ECTU Central Office POL03: ECTU Staff Induction and Training Policy

Version No:	3.0
Issue Date:	05 Oct 2026
Effective Date:	02 Nov 2026

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Tanya Tharakan, QA Manager	Author	05-Oct-2026	Signature on file Tanya Tharakan (05-Oct-2026 10:17:28 GMT+1)
Gina Cranswick, Trial Management Team Lead	Reviewer	05-Oct-2026	Signature on file
Joyce Thomson, Chief Operating Officer	Approver	05-Oct-2026	Signature on file

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	22 Feb 2022	Initial Creation
2.0	01 Jul 2024	Document updated to version 4 template. Processes regarding prolonged absences, DSPT assessment (3.5) and training requirements (3.6, 3.7) included. Significant changes to reflect current processes. Minor formatting changes.
3.0	02 Nov 2026	Update to section 3.3.8 regarding long absences which will be considered as longer than 4 weeks. All sections

		have been updated to reflect current processes. New sections 3.7 and 3.8 added. QMS template updated to v5.0

1.0 PURPOSE

1.1 The following document defines the Edinburgh Clinical Trials Unit (ECTU) policy on staff induction and training.

1.2 ICH-GCP E6 (R3) Guidelines and the Medicines for Human Use (Clinical Trials) Regulations (SI 2004 1031), as amended, specify that:

Section C.3 Essentiality of Trial Records of ICH GCP E6(R3)

(l) Documents that sponsor personnel involved in the trial conduct and individuals performing significant trial-related activities on their behalf are qualified by education, training and experience to undertake their activities;

(m) Documents that the investigator and those individuals delegated significant trial-related activities by the investigator are qualified by education, training and experience to undertake their activities, particularly where the activities are not part of their normal role;

1.3 In addition, the UK Policy Framework for Health and Social Care Research states that, "All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks."

2.0 SCOPE

This policy applies to all staff members within ECTU.

3.0 POLICY

Job descriptions are reviewed and graded as per University of Edinburgh (UoE) policy or NHS policy where applicable to ensure the appropriate criteria for each role are defined.

When staff are appointed within ECTU they will have demonstrated meeting the essential criteria stated within a graded job description through previous job experience, during the interview process, through training and GCP certification (where applicable), prior to appointment in post.

3.1 Staff Induction Process

3.1.1 All new ECTU staff will undergo an induction and training programme which will be tailored to suit their job description. This will be overseen by their line manager or designee and detailed within an induction pack (containing other relevant information about the job, responsibilities and general office information).

3.1.2 Before the new staff member joins the unit, the Usher HR (Usher.HRGovernance@ed.ac.uk) processes will initiate the setup of the UoE University User Name (UUN), email address and access to the University network via IS.

3.1.3 The line manager or delegate will ensure that an appropriate buddy is appointed and introduced to the new staff member on arrival into the department. This will ensure that new staff have informal support.

3.1.4 Staff are required to establish and maintain their training record in line with ECTU_SOP_QA_02 Maintaining an Electronic Staff Training Record.

3.1.5 Team representatives will conduct an induction relevant to the department for new staff members. Depending on the post, meetings are held with the Team Leads. A meeting with the QA manager for the QA induction is mandatory and preferably completed within the first 1-2 days of the start date or as soon as feasible.

3.2 Essential Training

3.2.1 Within the first 3 months of employment, as detailed in ECTU_SOP_OP_01 Development and Management of Policies, SOP (Standard Operating Procedures) and WPD (Working Practice Documents) staff should have undertaken the following training:

- USHER Institute/ University of Edinburgh training requirements – as defined in the current USHER training matrix
- ECTU training requirements – this is the responsibility of the individual's line manager and defined in the induction plan.
- Good Clinical Practice (GCP) E6(R3) Training (or provided evidence of their certificate to ECTU QA, should their GCP training be up to date as per section 3.3.2).

3.2.2 Continued training needs will be identified by individuals and their line managers in an ongoing basis against role responsibilities, requirements and progression opportunities. Competence will be documented appropriately in the ECTU e-training record.

3.2.3 Line managers will address any gaps in competency and knowledge. Should significant remedial actions be required, these will be carried out in accordance with University of Edinburgh/ Usher Institute HR policies and documented appropriately.

3.3 GCP Training

3.3.1 All members of staff will be required to undertake GCP Training. The training course should be part of the TransCelerate GCP training mutual recognition programme.

3.3.2 GCP training should be completed within the first 2 weeks of their appointment, to ensure it is undertaken prior to completing any regulatory tasks.

3.3.3 The GCP course can be completed either by attending an online or in-person course. If there is no in-person course available within the first 2 weeks of appointment, the staff member should complete the Introductory online course. It is acceptable to provide a GCP certificate from a previous job post, provided it was updated to the E6(R3) guidelines and the expiry is within 24 months of the start date at ECTU.

3.3.4 GCP training must be renewed every 24 months.

3.3.5 QA will maintain a GCP training Tracker which details current GCP certificate date and expiry date. Reminders will be sent by QA to individuals when expiry is approaching. It is the individual's responsibility to arrange and attend the training course. QA will also maintain an MRC GDPR Training Tracker and send reminders to applicable staff members.

