Global Health Sponsorship

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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). All Global Health research studies are sponsored solely by UoE.

1.2 The ACCORD Global Health Research Governance Team (The Global Health Clinical Research Facilitator and The Research Governance Assistant) act as the main points of contact for Chief Investigators planning Global Health (GH) research studies. The term 'Global Health' is often used to refer to research carried out in Low and Middle Income Countries (LMICs) by funders and research organisations. ACCORD are using this term to apply to all non-UK based (i.e. international research) irrespective of whether Low, Middle or High income contexts. The Global Health Research Governance Team may provide assistance at any stage of the study, but typically will be involved from funding applications, and subsequently help with sponsorship review, protocol design, research contracts, investigational product supply and research approvals.

1.3 New GH research studies intended for single sponsorship by UoE and subsequent amendments are reviewed by the Global Health Research Governance Team 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.

2 Purpose

2.1 To describe how ACCORD provides support to Chief Investigators of regulated and unregulated GH research, while ensuring sponsor obligations are met and that the relevant policies, procedures, guidelines and regulations are adhered to.

3 Scope

3.1 This SOP applies to ACCORD research governance staff, including the Global Health Clinical Research Facilitator, Research Governance Assistant, Clinical Research Facilitators and Research Governance Coordinators.

3.2 This SOP further applies to the ACCORD QA Manager and Senior Clinical Trials Monitor where QA and Monitoring tasks have been delegated to NHSL in appropriate contracts.

3.3 This SOP applies to all Global Health clinical research for which a Combined Risk Assessment is deemed appropriate (e.g. Clinical Trials of Investigational Medicinal Products (CTIMPs), First in Human studies and other invasive, experimental, or complex research involving one or more research sites, or medical device investigations) and other Global Health projects.

4 Responsibilities

4.1 It is the responsibility of the Chief Investigator of a GH study, 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 the Global Health Research Governance Team (The Global Health Clinical Research Facilitator and The Research Governance Assistant) to assign a lead Sponsorship reviewer.

4.3 The Global Health Clinical Research Facilitator, is responsible for:

- Reviewing relevant study documentation for regulated (e.g. Clinical Trial of Investigational Medicinal Product), complex and unregulated GH studies prior to sponsorship approval.
- Providing port to Chief Investigators of GH research from initial point of contact until all relevant UK and country-specific approvals are in place.
- Flagging projects for due diligence process with the relevant Research Funding Specialist where necessary.

- Consulting with ACCORD QA & Monitoring Teams and the Edinburgh Research Office Research Contracts, Governance and Integrity Team, where appropriate.
- Consulting with the UoE Insurance Team where appropriate.
- Consulting with the UoE Research Contracts, Governance and Integrity Team where appropriate.

4.4 The Research Governance Assistant is responsible for:

- Reviewing relevant study documentation for low-risk GH studies, including undergraduate, postgraduate and PhD student research studies.
- Providing support to Chief Investigators, student researchers and their Supervisors, from initial point of contact until all relevant UK and country-specific approvals are in place.
- Flagging studies with the UoE Insurance Team where appropriate.
- Consulting with the UoE Research Contracts, Governance and Integrity Team where appropriate.
- Consulting with the Global Health Clinical Research Facilitator where appropriate.

4.5 The QA Manager, or designee, is responsible for:

- Arranging the Combined Risk Assessment meeting at the request of the Global Health Clinical Research Facilitator.

5 Procedure

5.1 Identification of new Global Health studies

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

5.2 GH Sponsorship Information

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

- Chief Investigator (CI) name, employment and contact details
- Working title of the study
- Funding status of the study
- Contract status of the study
- Names of Partnering Institutions involved in the study
- Names of country where the study will be conducted

- 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 Global Health 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
- Provide the Investigator, or designee, with a list of documents required for sponsorship review;
    - The relevant Global Health Non-CTIMP Protocol template (see section 5.2.4 below)
    - The Global Health Participant Information Sheet and Global Health Consent Form
    - Draft Interview/Topic Guide (if applicable)
    - Any other study documents (e.g. recruitment materials, advertisement materials, letters, questionnaires, CVs)
    - Relevant UoE ethics form (e.g. EMREC form)
- On receipt of a complete document set (where possible), pass all relevant information to the assigned Sponsorship reviewer, at which point the Sponsorship review is initiated.

