# Global Health Sponsor Approval of Amendments

| | |
|---|---|
| Document No.: | GH002 v3.0 |
| Author: | Ellie McMaster |
| Issue Date: | 24 JUL 2025 |
| Effective Date: | 07 AUG 2025 |

## 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 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 amendments to existing 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 amendment, but typically will be involved in amendment review, sponsor classification of amendment, amendments to research contracts and amendment approvals.

1.3 GH amendments are changes made to a research project after approval from a review body has been given.

1.4 A GH amendment to information relating to a research project can be substantial or non-substantial in nature.

1.5 The sponsor will determine whether a GH amendment is substantial or not, and if it needs to be notified to the review body that provided initial approval(s).

1.6 The sponsor must be notified of all GH amendments.

## 2 Purpose

2.1 To document the procedure for reviewing and obtaining sponsorship approval for amendments to GH studies sponsored by UoE.

## 3 Scope

3.1.1 The SOP applies to all Chief Investigators of GH research requesting sponsorship approval for amendments to studies sponsored by UoE. This SOP also applies to the Global Health Clinical Research Facilitator, The Research Governance Assistant and any UoE research governance staff involved with the oversight of GH studies.

## 4 Responsibilities

4.1 It is the responsibility of the Chief Investigator (CI), or designee (for example Trial Manager) to;

- Submit proposed GH amendments to the UoE Research Governance Team in the Sponsor office (i.e. ACCORD). This can be done via the general enquiries inbox (resgov@accord.scot). All GH study amendments will be passed to the Global Health Research Governance Team and will be assigned a sponsor reviewer.
- Submit GH amendments to the appropriate review bodies in the country where the study is being conducted and, where applicable, a UK-based ethics committee.
- Respond to requests for clarifications, changes and rejections from the sponsor reviewer and review bodies.
- Provide the sponsor reviewer with a copy of the submission and approval from review bodies once obtained.
- File all GH amendment submissions/approvals in the Trial Master File (TMF) or Investigator Site File (ISF).
- Ensure all sites and third parties working on the study are aware of the GH amendments.
- Maintain a log of the GH amendment implementation dates at each site and/or country.

4.2 It is the responsibility of the sponsor reviewer to;

- Review and comment on the GH amendment documentation, classify the amendment as either substantial or non-substantial, and provide sponsor authorisation of amendment.
- Liaise with the relevant UoE Research Funding Specialist to ensure that due diligence has been carried out for any new partnering or collaborating

organisation/institution, which has been included in the GH study as part of the amendment.

- Liaise with the UoE Insurance Team to ascertain if the GH amendment will have any implications on the indemnity arrangements in place for the GH study.
- Notify a member of the Edinburgh Research Office Research Contracts, Governance and Integrity Team if any GH amendment changes will impact the current study agreements or require a new study agreement.
- Advise the CI, or designee, whether sponsorship of the study can continue on review of an amendment.
- Ensure all GH amendment submissions/approvals are filed in the TMF or Sponsor File.
- Issue written communication to the CI, or designee, to authorise implementation of the GH amendment.
- Maintain and update the ACCORD amendment tracker for GH studies that have undergone a combined risk assessment as per ACCORD SOP GS002.

# 5 Procedure

## 5.1 Continued Sponsorship Approval

5.1.1 The CI, or designee, will submit proposed GH amendments to the UoE Research Governance Team via email (resgov@accord.scot) or to the Sponsor reviewer responsible for the initial study review. Amendments must not be submitted to review bodies without prior authorisation from the Sponsor.

5.1.2 Where the GH study amendment includes the addition of a new organisation/institution, the sponsor reviewer will liaise with the relevant UoE Research Funding Specialist to discuss due diligence requirements and will follow up on progress until completion. For studies subject to a combined risk assessment (GS002), the sponsor reviewer will also notify the ACCORD QA Team to highlight the potential requirement for a vendor assessment in accordance with ACCORD SOP QA009 Vendor Assessment.

5.1.3 Where the GH study amendment includes the addition of a new country or a significant change that is likely to have an impact on the study insurance, the sponsor reviewer will liaise with the UoE Insurance Team to discuss the indemnity arrangements for the amendment.

