

R&D Governance Review of Amendments

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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 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 Amendments will be classified by the Amendment Tool as either ‘substantial’ or ‘non-substantial’ and as category ‘A’, ‘B’ or ‘C’, and given an implementation date;
 - **Category A** – applies to all NHS sites and approval must be given by R&D.
 - **Category B** – only applies to some NHS sites. 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 amendment.
 - **Category C** – If the amendment is categorised as substantial Category C, this will require approval. If it is categorised as a non-substantial Category C amendment, it will only be acknowledged.
- 1.4 Amendments 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 amendments 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 amendments for studies that NHSL co-Sponsor, Sponsor or host.
- 3.2 For locally sponsored studies, SOP GS011 (Sponsor Approval of Amendments) details the procedure for review of amendments 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 amendments 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) is responsible for providing the governance review for substantial amendments, and where applicable non-substantial amendments (category A or B), and determining impact on NHSL resources.
- 4.3 The R&D Amendments 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 amendments (GS007-WI01, GS007-WI02 and GS007-WI03).

5 Procedure

5.1 Notification of an Amendment

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

5.2 Pre-approval Amendments

- 5.2.1 On receipt of an amendment prior to R&D Management Approval (MA) (and where the R&D governance review has commenced), the R&D Amendments Officer, or designee,

will inform the R&D Governance Reviewer via email (GS007-WI01 R&D Receipt of Research Amendments).

- 5.2.2 The R&D Governance Reviewer will incorporate review of the amendment 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 Amendment Review

- 5.3.1 The R&D Amendments Officer, or designee, will process amendments for R&D governance review in accordance with GS007-WI02 (R&D Research Amendment Processing). This will include drafting the R&D Amendments Checklist (GS007-F01) and saving this to the R&D shared drive.
- 5.3.2 The R&D Governance Reviewer will review the amendment, taking the following into consideration, where applicable;
- Impact on NHSL resources and possible requirement for a contract amendment,
 - Identify which support departments and/or head of service approvals are required.
- 5.3.3 The R&D Governance Reviewer will document the amendment review on the R&D Amendments Checklist (GS007-F01).
- 5.3.4 The NRS Generic Review Manager or the R&D Commercial Lead will ensure amendment review is conducted in a timely manner, with any amendment related issues discussed at weekly team meetings or at regular Research Management Committee (RMC) meetings.
- 5.3.5 Once the amendment review is complete and continued management approval has been confirmed, the R&D Governance Reviewer will instruct the R&D Amendments Officer to generate an amendment approval letter.
- 5.3.6 The R&D Amendments Officer will prepare and issue the amendment approval letter (GS007-T01) in accordance with GS007-WI03 (R&D Research Amendment Approval).
- 5.3.7 The R&D Amendments Officer, or designee, will file the amendment documentation (paper and electronic) in accordance with GS001-WI03.




6 References and Related Documents

- GS007-F01 R&D Amendment Checklist
- GS007-T01 Amendment Approval Letter Template
- GS007-WI01 R&D Receipt of Research Amendments
- GS007-WI02 R&D Research Amendment Processing
- GS007-WI03 R&D Research Amendment Approval
- GS001 R&D Governance Review of Non-Commercial Studies
- GS011 Sponsor Approval of Amendments
- 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).

8 Approvals

Sign	Date
 Heather Charles (Dec 5, 2024 11:19 GMT) AUTHOR: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	Dec 5, 2024
 APPROVED: Lorn Mackenzie, QA Manager NHSL, ACCORD	Dec 5, 2024
 Gavin Robertson (Dec 5, 2024 11:43 GMT) AUTHORISED: Gavin Robertson, QA Coordinator NHSL, ACCORD	Dec 5, 2024











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Final Audit Report

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