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 ICH-GCP E6(R2) Guidelines and the Medicines for Human Use (Clinical Trials) Regulations (SI 2004 1031), as amended, specify 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 of GCP training required can be commensurate with the study type and role of the individual in the study team.

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 For CTIMP/CIMD studies hosted in NHSL, including studies sponsored by UoE and/or NHSL, researchers **in** NHS Lothian and/or conducting research with NHS Lothian participants, are required to undertake GCP training every two years.

3.2.2 Principal Investigators (PIs) and Chief Investigators (CIs) (who are not also acting as a PI), 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 local research site staff, involved in study specific activities, has undertaken GCP training. This training must be completed prior to beginning study specific activities.

3.2.5 If a research activity is part of a study team member's normal clinical role, the extent of GCP training required should be discussed and agreed with the study Sponsor.

3.2.6 GCP training will only be considered valid if the most recent training has occurred within the last 24 months.

Sponsored Studies

3.2.7 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 change to legislation.

3.2.8 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).

3.2.9 Valid GCP training is a course that is part of the Transcelerate GCP Training Mutual Recognition programme, or otherwise agreed with the Sponsor on a per study basis.

3.2.10 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.

3.2.11 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 are strongly encouraged to undertake GCP training in order to understand the principles of GCP. This is not a mandatory requirement unless deemed necessary by the sponsor.

4 REFERENCES AND RELATED DOCUMENTS

- ICH-GCP E6(R2) Guidelines
- The Medicines for Human Use (Clinical Trials) Regulations (SI 2004 No. 1031), as amended.
- 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.

6 APPROVALS

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