5.1.4 Where the GH study amendment has an impact on the contractual arrangements for the study, the sponsor reviewer will liaise with the relevant member of the Edinburgh

Research Office Research Contracts, Governance and Integrity Team to discuss new agreements or amendments to existing agreements and will follow up on progress until completion.

5.1.5 If the sponsor reviewer has comments on the GH amendment documentation or if additional information is required, the sponsor reviewer will liaise with the CI or designee to make any necessary changes to documentation and/or obtain additional information.

5.1.6 The CI, or designee, must obtain Sponsor approval of amendments prior to submission to the ethics committee/regulatory body in the country where the study is being conducted, and prior to submission to the UK-based ethics committee (where appropriate). Sponsor approval of the amendment will be communicated via the issuing of the sponsor classification and authorisation email.

5.1.7 For all GH studies that have undergone a risk assessment (GS002 Combined Risk Assessment), the Global Health Clinical Research Facilitator will;

- Email the ACCORD monitoring team and support departments (if applicable) providing a summary of the main amendment changes to allow them to determine impact and advise, where appropriate, if the study needs to be re-risk assessed.
- Consider the advice provided and the actual impact of any amendments on the risk assessment.
- Prompt the QA manager, or designee, to organise a risk assessment committee meeting to review the GH amendment documentation in accordance with SOP GS002 (Combined Risk Assessment), where considered appropriate.
- Log the GH amendment on the amendment tracker located on the ACCORD SharePoint, detailing the country-specific approvals required.

5.1.8 Where a GH amendment to a risk assessed GH study is deemed substantial, the Global Health Clinical Research Facilitator will complete the Global Health Substantial Amendment Checklist (GH002-T01) based on the documents and information provided. For international trials, a country specific checklist may be created to capture the requirement in individual countries. Once all sections of the checklist are completed (including approvals and issuing of the implementation email the checklist should be signed off and filed in the TMF or Sponsor File). In circumstances where items on the checklist have not yet been completed but all necessary approvals

have been obtained, the implementation email can be issued prior to the checklist being signed off.

5.1.9 If, following review of the amendment, the sponsor reviewer decides that sponsorship of the study can continue, they will inform the CI, or designee, by issuing the amendment classification (substantial or non-substantial) via email.

5.1.10 The email will include the document names and version numbers, conditions that must be met prior to implementation of the amendment and will outline who needs to be notified of the amendment (e.g. ethics committee/regulatory body in the country where the study is being conducted, UK-based ethics committee). Template guidance may be used as the basis for this email using GS011-T03 (Amendment Classification and Authorisation Template Email).

5.1.11 If the Global Health Clinical Research Facilitator indicates that sponsorship of the study cannot continue in line with the proposed amendment, they will inform the CI, or designee, and ask them to reconsider the GH amendment, taking into account sponsor comments/recommendations.

5.1.12 Should the terms of any agreement with the Sponsor be breached or if the Sponsor does not receive copies of all amendments and approvals, Sponsorship can be suspended or withdrawn, and a letter to this effect sent to the CI. This decision will be made by ACCORD Senior Management and UoE Head of Research Governance, or designees, for GH studies.

## 5.2 Implementation of Amendments

5.2.1 In line with the information provided in the sponsor classification email, the CI, or designee, will submit the GH amendment to the appropriate review bodies. The sponsor reviewer will be included in all correspondence with appropriate review bodies where possible or provided with copies of the submissions.

5.2.2 Once all required approvals have been obtained, the CI, or designee must notify the sponsor reviewer, providing the appropriate confirmation from the relevant review bodies (e.g. local ethics/IRB, regulatory authority).

5.2.3 For risk assessed GH studies, the Global Health Clinical Research Facilitator will email the CI, or designee, using template GS011-T02 (Amendment Implementation Template Email) to authorise implementation of the amendment. If required, the Global Health Clinical Research Facilitator will detail terms of this authorisation e.g. whether the CI, or designee, must inform all sites of the need to re-consent

participants if the amendment contains updated consent documentation. For trials conducted in multiple countries, separate implementation emails may be issued when evidence of the country-specific approvals have been obtained.

5.2.4 For all other GH studies, amendments can be implemented by the CI, or designee, provided all approvals and conditions outlines in the amendment classification email are met.

