

QUALITY POLICY

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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 Research Governance Framework (February 2006, 2nd ed.), 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.

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

4 REFERENCES AND RELATED DOCUMENTS

- Research Governance Framework for Health and Community Care (Scotland 2006 2nd ed)
- ICH-GCP E6 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.

6 APPROVALS

Sign	Date
Signature Kept on File AUTHOR: Heather Charles, QA Manager, NHS Lothian, ACCORD	
Signature Kept on File APPROVED: Fiona McArdle, Deputy R&D Director, NHSL, ACCORD	
Signature Kept on File AUTHORISED: Lorn Mackenzie, QA Coordinator, NHSL, ACCORD	

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