ECTU Central Office SOP ECTU_OP_01: Development and Management of ECTU QA Controlled Documents

Version No:	8.0
Issue Date:	27 May 2026
Effective Date:	10 Jun 2026

Authorship and Approval			
Name and Designation	Author/Reviewer/Approval	Date	Signature
Tanya Tharakan QA Manager	Author	13-May-2026	Tanya Tharakan (13-May-2026 09:57:26 GMT+1)
Julia Boyd, Senior Trial Manager	Reviewer	05-May-2026	
Joyce Thomson, Chief Operating Officer	Approver	07-May-2026	Joyce Thomson (07-May-2026 17:06:59 GMT+1)
Tanya Tharakan QA Manager	QA Authorisation	13-May-2026	Tanya Tharakan (13-May-2026 09:57:26 GMT+1)

Document Revision History		
Version No	Date	Summary of Revisions
1.0	1st Oct 2012	Initial creation
2.0	18 Aug 2014	Changes to process to incorporate Quality Assurance checks and review process
3.0	10 Aug 2015	SOP title changed. Wording changes to Section 1 and 2. Section 3.1 rewritten to explain process. Section 3.2 added and previous Section 3.2 now becomes Section 3.3. Naming convention for WPD changed in Section 3.3. Minor amendments to Sections 3.4, 3.5 and 3.6 Appendix 1 and 2 removed. Appendix 3 altered and changed to Appendix 1
4.0	29 Aug 2016	SOP revised as per audit recommendations. Sections 3.1 and 3.2 amalgamated into 3.1. Section 3.3 and 3.5 added. Subsequent alterations to the numbering of sections due to these changes. Naming convention for REDCap added to section 3.2. Document locations added to section 4
5.0	7 May 2018	Extensive alterations throughout. Document renumbered throughout. Review requirements altered in section 3.1.2. Data Management (DM) and Health Economics (HE) added to section 3.2.2 and 3.4.2. Effective date calculation added to section 3.4.1. SOP receipt process added to section 3.5. Section 3.8 added

6.0	18 Nov 2021	SOP author has changed. SOP updated extensively throughout. Section 3.0 Responsibilities, has been included, new SOP template v3.0 used.
7.0	14 Mar 2024	Substantial changes made throughout, most significantly with regard to the approval process, and electronic signatures. Use of Periodic Review Form has been amended. Author and QA Manager name have been replaced.
8.0	10 Jun 2026	Update at periodic review and following the new revisions to ICH GCP E6(R3). Substantive changes made throughout to reflect current processes. Policy, SOP and WPD templates added to the QMS. Title changed from 'Development and Management of Policies, SOP (Standard Operating Procedures) and WPD (Working Practice Documents)'

1.0 PURPOSE

ICH GCP and MHRA guidelines state there should be written Standard Operating Procedures (SOPs) in place to ensure that trials are conducted and data generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements. SOPs are relevant to all aspects of work in the Edinburgh Clinical Trial Unit (ECTU) and must be readily available to all relevant staff.

This SOP describes the preparation, review and approval process for all ECTU administered SOPs, WPD and Policies to ensure that these are written in a standard format and implemented according to a defined process.

2.0 SCOPE

This SOP relates to all ECTU Policies, SOPs and WPD controlled by ECTU Quality Assurance. This SOP applies to all ECTU staff.

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

3.0 RESPONSIBILITIES

3.1 The production and maintenance of SOPs within ECTU are the overall responsibility of QA and accountability of the ECTU Director. Specific duties may be delegated to others within the organisation.

3.2 It is the responsibility of all staff to:

- Identify and report the need for a new SOP or the need to review an existing one, when aware.
- Follow the procedures in this SOP when delegated as an author, reviewer or authoriser signatory for approval or authorisation of an SOP.
- Ensure they are familiar with relevant SOPs (ECTU and Sponsor), and that these are adhered to in the discharge of their duties.
- Document that they have read and understood both ECTU and Sponsor SOPs where applicable, relevant to their duties prior to undertaking the procedures.

