R&D Governance Review of Commercial Studies

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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 Before any commercial study involving NHSL patients and/or staff or resources can start, permission/management approval (MA) from NHSL Research and Development (R&D) must be obtained in writing.

2 Purpose

2.1 To document the procedure for NHSL research governance review of commercially sponsored clinical research studies, to ensure compliance with applicable legalisation and guidance prior to issue of R&D MA.

3 Scope

3.1 This SOP applies to NHSL research governance staff involved in the R&D governance review of commercially sponsored studies.

4 Responsibilities

4.1 It is the responsibility of the R&D Commercial Lead to organise the timely review of commercial studies by the NHSL commercial governance team and maintain oversight of the NHSL commercial research portfolio e.g. review/discussion of issues at weekly team meetings and regular Research Management Committee (RMC) meetings.

4.2 It is the responsibility of the R&D Governance Reviewer (e.g. R&D Commercial Lead, R&D Coordinator, Research Governance Officer) to;

- Conduct a National Contract Value Review (NCVR), where required;
- Escalate an NCVR budget, where required;
- Conduct a Study Wide Review (SWR), where required;
- Conduct a local R&D governance review, completing the Commercial Governance Review Checklist (GS0015-F01);
- Complete the Use of Portable Media Checklist (GS006-F01), if required;
- Refer studies for contract review.
- Draft the R&D MA letter and send to the R&D administration team.
- Ensure the Scottish Research Database Application (SReDA) is kept up to date for each study under review.

4.3 It is the responsibility of the Principal R&D Manager, or R&D Contracts Manager, to review Clinical Trial Agreements (CTAs).

4.4 The R&D Administration Team is responsible for;

- Creating a new study file on the R&D shared drive, assigning an R&D number, and uploading study documents to the study file and to SReDA where applicable,
- Informing the local Principal Investigator (PI) that a new commercial study has been received by R&D,
- Informing the R&D Coordinator(s) that a new commercial study, and all required documents/approvals, has been received for review,
- Starting the local R&D review clock once the PI has confirmed capacity to start within 8 weeks,
- Issuing the MA letter for signature and filing the MA letter.

4.5 The R&D Director, the Deputy R&D Director, the Principal R&D Manager, or the Head of Research Governance (NHSL) are responsible for signing the CTA and R&D MA letter.

5 Procedure

5.1 New Commercial Study Receipt

5.1.1 Notification of a new commercial research study (SWR and/or local governance review) will come via the NHS Research Scotland Permissions Coordination Centre (NRSPCC) to the R&D generic mailbox (loth.rdoffice@nhs.scot).

5.1.2 The R&D administration team will confirm receipt of the new study with the R&D Coordinator(s), or designee, who will add the study details to the 'Commercial Study Tracker', under the 'New Studies' tab on the R&D shared drive.

5.1.3 The R&D administration team will e-mail the local Investigator and request that they complete GS015-F05 (Study Information Form) providing CVs for the research team, if applicable.

5.1.4 For single-centre commercial studies, the R&D administration team will create a record on the Scottish Research Database Application (SReDA) and upload the study documents provide by NRS PCC.

5.1.5 R&D Governance Reviewers access the 'Commercial Study Tracker' to determine which study is next on the tracker for review.

5.1.6 The R&D Commercial Lead, or designee, may choose to prioritise a commercial study review over another on the tracker e.g. based on information provided by the Sponsor, PI, support department. This will discussed/agreed by e-mail communication or at weekly team meetings or regular RMC meetings.

5.2 National Contract Value Review (NCVR)

5.2.1 Where NHSL is identified as the lead in a commercial study, the NHSL R&D team may be asked to conduct a National Contract Value Review (NCVR) via NRS PCC in accordance with NRS-GUI-024 (National Contract Value Review Guidance) and NRS-GUI-019 (NRS PCC - Interactive Costing Tool).

5.2.2 Notification that the NCVR has been assigned to NHSL will come via NRS PCC to the Governance Reviewers.

5.2.3 The R&D Coordinator(s), or designee, will add the NCVR details to the 'NCVR' tab on the 'Commercial Study Tracker', on the R&D shared drive.

5.2.4 NRS PCC will request that the study Sponsor provides the Governance Reviewers with access to the interactive Costing Tool (iCT) on the Central Portfolio Management System (CPMS).

5.2.5 The R&D Governance Reviewer will assess the consistency of the research study protocol activities against the completed iCT and will negotiate the resource required to deliver the protocol at any UK-based NHS location, where required.

5.2.6 The R&D Governance Reviewer will request costs from the relevant support departments where required (e.g. Pharmacy, Labs, Radiology).

