SPONSORSHIP APPROVAL

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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 Medicines for Human Use (Clinical Trials) Regulations SI 2004/1031 (as amended), and the UK Policy Framework for Health and Social Care Research (2017) define the Sponsor as the individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a trial.

1.3 New research studies intended for Sponsorship by NHSL and/or UoE are reviewed to ensure that the design of the study meets appropriate standards and that all necessary arrangements are in place to ensure appropriate conduct and reporting.

1.4 Studies with NHS involvement (e.g. NHS patients, staff, facilities, data etc.) and UoE involvement (e.g. student or academic staffing etc.) will be co-Sponsored by NHSL and UoE following criteria set out in Appendix 1. Other studies will be single sponsored by either NHSL or UoE, or may be co-Sponsored by NHSL and a third party organisation.

2 PURPOSE

2.1 To document the procedure for obtaining Sponsorship approval from NHSL and/or UoE.

3 SCOPE

3.1 This SOP applies to all researchers requesting Sponsorship approval for studies single/co-Sponsored by NHSL and/or UoE, or for studies co-Sponsored by NHSL and a third party organisation e.g. another Higher Education Institution (HEI). This SOP applies to NHSL/UoE research governance staff involved with the oversight of studies, including performing Sponsorship review.

4 RESPONSIBILITIES

4.1 It is the responsibility of the Investigator or designee to provide all necessary study information/documentation to ACCORD.

4.2 It is the responsibility of the Research Governance Administration Team, or designee, to;

- Enter study details in the ACCORD Sponsorship tracker, assign an ACCORD Sponsorship identifier, and if required, send the Investigator the list of required documents,
- Forward study documentation to a lead Sponsorship reviewer,

4.3 It is the responsibility of the Sponsorship reviewer(s) to;

- Review relevant documentation prior to Sponsorship approval,
- Consult with the co-Sponsor organisation, Quality Assurance (QA) and Monitoring teams, where appropriate.

4.4 It is the responsibility of the Sponsorship reviewer, Research Governance Administration Team and R&D administration team to maintain the ACCORD Sponsorship Tracker on the ACCORD SharePoint.

5 PROCEDURE

5.1 Identification of New Studies

5.1.1 A new study can be identified by any member of ACCORD staff by various means; however it is recommended that Investigators contact the ACCORD UoE Research Governance team directly in the first instance. This can be done via the UoE Research Governance inbox (resgov@accord.scot).

5.2 Sponsorship Information

5.2.1 At initial contact, as a minimum, the Investigator or designee will provide the following information to ACCORD;

- Chief Investigator (CI) name & contact details
- CI's substantive employer, if not already known
- Honorary contract status e.g. honorary clinical/research contract with NHSL, honorary contract with UoE
- Working title of the study
- Estimated start date
- Multi-centre or single centre

5.2.2 On receipt of the enquiry, the Research Governance Administration Team, or designee, will;

- Liaise with the UoE Research Governance team to identify a named Sponsorship Reviewer.
- Assign a Sponsorship identifier to the study and record the available study details in the Sponsorship study tracker on SharePoint (if not already added by admin).
- Provide the Investigator, or designee, with a list of documents, required for review;
    - Draft Protocol
    - IRAS Forms (Full Data Set – non-CTIMPs only)

- Draft Outline Organisation Document(s)
- Draft Schedule of Events (or signed Schedule of Events Cost Attribution Tool (SoECAT) where requested by Funder).
- Draft Consent Form and Participant Information Sheet, if applicable
- Any other study documents e.g. recruitment materials, letters, CVs.

- On receipt of a complete document set (where possible), pass all relevant information to the assigned Sponsorship reviewer, at which point Sponsorship review is initiated.

5.3 Document & IRAS (non-CTIMP) Review or Combined Review (CTIMP)

5.3.1 The Sponsorship Reviewer will;

- Establish if the study will be sponsored solely by NHSL or UoE or if the study will be co-sponsored between NHSL and UoE or NHSL and a third party, in accordance with Appendix 1. The Sponsorship Reviewer can consult with the Heads of Research Governance (NHSL and/or UoE), or designees, if confirmation that Sponsorship or co-Sponsorship is required.
- Classify the study as CTIMP/non-CTIMP (using the MHRA's online algorithm, if required) or as a clinical investigation of a medical device/non-regulated device trial.
- Refer to the Sponsorship Review Guidance (GL003) when conducting a sponsorship review, where required.
- Use Sponsorship Checklist form (GS003-F01) and Sponsorship Review template (GS003-T01) for the purpose of documenting trial categorisation, checks and reviewer comments and Sponsor sign off. Use of GS003-T01 is not mandated in research subject to Combined Risk Assessment (ACCORD SOP GS002).

