Sponsor Approval of Modification

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

1.3 A modification to information relating to a research project can be substantial or non-substantial in nature.

1.4 The Sponsor will verify that the modification tool has correctly determined whether a modification is substantial (Route A or Route B) or not (Minor Modification or a Modification of an Important Detail), and if it needs to be notified to the review body(ies) that provided initial approval(s).

1.5 The Sponsor must be notified of all modifications.

2 Purpose

2.1 To document the procedure for reviewing and obtaining Sponsorship approval for modifications to studies sponsored by NHSL and/or UoE.

3 Scope

3.1 The SOP applies to all researchers requesting Sponsorship approval for modifications to studies sponsored by NHSL and/or UoE. This SOP also applies to NHSL/UoE research governance staff involved with the oversight of studies.

4 Responsibilities

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

- Complete the current version of the Modification Tool (available via the study approvals application system) following on-screen guidance notes.
- Submit proposed modifications to the Sponsor office i.e. ACCORD;
- Submit modifications to the appropriate review bodies as required according to the type of modification (route B substantial modification status should be indicated and justified in the cover letter – evidence of compatibility may also be required) and the instructions within the modification tool, provide the Sponsor reviewer with a copy of the submission, reviewer, and inform the Sponsor's office once all approvals are obtained;
- File all modification submissions/approvals in the Trial Master File (TMF) or Investigator Site File (ISF);
- Ensure all locations and third parties working on the study are aware of modifications.
- Maintain a log of the implementation dates of the modification at each location.

4.2 It is the responsibility of the Sponsorship Reviewer to;

- Review and comment on modification documentation, and verify that the current version of the modification tool has been used and has correctly decided whether an modification has been correctly classified, i.e. defined at a route A or B Substantial Modification (SM-A, SM-B), a Modification of an Important Detail (MID) or a Minor Modification (MM).;
- Advise the CI, or designee, whether sponsorship of the study can continue on review of a modification by issuing the classification email;
- Ensure all appropriate modification submissions/approvals are filed in the TMF or Sponsor File (if required), including electronic study files on the ACCORD Sharepoint for studies that have undergone a combined risk assessment as per ACCORD SOP GS002).
- Issue written communication to the CI, or designee, to authorise implementation of the modification.
- Maintain and update the ACCORD modification tracker for studies that have undergone a combined risk assessment as per ACCORD SOP GS002.

4.3 The ACCORD Administration Team are responsible for filing the continued NHSL R&D Management Approval letter on SharePoint.

5 Procedure

5.1 Continued Sponsorship Approval

5.1.1 The CI, or designee, will submit proposed modifications to the Sponsor office via e-mail (resgov@accord.scot) or to the Sponsor reviewer responsible for the initial study review, conducted in accordance with SOP GS003 (Sponsorship Approval). This submission will include the Modification Tool, when completed the declaration section should be left blank. This section will be completed by the Sponsor Reviewer. Modifications must not be submitted to review bodies without prior authorisation from the Sponsor.

5.1.2 Where the study modification includes the addition of new locations in the UK, and where these documents have not yet been reviewed by the Sponsor (i.e. prior to 05 June 2019), the CI may include a draft outline Organisation Information Document (OID) and a completed Schedule of Events (SoE) (or signed SoE Cost Attribution Tool (SoECAT), where available) for Sponsor review, in addition to other amended study documentation that requires Sponsor review.

5.1.3 If the Sponsor reviewer has comments on the modification documentation or if additional information is required, the Sponsorship reviewer will liaise with the CI or designee to make any necessary changes to documentation and/or obtain additional information.

5.1.4 The CI, or designee, must obtain Sponsor approval of modifications prior to submission to the Research Ethics Committee (REC), Research & Development (R&D) and/or the Competent Authority (e.g. MHRA), where required. Sponsor approval of the modification will be communicated via the issuing of the classification and authorisation email (See section 5.1.9).

