SPONSOR APPROVAL OF AMENDMENTS

DOCUMENT NO.:	**GS011 v8.0**
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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 Amendments are changes made to a research project after approval from a review body has been given.

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

1.4 The Sponsor will verify that the amendment tool has correctly determined whether an amendment is substantial or not, and if it needs to be notified to the review body that provided initial approval(s).

1.5 The Sponsor must be notified of all amendments.

2 PURPOSE

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

3 SCOPE

3.1 The SOP applies to all researchers requesting Sponsorship approval for amendments 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 Amendment Tool (available via IRAS) following on-screen guidance notes.
- Submit proposed amendments to the Sponsor office i.e. ACCORD;

- Submit amendments to the appropriate review bodies, provide the Sponsor reviewer with a copy of the submission, reviewer, and inform the Sponsor's office once all approvals are obtained;
- File all 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 amendments.
- Maintain a log of the implementation dates of the amendment at each site.

4.2 It is the responsibility of the Sponsorship Reviewer to;

- Review and comment on amendment documentation, and verify that the amendment tool has correctly decided whether an amendment is substantial or non-substantial;
- Advise the CI, or designee, whether sponsorship of the study can continue on review of an amendment;
- Ensure all amendment submissions/approvals are filed in the TMF or Sponsor File (if required);
- Issue written communication to the CI, or designee, to authorise implementation of the amendment.
- Maintain and update the ACCORD amendment 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 R&D Management Approval letter on SharePoint.

5 PROCEDURE

5.1 Continued Sponsorship Approval

5.1.1 The CI, or designee, will submit proposed amendments 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 Amendment Tool, when completed the declaration section should be left blank. This section will be completed by the Sponsor Reviewer. Amendments must not be submitted to review bodies without prior authorisation from the Sponsor.

5.1.2 Where the study amendment includes the addition of new sites 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 amendment 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 amendments prior to submission to the Research Ethics Committee (REC), Research & Development (R&D) or the Competent Authority (e.g. MHRA), where required. Sponsor approval of the amendment 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 amendment tool has classified amendments as non-substantial or substantial correctly, with input from a member of staff from NHSL research governance if necessary, based on 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 Amendment Tool and generate a locked PDF copy of the completed Amendment 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 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 amendment documentation in accordance with SOP GS002 (Combined Risk Assessment), where considered appropriate.
- Log the amendment on the amendment tracker located on the ACCORD SharePoint.

5.1.7 Where an amendment to a risk assessed study is deemed substantial, the Sponsorship reviewer will complete the Substantial Amendment Checklist (GS011-T01) based on the documents and information provided.

5.1.8 Where the amendment is limited to change of Principal Investigator (PI) at an existing research site(s) and/or the addition of new sites, sections 5.1.6 to 5.1.7 (with the exception of adding the amendment to the amendment tracker) of this SOP are not applicable provided the maximum number of sites stipulated in the risk assessment (GS002 Combined Risk Assessment) is not exceeded.

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

5.1.10 The email will include the return of the locked PDF copy of the completed Amendment Tool (if not already returned) and document who needs to be notified of the amendment (e.g. REC, R&D, MHRA) and the conditions to be met prior to the implementation of the amendment. Template guidance may be used as the basis for this e-mail using GS011-T03 (Amendment Classification and Authorisation Template Email) or GS011-T05 (Site-PI Amendment Classification-Implementation Template Email), as relevant. Use of the latter negates the need to provide a separate amendment 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 amendment, they will inform the CI, or designee, and ask them to reconsider the 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 NHSL and UoE Heads of Research Governance, or designees, for co-Sponsored 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 amendment 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 IRAS or the MHRA submission portal in Great Britain. 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, 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 (Amendment Implementation Template Email) to authorise implementation of the amendment at site(s). If required, the Sponsor reviewer 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.

5.2.4 Once the Sponsorship reviewer has authorised implementation of the amendment and any conditions 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 amendment at site(s). The CI, or designee, will maintain a log of when the amendment was implemented at each site. The amendment log template (GS011-T04) may be used by the CI, or designee, to document implementation of amendments.

5.2.5 For all other studies, amendments can be implemented by the CI, or designee, provided all approvals and conditions outlined in the amendment 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 e.g. TMF, ISF, Sponsor File.

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 Amendment 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 amendment.

6 REFERENCES AND RELATED DOCUMENTS

- GS011-T01 Substantial Amendment Checklist
- GS011-T02 Amendment Implementation Template Email
- GS011-T03 Amendment Classification and Authorisation Template Email
- GS011-T04 Amendment Log
- GS011-T05 Site-PI Amendment 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 amendments. An amendment log (GS011-T04) may be used to track amendment implementation dates. In addition, the Sponsor Reviewer is responsible for updating the ACCORD amendment tracker.
5.0	10 DEC 2019	Clarification added to confirm the Sponsor Reviewer is only required to update the ACCORD amendment tracker for studies which have
		undergone Combined Risk Assessment as per SOP GS002. Section 5.1.9 added to provide clarification regarding amendments consisting only of a change of PI and/or addition of new sites. Addition of GS011-T05 (Site-PI Amendment 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 amendment at site, if required. Minor updates made to GS011-T01 and GS011T02.
7.0	28 AUG 2020	Process for preparing and submitting amendments across the UK changed 02-Jun-20. Section 5.1 updated to reference completion of the Amendment Tool by the CI and verification of amendment 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.

8 APPROVALS

Sign	Date
Fiach O'Mahony Fiach O'Mahony (May 25, 2021 14:53 GMT+1) AUTHOR: Fiach O'Mahony, Clinical Research Facilitator, UoE, ACCORD	May 25, 2021
Paul Dearie Paul Dearie (May 25, 2021 16:30 GMT+1) APPROVED: Paul Dearie, Clinical Research Facilitation Manager, UoE, ACCORD	May 25, 2021
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	May 25, 2021

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