5.3.2 The Sponsor reviewer will conduct the initial Sponsorship review using the Sponsorship Review template (GS003-T01), as necessary, and provide initial comments to the Investigator, or designee. Non-CTIMP reviewers will compare the study documents will the IRAS full data set. CTIMP reviewers will compare the study documents with the information provided in the shared Combined Review system when available, which may not be at the time of receiving the documents listed in section 5.2.2 of this SOP.

5.3.3 For studies which are single sponsored by the UoE and impact on NHSL services, the Sponsorship reviewer will ensure that any Service Support Costs and/or Excess Treatment Costs associated with the study during the Sponsorship review are documented in the Schedule of Events (SoE), consulting with an NHSL R&D staff member if necessary.

5.4 Agreements and Indemnity

5.4.1 At the time of the initial Sponsorship review, the Sponsorship reviewer will:

- Liaise with the relevant NHSL and/or UoE contracts team to alert them that agreements may be required.

- Ensure that the Sponsor has adequate indemnity arrangements in place for the study.

5.4.2 Where required, the sponsorship reviewer and/or Investigator may refer to the UoE/NHSL's position and guidance on intellectual property (IP) and research results in Appendix 2.

5.4.3 Where the University of Edinburgh (UoE) is providing trial support (e.g. database/trial management/statistician) and such responsibilities are not captured in an agreement, responsibilities will be captured in the Responsibilities Record (GS003-T04). This requirement applies to research requiring a combined risk assessment (GS002), although it can also be used in other studies where deemed appropriate by the Sponsor Reviewer. The Trial Manager (TM) will prepare the document by customising (if necessary) for the study in question.

5.4.4 The content will then be agreed with the Sponsor Reviewer and the Chief Investigator (CI) before all the aforementioned individuals sign the document. The CI may instead provide an email as evidence of agreement with the content of the Responsibilities Record. The document will be authorised before the Regulatory Checks Complete email (see FA001) is delivered and it will be acknowledged in the Facilitation Checklist (FA001-T03). Preparation of the Responsibilities Record should be initiated as soon as the allocation of responsibilities become clear.

5.5 Risk Assessment

5.5.1 The Sponsorship Reviewer will prompt the QA Manager, or designee, to organise a combined risk assessment, where required, in accordance with SOP GS002 (Combined Risk Assessment).

5.6 Investigator Feedback

5.6.1 On receipt of updated documents following initial review, the Sponsorship Reviewer will review the updates and feedback any further comments to the Investigator, or designee, by e-mail.

5.6.2 If any issues remain that could give the Sponsorship Reviewer cause to decline Sponsorship, they will be communicated to the Heads of Research Governance (NHSL and/or UoE) or Senior Management Team (SMT) for guidance.

5.7 Confirmation of Sponsorship

5.7.1 Criteria for a third party NHSL co-Sponsoring partner to meet are listed in GS003-T02 (NHS Lothian Co-Sponsorship Criteria) and this document should be completed before an agreement is reached to co-Sponsor CTIMPs. The NHSL Head of Research Governance will ultimately be responsible for the

decision to enter a co-sponsorship arrangement between NHSL and a third party.

5.7.2 Once the Investigator feedback process is concluded with all queries answered to the satisfaction of the Sponsorship Reviewer, they will advise the Investigator that they can request Sponsor's authorisation of the relevant forms through IRAS or Combined Review, if required. Copies of insurance documents required for upload to IRAS/Combined Review will be provided. A Sponsorship letter will be drawn up and provided to the Investigators, if requested.

5.7.3 The Sponsorship Reviewer will provide the CI, or designee, with information about what to do next for example seeking approval from review bodies (i.e. REC, R&D, MHRA). Template guidance may be used using GS003-T03 (Sponsorship Guidance).

