SPONSORSHIP DUTIES AND RESPONSIBILITIES

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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 the sponsor of a clinical research study is:

"An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial"

1.3 NHSL and the UoE assume the role of sponsor in a study where a qualified representative of the relevant institution formally consents to this role. This must be documented. NHSL and the UoE can assume the role of the sponsor as an individual institution or collectively i.e. co-sponsorship. NHSL responsibilities and duties towards studies that are hosted are defined in the UK Policy Framework for Health and Social Care Research.

2 SCOPE

2.1 This policy is applicable to all researchers working within NHS Lothian and to researchers working in Clinical Trials of Investigational Medicinal Products (CTIMPs)/Clinical Investigation of a Medical Device (CIMDs) or non-CTIMPs at any location, sponsored/co-sponsored by NHSL and/or UoE.

2.2 This policy is also applicable to ACCORD staff members involved with research governance and facilitation.

3 POLICY

3.1 Responsibilities and Duties Retained

3.1.1 The following areas of sponsorship will not be transferred to another organisation and will be operationally undertaken by NHSL and the UoE, unless it is otherwise agreed and documented:

- *Quality assurance, including* audit and vendor assessment – procedures are described in ACCORD standard operating procedures (SOPs) under the "Quality Assurance" operational area.
- *Clinical trial monitoring, including source data verification* - procedures are described in ACCORD SOPs under the "Clinical Monitoring" operational area.
- *Record keeping (sponsor), including set up and maintenance of Trial Master Files (TMFs) and archiving* - procedures are described in ACCORD SOPs: "CR001 Establishing and Maintaining Trial Files – ISFs, TMFs and Sponsor Files and GS005 Archiving Essential Study Documentation.
- *The provision of indemnity/insurance* - procedures are described in ACCORD SOPs under the "Governance and Sponsorship" operational area.
- *Confirmation that appropriate finance is in place for the duration of a study* - procedures are described in ACCORD SOPs under the "Governance and Sponsorship" operational area.
- *Pharmacovigilance* - procedures are described in the ACCORD SOPs under the "Pharmacovigilance" operational area.

3.1.2 The following areas of sponsorship will not be transferred to another organisation by NHSL and UoE, unless it is otherwise agreed and documented. The following areas will be operationally performed by Investigators, or designees, in accordance with ACCORD procedures unless otherwise agreed and documented:

- *Protocol design* – procedures are described in ACCORD SOP: "CR007 Study Documents".
- *Clinical study report preparation, including dissemination of results e.g. publication, EudraCT reporting* - procedures are described in ACCORD SOP: "CR011 Clinical Study Report Preparation - CTIMPs".
- *Ethics and regulatory submissions and notifications* - procedures are described in ACCORD SOPs: "GS003 Sponsorship Approval" and "CR008 Preparing and Submitting Progress and Safety Reports".
- *Record keeping (investigator), including set up and maintenance of Investigator Site Files (ISFs) and archiving* - procedures are described in ACCORD SOPs*: "*CR001 Establishing and Maintaining Trial Files – ISF, TMFs and Sponsor Files", "CR009 Study Closure and Archiving" and other references can be found in the "Clinical Research" operational area SOPs where appropriate.

3.1.3 The wider conduct of clinical research by investigators is described in ACCORD SOPs under the "Clinical Research" operational area.

3.2 Responsibilities and Duties Delegated

3.2.1 The following areas of sponsorship will be transferred to another organisation or the Chief Investigator (CI) and will be operationally undertaken by another

organisation or the CI unless it is otherwise agreed and documented. It will be the responsibility of the sponsor or co-sponsors to ensure that the following responsibilities are formally transferred to another organisation or the CI in an agreement or equivalent document:

