R&D Governance Review of Non-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 non-commercial study, involving NHSL patients and/or staff resources, permission/management approval (MA) from NHSL Research and Development (R&D) must be obtained in writing.

2 Purpose

2.1 To document the procedures for NHSL research governance review of clinical research studies sponsored by non-commercial organisation, to ensure compliance with applicable legislation 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 locally sponsored and hosted non-commercial studies.

4 Responsibilities

4.1 It is the responsibility of the NRS Generic Review Manager to organise the timely review of non-commercial studies by the NHSL non-commercial governance team and maintain oversight of the NHSL non-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. NRS Generic Review Manager, R&D Coordinator, Research Governance Officer) to;

- Conduct a Study Wide Review (SWR), where required,
- Conduct a local R&D governance review, completing the Non-Commercial Governance Review Checklist (GS001-F02),
- Complete the Service Support Costs Form (GS001-F04),
- Complete the Use of Portable Media Checklist (GS006-F01), if required,
- 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 Contract Manager, to prepare and review trial agreements. The Principal R&D Manager is also responsible for authorising the Local Organisation Information Document (LOID) on behalf of NHSL.

4.4 The R&D Administration Team (e.g. R&D Administration Manager, R&D Administration Assistant) 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 non-commercial study has been received by R&D,
- Informing the R&D Coordinator(s) that a new non-commercial study, and all required documents/approvals, has been received for review,
- 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 trial agreements and the R&D MA letter.

5 Procedure

5.1 New Non-Commercial Study Receipt

5.1.1 Notification of a new non-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 'Non-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 GS001-F05 (Study Information Form), providing the LOID and CVs for the research team, if applicable.

5.1.4 For single-centre non-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 can access the 'Non-Commercial Study Tracker' to determine which study is next on the tracker for review.

5.1.6 The NRS Generic Review Manager, or designee, may choose to prioritise a non-commercial study review over another on the tracker e.g., based on information provided by the Sponsor, Principal Investigator (PI), support department. This will discussed/agreed by e-mail communication or at weekly team meetings or regular RMC meetings.

5.2 Study Wide Review

5.2.1 Where NHSL has been assigned the SWR, and once a 'Full Document Set' (FDS) is confirmed by NRS PCC, the study will be updated in the 'Non-Commercial Study Tracker' on the R&D shared drive by the R&D Governance Reviewer.

5.2.2 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).

5.2.3 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).

5.2.4 Where NHSL is the lead location 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).

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

5.3 Local Review

5.3.1 Upon confirmation of a FDS, and a valid LOID, the R&D administration team will assign an R&D number to the study, start the 'clock' in SReDA, and confirm with the R&D Coordinator(s) who will update the 'Non-Commercial Study Tracker', on the R&D shared drive.

5.3.2 The R&D Governance Reviewer will;D

- Confirm FDS on SReDA,
- Ensure that the submitted LOID form is completed and signed when agreed,
- Ensure that, together with the accompanying Local Information Pack, the LOID is an accurate reflection of the NHSL resources that will be used for the project,
- Check that all members of the research team listed on the Study Information Form (GS001-F05) have appropriate contracts with NHSL,
- Check that all relevant service(s)/support departments are identified and seek confirmation of support.

5.3.3 The R&D Governance Reviewer will review study documents and document this review in the Non-Commercial Governance Review Checklist (GS001-F02), this 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.

5.3.4 For eligibly funded studies or those categorised as 'Extended Review' in SReDA, where NHSL are the lead Scottish Health Board, the R&D Governance Reviewer, or designee, will identify service support costs and complete the Service Support Costs Form (GS001-F04). The form will be saved to the electronic study folder on the NHSL R&D shared Drive.

5.3.5 The NRS Generic Review Manager, or designee (e.g. R&D Coordinator(s)) will review the weekly RMC agenda for non-commercial studies that have obtained R&D MA, and where applicable use the completed Service Support Costs Form (GS001-F04) and the NRS Finance Tool to determine costs. The costs will be populated in the "Legacy SSC value" field in 'Recruitment Totals' tab in SReDA and GS001-F04 updated to confirm this action.

5.3.6 If members of the research team are not substantively employed by NHSL, the R&D Governance Reviewer will assess whether their involvement in the research will have a direct bearing on patient care. They will advise if a Letter of Access (LoA) or Honorary Research Contract (HRC) will be issued on receipt on a valid research passport system application in accordance with SOP GS006 (Research Passports).

5.3.7 The R&D Governance Reviewer will use the study documents to confirm compliance with data protection legislation, relevant NHSL policies and procedures and the

relevant NHSL R&D Generic Data Privacy Impact Assessment (DPIA). This review will be documented in the relevant section of the R&D Governance Checklist (GS001-F02).