5.1.5 The Sponsor reviewer will verify that the modification tool has classified modifications correctly, with input from a member of staff from NHSL research governance if necessary, based on the 2025 clinical trial regulations (where applicable), the instructions within the modification tool and available guidance, for example the Medicines and Healthcare products Regulatory Agency (MHRA) website, Health Research Authority (HRA) website, MHRA grey guide and REC SOPs. The Sponsor Reviewer will complete the declaration section of the Modification Tool and generate

a locked PDF copy of the completed Modification Tool by clicking the 'Lock for Submission' button.

5.1.6 For all studies that have undergone a risk assessment (GS002 Combined Risk Assessment), the Sponsorship reviewer will;

- Email the ACCORD monitoring team and support departments (if applicable) providing a summary of the main modification changes to allow them to determine impact and advise, where appropriate, if the study needs to be re-risk assessed.
- Consider the advice provided (including any potential location-level training and re-consent requirements) and the actual impact of any modifications on the risk assessment.
- Prompt the QA Manager, or designee, to organise a risk assessment committee meeting to review the modification documentation in accordance with SOP GS002 (Combined Risk Assessment), where considered appropriate.
- Log the modification on the modification tracker located on the ACCORD SharePoint.

5.1.7 Where a modification to a risk assessed study is deemed substantial (route A or route B), the Sponsorship reviewer will create a new Substantial Modification Checklist (GS011-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 – see section 5.2.3) 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.

5.1.8 MMs and selected MIDs where wider ACCORD input is considered unnecessary by the Sponsor Reviewer, for example the modification is limited to change of Principal Investigator (PI) at an existing research location(s) and/or the addition of new locations, section 5.1.6 (with the exception of adding the modification to the modification tracker) of this SOP is not applicable, provided the maximum number of locations stipulated in the risk assessment (GS002 Combined Risk Assessment) is not exceeded.

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

5.1.10 The email will include the return of the locked PDF copy of the completed Modification Tool (if not already returned) and document who needs to be notified of the modification (e.g. REC, R&D, MHRA) and the conditions to be met prior to the implementation of the modification. Template guidance may be used as the basis for this e-mail using GS011-T03 (Modification Classification and Authorisation Template Email) or GS011-T05 (Location-PI Modification Classification-Implementation Template Email), as relevant. Use of the latter negates the need to provide a separate modification implementation email, as detailed in section 5.2.3 of this SOP.

5.1.11 If the Sponsorship reviewer indicates that sponsorship of the study cannot continue in line with the proposed modification, they will inform the CI, or designee, and ask them to reconsider the modification, 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 modifications and approvals, Sponsorship can be suspended or withdrawn, and a letter to this effect sent to the CI. This decision will be made by NHSL and UoE Heads of Research Governance, or designees, for co-Sponsored studies.

5.2 Implementation of Modifications

5.2.1 In line with the information provided in the Sponsor classification email, the CI, or designee, will submit the modification to the appropriate review bodies. The Sponsorship reviewer will be included in all correspondence with appropriate review bodies when possible or provided with copies of the submissions if submitted via the online application portal in the UK. Other submissions portals should be used for submissions to authorities in other territories, as required.

5.2.2 Once all required approvals have been obtained, as applicable depending on the amendment classification, the CI or designee must notify the Sponsorship reviewer, providing the appropriate confirmation from REC, R&D, MHRA etc. (where applicable).

5.2.3 For risk-assessed studies the Sponsorship reviewer will email the CI or designee, using template GS011-T02 (Modification Implementation Template Email) to authorise implementation of the modification at location(s). If required, the Sponsor reviewer will detail terms of this authorisation e.g. whether the CI, or designee, must inform all

locations of the need to re-consent participants if the modification contains updated consent documentation. For trials with international locations separate implementation emails may be issued when evidence of the country specific approvals have been obtained.