5.2.3 Unless the local (in-country) ethics committee(s) request that specific local templates are used to complete the study documents, ACCORD strongly recommends that GH Investigators use the relevant Global Health Protocol template (GH001-T01, GH001-T02 or GH001-T03) and the Global Health Participant Information Sheet (GH001-T04) and the Global Health Consent Form (GH001-T05) to create the study documents. ACCORD will work flexibly with GH Investigators for GH studies, accepting mandatory local templates while still ensuring UoE legal and Sponsor oversight responsibilities are covered. During the sponsor review, the Sponsorship reviewer will need to provide additional governance content to local templates to ensure UoE sponsor oversight processes and responsibilities are included.

5.2.4 Three Global Health Non-CTIMP Protocol templates have been provided:

- One suited to studies limited to analysis of datasets (GH001-T02)
- Another suited to studies limited to Qualitative methods of research (GH001-T03)

- A template for Non-CTIMP studies that do not match the previous two descriptions (GH001-T01)

5.3 Sponsorship Review

5.3.1 All new Global Health studies (excluding student GH research studies) will be taken to the Early Projects meeting, unless otherwise agreed, to ensure that key people are aware of the study and have the opportunity to identify any potential issues.

5.3.2 The Global Health Clinical Research Facilitator, or designee, will;

- Classify the study as CTIMP/non-CTIMP or as a clinical investigation of a medical device/non-regulated device trial, and will check the regulatory guidelines in the country where the study will be conducted, to ensure compliance with local regulations.
- Ensure that there are funds in place for the additional costs of setting up GH research e.g. cost of professional translational services, insurance and monitoring activities (where applicable).
- Review relevant documentation to ensure that necessary local adaptations of study documents are highlighted to the CI or designee e.g. standard of care, the legal age of children for consent, IMP/Trial classification, cultural practice and standards of literacy.
- Use Sponsorship Checklist form (GS003-F01) and the Global Health Sponsorship Review template for the purpose of documenting trial categorisation, checks and reviewer comments and sponsor sign off.

5.3.3 The GH Facilitation Checklist (FA001-T07), or relevant parts of the appropriate checklist, will be completed for all regulated, risk-assessed or complex GH studies by the GH Clinical Research Facilitator, or designee.

5.4 Due Diligence, Agreements and Indemnity

5.4.1 At the time of the initial sponsorship review, the Sponsorship reviewer (i.e. a member of the Global Health Research Governance Team) will;

- Liaise with the relevant UoE Research Funding Specialist to ensure that due diligence has been carried out for the partnering or collaborating organisation/institution in the country where the study is being conducted.
- Discuss any legal or contract considerations with a member of the Edinburgh Research Office Research Contracts, Governance and Integrity Team, and with relevant members of the ACCORD team where applicable. For example, requirements to have a Collaboration Agreement with GH study collaborators

detailing the delegation of tasks, such as obtaining country-specific approvals (including amendments), 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). Also, discussion of acceptable sub-contracting parameters.

- Liaise with the UoE Insurance Team to ascertain if any particular insurance arrangements are required and to ensure that the sponsor has adequate indemnity arrangements in place for the GH study.

5.5 Risk Assessment

5.5.1 The Global Health Clinical Research Facilitator will prompt the Quality Assurance (QA) Manager, or designee, to organise a combined Risk Assessment, where required, in accordance with SOP GS002 (Combined Risk Assessment). This will be done in parallel with the sponsorship review or at the earliest opportunity thereafter i.e. when the study documents are at a sufficiently advanced stage.

5.5.2 For studies subject to a combined risk assessment (GS002), the Global Health Clinical Research Facilitator will 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. Where applicable, a vendor oversight plan may be implemented to track multiple vendors for a study. The requirement of a vendor oversight plan will be detailed in the risk assessment and GH Facilitation Checklist.

5.5.3 The Global Health Clinical Research Facilitator will provide an update on risk assessed GH studies at monthly Sponsorship meetings.

5.6 Chief Investigator Feedback

5.6.1 Once the initial sponsorship review is complete, the Sponsorship reviewer will provide feedback to the Chief Investigator or designee.

5.6.2 The Sponsorship reviewer will review any updates to documents and feedback any further comments to the Chief Investigator, or designee by email.

5.6.3 If any issues remain that could give the Sponsorship reviewer cause to decline Sponsorship, they will be communicate to the Head of Research Governance (UoE) or the ACCORD Senior Management Team (SMT) for guidance.