5.2.7 The R&D Governance Reviewer will liaise with the study team and/or the Sponsor regarding any questions/comments until a budget is agreed.

5.3 Study Wide Review

5.3.1 Where NHSL has been assigned the SWR and once a 'Full Document Set' (FDS) is confirmed by NRS PCC, the study will be moved to the "FDS" tab in the 'Commercial Study Tracker' on the R&D shared drive by the Research Governance Reviewer.

5.3.2 The R&D Governance Reviewer will conduct the SWR in accordance with NRS-SOP-004 (Procedure for Study Wide Review). This will be documented on the Health Research Authority (HRA) Assessment Review Portal (HARP). Note that budget review is not part of SWR (see section 5.2)

5.3.3 The R&D Governance Reviewer will record progress of the SWR on SReDA, ensuring that 'clock stops' and 'clock starts' are documented in accordance with NRS-GUI-001 (Guidance for Measuring NRS Approval Times).

5.3.4 Where NHSL is the lead site and required to undertake a SWR for a Clinical Trial of an Investigational Medicinal Product (CTIMP), the R&D Governance Reviewer will conduct the SWR in accordance with NRS-GUI-022 (CTIMP Combined Review – Study Wide Review Guideline).

5.3.5 The R&D Governance Reviewer will notify the pharmacy team where Lothian have been assigned the SWR of a Scottish-led CTIMP i.e. where a pharmacy review is required (SOP NRS-SOP-004).

5.4 Local Review

5.4.1 The PI will be contacted to confirm that they have capacity to take part in the study. This contact may be during SWR by the R&D Governance Reviewer or by the administration team prior to initiation of local R&D governance review i.e. when NHSL is not responsible for SWR. Local review will only be initiated on confirmation of capacity to start the study within approximately 8 weeks.

5.4.2 If the PI does not have capacity to start the study within approximately 8 weeks, they will be asked to contact the R&D office approximately 4 weeks before they have the capacity to start the study.

5.4.3 On receipt of this confirmation from the PI, confirmation of local FDS will be documented in SReDA and an R&D number will be assigned by the R&D administration team.

5.4.4 The Governance Reviewer will contact the Sponsor or Contract Research Organisation (CRO) to request access to the site level iCT on CPMS following NRS-GUI-019 (NRS PCC – Interactive Costing Tool). This is separate to the NCVR process (section 5.2).

5.4.5 The Governance Reviewer will save a copy of the NHSL iCT export to the relevant study folder in the R&D shared drive and send a copy to the PI/study team, support departments, and service authorisers.

5.4.6 Where a change to the budget is required the Governance Reviewer will make an NCVR escalation following NRS-GUI-013 National Contract Value Review Escalation Process Guidance.

5.4.7 The R&D Governance Reviewer will review study documents in order to document all the governance checks in the Commercial Governance Review Checklist (GS015-F01), which will include support departments and relevant service(s) authorisation i.e. confirmation of capacity to take part in the study. The R&D Governance Reviewer can refer to GL006 (Guidance: R&D Governance Review of Studies) for additional guidance on local review requirements e.g. tissue governance, Caldicott approval, IT security risk assessment.

5.4.8 The R&D Governance Reviewer will use the study documents to confirm compliance with data protection legislation, relevant NHSL policies and procedures and the NHSL R&D Generic Data Privacy Impact Assessment (DPIA, Studies Hosted by NHSL). This

review will be documented in the relevant section of the R&D Governance Checklist (GS015-F01).

5.4.9 Where the reviewer believes that there are aspects of the projects that do not comply with data protection legislation, NHSL policies and procedures or the NHSL R&D Generic DPIA (Studies Hosted by NHSL), this will be raised with the study Sponsor, PI and/or NHSL Information Governance, where appropriate. R&D MA will not be issued until compliance in all areas is confirmed.

5.4.10 The R&D Governance Reviewer will document compliance with the NHSL R&D Generic DPIA (Studies Hosted by NHSL) in the 'Local Information' tab in SReDA. If a study specific DPIA has been provided, this will also be documented in the 'Local Information' tab in SReDA.

5.4.11 Where there are outstanding items or issues that have not been addressed, the R&D Governance Reviewer will send an e-mail to the PI/local contact, and any other relevant parties (e.g. service and/or support departments, Sponsor contact), and a copy of the e-mail(s) will be retained on the NHSL R&D shared drive.

5.4.12 Where the R&D Governance Reviewer needs additional support with a local review, the issue may be escalated to their line manager and/or the issue(s) may be discussed at the next team meeting or RMC Meeting.