5.2.4 Once the Sponsorship reviewer has authorised implementation of the modification and any conditions (stipulated by the Sponsor reviewer) of implementation have been met, the CI or designee (e.g. Trial Manager) will issue written communication to the Principal Investigator(s) to authorise implementation of the modification at location(s). The CI, or designee, will maintain a log of when the modification was implemented at each location. The modification log template (GS011-T04) may be used by the CI, or designee, to document implementation of modifications.

5.2.5 For all other studies, modifications can be implemented by the CI, or designee, provided all approvals and conditions outlined in the modification classification email are met.

5.2.6 The Sponsorship reviewer and CI will ensure copies of submission(s) and relevant approvals/correspondence are filed in appropriate files as specified in section 4.2 of this SOP.

5.2.7 The ACCORD administration team will save the continued R&D Management Approval letter to the ACCORD SharePoint site.

5.2.8 For risk-assessed studies the Sponsor Reviewer, or designee, will ensure the Modification tracker located on the ACCORD SharePoint is updated with relevant information.

5.2.9 The CI, or designee, must ensure that all third parties working on the study are aware of the modification.

6 References and Related Documents

- GS011-T01 Substantial Modification Checklist
- GS011-T02 Modification Implementation Template Email
- GS011-T03 Modification Classification and Authorisation Template Email
- GS011-T04 Modification Log
- GS011-T05 Location-PI Modification Classification-Implementation Template Email
- GS002 Combined Risk Assessment

- GS003 Sponsorship Approval

7 Document History

Version Number	Effective Date	Reason for Change
1.0	28 FEB 2019	Process moved from GS003 Sponsorship Approval to a new SOP.
2.0	05 JUN 2019	Addition of instruction for CI to submit draft OID and SoE (or SoECAT) for Sponsor review, where necessary (Section 5.1.2). Updates to GS011-T01 and GS011-T03 following the implementation of the UK Local Information Pack (05 June 2019).
3.0	N/A	Template names have been clarified in the SOP. Footers added to GS011-T02 and GS011-T03. Minor administrative change made to GS011-T03. SOP updated prior to effective date of 16-Oct-19.
4.0	16 OCT 2019	Responsibility added for the CI to maintain a tracker of implementation dates for modifications. An modification log (GS011-T04) may be used to track modification implementation dates. In addition, the Sponsor Reviewer is responsible for updating the ACCORD modification tracker.
5.0	10 DEC 2019	Clarification added to confirm the Sponsor Reviewer is only required to update the ACCORD modification tracker for studies which have
		undergone Combined Risk Assessment as per SOP GS002. Section 5.1.9 added to provide clarification regarding modifications consisting only of a change of PI and/or addition of new sites. Addition of GS011-T05 (Site-PI Modification Classification-Implementation Template Email).
6.0	04 MAY 2020	Further detail added to section 5.2.3 regarding the Sponsor reviewer detailing terms of an authorisation of modification at site, if required. Minor updates made to GS011-T01 and GS011T02.

7.0	28 AUG 2020	Process for preparing and submitting modifications across the UK changed 02-Jun-20. Section 5.1 updated to reference completion of the Modification Tool by the CI and verification of modification classification by the Sponsor. Minor updates made to GS011-T01 and GS011-T03.
8.0	11 JUN 2021	SOP updated at 5.1.5 to reflect sponsorship review conducted by UoE on behalf of both organisations. 5.2.1 amended to reference the MHRA submission portal in Great Britain, and other submission portals in other territories, when required. GS011-T03 updated to reflect new process.
9.0	28 APR 2026	Update to accommodate 2025 UK Clinical Trial Regulations

8 Approvals

Sign	Date
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Paul Dearie Paul Dearie (06-Feb-2026 11:18:32 GMT) APPROVED: Paul Dearie, Clinical Research Facilitation Manager, UoE, ACCORD	06-Feb-2026
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	10-Feb-2026

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Final Audit Report 2026-02-10

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