

END OF STUDY DATE

DOCUMENT NO.:	AD005 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 In most cases the end of study will be the date of the last visit of the last participant or completion of study follow-up. When a study has come to an end, it is important that end dates documented in SReDA are accurate to ensure data quality and end of study reporting timelines are met.

2 PURPOSE

- 2.1 The purpose of this SOP is to define a clear process for ascertaining study end dates in SReDA are accurate.

3 SCOPE

- 3.1 This SOP applies to ACCORD Administration Staff.

4 RESPONSIBILITIES

- 4.1 It is the responsibility of the Administration Team to:
 - Run a monthly report in SReDA to review active study end dates;
 - Confirm study end dates with the research team and update SReDA and the sponsorship tracker on the ACCORD SharePoint accordingly;
 - Communicate any study end date updates or extensions to study end dates to ACCORD representatives;
 - Issue end of study acknowledgement emails to the study team.

5 PROCEDURE

5.1 Studies Past End Dates Report

- 5.1.1 The Administration Team will run a monthly report from SReDA to review active studies running within NHSL that have recently ended or are due to end that month.
- 5.1.2 For studies that fall into these categories, the Administration Team will send an email to the Principal Investigator (PI) copying in the site contact, or

designee, requesting confirmation of the end of study information i.e. study end date, recruitment end date or study extension details if appropriate.

- 5.1.3 If there has been no communication after two attempts, this will be escalated to the NHSL Head of Research Governance for action.

5.2 Updates or Extensions to Study End Dates

- 5.2.1 On receipt of updated end of study information from the PI, or designee, the Administration Team will email the PI, or designee, to acknowledge receipt of their e-mail, update SReDA and save correspondence to the NHSL R&D Shared Drive and SReDA.
- 5.2.2 For all studies, the ACCORD Administration Team will inform relevant support departments of any end of study updates or extension.
- 5.2.3 For studies sponsored by NHSL and/or UoE, the Administration Team will inform the ACCORD Sponsor Representative of any updates or extensions to study end dates as this may incur a substantial or non-substantial amendment. In addition, those studies which are monitored by the ACCORD Monitoring Team, the Administration Team will inform the assigned ACCORD Clinical Trial Monitor of any updates or extensions to study end dates.
- 5.2.4 For eligibly funded studies or adopted studies, the Administration Team will inform the Project Information Manager, or designee, of any updates or extensions to study end dates.
- 5.2.5 For commercial studies, the Administration Team will inform the NRS Portfolio Administration Officer, or designee, of any updates or extensions to study end dates.

5.3 End of Study Acknowledgement

- 5.3.1 Where the PI, or designee, confirm that the study has ended, the Administration Team will email the PI, and designee if applicable, to acknowledge receipt of their e-mail, update SReDA and and save correspondence to the NHSL R&D Shared Drive and SReDA.
- 5.3.2 For studies sponsored by UoE/NHSL, the Administration Team will update the sponsorship tracker on the ACCORD SharePoint by adding the study end date and changing the study status to 'CLOSED'.
- 5.3.3 The Administration Team will communicate the confirmed study end date to the appropriate ACCORD personnel (see 5.2.2-5.2.5).

6 REFERENCES AND RELATED DOCUMENTS




- AD005-T01 End of Study Letter Template

Parties using this SOP must visit www.accord.scot to guarantee adherence to the latest version.

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	18 OCT 2017	New SOP
2.0	07 NOV 2019	5.2.4 updated to remove reference to the Information and Knowledge Manager and replace with the Project Information Manager
3.0	17 SEP 2021	Sections 4.1 and 5.3 updated to add Administration Team responsibilities for updating study status and study end date to the sponsorship tracker on the ACCORD SharePoint.
4.0	28 SEP 2023	Reference to NHSL R&D Shared Drive added at sections 5.2.1 and 5.3.1.

8 APPROVALS

Sign	Date
 Lesley Saeed (Sep 14, 2023 10:45 GMT+1) AUTHOR: Lesley Saeed, Admin Team Manager, NHSL, ACCORD	Sep 14, 2023
 Kenneth Scott (Sep 14, 2023 11:04 GMT+1) APPROVED: Kenny Scott, NRS Generic Review Manager, NHSL, ACCORD	Sep 14, 2023
 Gavin Robertson (Sep 14, 2023 10:46 GMT+1) AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	Sep 14, 2023












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Final Audit Report

2023-09-14

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