

QUALITY POLICY

DOCUMENT NO.:	POL006 v4.0
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ISSUE DATE:	16 OCT 2024
EFFECTIVE DATE:	30 OCT 2024

1 Introduction

- 1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).
- 1.2 ACCORD provides a streamlined support service for the clinical research community, from study inception to study close down, and are here to help our researchers and our organisations meet research governance and regulatory requirements, ensuring we all fulfill legal, ethical and scientific obligations to the healthcare research process.

2 Scope

- 2.1 This Quality Policy is applicable to all ACCORD personnel.

3 Policy

- 3.1 To maintain a **Quality Management System (QMS)** consisting of policies, guidelines and Standard Operating Procedures (SOPs) designed and implemented to ensure that NHSL and/or UoE can fulfil their obligations and responsibilities as Sponsors or host of clinical research, in accordance with Good Clinical Practice (GCP), the UK Policy Framework for Health and Social Care Research, and applicable regulatory requirements.
- 3.2 To use **Risk Analysis** tools to ensure the most effective use of ACCORD and study resources, to demonstrate an evidence based approach to research oversight, to determine audit schedules and to classify studies Sponsored or hosted by the NHSL and/or UoE.
- 3.3 To ensure **Audits** are performed to evaluate conduct and compliance with study protocols, policies, guidelines, SOPs, GCP and any regulatory requirements.
- 3.4 To ensure that affordable opportunities are available to clinical researchers and ACCORD personnel to undertake appropriate **Training**.
- 3.5 To provide appropriate **Guidance** and advice to clinical researchers and ACCORD personnel regarding the conduct of compliant research.

- 3.6 To devise effective Corrective and Preventative Action and implement Quality Improvement as required.




4 References and related documents

- UK Policy Framework for Health and Social Care Research
- ICH-GCP E6(R2) guidelines

5 Document history

Version Number	Effective Date	Reason for Change
1.0	16 NOV 2015	New Policy.
2.0	16 SEPT 2016	Removal of reference to Key Performance Indicators.
3.0	05 OCT 2018	Change of author. Updated applicable references.
4.0	30 OCT 2024	Following periodic review, policy moved over to updated policy template

6 Approvals

Sign	Date
 AUTHOR: Lorn Mackenzie, QA Manager, NHS Lothian, ACCORD	Oct 14, 2024
 <small>Heather Charles (Oct 14, 2024 13:45 GMT+1)</small> APPROVED: Heather Charles, Head of Research Governance, NHSL, ACCORD	Oct 14, 2024
 <small>Gavin Robertson (Oct 14, 2024 13:40 GMT+1)</small> AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	Oct 14, 2024












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Final Audit Report

2024-10-14

Created:	2024-10-14 (British Summer Time)
By:	Roisin Ellis (v1relli8@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAYAMFfPXceuq6Q5lrXpyXNY0o1we0CnI6

"POL006 Quality Policy v4.0" History

-  Document created by Roisin Ellis (v1relli8@exseed.ed.ac.uk)
2024-10-14 - 1:32:15 PM GMT+1- IP address: 62.253.82.231
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2024-10-14 - 1:34:30 PM GMT+1
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2024-10-14 - 1:34:30 PM GMT+1
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2024-10-14 - 1:38:37 PM GMT+1- IP address: 52.102.17.117
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Signature Date: 2024-10-14 - 1:45:05 PM GMT+1 - Time Source: server- IP address: 62.253.82.231
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2024-10-14 - 2:23:49 PM GMT+1- IP address: 52.102.16.149
-  Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2024-10-14 - 2:24:02 PM GMT+1 - Time Source: server- IP address: 62.253.82.232

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