3.3 It is the responsibility of the Team Manager/ Lead to:

- Delegate authoring and reviewing duties to appropriate members of their staff when the need arises.
- Review and approve SOPs owned by their team in a timely manner, or to delegate these duties when required. This includes checking the content and layout of the SOPs and ensuring that the document is in the correct template.
- Ensure that staff are aware of their reading list and its status and where required, ensure further training is conducted for new members of staff. This must be completed as a new version is available or prior to conducting the process, and documented in the training folder.
- Ensure that the periodic review of each of their departmental SOPs are performed appropriately.

3.4 It is the responsibility of QA to act as document controller and to:

- Process, manage, distribute and archive electronic SOPs, Paper QA documents are no longer maintained and previous versions will be archived in 3.35 Secure Storage and Archive room in the ECTU office.
- Provide document numbering and version control.
- Manage Master SOP Folders.
- Notify the owning Team Manager/Author that an SOP is due for periodic review.
- Inform relevant managers and staff members of the implementation of new SOPs and revisions.
- Ensure current versions of SOPs are available to all ECTU staff members.

3.5 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. (QA010 ECTU SOP Approvers list see section 5). There is usually one Approver for an SOP.

3.6 Authorisation of approved SOPs is the responsibility of QA.

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

4.0 PROCEDURE

Definitions

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. A WPD can act as a stand-alone document as well. For e.g., ECTU WPD_TM_W4: Requesting and Recording Protocol Deviation Logs and Protocol Violations in ACCORD Sponsored Studies
Master Document	A unique, QA controlled document, approved by author(s), reviewer(s) and approver 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 to ECTU.

Effective Date	The date from which a document becomes valid and is allowed for use in ECTU.
Periodic Review Date (PRD)	The date before which the SOP should be reviewed (typically 2 years from the previous effective date).

4.1 SOP Format

All new SOPs must be prepared in the format set out in the template (OP-T07, 08 and 09) using Arial font, size 11pt, as shown in this document. The current version of the template is held electronically on the shared drive (see Section 5)

4.1.1 Each SOP must include the following on the front page:

- ECTU SOP document number, allocated by QA.
- SOP version number
- Title of SOP
- Issue Date and Effective Date of the SOP allocated by QA.
- Author(s) of the SOP
- Reviewer(s) of the SOP
- Approver of the SOP
- Authorisation by QA
- Dates when approval was received
- Document Revision History

4.1.2 The header of each page must bear the:

- ECTU logo
- ECTU SOP document identifier and version number
- Effective Date.

4.1.3 The footer must contain the following:

- Page number and the total number of pages, including appendices.
- SOP template ID and version.
- Statement regarding the user's responsibility to use the current version. If the SOP is printed, it is valid for the duration of the task that it is printed for or till the next version is released whichever is earlier, after which the paper copy should be destroyed.

4.1.4 The SOP must be structured in numbered sections with subsection indent as demonstrated in this document. Each paragraph within sections should be numbered or listed as appropriate.

4.1.5 The following sections must be included with additional sections being added if required and approved:

- Document Revision History – note of dates of review and list of modifications to the SOP following review (periodic reviews must be noted even if no changes are required).
- Purpose – brief statement outlining the purpose of the SOP.
- Scope – brief statement outlining the limits of the process/procedure including the

personnel and areas to which the document pertains.

- Responsibilities – statement detailing the persons/ departments responsible for major tasks associated with the SOP and their responsibilities.
- Procedure – details of how the task is performed. This must be written in a logical, methodical and unambiguous manner. The information must be clear and concise, reflect the task and comply with current regulations, organisational policies and ACCORD documents where applicable.
- Relevant Documents and References – documents which impact on the procedure including other SOPs, WPDs, policies, associated documents like templates and regulatory documents. Journals, websites and publications, standard documents should be included where applicable.
- List of Appendices (if applicable).
- Appendices (if applicable).

