GCP and SOP Training

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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 The International Council for Harmonisation (ICH) Guideline for Good Clinical Practice E6(R3) and the Medicines for Human Use (Clinical Trials) Regulations, as amended, require that:

"Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his or her respective task(s)"

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 Scope

2.1 This policy is applicable to all researchers working within NHS Lothian and to researchers working in studies at any location, sponsored by UoE and/or NHS Lothian. This policy is also applicable to ACCORD staff members.

3 Policy

3.1 ACCORD Provision of Research Training Opportunities

3.1.1 ACCORD will ensure that regular opportunities to undertake GCP training are provided to UoE and NHS Lothian researchers and local members of staff involved in research activities. ACCORD will ensure that more than one method of training is provided (e.g. classroom based education and individual electronic learning opportunities) to cater for a range of needs and circumstances.

3.1.2 ACCORD will provide details regarding up-coming GCP training opportunities and a point of contact to researchers regarding GCP and regulatory requirements for clinical research.

3.1.3 Evidence of GCP training will be provided to participants at the successful conclusion of training activities.

3.1.4 The level, content and frequency of GCP training should be proportionate to the complexity of the study, the risks to participants, and the responsibilities delegated to the individual. Training should ensure personnel are suitably qualified and competent to perform their assigned trial activities.

3.1.5 ACCORD will provide training to UoE and NHS Lothian researchers regarding ACCORD clinical research Standard Operating Procedures (SOPs) at agreed convenient times.

3.2 GCP Training Requirements for Researchers in Clinical Trials of Investigational Medicinal Products (CTIMPs) or Clinical Investigations of Medical Devices (CIMD)

NHSL Hosted Studies

3.2.1 ACCORD will provide training to UoE and NHS Lothian researchers regarding ACCORD clinical research Standard Operating Procedures (SOPs) at agreed convenient times.

3.2.2 Principal Investigators (PIs) and Chief Investigators (CIs) are required to provide evidence of GCP training to ACCORD before Research and Development (R&D) management approval can be granted for a particular study.

3.2.3 Evidence of PI / CI GCP training can consist of a training certificate/qualification. The evidence must state the date of the most recent GCP training to the nearest month and year. Evidence of GCP training should also be retained by the researcher.

3.2.4 Each PI is responsible for ensuring that personnel conducting study-specific activities are appropriately trained, qualified and competent for their delegated responsibilities. Training may include full GCP training, role-specific GCP training or task-specific training, as appropriate to the duties being undertaken.

3.2.5 This training must be completed prior to beginning study specific activities.

3.2.6 Where delegated trial activities form part of an individual's normal clinical duties, a proportionate approach to GCP training may be adopted. The sponsor should document the training requirements appropriate to the delegated activities and associated risks.

3.2.7 GCP training will only be considered valid if the most recent training has occurred within the last 24 months. In addition to a valid GCP certificate, local research site staff should have a current CV signed and dated within 24 months.

Sponsored Studies

3.2.8 For multicentre CTIMP/CIMD studies conducted out with NHSL and sponsored by UoE and/or NHSL, researchers are required to undertake GCP training. The frequency of GCP training may be dictated by local site policy however re-training may be required where there is a change to legislation.

3.2.9 Evidence of valid GCP training for the CI and any local co-investigators shall be checked by Research Governance upon receipt of application for Sponsorship and confirmed prior to Sponsor Authorisation to Open (SATO).

3.2.10 Acceptable GCP training should be recognised by the Sponsor and aligned with current ICH E6(R3) principles. Training delivered through the TransCelerate GCP Mutual Recognition Programme remains acceptable evidence of training. Alternative training programmes may be accepted where approved by the Sponsor.

3.2.11 The PI is responsible for ensuring that all members of staff conducting study specific procedures at their local site have completed GCP training before beginning study specific activities. Evidence of GCP training for all researchers named on the delegation log must be kept in the Trial Master File or Investigator Site File.

3.2.12 If a research activity is part of a study team member's normal clinical role, commensurate GCP training may be permitted by the Sponsor.

3.3 GCP Training Requirements for Researchers in non-CTIMP studies

3.3.1 All members of staff involved in study-specific activities should receive training appropriate to the activities they perform. For non-CTIMP studies, this may include GCP training, research practice training or other study-specific training considered appropriate by the Sponsor.

4 References and Related Documents

- ICH Harmonised Guideline E6(R3) Good Clinical Practice (2025)
- Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.
- UK Policy Framework for Health and Social Care Research

5 Document History

Version Number	Effective Date	Reason for Change
1.0	23 DEC 2010	New Policy.

2.0	18 APR 2016	New Policy template. Minor text changes throughout.
3.0	10 MAY 2018	Update to the ICH-GCP E6(R2) Guidelines and the UK Policy Framework for Health and Social Care Research.
4.0	13 MAY 2020	Additional clarity added re. requirements for GCP training for sponsored and hosted studies.
5.0	21 MAY 2024	Addition at section 3.2.6: clarification regarding the requirement for local research site staff to have a current CV signed and dated within two years.
6.0	30 JUL 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3). Transfer to current policy template.

6 Approvals

Sign	Date
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