R&D Governance Review of Modifications

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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 e.g., a favourable opinion from a Research Ethics Committee (REC) authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) and/or R&D permission.

1.3 Modifications will be classified by the Modifications Tool as either 'substantial' or 'non-substantial'.

1.4 Substantial modifications are classified as Route A or Route B Modifications. This classification is only relevant to modifications that require approval from the Medicine and Healthcare products Regulatory Agency (MHRA) e.g. where a modification is classified as 'Route A', MHRA approval is needed, if 'Route B' it is eligible for automatic approval from the MHRA.

1.5 Non-substantial modifications are classified as 'modifications of an important detail' that the MHRA and Research Ethics Committee (REC) must be made aware of, or 'minor modifications' which may be implemented at any time and without informing the MHRA/REC at the point of implementation.

1.6 For the purposes of R&D review, all modifications are further classified as category 'A', 'B' or 'C', and given an implementation date;

- Category A – applies to all NHS locations and approval must be given by R&D.
- Category B – only applies to some NHS locations. If it is relevant to NHSL, R&D approval will be required. If it is not relevant to NHSL or substantial, it will be treated as a non-substantial Category C *modification*.
- Category C – If the modification is categorised as substantial Category C, this will require approval. If it is categorised as a non-substantial Category C modification, it will only be acknowledged unless approval is deemed necessary e.g. if protocol changes indicate that modification requires R&D approval.

1.7 Modifications to an Investigator's Brochure (IB), a Summary of Product Characteristics (SPC) and/or to an Investigational Medicinal Product Dossier (IMPD), whether substantial Category A or C, will be acknowledged only.

2 Purpose

2.1 The purpose of this standard operation procedure (SOP) is to outline the process of reviewing modifications and issuing continuing R&D management approval for studies that NHSL either co-Sponsor, Sponsor or host.

3 Scope

3.1 This procedure applies to all NHSL research governance and staff involved in the receipt, processing, review and approval of modifications for studies that NHSL co-Sponsor, Sponsor or host.

3.2 For locally sponsored studies, SOP GS011 (Sponsor Approval of Modifications) details the procedure for review of modifications to establish continuing Sponsor approval and is out with the scope of this SOP. Documents will be named using the NRS naming convention (NRS-GUI-009).

4 Responsibilities

4.1 The NRS Generic Review Manager and the R&D Commercial Lead are responsible for maintaining oversight of non-commercial and commercial modifications requiring

NHSL R&D approval, respectively, at weekly team meetings or at regular Research Management Committee (RMC) meetings.

4.2 The R&D Governance Reviewer (e.g. NRS Generic Review Manager, R&D Commercial Lead, R&D Coordinator, Research Governance Officer (RGO)) is responsible for providing the governance review for substantial modifications, and where applicable non-substantial modifications (category A or B), and determining impact on NHSL resources.

4.3 The R&D Modifications Officer, or designee (e.g. R&D administration team), is responsible for;

- Following the work instructions associated with this SOP for the receipt, processing and approval of modifications (GS007-WI01, GS007-WI02 and GS007-WI03).

5 Procedure

5.1 Notification of a Modification

5.1.1 Modifications received by NHSL R&D will be receipted and processed by the R&D Modifications Officer, or designee, in accordance with GS007-WI01 (R&D Receipt of Research Modifications) and GS007-WI02 (R&D Research Modification Processing).

5.2 Pre-approval Modifications

5.2.1 On receipt of an modification prior to R&D Management Approval (MA) (and where the R&D governance review has commenced), the R&D Modifications Officer, or designee, will inform the R&D Governance Reviewer via email (GS007-WI01 R&D Receipt of Research Modifications).

5.2.2 The R&D Governance Reviewer will incorporate review of the modification prior to issuing R&D MA as per SOP GS001 (R&D Governance Review of Non- Commercial Studies) or SOP GS015 (R&D Governance Review of Commercial Studies).

5.3 Modification Review

5.3.1 The R&D Modifications Officer, or designee, will process modifications for R&D governance review in accordance with GS007-WI02 (R&D Research Modification

Processing). This will include drafting the R&D Modification Checklist (GS007-F01) and saving this to the R&D shared drive.

5.3.2 The R&D Governance Reviewer will review the modification, taking the following into consideration, where applicable;

- Impact on NHSL resources and possible requirement for a contract modification,
- Identify which support departments and/or head of service approvals are required.

5.3.3 The R&D Governance Reviewer will document the modification review on the R&D Modification Checklist (GS007-F01).

5.3.4 The NRS Generic Review Manager or the R&D Commercial Lead will ensure modification review is conducted in a timely manner, with any modification related issues discussed at weekly team meetings or at regular Research Management Committee (RMC) meetings.

5.3.5 Once the modification review is complete and continued management approval has been confirmed, the R&D Governance Reviewer will inform the R&D Modifications Officer the checklist is complete, and the amendment approval letter is ready to be signed.

5.3.6 The R&D Modifications Officer will issue the modification approval letter (GS007-T01) in accordance with GS007-WI03 (R&D Research Modification Approval).

5.3.7 The R&D Modifications Officer, or designee, will file the modification documentation (paper and electronic) in accordance with GS001-WI03.

5.3.8 If applicable, the R&D Governance Reviewer will send notification of the updated budget to R&D Finance.

6 References and Related Documents

- GS007-F01 R&D Modification Checklist
- GS007-T01 Modification Approval Letter Template
- GS007-WI01 R&D Receipt of Research Modifications
- GS007-WI02 R&D Research Modification Processing
- GS007-WI03 R&D Research Modification Approval
- GS001 R&D Governance Review of Non-Commercial Studies
- GS011 Sponsor Approval of Modifications
- GS015 R&D Governance Review of Commercial Studies
- NRS-GUI-009 NRS Permission CC - Document Standard Naming Convention

7 Document History

Version Number	Effective Date	Reason for Change
1.0	21 JUL 2016	New SOP
2.0	21 JUL 2016	Typo. Corrected on page 4.
3.0	27 APR 2017	Review of new process. Minor clarification to text throughout.
4.0	03 JUN 2019	Change of author. Minor clarifications to text throughout
5.0	16 OCT 2023	SOP re-written to align with new work instructions (GS007-WI01, GS007-WI02 & GS007-WI03), update to SOP GS001 (R&D Governance Review of Non-Commercial Studies). Also makes reference to new SOP GS015 (R&D Governance Review of Commercial Studies). Addition of GS007-T01.
6.0	06 JAN 2025	Author change and reference to NRS naming convention guidance (NRS-GUI-009) added. R&D Amendment Officer responsibilities aligned with GS001-WI01, adding filing amendment acknowledgements and approvals (paper & electronic).
7.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3). Author change. Clarification around Category C non-substantial amendments with protocol changes added to introduction. Addition of RGO role to R&D Governance team members responsible for amendment review. GS007-F01 (v7.0), GS007-

		T01 (v4.0), GS007-WI01 (v2.0), GS007-WI02 (v3.0) and GS007-WI03 (v3.0) also updated.

8 Approvals

Sign	Date
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L. Mackenzie APPROVED: Lorn Mackenzie, QA Manager NHSL, ACCORD	26-Feb-2026
Gavin Robertson (26-Feb-2026 12:42:07 GMT) AUTHORISED: Gavin Robertson, QA Coordinator NHSL, ACCORD	26-Feb-2026

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