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.

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Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval/ Authorisation	Date	Signature
Tanya Tharakan, QA Manager	Author	27 Feb 2024	See Retained Approval Email dated 27 Feb 2024
Julia Boyd, Senior Trial Manager	Reviewer	28 Feb 2024	See Retained Approval Email dated 28 Feb 2024
Joyce Thomson, Chief Operating Officer	Reviewer	27 Feb 2024	See Retained Approval Email dated 27 Feb 2024
Tanya Tharakan, QA Manager	Approval	27 Feb 2024	See Retained Approval Email dated 27 Feb 2024

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.

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1.0   PURPOSE

Edinburgh Clinical Trials Unit (ECTU) has written Standard Operating Procedures (SOPs) and Working Practice Documents (WPDs) 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 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 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 also unless directed otherwise.

3.0   RESPONSIBILITIES

3.1   It is the responsibility of QA to ensure that this procedure is performed as described, that it is reviewed and updated as necessary, and that relevant support documentation is maintained.

3.2   It is the responsibility of QA or delegate to process, manage, distribute and archive QA controlled SOPs according to this procedure.

3.3   QA is responsible for the timely notification to the owning Author/Team Manager that their SOPs is due for periodic review.

3.4   Each Author/Team Manager is responsible for ensuring that the periodic review of each of their departmental SOPs is performed appropriately.

3.5   The owning Author/Team Manager is responsible for the content and layout of the SOPs. This includes making sure that the document is in the correct template.

3.6   The owning Author/Team Manager and QA must ensure that the content of the SOPs is consistent with the current regulatory guidelines.

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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 an 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

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to the document the Issue Date remains the same, and the Effective Date will be extended by 2 years from the date 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. 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 2024 Tracker) informing them of the issue of an approved SOP and the date it will become effective.

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4.2.7 When an individual receives an email from QA advising them of a new or updated SOP/WPD, a Read Receipt email will be completed and returned to the ECTU QA Inbox.

4.2.8 QA will monitor the read receipting of SOPs by individuals and will provide management with updates as required.

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 4.6.2.

4.5 Closure and Documentation of Periodic Review

4.6.1 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.

4.6.2 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 that require amendment. 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

4.6.3 Once approved, the final draft of the SOP will be filed electronically on the shared drive, the new version will be made effective and the Master Document created and distributed as described in previous sections.

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

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4.7 Archiving of Superseded / Obsolete SOPs

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

4.7.2   When an SOP has been made obsolete QA will notify the appropriate individuals within ETCU via email distribution.

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

4.7.4   Electronic copies of SOP will be moved from the 'Current' folder to the appropriate 'Previous' folder on the ECT Unit shared drive, and retained indefinitely. 'Superseded' or 'obsolete' will be added to the file name as appropriate, and watermarked if it is a word document

4.7.5   The SOP distribution list will be updated to reflect the new document. The previous version will be highlighted and concealed from view.

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
- ECTU SOP Approvers list (QA010)

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