5.7.4 The Sponsorship reviewer will ensure the Sponsorship Review template (GS003-T01) is finalised at the conclusion of Investigator feedback, where necessary. The Sponsorship reviewer will ensure that the Sponsorship Checklist form (GS003-F01) is finalised and signed in tandem to the IRAS authorisation for non-regulated studies. The Sponsorship Checklist will be signed at the earliest convenience for CTIMPs and CIMDs and before submissions to the bodies listed in 5.7.3.

5.7.5 Sponsorship review documentation will be saved electronically in the appropriate study specific Sponsorship Review folder on SharePoint by the Sponsorship reviewer (or designee), including a pdf of the authorised IRAS form(s) for non-CTIMPs.

5.7.6 For studies that have undergone risk assessment, a hard copy of this documentation will be filed in the Trial Master File (if held by the co-Sponsors) or in the Sponsor File by the Sponsorship Reviewer, or designee.

5.7.7 The Sponsorship Reviewer, and Research Governance Administration Team, will update the Sponsorship tracker with any relevant study information (other than that detailed in section 5.7.8) and will continue to do so throughout the life of the study.

5.7.8 The R&D administration team will add the following information to the sponsorship tracker for all locally sponsored studies that require R&D management approval;

- R&D number,
- Date of R&D management approval,
- Study status e.g. active, in follow-up, closed,
- Start date,
- End date.

5.7.9 NHSL/UoE research governance staff will provide the Investigator, or designee, with any necessary guidance throughout the life of the study.

5.7.10 The Investigator or designee will submit proposed amendments to the Sponsorship Reviewer, or to resgov@accord.scot, for continued Sponsorship approval following SOP GS011 Sponsor Approval of Amendments.

5.7.11 For regulated studies, once all relevant approvals are in place, the Sponsor Reviewer will provide written authorisation to start the clinical trial ('Regulatory Release') to the CI in accordance with ACCORD SOP FA001 (Facilitating a Regulated or Complex Research Project) and SOP GS010 (Sponsor IMP Management).

5.8 Sponsorship of Projects that include International sites

5.8.1 The Sponsor reviewer (UoE and/or NHSL) must take into consideration additional country-specific requirements when reviewing a project that includes international sites, and ensure all necessary arrangements are in place and documented in the Sponsorship Checklist (GS003-F01), the Facilitation Checklist (FA001-T03) and the Substantial Amendment Checklist (GS011-T01), where applicable.

5.8.2 For Global Health studies (e.g. studies conducted in Low and Middle Income Countries), country-specific requirements will be considered following ACCORD SOP GH001 (Global Health Sponsorship).

5.8.3 The Investigator, or designee will provide all necessary study information/documentation related to opening an international site to the Sponsor Reviewer, providing a Country-level Feasibility Questionnaire (GS003-F02) for each non-UK country included.

5.8.4 The Sponsor Reviewer will;

- Arrange a combined risk assessment, where applicable, following section 5.5.
- For studies subject to a combined risk assessment, inform the QA Manager at the earliest opportunity of vendors providing services in the conduct of the study. Vendors will be assessed following SOP QA009.
- Ensure that there are funds in place for the additional costs of setting up an international e.g. cost of professional translational services, establishment of a Legal Representative in another territory (e.g. the EU), insurance and monitoring activities and QA activities.
- Review relevant documentation to ensure that necessary local adaptions of study documents are highlighted to the CI/Project Manager e.g. standard

of care, the legal age of children, IMP/Trial classification, cultural practice and standards of literacy.

- Ensure translation activities are carried out by a certified translator for regulated studies.
- Advise the Trial team of non-regulated studies that, although documents do not require translation by a certified translator, they must ensure that translations are carried out by persons with an appropriate understanding of clinical studies and medical terminology.
- Consider the differences in definition of personal data and its governing legislation in different countries e.g. the Patient Information Sheet (PIS) must state if data may be sent to another country with a lower level of data protection.
- Discuss any legal considerations with a member of the UoE/NHSL Contracts Team e.g. requirement to have a lead site agreement detailing the delegation of tasks such as obtaining country-level approvals (including amendments), establishing a legal representative, maintaining a country level Trial Master File (TMF) and Investigator Site File (ISF), fulfilling local safety reporting requirements (including serious breaches and urgent safety measures) to relevant regulatory and ethical committees, carrying out monitoring or auditing activities as directed by the monitoring plan (including close-out activities and archiving).
- Ascertain if any particular insurance arrangements are required, for the international aspects of the study, with the UoE Insurance Office/NHSL Principal R&D Manager as applicable, based on Sponsorship arrangements.