5.2.5 The sponsor reviewer and CI, or designee, will ensure copies of the submission(s) and relevant approvals/correspondence are filed in appropriate files e.g. TMF, ISF, Sponsor File.

5.2.6 For risk assessed GH studies, the Global Health Clinical Research Facilitator will ensure the Amendment tracker located on the ACCORD SharePoint is updated with relevant information.

5.2.7 The CI, or designee, must ensure that all third parties working on the GH study are aware of the amendment.

### 5.3 Transfer of Sponsorship Amendment

5.3.1 For GH studies where the transfer of sponsorship is either incoming (i.e. to UoE) or outgoing to another institution, please refer to the process as outlined in GL009.

## 6 References and Related Documents

- GH002-T01 Global Health Substantial Amendment Checklist
- GS011 Sponsor Approval of Amendments
- GS011-T02 Amendment Implementation Template Email
- GS011-T03 Amendment Classification and Authorisation Template Email
- QA009 Vendor Assessment
- GS002 Combined Risk Assessment
- GL009 Transfer of Sponsorship

## 7 Document History

| Version Number | Effective Date | Reason for Change |
|---|---|---|
| 1.0 | 23 JUN 2021 | New SOP |
| 2.0 | 15 JUN 2023 | Minor revisions to definition of 'Global Health'. |

| | | |
|---|---|---|
| 3.0 | 07 AUG 2025 | Minor revisions to include The Research Governance Assistant as part of the Global Health Research Governance Team; Addition of sponsor actions if copies of amendment approvals are not received; Minor clarification on country-specific substantial amendment checklist and amendment implementation emails; Addition of Transfer of Sponsorship guidance. |

## 8 Approvals

| Sign | Date |
|---|---|
| Ellie Mcmaster<br>Ellie Mcmaster (22-Jul-2025 14:20 GMT+1)<br>AUTHOR: Ellie McMaster, Global Health Clinical Research Facilitator, UoE, ACCORD | 22-Jul-2025 |
| Paul Dearie<br>Paul Dearie (22-Jul-2025 12:40 GMT+1)<br>APPROVED: Paul Dearie, Clinical Research Facilitation Manager, UoE, ACCORD | 22-Jul-2025 |
| L. Mackenzie<br>AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD | 22-Jul-2025 |

# GH002 Global Health Sponsor Approval of Amendments v3.0

Final Audit Report 2025-07-22

| | |
|---|---|
| Created: | 2025-07-22 (British Summer Time) |
| By: | Roisin Ellis (v1relli8@exseed.ed.ac.uk) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAAjiIW2F6yuepD0iRzbICZwhYUTjA20cWM |

## "GH002 Global Health Sponsor Approval of Amendments v3.0" History

Document created by Roisin Ellis (v1relli8@exseed.ed.ac.uk)
2025-07-22 - 12:37:45 PM GMT+1- IP address: 62.253.82.243

Document emailed to Ellie Mcmaster (Ellie.Mcmaster@ed.ac.uk) for signature
2025-07-22 - 12:39:16 PM GMT+1

Document emailed to Paul Dearie (paul.dearie@ed.ac.uk) for signature
2025-07-22 - 12:39:16 PM GMT+1

Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2025-07-22 - 12:39:16 PM GMT+1

Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2025-07-22 - 12:39:50 PM GMT+1- IP address: 52.102.17.85

Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2025-07-22 - 12:40:09 PM GMT+1 - Time Source: server- IP address: 62.253.82.242

Email viewed by Paul Dearie (paul.dearie@ed.ac.uk)
2025-07-22 - 12:40:25 PM GMT+1- IP address: 104.47.11.254

Document e-signed by Paul Dearie (paul.dearie@ed.ac.uk)
Signature Date: 2025-07-22 - 12:40:37 PM GMT+1 - Time Source: server- IP address: 86.163.60.162

Email viewed by Ellie Mcmaster (Ellie.Mcmaster@ed.ac.uk)
2025-07-22 - 2:20:26 PM GMT+1- IP address: 104.47.11.254

Document e-signed by Ellie Mcmaster (Ellie.Mcmaster@ed.ac.uk)
Signature Date: 2025-07-22 - 2:20:52 PM GMT+1 - Time Source: server- IP address: 81.111.14.205

Agreement completed.

2025-07-22 - 2:20:52 PM GMT+1