

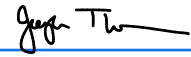





## ECTU Central Office SOP\_OP\_19: ECTU File and/or Email Access for External & ECTU Staff

Version No:	2.0
Issue Date:	16 Apr 2026
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Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval/ Authorisation	Date	Signature
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Tanya Tharakan, QA Manager	QA Authorisation	16-Apr-2026	 <a href="#">Tanya Tharakan (16-Apr-2026 13:12:36 GMT+1)</a>

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	08 Nov 2023	Initial creation
2.0	11 May 2026	The title has been amended to reflect the changes to the SOP. Included sections 4.2.2 and 4.2.3 to address temporary requests. Updates throughout the document to reflect current processes.

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## 1.0 PURPOSE

There are occasions when access for persons outside ECTU is requested for generic email inboxes or electronic ECTU project folders held within the University of Edinburgh DataStore location. There are certain considerations that need to be taken into account before deciding if access can be provided before the conclusion of the trial.

This SOP describes the process required to be followed when providing ECTU file or folders, mail box and folder access to a third party who is not a substantive ECTU staff member.

## 2.0 SCOPE

This SOP applies to those in ECTU who seek to provide access to electronic folders held on the ECTU shared drive and/or ECTU project email inboxes to a third party who do not currently have access and are not a substantive staff member of ECTU.

## 3.0 RESPONSIBILITIES

It is the responsibility of the ECTU staff member who is seeking access on the behalf of a third party to advise their Team Lead/Line Manager of the request and obtain approval to proceed with granting access.

The Team Lead/Line Manager is responsible for assessing the legitimacy of this request.

It is the person seeking access on behalf of a third party who is responsible for ensuring that relevant SOPs/WPDs/Policies are read and any updates communicated to third party and read receipts retained, where applicable.

QA will maintain and annually review a tracker (OP-T04 External Access to ECTU Folder and Email Inbox Tracker) of those external to ECTU who have access to drives.

The Trial Manager is responsible for following the process to request access via the Business Team Lead and/ or ECTU Chief Operating Officer, and to request removal of access when it is no longer required and informing QA.

## 4.0 PROCEDURE

### 4.1 Assessment of the access request

4.1.1 Once it is identified that an individual external to ECTU requires access to electronic files or folders on the ECTU DataStore and/ or ECTU project email inbox, the staff member requesting this should discuss the request with their Team Lead/Line Manager.

4.1.2 The following information should be provided to Team Lead/Line manager for consideration:

- Name of individual who requires access
- What access is required and at what folder hierarchy / email account level

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- If read only access or read write access is required.
- Why is access required (Note: special consideration must be given to the impact of access, for example trial confidentiality, ability to send email from a trial mailbox with attachments, accidental deletions etc.)
- Their current status regarding UoE Credentials
- Evidence of appropriate training i.e. GCP training within a 2 year validity period, along with trial specific training, as required.

## 4.2 Types of access requests

### 4.2.1 Long-term access to files/ folders and/or email inbox

If **read-write** access is required for a **longer term**, for example, when trial management has been handed over to a third party, the Team Lead will discuss at the Operational meeting and provide feedback, whether approved or rejected, to the team member who requested access via email copying in the ECTU QA inbox. This should be retained in TMF Section 6, preferably in a PDF format.

**For Files/ Folders:** The email must include the name of third party, folders they require access to (File path), the date they require access and for how long.

**For Email Inbox:** The email must include the name of third party, email inbox they require access to, the date they require access and for how long

**For Files/ Folders and Inbox:** Follow the above steps for Files/ Folders and Email Inbox.

The above information will be added to OP-T04 External Access to ECTU Folders and Email Inbox Tracker (see section 5)

#### 4.2.1.1 If access has been approved

The member of ECTU requesting access must:

- a) Consult with the QA Manager to generate the list of SOPs/ WPDs/ Policies based on those tasks that will be undertaken once access has been provided. This list will then be communicated to both the person requesting access for completion and the recipient, via the QA mailbox. This will be recorded in the OP-T04 External Access to ECTU Folders and Email Inbox Tracker.
- b) Obtain the read receipt confirmation for all documents on the list generated in point (a) and communicate this to the QA mailbox. This will provide confirmation that the individual is suitably trained in those ECTU procedures appropriate to the task they will be performing. QA will retain the email as evidence of read receipts. This will be recorded in the OP T04 External Access to ECTU Folders and Email Inbox Tracker
- c) Obtain a signed and dated [ECTU Declaration of Confidentiality Form](#)

The above documents should be retained in TMF Section 6.