5.4.13 The R&D Governance Reviewer will record progress of the local review on SReDA, ensuring that 'clock stops' and 'clock starts' are documented in accordance with NRS-GUI-001 (Guidance for Measuring NRS Approval Times).

5.4.14 The R&D Governance Reviewer and the R&D administration team will save all relevant e-mail communications with the Sponsor/CRO, PI, support departments and service sign offs in the relevant study folder in the R&D shared drive.

5.5 Agreements

5.5.1 The R&D Governance Reviewer will check the CTA, required for all commercial research studies, in accordance with GS001-WI01 (Regulated Study Agreement Preparation – Host).

5.5.2 The R&D Governance Reviewer will send the CTA to the Principal R&D Manager and/or the R&D Contracts Manager for review, where required.

5.5.3 Once agreed, the R&D Governance Reviewer, or delegate, will send the CTA to the Sponsor and/or CRO to initiate the signature process.

5.5.4 Site agreements will only be signed by an NHSL authorised signatory e.g. R&D Director, the Deputy R&D Director, the Principal R&D Manager and the Head of Research Governance (NHSL).

5.6 Management Approval

5.6.1 When all outstanding items related to the local review have been received and all issues resolved, the R&D Governance Reviewer will complete the name and date fields on the Commercial Governance Review Checklist (GS015-F01) denoting that the study is ready for MA. The R&D Governance Reviewer will update SReDA (with the relevant financial recruitment information) and the 'Commercial Study Tracker' and file the completed form in the relevant study folder on the R&D shared drive.

5.6.2 The R&D Governance Reviewer will draft the R&D MA letter using GS001-T01 (Management Approval Letter Template) and inform the administration team by e-mail (loth.accord@nhs.scot) that the study is ready for MA, including a copy of the site agreement to be attached to the MA e-mail.

5.6.3 The R&D administration team will arrange for the MA letter to be electronically signed by one of the authorised signatories for R&D MA letters; the R&D Director, the Deputy R&D Director, the Principal R&D Manager, and the Head of Research Governance (NHSL).

5.6.4 The R&D administration team will ensure that the MA letter is addressed to the PI, and will e-mail the signed MA letter and site agreement to the PI, copying relevant internal and external stakeholders e.g. those responsible for service and support department sign off.

5.6.5 The R&D administration team will file the electronic copy of the MA in the relevant study folder in the R&D shared drive and upload to SReDA.

5.7 Escalation of Service Confirmation of Local Capacity

5.7.1 Where an R&D Governance reviewer has been unable to obtain confirmation of local capacity from a service department within 10 working days, they will follow the process detailed in Appendix 1 (Escalation of Service Confirmation of Local Capacity).

5.7.2 The R&D Commercial Lead, or designee, will maintain an Approvals Escalation Tracker' in the R&D shared drive. This will be reviewed regularly for trends e.g. where a specific authoriser is repeatedly unable to meet the required timelines for review/authorisation. The NRS Generic Review Manager, or designee, may seek RMC/R&D Director support to request that an alternative authoriser is assigned by the service or the Medical Director.

5.8 Commercial Amendments

5.8.1 For continuing MA of amendments to commercially sponsored studies, SOP GS007 (R&D Review of Amendments) details the governance review process. This includes the process to be followed when an amendment is received prior to issue R&D MA.

6 References and Related Documents

- GS015-F01 Commercial Governance Review Checklist
- GS015-F02 Study Information Form (Commercial)
- GS001-T01 Management Approval Letter Template
- GS001-W01 Regulated Study Agreement Preparation – Host
- GL006 Guidance: R&D Governance Review of Studies
- GS006-F01 Use of Portable Media Checklist
- GS007 R&D Review of Amendments
- Research & Development (R&D) Generic Data Protection Impact Assessment – Studies Hosted by NHS Lothian
- NRS-SOP-004 Procedure for Study Wide Review
- NRS-GUI-001 Guidance for Measuring NRS Approval Times
- NRS-GUI-022 (CTIMP Combined Review – Study Wide Review Guideline)
- NRS-GUI-019 NRS PCC - Interactive Costing Tool
- NRS-GUI-024 National Contract Value Review Guidance
- NHSL R&D Generic Data Privacy Impact Assessment (DPIA) for Research
- NRS-GUI-013 National Contract Value Review Escalation Process Guidance

7 Document History

Version Number	Effective Date	Reason for Change
1.0	16 OCT 2023	New SOP. Process previously covered in SOP GS001 (updated for R&D governance review of non-commercial studies).
2.0	15 SEP 2025	Addition of a new Study Information Form (GS015-F02), and update relating to budget review process, now only conducted as part of the NCVR process. Addition of a new escalation process (5.7 and Appendix 1). A requirement to updated SReDA with DPIA information added to section 5 (see references). Filing responsibilities in section 5.4.11 added.

