RECORDING AND REPORTING STUDY DATA

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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 ICH-GCP E6(R2) guidelines state that:

"The investigator should ensure the accuracy, completeness, legibility and timeliness of the data reported to the sponsor in the CRFs and in all required reports."

"Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained."

2 PURPOSE

2.1 To describe the procedure for recording and managing research study data on source documents and case report forms (CRFs). .

3 SCOPE

3.1 This SOP applies to study teams conducting clinical research that is sponsored by the UoE and/or NHSL.

4 RESPONSIBILITIES

4.1 The Chief Investigator (CI), or designee, is responsible for designing the CRFs in accordance with CR013 (CRF Design and Implementation).

4.2 The Principal Investigator (PI), or designee, is responsible for recording and reporting study data on the relevant documents and regularly reviewing the CRFs/Source documents for any discrepancies/deviations.

5 PROCEDURE

5.1.1 Study data will be recorded on source documents and on study specific CRFs. Data reported on CRFs will be derived from source documents.

5.1.2 The CRFs will be designed at the beginning of the trial by the CI, or designee, in accordance with SOP CR013 (CRF Design and Implementation).

5.1.3 Recording and reporting study data on the relevant documents will be done by the PI or a member of the research study team who has been delegated responsibility to do so by the PI. This delegation of responsibility will be documented in the study delegation log and this will be kept in the Investigator Site File (ISF).

5.1.4 All study data recorded on the CRF/source document will be accurate, legible and complete.

5.1.5 All study data will be recorded on paper CRFs/source documents in ink.

5.1.6 Data fields will not be left blank. Not Applicable (NA), Not Known (NK) or Not Done (ND) will be entered on the CRF/Source document as appropriate.

5.1.7 All study data recorded on the CRF will be consistent with the source data. The reasons for any discrepancies between the source data and the study data will be documented and filed in the ISF.

5.1.8 In some cases study data may not be recorded in the source document but is instead recorded directly onto the CRF. It will be documented in the study protocol that the CRF will act as the source for the specified study data points.

5.1.9 To make a correction to the study data on paper documentation the original entry will be scored through once so that it is not obscured. The new entry will be recorded next to the scored through entry on the document. All corrections will be initialled and dated by the individual making the changes. Correction fluid will never be used.

5.1.10 Electronic CRFs/Source documents will have an appropriate audit trail so that a record is kept of all corrections made to the document and of who made each correction.

5.2 Managing Study Data

5.2.1 The CRFs will be kept by the Investigator in the ISF. If the CRFs are kept somewhere other than the ISF, the location of these will be documented in a file note and this will be kept in the ISF.

5.2.2 In some cases the study database may be held at an external location/site. The data management system must be designed to ensure that data are transferred in a secure fashion.

5.2.3 Identifiable subject data will not be sent externally to the sponsor or approved external organisation by any member of the study teams without authorisation from the sponsor, in accordance with approved procedures.

5.2.4 Study data may be entered into to a study specific database from the CRF in accordance with study data entry procedures. The data will be entered exactly as it has been reported on the CRF.

5.2.5 The PI must regularly review CRFs/Source documents to check for any discrepancies/deviations and will authorise the completed document by a dated signature.

5.2.6 At the end of the study, data will be archived as per SOP CR009 (Study Closure and Archiving).

5.2.7 The investigator will take measures to prevent accidental or premature destruction of these documents.

6 REFERENCES AND RELATED DOCUMENTS

- SOP CR009 Study Closure and Archiving
- SOP CR013 CRF Design and Implementation
- The Medicines for Human Use (Clinical Trials) Act (SI 1031), as amended
- ICH-GCP E6(R2) Guidelines

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	22 MAR 2011	New Procedure
2.0	08 NOV 2016	Minor edits made throughout. Reference added to SOP CR013 in section 5.1.2.
3.0	04 DEC 2018	Minor administrative changes.

8 APPROVALS

Sign	Date
SIGNATURE KEPT ON FILE AUTHOR: Javier Rojas, Clinical Trials Monitor, NHS Lothian, ACCORD	
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