- *Statistical analysis* – all important details of study design and conduct and the principal features of its proposed statistical analysis must be clearly specified in a statistical analysis plan, or the study protocol, before the trial begins unless the sponsor or co-sponsors formally state otherwise. The sponsor or co-sponsors expect the responsible organisation/CI will ensure that statistical analysis is undertaken by appropriately qualified individuals. Study scope, context, design, conduct, data analysis techniques, safety/tolerability and reporting must all be considered in the preparation of a statistical analysis plan and the conduct of statistical analysis. ICH E9 Guidelines (Statistical Principles for Clinical Trials) must also be observed where applicable. The protocol and subsequent amendments pertaining to study design or methodology must be approved by the trial statistician.
- *Data capture and data management* - the sponsor or co-sponsors expect the responsible organisation/CI will utilise appropriately qualified individuals to design and implement data capture and data management systems in line with ICH-GCP E6(R2) guidelines unless the sponsor or co-sponsors formally state otherwise. When using electronic data systems, the organisation/CI must ensure that data processing systems conform to the requirements of the study, the ACCORD Computer Systems Validation Policy (POL007) and the ACCORD Computer System Validation Checklist referenced in ACCORD SOP “GS002 Combined Risk Assessment”, where appropriate.
- *Data Monitoring* - the sponsor or co-sponsors expect the responsible organisation or Investigator to establish an independent data monitoring and safety committee (DMC) prior to study start-up for new Clinical Trials of Investigational Medicinal Products CTIMPs unless the sponsor or co-sponsors formally state that a DMC is not required in accordance with risk assessment. The DMC Charter will be prepared as per ACCORD SOP CR015 Data Monitoring Committee and Trial Steering Committee Charters. The DMC will assess the progress of the study, safety data, critical efficacy endpoints, any other relevant factors and make recommendations as to whether the study should continue, be modified, suspended or terminated. The DMC must operate according to written procedures and the proceedings and outcomes of meetings must be recorded.
- *Investigational Products* - the sponsor or co-sponsors expect the responsible organisation or CI to supply each Investigator with the Investigational Product, together with an Investigator’s Brochure or equivalent, an Investigational Product dossier and written instructions for the handling and storage of the Investigational Product. The Investigational Product must be labelled and packaged according to EU Guidelines for Good Manufacturing Practice (GMP) – Medicinal Products

for Human and Veterinary Use, Annex 13. Furthermore, the Investigational Product must be manufactured in accordance with GMP and regulatory requirements. In addition, the Investigational Product must be manufactured, packaged, labelled, coded, supplied and handled in accordance with the ACCORD SOP GS010 Sponsor Investigational Medicinal Product (IMP) Management, ICH-GCP E6(R2) guidelines, sections 5.12, 5.13 and 5.14.

- *Biological Sample Analysis* - the sponsor or co-sponsors expect the responsible organisation or Investigator to have systems in place to ensure that biological samples are stored, delivered to the site of analysis, analysed and destroyed in compliance with written study procedures. Biological specimens must be processed in accordance with the European Medicines Agency (EMA) Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (2012).

4 REFERENCES AND RELATED DOCUMENTS

- ICH-GCP E6(R2) Guidelines
- European Medicines Agency (EMA) Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (2012)
- UK Policy Framework for Health and Social Care Research.
- EU Guidelines for Good Manufacturing Practice (GMP) – Medicinal Products for Human and Veterinary Use, Annex 13
- ICH E9 Guidelines (Statistical Principles for Clinical Trials)
- Framework Agreement between NHSL and UoE in relation to R&D Activities

5 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	23 DEC 2010	Minor administrative changes
2.0	21 JUL 2016	New Policy template. References to new and revised SOPs added to text throughout (CR001, GS002, GS003, GS005 and PV001). Reference to EMA reflection paper for laboratories added to Sections 3.2.1 and 4.
3.0	25 JUL 2018	Update to the ICH-GCP E6 (R2), Guidelines and the UK Policy Framework for Health and Social Care Research. Revised SOPs added to text (CR015, GS010 and POL007). Minor administrative changes throughout.

6 APPROVALS

Sign	Date
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