# 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 tasks"*

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 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)

3.2.1 Researchers **in** NHS Lothian and/or conducting research with NHS Lothian participants, working on a study(ies) sponsored by UoE and/or NHS Lothian, are required to undertake GCP training.

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 can consist of a training certificate/qualification or an entry on a Curriculum Vitae (CV) or résumé. 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.

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

3.2.6 Researchers **outside** NHS Lothian, not conducting research with NHS Lothian participants but working on a study(ies) sponsored by UoE and/or NHS Lothian, are required to undertake GCP training.

3.2.7 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.

3.2.8 Research governance staff members will ensure that the CI formally acknowledges this requirement before the study commences.

3.2.9 Researchers in NHS Lothian, working on a study(ies) that is **not** sponsored by UoE and/or NHS Lothian are recommended to undertake GCP training.

3.2.10 PIs and CIs who are not also acting as a PI, will be contacted via written correspondence, by research governance staff members, and reminded that ACCORD policy recommends them to have undertaken GCP training within the previous 24 months before commencing study specific activities.

3.2.11 An insert in the project specific NHS Lothian management approval letter will indicate this and copy the study sponsor.

3.2.12 Each PI is responsible for ensuring that local research site staff members have undertaken GCP training before beginning study specific activities. This will also be stated in the aforementioned correspondence.

### 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. |

## 6 APPROVALS

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