5.7 Confirmation of Sponsorship

5.7.1 Once the Chief Investigator feedback process is concluded with all queries answered to the satisfaction of the Sponsorship reviewer and, where applicable, the risk assessment is complete or sufficiently progressed, they will provide sponsorship approval in the form of an email to the Chief Investigator to confirm that they can proceed to submit the study documentation to the ethics committee in the country where the study is to be conducted. The Sponsorship reviewer will include all study document dates/versions in the sponsorship approval email. The Investigator or designee must include the Sponsorship reviewer in all email submissions to the ethics committee and competent authority (where relevant) in the country where the study is to be conducted. If this is not possible, copies of the submissions must be provided to the Sponsorship reviewer. Where submissions are not in the English language, translated English versions should be provided as an additional requirement. Copies of insurance documents for the submission can be provided when necessary. A sponsorship letter will be drawn up and provided to Chief Investigators, if requested.

5.7.2 The Chief Investigator will be required to seek a favourable opinion letter from a UoE ethics committee (e.g. Edinburgh Medical School Research Ethics Committee (EMREC)) or other relevant ethics committee based in the UK, in addition to a favourable opinion from an ethics committee in the country where the study is to be conducted. If the study is regulated, there will also be a requirement for the Chief Investigator to seek regulatory body approval in the country where the study is being conducted.

5.7.3 The Sponsorship reviewer will ensure the Global Health sponsorship review template is used for the initial sponsorship review and the sponsorship checklist form (GS003-F01) and (where relevant) the GH Facilitation Checklist (FA001-T07) is finalised and signed once all country-specific and relevant UK-based approvals are obtained for the GH study.

5.7.4 Sponsorship review documentation will be saved electronically in the appropriate study specific sponsorship review folder on SharePoint by the Sponsorship reviewer, including copies of the country-specific and relevant UK-based approvals.

5.7.5 The Sponsorship reviewer will update the sponsorship tracker with any relevant study information and will continue to do so throughout the life of the GH study.

5.7.6 For CTIMP, risk assessed or complex GH studies: once all sections of the GH Facilitation Checklist (FA001-T07) have been completed (and prior to regulatory

checks complete confirmation) the Global Health Clinical Research Facilitator, or designee, will liaise with the appointed ACCORD Clinical Trial Monitor to discuss the status of the trial and conduct a formal handover.

5.7.7 For CTIMP, risk assessed or complex GH studies: once all relevant approvals are in place, the Global Health Clinical Research Facilitator will provide written authorisation to start the clinical trial ('Regulatory Release') to the Chief Investigator in accordance with ACCORD SOP FA001 (Facilitating a Regulated or Complex Research Project) and SOP GS010 (Sponsor IMP Management).

5.8 Sponsor Approval of GH Amendments

5.8.1 The Chief Investigator or designee will submit proposed amendments to the UoE Research Governance Team for continued sponsorship approval following SOP GH002 Sponsor Approval of Global Health Amendments.

6 References and Related Documents

- FA001 Facilitating a Regulated or Complex Research Project
- FA001-T07 Global Health Facilitation Checklist
- GS002 Combined Risk Assessment
- GS003 Sponsorship Approval
- GS003-F01 Sponsorship Checklist
- QA009 Vendor Assessment
- GS010 Sponsor IMP / Intervention Management
- GH001-T01 Global Health Non-CTIMP Protocol Template
- GH001-T02 Global Health Data Only Protocol Template
- GH001-T03 Global Health Qualitative Protocol Template
- GH001-T04 Global Health PIS Template
- GH001-T05 Global Health CF Template
- GH002 Sponsor Approval of Global Health Amendments
- CR007 Study Documents

7 Document History

Version Number	Effective Date	Reason for Change
1.0	23 JUN 2021	New SOP
2.0	09 DEC 2022	Addition of Protocol Templates GH001-T01, T02, T03, PIS Template GH001-T04 and CF Template

		GH001-T05. Minor administrative changes throughout.
3.0	15 JUN 2023	Minor revisions to definition of 'Global Health'.
4.0	07 AUG 2025	Minor revisions to include The Research Governance Assistant as part of the Global Health Governance Team and clarifications on responsibilities; Addition of responsibilities for Research Governance Administration Team; Minor revisions to confirmation of sponsorship process.

8 Approvals

Sign	Date
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Paul Dearie Paul Dearie (22-Jul-2025 12:40 GMT+1) APPROVED: Paul Dearie, Clinical Research Facilitation Manager, UoE, ACCORD	22-Jul-2025
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	22-Jul-2025

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