6 REFERENCES AND RELATED DOCUMENTS

- FA001 Facilitating a Regulated or Complex Research Project
- GL003 Sponsorship Review Guidance
- GS003-F01 Sponsorship Checklist
- GS003-F02 Country-level Feasibility Questionnaire
- GS003-T01 Sponsorship Review
- GS003-T02 NHS Lothian Co-Sponsorship Criteria
- GS003-T03 Sponsorship Guidance
- GS003-T04 Responsibilities Record
- POL002 Sponsorship Policy
- GS002 Combined Risk Assessment
- GS007 R&D Governance Review of Amendments
- GS010 Sponsor IMP/Intervention Management
- GS011 Sponsor Approval of Amendments
- CR007 Study Documents
- QA009 Vendor Assessment
- GH001 Global Health Sponsorship
- Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- UK Policy Framework for Health and Social Care Research (2017)
- Add Responsibilities Record

- Framework Agreement between Lothian Health Board and the University Court of the University of Edinburgh in Relation to Research and Development Activities
- MHRA's online algorithm: Is it a clinical trial of a medicinal product? https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0 – 5.0	14 DEC 2015 - 01 APR 2021	Reason for version change available from QA@accord.scot on request
6.0	29 JUN 2021	Removal of reference to the ACCORD enquiries@accord.scot mailbox. Requests for sponsorship approval to be sent directly to resgov@accord.scot. R&D admin team responsibilities defined in sections 4.4 and 5.7.8. Reference to GH001 added.
7.0	10 NOV 2022	Minor updates to Sponsor processes at sections 5.3 and 5.7, including reference to the Combined Review system. GS003-F01 updated (now v5.0)
8.0	14 MAR 2023	Addition of Appendix 2 (Section 10); Intellectual Property (IP) and Research Results - Ownership and Licensing. This is referred to in the main body of the text (Section 5.4).
9.0	05 DEC 2023	Minor change to section 5.2.1 to ensure we obtain all relevant information on CI employment status. Appendix 1 updated to clarify the UoE/NHSL position on sponsorship of studies where the CI is not substantively employed by UoE/NHSL. Change of author.
10.0	10 MAY 2024	Addition of a new template (GS003-T04) to capture trial support responsibilities (see section 5.4.3 and 5.4.4). 03-May-24: SOP updated to correct a formatting issue at 5.4.4, prior to effective date, and then re-signed.
11.0	11 JUL 2024	Clarification added to appendix 1, section 9.5 stating that the default position for Sponsoring a research project is that UoE and NHSL will only agree to Sponsor/Co-Sponsor student research where the University of Edinburgh is the awarding institution of the qualification. Section 9.3 clarified to be brought in line with section 1.4.

8 APPROVALS

Sign	Date
Paul Dearie Paul Dearie (Jun 25, 2024 15:54 GMT+1) AUTHOR: Paul Dearie, Clinical Research Facilitation Manager, UoE, ACCORD	Jun 25, 2024
Heather Charles Heather Charles (Jun 25, 2024 16:04 GMT+1) APPROVED: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	Jun 25, 2024
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHS Lothian, ACCORD	Jun 25, 2024

APPENDIX 1: Sponsorship or Co-Sponsorship

9.1 The default Sponsorship model for clinical research projects led from Edinburgh is co-Sponsorship by UoE and NHSL, as documented in the Framework

Agreement between Lothian Health Board and the University Court of the University of Edinburgh in Relation to Research and Development Activities.

9.2 Research projects may be single Sponsored by either UoE or NHSL, or NHSL may co-Sponsor with a third party organisation, under exceptional circumstances as described below;

9.3 The following research will be single Sponsored by UoE:

- Research, led by a UoE substantive employee or student, that will not involve NHS patients, tissue, data and/or premises/facilities/staff members (except ACCORD staff members). This includes all studies with no research sites in the UK.
- Research where regulatory requirements and/or funding stipulations require UoE to act as a single Sponsor.