4.3 SOP Development Process

4.3.1 Once the need for an SOP and has been highlighted, an author (or authors) will be identified and the SOP will be drafted using the most recent, approved version of the ECTU Central Office SOP Template available on the ECTU DataStore.

4.3.2 The SOP identifier is based on the team or process that the SOP is relevant to. Identifiers are listed below:

Operations	ECTU_OP
Statistics	ECTU_ST
Health Economics	ECTU_HE
Programming	ECTU_IT
REDCap	ECTU_REDCap
Data Management	ECTU_DM
Trial Management	ECTU_TM
Quality Assurance	ECTU_QA

4.3.3 SOPs will be named according to the following ECTU format: ECTU Central Office SOP/WPD <identifier>_<number>: Title

4.3.4 The Team Manager/ Lead allocates the writing of the SOP to a member of staff, not excluding themselves, who is either a process/procedure user or a person experienced in the subject of the SOP.

4.3.5 The author writes the first draft ensuring it is clearly marked as DRAFT by watermark and track changes are turned on.

4.3.6 The author circulates the draft version to designated reviewers for review and comment, makes revisions as appropriate until a final version is achieved and agreed by the Approver.

4.3.7 QA can support in designating members of the review team and completing the actions mentioned in 4.3.4 to 4.3.6. The author sends the final draft to the QA Manager or the ECTU QA Inbox. A copy will be saved by QA in the 'Drafts and Updates in Progress' for the respective department on DataStore\SOP\Finalised SOP and WPD.

4.3.8 The documents may also be circulated via a shared link with access provided to those who are involved in the development of the SOP.

4.3.9 If there are further recommendations from QA, this will be agreed upon by all parties before QA proceeds for the final authorisation process and administration.

4.4 Approval & Distribution

4.4.1 Approval must be given by the designated Author(s), Reviewer(s) and Approver and authorisation received from QA before an SOP is implemented. Policies do not need to be authorised by QA.

4.4.2 Once a final version has been agreed, QA will generate an electronic SOP Master Document in word format, by accepting all tracked changes, removing 'Draft' from the file name and watermark, and arrange for signing and dating by authorised signatories. The Master Document will be moved by QA from 'Drafts and Updates in Progress' folder to the 'Pending Effective Date' folder for the respective department on the ECTU Shared Drive. QA will provide the next sequential SOP number to identify the SOP.

4.4.3 The Master Document will be sent for signature to all concerned (Author(s), Reviewer(s), Approver & QA Manager). (See section 4.5 on types of approvals)

4.4.4 Once all signatures are received, QA will send an email to all ECTU staff highlighting the relevant departments according to 'SOPs read by individuals' excel sheet or the responsibilities set by the SOP, informing them of the issue of an approved SOP and the date it will become effective.

4.4.5 On the effective date, a pdf copy of the finalised SOP will be updated on the ECTU webpage, and moved from the 'Pending Effective Date' folder to the SOP 'Current' folder. A word version will be saved in 'Word for editing folder'. Templates may be in effect earlier than the SOP where deemed necessary.

4.4.6 When ECTU QA are notified of updates to ACCORD SOPs/policies via the ECTU QA email inbox, the same process is followed and ECTU will be informed via email.

4.4.7 When an email from QA regarding a new or updated SOP is received, it is the responsibility of the individual to read the SOP attached with the email, and complete the Read Receipt on their REDCap e-training record. Read receipting must be done before the Effective Date of a new or revised SOP or prior to undertaking the procedure (if applicable).

4.4.8 In the case of staff employed after the effective date, SOPs should be read and read receipted before undertaking the procedure unsupervised. All staff will be issued a ECTU Core SOPs Read Receipt list (QA002) according to their department/ role which needs to be completed by the individual with the version number, signed and dated on completion of reading the document. The timeframe for reading the documents is mentioned in ECTU Core SOPs Read Receipt list. The documents listed in bold text must be read within 2 weeks, and the remaining can be completed within 3 months of the joining date. Once completed, the ECTU Core SOPs Read Receipt List will be uploaded to their e-training record as detailed in ECTU_SOP_QA_02: Maintaining an Electronic Staff Training Record.

