed in section 4.2. For new or new versions of SOPs, all signatures must be dated before the issue date.

4.2 Making SOPs Effective

4.2.1 Following the approval and authorisation of the final SOP, QA will process the document to make it effective.

4.2.2 A Word and pdf copy of the approved SOP will be added to the Pending Effective Date folder on the shared drive. The document will then be sent for signatures via Adobe Acrobat Sign. If the document was sent for email approval, signatures will be replaced with 'See retained approval email dated XX XXX XXXX'.

4.2.3 Once the SOP is effective, the pdf copy of the Master Document will be moved to the 'Current' folder and uploaded onto ECTU SOP webpage. The Word copy will be retained in the 'Word Versions for editing only' folder. The paper Master Document will be printed and filed in the appropriate folder within ECTU Office by QA.

4.2.4 Electronic SOPs on the shared drive will be read only for ECTU staff members with the exception of QA and deputies.

4.2.5 If a further change to an SOP/WPD is required after the SOP/WPD has been issued, but prior to the effective date, QA may recall the SOP/WPD and issue an amended version without a change to the version number. QA will inform relevant staff of the changes made and advise as to whether or not it is necessary for staff to read and sign off the SOP again.

4.2.6 QA will send an email to ECTU highlighting the relevant departments according to the ECTU SOP distribution list, (SOPs read by individuals Tracker) informing them of the issue of an approved SOP and the date it will become effective.

4.2.7 When an individual receives an email from QA advising them of a new or updated SOP/WPD, a Read Receipt is expected to be completed electronically via the e-Training Record on the REDCap database before the effective date or prior to undertaking study specific tasks. Where appropriate and agreed with the QA Manager, the SOP can be marked as "Not Applicable".

4.2.8 The Line manager will monitor read receipts as part of the e-Training Record review and outcomes will be recorded on the e-Training record. The review may take place at specific time points, for example, the staff member's probation review or annual review, or during QA internal audits. The QA Manager will provide updates to the line manager/ ECTU management as appropriate.

4.2.9 The ECTU internal audit schedule will be specified from Q3 of the current year, until the same time point for the following year. The audit schedule will be discussed and finalised with the Chief Operating Officer, 2-3 months in advance. The schedule will be informed to all departments via email, and the respective Monthly Communications Meeting.

4.3 Initiation of Periodic Review

4.3.1 QA will regularly review and determine which SOPs are approaching their Periodic Review Date (PRD).

4.3.2 QA will notify the Author and authorised signatories via email that an SOP is upcoming for periodic review. The editable word copy of the current version of the SOP will be attached, watermarked and named as being in draft, with tracked changes enabled. This will be sent out typically 1-2 months prior to the documents PRD.

4.3.3 The notification will be logged electronically in the ECTU Central Office SOP, WPD and Policy List on the shared drive.

4.3.4 At the discretion of QA, an extension of up to four weeks beyond the PRD can be requested, for example, the author of the document is on leave due to unforeseen circumstances. After this time, if the SOP has still not been finalised, the PRD will be extended by an agreed period according to the process in 4.4.2.

4.4 Closure and Documentation of Periodic Review

4.4.1 If no revisions to the SOP are required, the PRD will be extended, typically by 2 years, but there will be no change to the issue date, or version number of the SOP. A statement will be added to the version history to reflect this.

4.4.2 Revisions to the SOP must be completed with tracked changes and should be returned to QA ideally by 1-2 weeks before PRD. QA will contact the Author/ reviewing team for follow-up of non-returned SOPs. If an SOP requires a revision, or will require a revision in the near future, but there is a valid reason why this cannot be completed before the PRD, the document owner should inform QA. If agreed, QA may then extend the PRD for a short time, for example 3-6 months. This should be recorded in the ECTU Central Office SOP, WPD and Policy List (see section 5)

4.4.3 Once approved, the final draft of the SOP will follow the processes described in ECTU_SOP_OP_01: Development and Management of Policies, SOP (Standard Operating Procedures) and WPD (Working Practice Documents), and filed electronically on the shared drive. The new version will be made effective and distributed as described in previous sections.

4.4.4 When all actions have been completed, the status of the document will be updated in the ECTU Central Office SOP, WPD and Policy List.

4.5 Archiving of Superseded / Obsolete SOPs and Associated Documents

4.5.1 When an SOP or associated document is deemed superseded or obsolete it must be removed from general circulation.

4.5.2 When an SOP or associated document has been made obsolete QA will notify the appropriate individuals within ETCU via email distribution from the ECTU QA mail address.

4.5.3 ECTU webpage will be updated to include the revised version of the SOP and superseded/obsolete versions removed as appropriate.

4.5.4 Electronic copies of SOP or associated documents will be moved from the 'Current' folder to the appropriate 'Previous' or 'Obsolete' folder on the ECTU Unit shared drive, and retained indefinitely. For SOPs, 'Superseded' or 'obsolete' will be added to the file name as appropriate, and watermarked if it is a word document. PDF documents will be edited using text.

4.5.5 For new SOPs, the SOP distribution list will be updated to reflect the new document. For all SOPs, the ECTU Central Office SOP, WPD and Policy List will be updated by QA. Documents associated with an SOP must be reviewed along with the SOP and follow archive procedures as detailed above. Individual departments will coordinate with QA to maintain version control of the templates and associated documents.

5.0 RELEVANT DOCUMENTS AND REFERENCES

- ECTU Central Office SOP, WPD and Policy List
- ECTU SOP Distribution List - SOPs read by individuals 2024
- SOP and WPD Templates
- ECTU Policies and templates
- ECTU SOP Approvers list (QA010)

ECTU_SOP_ QA_01 QA Management of ECTU Controlled Standard Operating Procedures (SOPs), Working Practice Documents (WPDs) and Policies and their Periodic Review v3.0

Final Audit Report 2025-03-20

Created:	2025-03-19 (Greenwich Mean Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAtpOsJ0InLuIDLgjS-8AxQxAUPcgql9Vz

"ECTU_SOP_ QA_01 QA Management of ECTU Controlled Standard Operating Procedures (SOPs), Working Practice Documents (WPDs) and Policies and their Periodic Review v3.0" History

Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2025-03-19 - 17:25:38 GMT- IP address: 192.41.114.230

Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2025-03-19 - 17:28:37 GMT

Document emailed to Julia Boyd (Julia.Boyd@ed.ac.uk) for signature
2025-03-19 - 17:28:37 GMT

Document emailed to Joyce Thomson (joyce.thomson@ed.ac.uk) for signature
2025-03-19 - 17:28:37 GMT

Email viewed by Julia Boyd (Julia.Boyd@ed.ac.uk)
2025-03-19 - 17:30:11 GMT- IP address: 104.47.11.126

Document e-signed by Julia Boyd (Julia.Boyd@ed.ac.uk)
Signature Date: 2025-03-19 - 17:30:33 GMT - Time Source: server- IP address: 192.41.114.229

Email viewed by Joyce Thomson (joyce.thomson@ed.ac.uk)
2025-03-20 - 11:29:33 GMT- IP address: 104.47.11.126

Document e-signed by Joyce Thomson (joyce.thomson@ed.ac.uk)
Signature Date: 2025-03-20 - 11:30:54 GMT - Time Source: server- IP address: 5.64.191.62

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

Signature Date: 2025-03-20 - 11:39:18 GMT - Time Source: server- IP address: 192.41.114.230

Agreement completed.

2025-03-20 - 11:39:18 GMT