8 Approvals

Sign	Date
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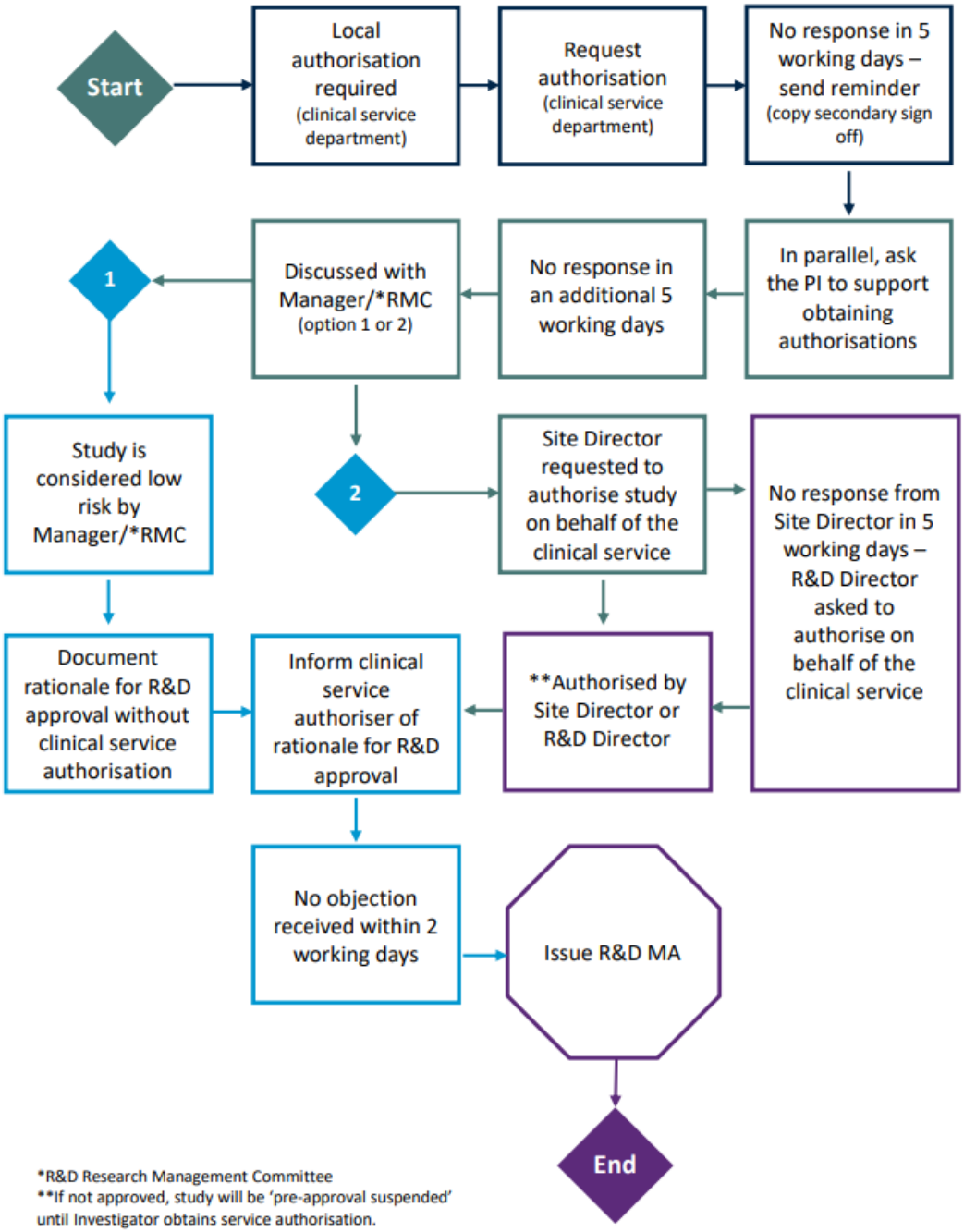
Heather Charles Heather Charles (09-Sep-2025 14:11:09 GMT+1) APPROVED: Heather Charles, Head of Research Governance, NHSL, ACCORD	09-Sep-2025
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	09-Sep-2025

9 APPENDIX 1: Escalation of Service Confirmation of Local Capacity



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