4.4.9 All ECTU controlled SOPs will be administered and managed by QA according to ECTU_SOP_QA_01 QA Management of ECTU Controlled Standard Operating Procedures, Working Practice Documents, Policies and their Periodic Review.

4.5 Types of Approval

4.5.1 **Electronic Approval (E-signatures)**

4.5.1.1 All ECTU staff are assigned Adobe Sign with their University of Edinburgh account and can login with their University credentials.

4.5.1.2 Prior to using Adobe Sign the first time, authorised users must firstly configure the following settings in their account;

- Time zone must be set to 'GMT'
- Language Preference should be set to 'English UK'

.

4.5.1.3 The SOP, along with any associated documents requiring approval, will be sent via Adobe Sign.

4.5.1.4 If signatures are not dated, the audit trail of the document will evidence the date on which the document was signed. The audit trail will be saved along with the SOP.

4.5.1.5 Once all electronic signatures are received, QA will complete authorisation by assigning Issue and Effective dates (from step 4.4.4)

4.5.2 **Email Approval** (to be used only if Adobe Sign is not available)

4.5.2.1 The SOP Master Document, along with any associated documents will be sent to the authorised signatories for email approval using the standard format of "Please take this email as confirmation of my signature for the document listed below", along with their Name, Role, Date and Document Title/version.

4.5.2.2 The emails of approval will be retained in the appropriate folders for the SOP on DataStore.

4.5.2.3 Once all signatures have been received, QA will complete authorisation by assigning Issue and Effective dates (from step 4.4.4)

4.5.3 The electronic signature is the preferred method for obtaining approvals. In lieu of an e-signature, email confirmation of approvals or wet signatures (where applicable) will be accepted. For example, if Adobe Sign is under maintenance.

4.5.4 A pdf and word copy of the approved SOP and any supporting documents will be saved to the appropriate folders on ECTU DataStore. This folder will be read-only for all individuals with the exception of QA and three deputies. The folder permissions of this folder are controlled by QA via the Group Maintenance Manager.

4.6 Revision of SOPs

4.6.1 No SOP may be revised without the approval from QA and/or according to review procedures.

4.6.2 Outside of the standard periodic review an assessment of an SOP must take place when it is identified that the process or procedures have changed and are no longer

reflected in the current SOP, or when there are changes to legislation or regulatory requirements supporting the SOP.

4.6.3 QA will maintain oversight of the documents that need to be reviewed. Staff members may inform the Team Manager/ Lead and QA of the need for review. QA will release an electronic copy of the current Word version of the SOP to the author for amendment. It is the responsibility of the author and/or reviewer to check the SOP Updates Tracker, ensure any recommendations and suggestions have been considered and close the entry. The process then follows that detailed from section 4.3.6 onwards.

4.6.4 At any given time, there should be only one copy in circulation, no copies of the document should be made/ retained elsewhere. Any copies stored locally by the reviewer should be deleted once the review has been completed and forwarded to the QA team Documents shared via email for review must be labelled with the initials of the person editing the document along with the date, before forwarding.

4.6.5 Documents associated with the SOP must also be reviewed, updated and approved during the review process.

4.7 Periodic Review of SOPs

4.7.1 All ECTU SOPs will be subject to routine Periodic Review (typically every 2 years from the Effective Date) to ensure that the SOP continues to reflect the task performed and current regulatory requirements. This process is managed by QA and is conducted according to ECTU_SOP_QA_01 QA Management of ECTU Controlled Standard Operating Procedures, Working Practice Documents, Policies and their Periodic Review.

4.7.2 QA will typically notify the Author and authorised signatories 1-2 months prior to the SOP's Periodic Review Date (PRD). Associated supporting documents must also be reviewed.

