ACCEPTING A NEW RESEARCH PROJECT FOR MANAGEMENT APPROVAL

DOCUMENT NO.:	**AD003 v4.0**
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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 Management Approval (MA) is required for all research projects undertaken within NHSL. Researchers must provide a valid document set to enable the Research & Development (R&D) Management Approval process to proceed.

1.3 The Scottish Research Database Application (SReDA) is a web-based application developed specifically for R&D Offices across Scotland. SReDA is an electronic document repository for all study documentation and has the ability to generate reports on study activity.

2 PURPOSE

2.1 The purpose of this SOP is to document a clear process for accepting, creating and maintaining an electronic file for new project submissions to the ACCORD Office for R&D MA.

3 SCOPE

3.1 This SOP applies to Administration Staff responsible for establishing and maintaining an electronic research project file in the ACCORD Office.

4 RESPONSIBILITIES

4.1 It is the responsibility of the Administration Team to;

- Assign a new project with an R&D number;
- Create and maintain electronic files;
- Inform the NHSL Governance Reviewer of a new project submission.

4.2 It is the responsibility of the NHSL Governance Reviewer to;

- Inform the Administration Team when an R&D number can be allocated to a commercial study.

- Inform the Administration Team of additional documents received during the R&D Governance review;
- Inform the Administration Team when a research project is valid for MA.

5 PROCEDURE

5.1 Notification of a New Project

5.1.1 The Administration Team will be notified of a new project submission by NHS Research Scotland Permission Coordinating Centre (NRSPCC).

5.1.2 For Single Centre Studies: The administration team will create a new entry on SReDA for the project. The temporary Project ID will be set as the IRAS code followed by *SC* (Single Centre) until an R&D number can be allocated. Before creating a new record for single centre projects, the Administration Team will perform a search on SReDA to ensure the project does not already exist.

For Multi Centre Studies: NRSPCC will create an entry on SReDA for the project. The administration team will set a temporary Project ID as the IRAS code for Commercial projects or the NRS number for non-commercial projects until an R&D number can be allocated.

5.1.3 For Non-Commercial Studies: On receipt of a Full Document Set (FDS) and Localised Organisational Information Document (LOID) the Administration Team will issue an R&D number made up of two components (year / 4 digit number i.e. YYYY/XXXX). The project will be assigned the next available number from the project tracking spreadsheet located on the NHSL F-drive.

5.1.4 For Commercial Studies: On receipt of a FDS, and confirmation from the Principal Investigator (PI) that Lothian will be a participating site, the Administration Team will issue an R&D number made up of two components (year / 4 digit number i.e. YYYY/XXXX). The project will be assigned the next available number from the project tracking spreadsheet located on the NHSL F-drive. An additional C will be added to the end of the R&D number sequence.

5.1.5 At the beginning of each calendar year the Project ID log numbering will revert back to 0001 and will increase sequentially for each new study allocated a project number.

5.1.6 For Research Tissue Bank or Research Databases the above code will end in TB or DB.

5.1.7 For Bioresource studies there will be an additional code predetermined from the Tissue Governance Sample Answer Form i.e. YYYY/XXXX/SRXXX.

5.1.8 If the study is UoE and/or NHSL sponsored, and is a regulated Clinical Trial of an Investigational Medicinal Product (CTIMP) or a Clinical Investigation of a Medical Device, the R&D number sequence will have TMF added to the end i.e. YYYY/XXXX/TMF.

5.1.9 If the study is a Phase I study running through the Edinburgh Clinical Research Facility, the standard electronic folder icon will be replaced with a red icon on the F Drive. In addition the R&D number on SReDA will contain two asterisks i.e. YYYY/XXXX/**.

