

ECTU Central Office POL06: Quality Policy

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	16 Mar 2026	Initial Creation/ Previously POL006 ACCORD Quality Policy.

The user of this document is responsible for ensuring it is the current version.

1.0 PURPOSE

The Edinburgh Clinical Trials Unit (ECTU) sits within the Usher Institute, the School of Population Health Sciences, University of Edinburgh.

ECTU provides an infrastructure to design, plan and deliver clinical research studies across a varied portfolio of clinical specialties and methodologies, offering various levels of support according to the project, protocol and the needs of the research team.

Along with ACCORD (the Sponsors' office), ECTU provides an environment for academic collaboration with the clinical research community, from study inception to study close down, to fulfil legal, ethical and scientific obligations to the healthcare research process.

2.0 SCOPE

This Quality Policy is applicable to all ECTU personnel.

This policy will be reviewed every 2 years.

3.0 POLICY

3.1 To maintain a Quality Management System (QMS) consisting of Policies, Standard Operating Procedures (SOPs), Working Practice Documents (WPDs), Templates, Trackers, Work Instructions and guidance documents, designed and implemented to ensure that ECTU can fulfil its obligations and responsibilities as a clinical trials unit, in accordance with Good Clinical Practice (GCP), Medicines and Healthcare products Regulatory Agency (MHRA), the UK Policy Framework for Health and Social Care Research, and applicable regulatory requirements.

3.2 To ensure Internal Audits are performed to evaluate conduct and compliance with study protocols, policies, guidelines, SOPs, GCP and any regulatory requirements.

3.3 To ensure that ECTU personnel are trained sufficiently for GCP compliance and monitored for continuity and compliance.

3.4 To identify opportunities for ECTU personnel to undertake appropriate training and education for continual improvement.

3.5 To provide appropriate guidance and advice to ECTU personnel regarding the conduct of compliant research.

3.6 To devise effective Corrective and Preventative Action when required and implement Quality Improvement as a continuous process.

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4.0 RELEVANT DOCUMENTS AND REFERENCES

[ACCORD Website](#)

- POL006 ACCORD Quality Policy

Others

- UK Policy Framework for Health and Social Care Research
- ICH-GCP E6(R3) guidelines
- Medicines and Healthcare products Regulatory Agency (MHRA)

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Final Audit Report

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