5.3.8 Where the reviewer believes that there are aspects of the study that do not comply with data protection legislation, NHSL policies and procedures or the relevant NHSL R&D Generic DPIA, 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.

5.3.9 The R&D Governance Reviewer will document compliance with the relevant NHSL R&D Generic DPIA 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.

5.3.10 Where there are outstanding items or issues, 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.

5.3.11 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.

5.3.12 The Research 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).

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

5.4 Agreements

5.4.1 The R&D Governance Reviewer will confirm receipt of a site agreement for all studies that fall under regulations for CTIMPs/Clinical Investigations of Medical Devices (CIMDs)/)/other clinical trial to study novel intervention (top 4 categories in IRAS). For other studies, the LOID will be used as the agreement.

5.4.2 The Research Governance Reviewer will send agreements to the Principal R&D Manager, or R&D Contracts Manager, for review and authorisation in accordance with work instruction GS001-W01 (Regulated Study Agreement Preparation).

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

5.5 Management Approval

5.5.1 When all outstanding items related to the local review have been received and issues resolved, the R&D Governance Reviewer will complete the name and date fields on the checklist (GS001-F02) denoting that the study is ready for MA. They will update SReDA and the 'Non-Commercial Study Tracker' and file the completed form in the relevant study folder on the R&D shared drive.

5.5.2 The R&D Governance Reviewer will draft the R&D MA letter using GS001-T01 (Management Approval Letter Template) and send this to the R&D administration team by e-mail (loth.accord@nhs.scot) informing them that the study is ready for MA.

5.5.3 The R&D administration team will arrange for the MA letter to be e-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).

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

5.5.5 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.

5.5.6 For studies sponsored by NHSL and/or UoE, the R&D administration team will save the MA letter to the ACCORD SharePoint site in the relevant study folder.

5.5.7 The R&D administration team will file a copy of the R&D MA letter in the Trial Master File and/or Sponsor File for studies sponsored by NHSL and/or UoE that have undergone Combined Risk Assessment (SOP GS002) i.e. studies with an R&D number ending 'TMF'. A copy of the signed LOID will be filed for these studies where ACCORD hold the TMF i.e. hard copy files labelled 'TMF'.

5.6 Escalation of Service Confirmation of Local Capacity

5.6.1 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).

5.6.2 The NRS Generic Review Manager, 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.

5.7 Non-Commercial Modifications

5.7.1 For continuing MA of modifications to studies sponsored by non-commercial organisations, SOP GS007 (R&D Review of Modifications) details the governance review process. This includes the process to be followed when a modification is received prior to issue R&D MA.

6 References and Related Documents

- GS001-W01 Regulated Study Agreement Preparation – Host
- GS001-T01 Management Approval Letter Template (with optional inserts)
- GS001-F02 Non-Commercial Governance Review Checklist
- GS001-F04 Service Support Costs Form
- GS001-F05 Study Information Form (Non-Commercial)
- GS003 – Sponsorship Approval
- GS006 – Research Passports
- GS007 – R&D Review of Modifications
- Research & Development (R&D) Generic Data Protection Impact Assessment – NHS Lothian and the University of Edinburgh Co-Sponsored Studies
- Research & Development (R&D) Generic Data Protection Impact Assessment – Studies Singly Sponsored by NHS Lothian
- Research & Development (R&D) Generic Data Protection Impact Assessment – Studies Hosted by NHS Lothian
- UK Policy Framework for Health and Social Care Research

- 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)