4.7.3 If no revisions to the SOP are required, the author will document this in the "Document Revision History" of the SOP by stating "No document revision required". The PRD will be extended, typically by 2 years which will be reflected in the Effective Date, but there will be no change to the issue date, or version number of the SOP

4.7.4 Revisions to the SOP should be returned to QA prior to the PRD and ideally by 1-2 weeks before. QA will contact the Author for follow-up of non-returned SOPs.

4.7.5 If there is a valid reason why the review cannot be completed before the PRD, the document author should inform QA. If agreed, QA may extend the PRD, for example, 3-6 months depending on the situation.

4.7.6 Once approved the new version will be made effective as described in the sections above.

4.7.7 Electronic copies of the SOP will be moved to the appropriate 'Previous' folder on the ECTU DataStore, 'superseded' or 'obsolete' will be added to the file name as appropriate.

4.8 Retention Period / Archive

4.8.1 All drafts and approved QA documents will be retained indefinitely on the ECTU DataStore.

4.8.2 Superseded and obsolete QA associated documents, and electronic copies, will be archived indefinitely by the QA Manager or designee, in the appropriate folder on the ECTU DataStore.

4.8.3 Historic paper versions will be archived in the 3.35 Secure Storage and Archive room. Following the issue of this SOP, paper versions will no longer be maintained.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ACCORD Website:

- ACCORD AD007: Use of Electronic Signatures in Accord
- ACCORD QA001: Standard Operating Procedure Preparation and Control

ECTU Website:

- ECTU_SOP_QA_01 QA Management of ECTU controlled Standard Operating Procedures, Working Practice Documents and their Periodic Review
- ECTU_SOP_QA_02 Maintaining an Electronic Staff Training Record
- OP-T07 ECTU Central Office Policy Template
- OP-T08 ECTU Central Office SOP Template
- OP-T09 ECTU Central Office WPD Template
- QA002 ECTU Core SOPs Read Receipt list

ECTU DataStore

- SOP Updates Tracker (\ECT Unit\QA\SOP Quality Assurance)
- SOPs read by individuals excel (\ECT Unit\QA\SOP Quality Assurance)
- QA010 ECTU SOP Approvers List (\ECT Unit\SOPs\Finalised SOP and WPD\QA\Supporting Documents and Templates\Current\pdf)

Others

- ICH Harmonised Guideline for Good Clinical Practice E6(R3)
- SI 2004/1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 and amended regulations.

ECTU_SOP_OP_01 Development and Management of ECTU QA Documents v8.0 and associated documents

Final Audit Report 2026-05-13

Created:	2026-05-05 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAA32cr9zGevTiYhAoE6_IYyx60nvjv9w7x

"ECTU_SOP_OP_01 Development and Management of ECTU Q A Documents v8.0 and associated documents" History

Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2026-05-05 - 14:11:02 GMT+1- IP address: 192.41.114.230

Document emailed to Julia Boyd (Julia.Boyd@ed.ac.uk) for signature
2026-05-05 - 14:17:29 GMT+1

Document emailed to Joyce Thomson (joyce.thomson@ed.ac.uk) for signature
2026-05-05 - 14:17:29 GMT+1

Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2026-05-05 - 14:17:29 GMT+1

Email viewed by Julia Boyd (Julia.Boyd@ed.ac.uk)
2026-05-05 - 14:29:40 GMT+1- IP address: 104.47.11.254

Document e-signed by Julia Boyd (Julia.Boyd@ed.ac.uk)
Signature Date: 2026-05-05 - 14:30:13 GMT+1 - Time Source: server- IP address: 77.101.39.166

Document e-signed by Joyce Thomson (joyce.thomson@ed.ac.uk)
Signature Date: 2026-05-07 - 17:06:59 GMT+1 - Time Source: server- IP address: 192.41.125.249 - Signature appearance selected: DRAW

Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Signature Date: 2026-05-13 - 09:57:26 GMT+1 - Time Source: server- IP address: 192.41.114.230 - Signature appearance selected: DRAW

Agreement completed.
2026-05-13 - 09:57:26 GMT+1