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.
2.0	02 Nov 2026	Updated section 3.1.2 with reference to SOP management for external (non-ACCORD) sponsors. A new section 3.2 has been added. QMS footer updated.

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, deliver and disseminate 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 Sponsors, both external to UoE and with ACCORD (the UoE/NHSL joint Sponsors' office), ECTU provides an environment for academic collaboration with the clinical research community, from study inception to study close down and dissemination, 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 QMS specific documentation, auditing, guidance and training

3.1.1 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.

3.1.2 ECTU staff will follow and comply with the relevant sponsor SOPs applicable to the project. Staff will ensure that project activities are conducted in accordance with the current approved version of the SOP and associated documents. Where external sponsor SOPs are not available, the ACCORD SOPs will be followed for the process. In such cases, where ACCORD is referenced in these documents, the external sponsor will be inferred.

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

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

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

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

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

3.2 Non-QMS documentation

3.2.1 Certain documents do not fall within the scope of GCP or applicable regulatory requirements and therefore do not require adherence to the standard QMS documentation process or associated procedural steps, for example, Process Guidance Documents, finance and finance related documentation, documents related to People & Money (P&M) and HR documentation.

3.2.2 Process Guidance Documents (PGD)

- May be created by a staff member or process owner where written guidance is considered beneficial and there is no regulatory requirement for an SOP.
- An example of a PGD is the document that defines the non-GCP activity before 'project team set-up' as detailed in Table 1.3 Key trial/project management considerations in the MHRA grey guide, page 40.
- PGDs are owned and approved by the relevant process owner or a suitably knowledgeable delegate and are reviewed or updated as required.
- They are managed outside the ECTU QMS and therefore do not require QA Manager approval, a predefined review cycle or inclusion in staff training records.
- PGDs shall include sufficient information to support the intended audience, A modified version of the OP T08 ECTU Central Office SOP template may be used if appropriate.
- Current PGDs can be hosted via the ECTU website and managed by the relevant process owner/team.

4.0 RELEVANT DOCUMENTS AND REFERENCES

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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