7 Document History

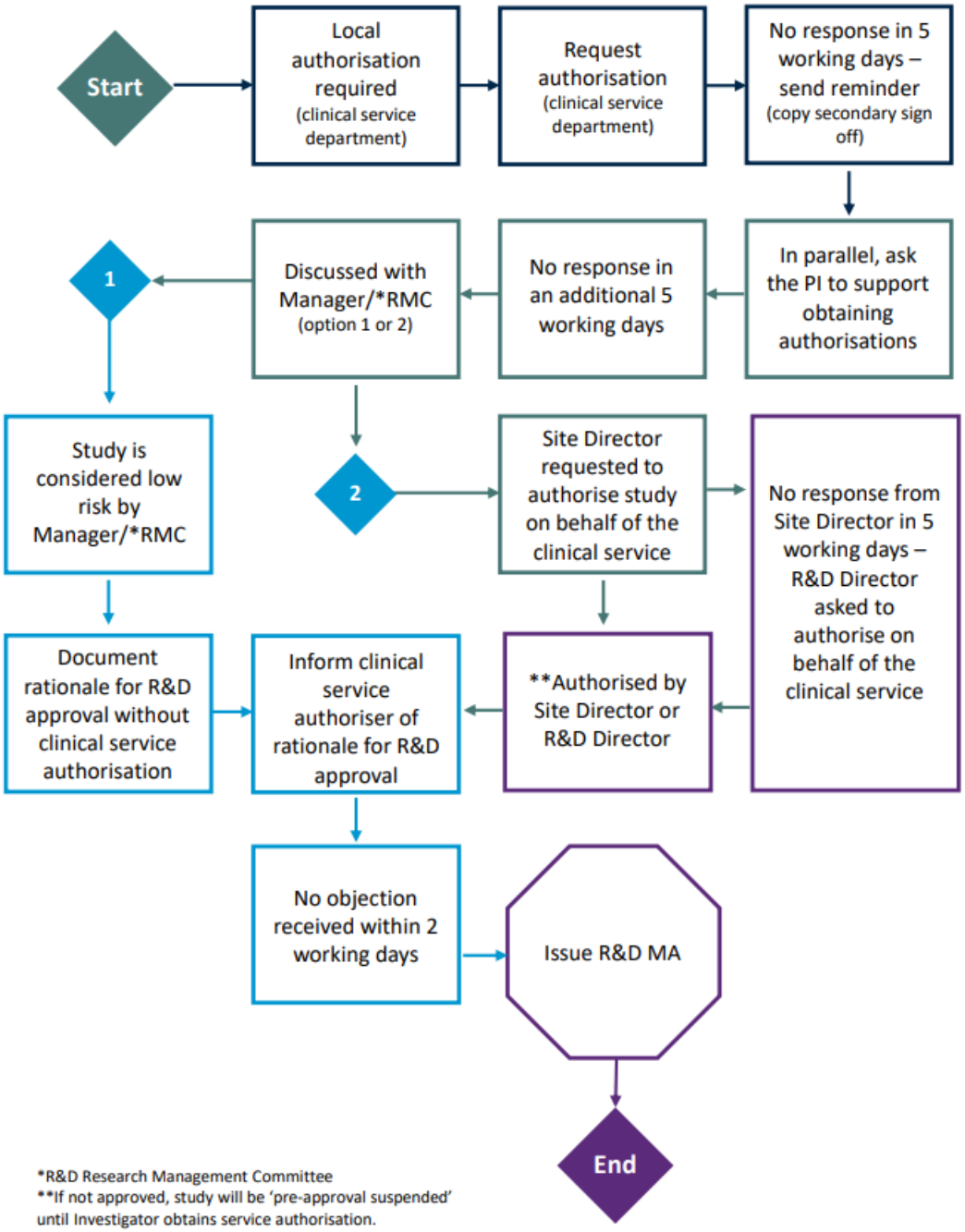
Version Number	Effective Date	Reason for Change
1.0 – 6.0	25 APR 2011 - 05 JUN 2019	Reason for version change available from loth.qa@nhs.scot on request.
7.0	23 MAR 2021	Section 5.1.9 added to document data protection compliance checks conducted by the governance reviewer and reference to the NHSL R&D Generic DPIA added. Wording of section 5.4.1 updated.
8.0	07 MAR 2023	Section 5.1.7 updated regarding location of completed SSC Form. Minor updates to section 5.2.3 to clarify document set for studies identified through the NHS Lothian Bioresource.
9.0	16 OCT 2023	Title and scope of SOP changes to cover non-commercial studies only (see new SOP GS015 R&D Review of Commercial Studies). SOP updated to describe local receipt processes, and national processes (e.g. study wide review, service support costs on SReDA). Sections of the SOP that provide guidance around tissue governance, Caldicott and IT security approvals removed to new guidance document (GL006. Addition of new form (GS001-F05 Study Information Form).
10.0	15 SEP 2025	Addition of a new escalation process (5.6 and Appendix 1). A requirement to updated SReDA with DPIA information added to section 5, noting that there is now more than one generic DPIA (see references). Reference to studies now categorised as 'Extended Review' (section 5.3.4) and filing responsibilities in section 5.5.7 updated to include filing of the LOID, where applicable
11.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3), and minor administrative changes.

		Minor updates also made to GS001-F02 Governance Review Checklist (v13.0), GS001-F05 Study Information Form (v4.0) and GS001-W01 Regulated Study Agreement Preparation-Host (v6.0).

8 Approvals

Sign	Date
Kenneth Scott Kenneth Scott (26-Feb-2026 13:43:56 GMT) AUTHOR: Kenneth Scott, NRS Generic Review Manager, NHSL, ACCORD	26-Feb-2026
Heather Charles Heather Charles (26-Feb-2026 13:41:29 GMT) APPROVED: Heather Charles, Head of Research Governance, NHSL, ACCORD	26-Feb-2026
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	26-Feb-2026

9 APPENDIX 1: Escalation of Service Confirmation of Local Capacity



*R&D Research Management Committee
**If not approved, study will be 'pre-approval suspended' until Investigator obtains service authorisation.

GS001 RD Governance Review of Non-Commercial Studies v11.0

Final Audit Report 2026-02-26

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