

PROJECT DATA ENTRY ON SREDA

DOCUMENT NO.:	AD004 v4.0
AUTHOR:	Lesley Saeed
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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 Research activity in NHS Research Scotland is recorded on the Scottish Research Database Application (SReDA) for project management and reporting purposes.
- 1.3 For single centre studies, ACCORD office staff will create the study record and enter the required minimum dataset on SReDA.
- 1.4 For multicentre studies NHS Research Scotland Permissions Coordinating Centre (NRS PCC) create the study record on SReDA and enter the project level fields of the required minimum dataset, ACCORD office staff will enter Health Board local data.

2 PURPOSE

- 2.1 The purpose of this SOP is to define the required minimum dataset to facilitate consistent and efficient working of research data in SReDA.

3 SCOPE

- 3.1 This SOP covers the procedure of entry of research data into SReDA by ACCORD staff.

4 RESPONSIBILITIES

- 4.1 It is the responsibility of the Administration Team, to enter data onto SReDA from the project submission documents i.e. IRAS Form or Project Study Information Form.

5 PROCEDURE

5.1 Data Entry

- 5.1.1 The following tables detail the required minimum dataset for studies that require Research & Development Management Approval.

Study Details/Project Information Tab

SReDA Field	Source
Short Title	IRAS Form or Project Study Information form Page 1
Research Title	IRAS Form QA1 or Project Study Information form QA6
IRAS Project Code	First 5/6 numbers at the bottom right-hand corner of the IRAS Form or Project Study Information form Page 1
Project ID	Created by Administration Team member
REC Number	IRAS Form QA5-1 or REC Correspondence
EudraCT Number	Only applies to CTIMP studies. IRAS form QA5 or Project Study Information form Page 1
ISRCTN	IRAS Form QA5-1 or Project Study Information form Page 1
Protocol ID	Add protocol number (if available)
Main Ethics Status	REC Favourable Opinion
Study Type	IRAS Form Filter Q2 or Project Study Information form
Education Qualification Aim	IRAS Form QA3
Lead Nation	IRAS Form Q3a or Project Study Information form QA2 (only for Single Centre Projects)
Participating Nations	IRAS Form Q3 or Project Study Information form QA1 (only for Single Centre Projects)
UKCRC Health Category	Research Governance Team
MHRA Authorisation Required	Project Study Information form
Project Type	Research Governance Team

Study Details/Stakeholders Tab

SReDA Field	Source
Chief Investigator	IRAS Form or Project Study Information form QA2 (only for Single Centre Projects)
Principal Investigator	Localised OID (only for non-commercial studies)
Funder Name	IRAS QA65 or Project Study Information form Page 1 or funding correspondence (only for Single Centre Projects)
Sponsor	IRAS Form QA64 or Project Study Information form QB1-1 (only for Single Centre Projects)

Study Details/Research Tab

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SReDA Field	Source
Primary Research Question	IRAS Form QA10 or Project Study Information Form - E2-1
Secondary Research Question	IRAS Form QA11 or Project Study Information Form - E2-2
Outcome Measure	IRAS Form QA57 or Project Study Information Form - E5-1
Methodology	IRAS Form QA7 or Project Study Information Form E8
Minimum Age of Participants	IRAS Form A15 or Project Study Information Form - F1
Maximum Age of Participants	IRAS Form A15 or Project Study Information Form - F1
Trial Phase	IRAS Form QA9 or Project Study Information Form E7

Study Details/ Local Information

SReDA Field	Source
R&D Officer	Research Governance Team
Project Status	Proposed/Active/Withdrawn/Follow-Up/Completed etc
Location Status	Proposed/Active/Withdrawn/Follow-Up/Completed etc
Ethical Status	REC Correspondence
Is Lead Centre?	Yes if CI is NHS Lothian or Edinburgh University employed
Lead Centre Name	IRAS Form QA68 or from CI information
REC Approval Date	REC Favourable Opinion
Permission Granted Date	Management Approval Letter
Actual Start Date	Management Permission Letter
Actual End Date	Localised OID (or Contract for commercial studies)
Ethics Approval Date	REC Favourable Opinion
Location Start Date	Management Permission Letter
Location End Date	Localised OID (or Contract for commercial studies)

Study Details/Locations Tab

SReDA Field	Source
Study Locations	Localised OID (for non-commercial studies only)

Governance/Checklist Tab

SReDA Field	Source
Full Document Set	Date FDS received
Localised OID	Date Localised OID received (for non-commercial studies only)
Local Management Permission Letter	Date permission letter issued

Recruitment Tab/Targets and Dates

SReDA Field	Source
Local Recruitment Target	Localised OID for non-commercial studies and the Contract for commercial studies

Recruitment Tab/Recruitment Totals

SReDA Field	Source
Current Target Recruitment End	Study contact
RGL from Sponsor	Study contact




6 REFERENCES AND RELATED DOCUMENTS

- NRS-SOP-008 – Procedures for Use of SReDA within the NHS Research Scotland Research & Development offices
- NRS-GUI-001 – Guidance for Measuring NRS Approval Times

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.
3.0	18 JUN 2021	To align with SReDA, and updated to processes and local and national level.
4.0	22 JUN 2023	Reference to Project Study Information Form added throughout, and other minor administrative changes where required.

8 APPROVALS

Sign	Date
 <small>Lesley Saeed (Jun 6, 2023 08:43 GMT+1)</small> AUTHOR: Lesley Saeed, R&D Administration Manager, NHSL, ACCORD	Jun 6, 2023
 APPROVED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	Jun 6, 2023
 <small>Gavin Robertson (Jun 6, 2023 08:26 GMT+1)</small> AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	Jun 6, 2023












AD004 - Project Data Entry on SReDA v4.0

Final Audit Report

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