5.1.10 For research studies involving an AT(I)MP or GM(O), requiring review by the Advanced Therapy and Gene Modification Safety Committee (ATGMSC) as per SOP GS012 (Advanced Therapy and Gene Modification Safety Committee Approval for Research), the standard electronic folder icon will be replaced with a red icon on the F Drive. In addition, the first sub-folder in the file hierarchy will be named '[R&D Number] – Amendments need to go to ATGMSC for approval'

5.2 Validating Document Set for Single Centre Studies

5.2.1 On receipt of a submission for R&D MA, the Administration Team will perform the following checks to ensure the application is a valid full document set:

- Fully signed IRAS Form or Project Study Information form for 'Combined Review' studies
- Protocol
- Participant Information Sheet/Consent Form
- Questionnaires/Invitation Letters/Drug Diary etc.
- Funding Award Letter (If applicable)
- Insurance Certificate (if study NOT sponsored by NHS and/or UoE)

5.2.2 If the submission is not a valid document set, the Administration Team will request missing documents from the researcher.

5.2.3 The Administration Team will request the LOID for non-commercial projects.

5.3 Creating a New Electronic File

5.3.1 The Administration Team will create a new electronic file on the NHSL F-Drive named as the assigned R&D number. This electronic file will contain a copy of the template folder, sections include;

Amendments: Amended study documentation and associated approvals filed in order of receipt i.e. a-z or 1-X.
Caldicott & IG-IT: Caldicott application forms and emails
CofC and Local MA: Governance review checklist, Management Approval, Scottish Generic Report
Correspondence: Relevant emails/letters/Head of Service Approvals

Ethics: Ethics correspondence/letters of opinion
Finance & Agreements: Study agreements, insurance/indemnity, service support costs, grant award letter and application, costing templates.
Investigator(s) Information: CV/GCP certificate
Project Information: Current version of study documentation
R&D: IRAS Form, Localised OID
Regulatory Approvals: MHRA Approval, ARSAC.

5.3.2 For single centre studies, the Administration Team will upload the document set to SReDA, once the MA letter has been issued. For multicentre studies, the Administration Team will upload local documents only to SReDA. Superseded documents will be saved to relevant subfolders on the NHSL F-Drive.

5.3.3 Once a valid document set has been confirmed, the Administration Team will send an email to the initial contact copying in the PI / Chief Investigator (CI) and NHSL Governance Reviewer to confirm Project ID, receipt of documents and advise a member of the Governance team will be in contact.

5.4 Maintaining an Electronic File

5.4.1 During the Governance Review additional documents may be received by the NHSL Governance Reviewer e.g. amendments, regulatory approvals, Head of Service approval, CVs.

5.4.2 The NHSL Governance Reviewer will ensure these are forwarded to the Administration Team, who will ensure all documents are saved to the electronic file on the F Drive, uploaded to SReDA, and superseded versions archived accordingly.

5.5 Management Approval

5.5.1 The Administration Team will be informed by the NHSL Governance Reviewer when the project is valid for MA as per SOP GS001 (R&D Management Approval).

5.5.2 The Administration Team will ensure the MA letter is saved to the electronic file on the F-Drive, uploaded to SReDA and for studies sponsored by NHSL and/or UoE, the Administration Team will save the MA letter to the ACCORD SharePoint site in the relevant study folder.

6 REFERENCES AND RELATED DOCUMENTS

- AD004 Project Data Entry on SReDA
- GS001 R&D Management Approval
- GS012 Advanced Therapy and Gene Modification Safety Committee Approval for Research

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	19 JUL 2017	New SOP
2.0	11 JUN 2019	To align with updated SReDA and implementation of the UK Local Information Pack. Change of author. AD003-F01 now obsolete.
3.0	20 OCT 2020	Procedure for adding a flag on the S Drive for studies reviewed by ATGMSC added at 5.1.10
4.0	04 JAN 2023	Additional responsibilities added to 4.2. Clarification added at 5.1.3 and 5.1.4 for assigning R&D numbers to non-commercial and commercial studies, respectively. Minor administrative changes throughout.

8 APPROVALS

Sign	Date
Lesley Saeed Lesley Saeed (Dec 21, 2022 07:44 GMT) AUTHOR: Lesley Saeed, R&D Administration Manager, NHSL, ACCORD	Dec 21, 2022
Kenneth Scott Kenneth Scott (Dec 21, 2022 09:27 GMT) APPROVED: Kenneth Scott, NRS Generic Review Manager, NHSL, ACCORD	Dec 21, 2022
Gavin Robertson (Dec 21, 2022 08:11 GMT) AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	Dec 21, 2022

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Final Audit Report 2022-12-21

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