ECTU Central Office SOP ECTU_OP_01: Development and Management of Policies, SOP (Standard Operating Procedures) and WPD (Working Practice Documents)

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Authorship and Approval			
Name and Designation	Author/Reviewer/Approval	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	Approver	27 Feb 2024	See Retained Approval Emails dated 27 Feb 2024
Tanya Tharakan QA Manager	QA Authorisation	27 Feb 2024	See Retained Approval Email dated 27 Feb 2024

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.

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 SOPs, WPD and Policies 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 and Policy as well, 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.
- 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, and that these are adhered to in the discharge of their duties.
- Document that they have read and understood SOPs, 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, WPDs and Policies 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, WPDs or Policy 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 procedure, and documented in the training folder.
- Ensure that the periodic review of each of their departmental SOPs and WPDs are performed appropriately.

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

- Process, manage, distribute and archive electronic and paper SOPs, WPDs and Policies.
- Provide document numbering and version control.
- Manage Master SOP Folders (paper (where applicable) and electronic).
- 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.

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.
Master Document	A unique, QA controlled document, approved, 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 SOP should be reviewed (typically 2 years from the effective date or previous PRD).

4.1 SOP Format

All new SOPs must be prepared in the format set out in the ECTU SOP Template 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 SOP/WPD/ Policies, allocated by QA.
  Note: Policies that are currently in circulation will include a date of issue at the succeeding periodic review.
- Author(s) of SOP
- Reviewer(s) of SOP
- Approval sign off of 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
- Effective Date.
- ECTU SOP document identifier and version number

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, after which the paper copy is 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 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 amendments 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 and organisational policies. This section must include specific equipment or materials required and Health & Safety requirements as applicable.
- Relevant Documents and References – documents which impact on the procedure including other SOPs, WPDs, risk assessments, organisational policies and regulatory documents. Journals, websites and publications, standard documents referenced in the SOP should be included as well.
- 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 shared drive. QA will provide the next sequential SOP number to identify the SOP.

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

Admin	ECTU_AD
Operations	ECTU_OP
Statistics	ECTU_ST
Health Economics	ECTU_HE
IT	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 version number (for example v 2.0, must be included)

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 The author sends the final draft to the QA Inbox. 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 Author(s), designated, 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.

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)

4.4.4 Once all signatures are received, QA will send an email to all ECTU staff highlighting the relevant departments according to the responsibilities set by the SOP, informing them of the issue of an approved SOP and the date it will become effective. A pdf copy of the finalized SOP will be updated on the ECTU SOP webpage.

4.4.5 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.

4.4.6 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 or on the ECTU webpage, and to return a Read Receipt email in the standard format to the ECTU QA Inbox. Read receipting must be done before the Effective Date of a new or revised SOP or prior to undertaking the procedure (if applicable).

4.4.7 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 stored in the staff's training folder.

4.4.8 QA will file the Read Receipt emails in the appropriate individual's folder in the QA Inbox, and monitor the progress using the SOPs read by individuals Tracker

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 Prior to using Adobe Acrobat Sign, 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'

4.5.1.2 The QA Manager, or designee, will maintain a list of named authorised users, in the QA/ Adobe Acrobat Sign folder on the ECTU shared drive.

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

4.5.1.4 If signatures are not dated, the audit trail of the document will evidence the date 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 4.4.5)

4.5.2 Email Approval

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.

4.5.2.2 The emails of approval will be retained in the appropriate folders for the SOP on the shared drive

4.5.2.3 Once all signatures have been received, the Issue Date and Effective Date will be assigned by the QA Manager or designee.

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 Acrobat Sign is under maintenance.

A pdf and word copy of the approved SOP and any supporting documents will be saved to the appropriate folder on the ECTU shared drive. 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. A master paper copy of the approved QA document will be retained in the rolling storage, and previous/ obsolete paper and electronic versions will be archived.

4.6 Revision of SOPs

4.6.1 No SOP may be revised without the approval from appropriate management, QA and 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. The document must be marked as being in draft and 'Track Changes' must be in force to document the changes to the SOP. The process then follows that detailed from section 4.3.6. At any given time, there should be only one copy in circulation, no copies of the document should be made/ retained elsewhere. Documents shared via email for review must be labelled with the initials of the person editing the document along with

the date, before forwarding.

4.6.4 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 QA will release an electronic copy of the current word version of the SOP, watermarked as Draft, to the author for amendment. Tracked changes should be enabled. 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.

4.7.4 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 must be completed with tracked changes and 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.

4.7.6 When reviewing an SOP, reference should be made to 'SOP Updates Tracker' and any updates made to the SOP as required. The Tracker should be completed by the author documenting actions taken.

4.7.7 If an SOP will require revision in the near future, but there is a valid reason why this cannot be completed before the PRD, the document author should inform QA. If agreed, QA may allow a short grace period or extend the PRD for a short time, for example, 3-6 months.

4.7.8 Once approved (see section 4.5), the new version will be made effective and the Master Document will be created and distributed by QA as described in the sections above (Section 4.4).

4.7.9 Paper copies of any superseded or obsolete SOPs will be marked as such and archived by QA.

4.7.10 Electronic copies of SOP/WPD will be moved to the appropriate 'Previous' folder on the ECT Unit shared drive, 'superseded' or 'obsolete' will be added to the file name as appropriate.

4.8 Working Practice Document (WPD) and Policy Development and Review.

4.8.1 The development, review and circulation of WPD and Policies will follow the same process as that described for SOPs in this SOP.

4.9 Retention Period / Archive

All approved SOP/WPD and policy documents will be retained indefinitely in the ECTU shared drive.

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 shared drive.

5.0 RELEVANT DOCUMENTS AND REFERENCES

- ICH Topic E6 Guideline for Good Clinical Practice – CPMP/ICH/135/95 July 2002
- SI 2004/1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 and amended regulations.
- ECTU_SOP_QA_01 – QA Management of ECTU controlled Standard Operating Procedures, Working Practice Documents and their Periodic Review.
- SOP and WPD Templates
- Policy Template
- SOP Updates Tracker
- SOPs read by individuals Tracker
- ECTU Core SOPs Read Receipt list (QA002)
- ACCORD AD007: Use of Electronic Signatures in Accord
- ACCORD QA001: Standard Operating Procedure Preparation and Control - SOPs | Accord