3.3.6 Following the initial GCP training and certification, staff should complete a refresher course at least once every 24 months. If training lapses by more than 3 months, the full introductory training course must be completed. Where necessary, the QA Manager will escalate any gaps in GCP training to the line manager.

3.3.7 GCP training should be evidenced within individuals training record.

3.3.8 If the staff member has been on a prolonged period of absence (more than 4 weeks and/ or subject to the line manager's discretion) refer to section 3.6 Training Reviews and Retraining, to determine the course of action.

3.4 Policies, Standard Operating Procedures (SOPs) and Working Practice Documents (WPDs)

3.4.1 All ECTU staff members will have access to ECTU's Policies**,** SOPs and WPDs and the relevant sponsor documents to provide training and guidance 3.4.2. It is the responsibility of each individual to ensure SOPs and other QA documents applicable to their role are read and understood and the read receipt process followed as indicated during their QA induction.

3.4.2 QA will ensure the relevant documents are distributed to the appropriate individuals for awareness and reading. New staff members will be provided with a reading list according to their job role during their QA induction within the first two weeks of their start date.

3.5 Data Security and Protection Toolkit (DSPT) Assessment

3.5.1 All ECTU staff members are required to complete the below University of Edinburgh courses on an annual basis, to meet the prerequisite for DSPT -

- Data Protection Essentials
- Information Security Essentials

3.5.2 The training will be evidenced in the individuals' training records. Annual training record reviews by the line manager will verify the completion of the necessary courses.

3.6 Training Reviews and Retraining

3.6.1 Training record reviews are conducted annually (at a minimum) in line with ECTU WPD_QA_W1: Training Record Review of Electronic Staff Training Record. There are circumstances which may prompt training reviews by the QA Manager and/or line manager, for example, returning to work after maternity leave, prolonged sick leave/ absence, secondment, requests from staff etc. Prolonged absences may be identified as a period of more than 4 weeks. The review may require the staff member to conduct

additional training or retraining. This will be determined based on the training review conducted by the line manager and/ or QA manager.

3.7 Return to Work QA induction

3.7.1 The QA manager can conduct a return-to-work QA induction if requested by the line manager. This is not a mandatory requirement and will be discussed between the line manager and the QA manager based on the length of absence.

3.8 Completion of Induction/ Training

3.8.1 In the case where the induction schedule or subsequent training check points (e.g., probation) have not been completed satisfactorily, access to ECTU DataStore and systems may be restricted following discussion between the line manager and the QA manager.

4.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website:

- ECTU SOP_QA_02: Maintaining an Electronic Staff Training Record
- ECTU_SOP_OP_01: Development and Management of ECTU QA Controlled Documents

Others:

- ECTU Induction Pack. (\ECT Unit\1. ECTU FILING SYSTEM - AMENDED 2010\ECTU Administration\HUMAN RESOURCES\Induction Pack\Current Induction Pack)
- Usher Training Matrix.pdf
- Usher Institute Induction pack
- University of Edinburgh Induction Checklist for New Employees and Managers (P&M)
- Data Protection Essentials (on P&M Learn)
- Information Security Essentials (on P&M Learn)

ECTU Central Office POL03 - Staff Induction and Training Policy v3.0

Final Audit Report 2026-10-05

Created:	2026-10-05 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAZTO4d8IPRjRsba4vzsYoDF-n8kJPduRv

"ECTU Central Office POL03 - Staff Induction and Training Policy v3.0" History

Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2026-10-05 - 10:11:41 GMT+1- IP address: 192.41.114.230

Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2026-10-05 - 10:17:21 GMT+1

Document emailed to Gina Cranswick (gina.cranswick@ed.ac.uk) for signature
2026-10-05 - 10:17:21 GMT+1

Document emailed to Joyce Thomson (joyce.thomson@ed.ac.uk) for signature
2026-10-05 - 10:17:22 GMT+1

Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Signature Date: 2026-10-05 - 10:17:28 GMT+1 - Time Source: server- IP address: 192.41.114.230 - Signature appearance selected: DRAW

Email viewed by Joyce Thomson (joyce.thomson@ed.ac.uk)
2026-10-05 - 10:24:48 GMT+1- IP address: 104.47.11.62

Email viewed by Gina Cranswick (gina.cranswick@ed.ac.uk)
2026-10-05 - 10:25:14 GMT+1- IP address: 104.47.11.126

Document e-signed by Joyce Thomson (joyce.thomson@ed.ac.uk)
Signature Date: 2026-10-05 - 10:25:22 GMT+1 - Time Source: server- IP address: 192.41.114.227 - Signature appearance selected: IMAGE

Document e-signed by Gina Cranswick (gina.cranswick@ed.ac.uk)
Signature Date: 2026-10-05 - 10:26:03 GMT+1 - Time Source: server- IP address: 151.224.226.213 - Signature appearance selected: IMAGE

Adobe Acrobat Sign

Agreement completed.

2026-10-05 - 10:26:03 GMT+1

Adobe Acrobat Sign