9.4 The following research will be single Sponsored by NHSL or Co-sponsored with a third institution:

- Research where the CI does not have, and is unable to obtain, an honorary contract with the UoE.
- Research where the CI is employed by NHS Lothian and the research will not involve UoE staff members (except ACCORD staff members), resources and/or premises/facilities.
- Research where regulatory requirements and/or funding stipulations require NHSL to act as a single sponsor

9.5 In the case of either the UoE or NHSL single Sponsoring a research project, and in accordance with the Framework Agreement, any devolving of responsibilities to the other party must be agreed before any research can commence.

The default position is that the UoE and NHSL will only agree to Sponsor/Co-Sponsor research where the CI is substantively employed by one of these organisations or for student research where University of Edinburgh is the awarding institution of the qualification. Under exceptional circumstances, and in agreement with the ACCORD Senior Management Team, we will consider sponsoring/co-sponsoring a study where a CI is employed by another NHS Health Board/organisation (e.g. NHS Education for Scotland) and holds a valid honorary clinical contract with NHSL (e.g. where the CI has clinical sessions in Lothian).

10 APPENDIX 2: Intellectual Property (IP) and Research Results - Ownership and Licensing

10.1 Most UoE/NHSL (co-)sponsored research is and will be led and designed by a UoE/NHSL employee, with clinical trials and medical device investigations typically led and designed by an academic/clinician. In the vast majority of clinical trials, UoE will employ the CI and/or the author of the Protocol, and will therefore own the results and IP generated during the trial. In the event that the CI and/or the author of the Protocol is employed by NHSL, the ownership of results and IP should be clarified with NHSL, via the Principal R&D Manager or designee.

10.2 UoE/NHSL (co-)sponsored research may require collaboration or the provision of services/resources/materials of 3rd party organisations, including commercial organisations. Such a collaboration will not alter the requirement, outlined in section 1.1.1 of this document, for the research to be led and designed by a UoE/NHSL employee. As such, a 3rd party cannot instruct the (co-) sponsor(s) organisations or representatives in relation to research design, appropriateness of the ACCORD Quality Management System and associated documents although requests for variations may be considered by the ACCORD Quality Assurance Manager.

10.3 In **all** UoE/NHSL (co-)sponsored research (including collaborative research / research involving the provision of services/resources/materials of 3rd party organisations), representatives of the (co-)sponsors should be cognizant of the following starting IP positions:

(i) each party retains ownership of the background IP owned by it prior to the start of or developed outwith the study; and

(ii) the (co-)sponsor(s), or one of them, shall own all results, including IP rights subsisting within results, of the (co-)sponsored study.

10.4 Any deviation to the above must be approved by Edinburgh Innovations in relation to research led/designed by a UoE employee or in which UoE contributes to the development of the results, including IP rights subsisting within the results, of the (co)-sponsored study.

10.5 If our proposed IP positions are accepted by all parties, in the case of an academic institution or NHS clinical site, a non-exclusive licence may be granted to use results, including IP rights subsisting within results, for academic research and teaching (and including clinical patient care in the case of an NHS site). This may have additional limitations on the scope of use. For example, the scope may be limited to in-house research use or for use in academic publications only. Commercial organisations may be granted a non-exclusive licence for internal research and development only. Any request beyond that must be approved by Edinburgh Innovations.

10.6 An option to negotiate the terms of a fee/royalty bearing licence to use the results for commercial purposes may be granted to a collaborating organisation negotiated and agreed by Edinburgh Innovations. This includes the option to

negotiate the terms of a licence to a particular set of results or certain IP rights subsisting within the results.

10.7 It is anticipated that any alternative IP positions should represent tangible benefit to the co-sponsors and NHS patients, where applicable. A request should also be made for a product discount for NHS Scotland as part of any licensing deal. Sponsor representatives, the Principal R&D Manager and Edinburgh Innovations may discuss Edinburgh Innovations proposed solutions and alternative IP positions if requested by a collaborator with the ACCORD Senior Management Team (SMT) and other senior UoE and NHSL representatives, as well as representatives of UoE Edinburgh Innovation (EI) where required.

10.8 The IP position set out in section 10.3 of this document, the grant (if any) of a licence (as described in section 10.4 above) and the grant (if any) of an option to negotiate the terms of a commercial licence (as described in section 10.5 above) or alternative positions must be captured in a legal agreement among the co-sponsor(s) and collaborating organisation which has been approved by Edinburgh Innovations.

GS003 SOP Sponsorship Approval v11.0

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