- d) The study delegation log, if appropriate, should be updated to reflect the responsibilities/tasks to be performed following access being provided.

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**Note: In the case of requests for email access, IS should contact the mailbox Administrator to validate the request before granting access.**

#### 4.2.1.2 If access has been denied

In the case where access has been denied, (for example, where the risk of access is deemed too high, or the request not justified) alternative methods of sharing information will be considered by the Operations team, and conveyed to the Trial Manager/ Team Lead and the requester.

### 4.2.2 For read only temporary access to DataStore

If **read only** access is required for a **shorter term**, for example, when the sponsor monitor is inspecting files for a TMF audit, and would require access to a study folder for up to two weeks, see Section 4.3. Short-term access requests should be discussed with the QA Manager to determine the requirement for SOP read receipts.

**Note:** UoE VPN should be set up as soon as possible. If the visitor is using an NHS laptop, for example, the restrictions on these devices make access difficult. It would be preferable if UoE VPN is set up prior to the date of access.

### 4.2.3 For temporary read-write access

If read-write access is required for internal ECTU staff, for example to the 'Completed Projects' folder for further statistical work, the requestor must contact either the Chief Operating Officer, Business Team Lead or the QA Manager.

## 4.3 Contacting IS to execute approved access requests

4.3.1 The Trial Manager or designee will contact the Business Team Lead, copying the Chief Operating Officer and the QA inbox, requesting them to email the UoE IS helpdesk for access to be granted. IS will only approve requests that come in from authorised staff in ECTU. They will require the following information to allow access to be given:

- Project Name/ Folder
- Name of the person (and email ID if available)
- Individuals' UUN (If the third party is not a member of UoE, Team Lead/Line Manager will need to first contact Usher to set up an UoE visitor status)
- Purpose/ reason for requesting access
- Time frame - Date from the time access is required to when it must be removed
- Details of the folder to be accessed (file path should be provided, note it may only be possible to provide access to folder at a higher level within the structure i.e., project folder, and not specific folders within that project folder.)
- Specify if **READ ONLY** access is required. IS will automatically grant read-write access if not specified.

4.3.2 If IS grants access without the request coming in from authorised ECTU personnel, or read-write access was granted in error, or if any other similar event has occurred, this

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should be reported to the Chief Operating Officer or the QA Manager as a data security incident.

4.3.3 Once IS have provided access this should be communicated to those involved, copying in the QA inbox.

#### **4.4 Once access has been provided by IS**

4.4.1 A record of those individuals external to ECTU who have access to ECTU files/email inboxes will be maintained by QA.

4.4.2 Where applicable, it is the responsibility of QA to ensure that any updates to SOPs/WPDs/Policies that were originally read or new documents that become relevant are communicated and a read receipt retained.

#### **4.5 When access is no longer required**

4.5.1 If the timeframe is not stated as per 4.3.1, when access is no longer required to folders on DataStore and/or ECTU email inboxes the Trial Manager will inform the Business Team Lead/ Chief Operating Officer, who will then contact IS and request that access is removed. QA will be informed once this has been completed.

4.5.2 For temporary read-write access for internal staff, the requesting staff member or staff member(s) working on the study will inform the Business Team Lead/ Chief Operating Officer or the QA Manager when access is to be removed.

4.5.3 QA will update the tracker with appropriate dates.

4.5.4 QA will review the tracker on an annual basis and ensure that all who have access still require it. The document will be saved in the QA folder in DataStore (\ECT Unit\QA).

#### **5.0 RELEVANT DOCUMENTS AND REFERENCES**

- [ECTU Declaration of Confidentiality Form](#)  
(\ECT Unit\1. ECTU FILING SYSTEM - AMENDED 2010\ECTU Administration\HUMAN RESOURCES\Induction Pack\Current Induction Pack)
- OP-T04 Access to ECTU Folders and Email Inbox Tracker template  
(ECT Unit\SOPs\Finalised SOP and WPD\OP\Supporting Documents and Templates\Current)

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# ECTU\_SOP\_OP\_19\_ECTU File andor Email Access for External & ECTU Staff v2.0

Final Audit Report

2026-04-16

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