RECORDING AND REPORTING STUDY DATA

DOCUMENT NO.:	**CR004 v6.0**
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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 Clinical data can originate from various sources and depending on the complexity of trial design and the number of data points, the source data requirements are likely to vary on a per study basis. For this reason, the location of source documents and associated source data should be clearly identified at all points within the data capture process.

1.3 ICH-GCP E6(R2) guidelines state that:

Source data is "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)."

"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) to ensure data quality, data integrity and compliance with GCP and applicable legislation. .

3 SCOPE

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

3.2 The scope of this SOP includes all information in original documents, data and records used for reconstructing and evaluating an investigation. This includes electronic systems for the creation and capture of electronic data including but not limited to; electronic case report forms (eCRFs), electronic patient data capture devices used to collect Patient Reported Outcomes (ePRO), electronic health records (eHR).

4 RESPONSIBILITIES

4.1 The Chief Investigator (CI), or designee, is responsible for designing the CRFs in accordance with CR013 (CRF Design and Implementation). For trials including Adults with incapacity (AWI) consent, the CI or designee is responsible for making CR004-T02 (Example Text for Medical Notes AWI Consent) trial specific and circulating to all sites during site set up.

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.

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 The CI or designee (e.g. Trial Manager or Clinical Trials Monitor) will create a study specific Source Data Plan (CR004-T01), unless otherwise agreed with the Clinical Trials Monitor. The Source Data Plan (CR004-T01) will be made trial specific, highlighting the essential data points as required by the protocol including source codes (e.g. ELF - eligibility form) denoting the location where the data point is first documented.

5.1.4 The trial specific Source Data Plan (CR004-T01) will then be circulated to sites. The PI or designee at each site is required to localise CR004-T01 and confirm the source document for each essential data point as required by the protocol. This must be completed by each site and reviewed by the Clinical Trials Monitor prior to Sponsor Authorisation To Open (SATO) in accordance with SOP CM001 (Site Initiation and Sponsor Authorisation). The original localised and completed CR004-T01 will be filed in the Investigator Site File (ISF) and a copy sent to the Trial Manager for filing in the Trial Master File (TMF).

5.1.5 If there is any change in location of source data or documents throughout the trial, the PI or designee is responsible for updating CR004-T01 (Source Data Plan) and providing a copy for the TMF. Previous versions of the form should be superseded and retained in the ISF.

5.1.6 Each trial which includes Adults with Incapacity (AWI) consent must provide a template to assist site teams with source documentation of the consent process in the medical notes. The Example Text for Medical Notes AWI Consent template (CR004-T02) is to be made trial specific by the CI or designee (e.g. Trial Manager or Clinical Trials Monitor) before being circulated to sites. It is not mandatory for sites to use CR004-T02 if local processes are already in place which document the AWI consent process in the medical notes to an equivalent standard. A copy of CR004-T02 must still be provided to all sites by the CI or designee during set up to ensure site teams have clear guidance on the source data expectations. Evidence of CR004-T02 being sent to all sites on trials with AWI consent will be filed in the TMF.

5.1.7 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 ISF.

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

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

5.1.10 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.

5.1.11 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.

5.1.12 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.

5.1.13 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, and explained (if necessary). Correction fluid will never be used.

5.1.14 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 PI will have contemporaneous access to all data collected on participants enrolled at their site. This includes access to view centrally collected data e.g. follow up questionnaires or patient reported outcomes.

5.2.2 The CRFs will be kept by the Investigator in the ISF in a secure location. 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.

5.2.3 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.

5.2.4 Identifiable subject data will not be sent externally to the sponsor or external organisation by any member of the study teams without authorisation from the sponsor

5.2.5 Study data may be entered into 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.

5.2.6 The PI must regularly review CRFs/Source documents to check for any discrepancies/deviations and will authorise the completed document by a dated signature. If any changes are made to the CRFs/Source documents after the initial PI dated signature then the PI will need to re-sign the document to show oversight of the changes.

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

5.2.8 The Investigator will take measures to prevent accidental or premature destruction of these documents.

6 REFERENCES AND RELATED DOCUMENTS

- CR004-T01 Source Data Plan
- CR004-T02 Example Text for Medical Notes AWI Consent
- 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.
4.0	30 JUN 2020	Implementation of Source Data Plan (CR004-T01)
5.0	25 NOV 2022	Minor edits made. Included ICH-GCP E6(R2) definition of source data and clarification on PI oversight requirements for changes to CRF/Source documents. Minor updates to Source Data Plan (CR004-T01)
6.0	05 FEB 2024	Implementation of Example Text for Medical Notes AWI Consent (CR004-T02)

8 APPROVALS

Sign	Date
Mhairi Moore Mhairi Moore (Jan 18, 2024 14:13 GMT) AUTHOR: Mhairi Moore, Clinical Trials Monitor, NHS Lothian, ACCORD	Jan 18, 2024
Alice Graves Alice Graves (Jan 18, 2024 14:05 GMT) APPROVED: Alice Graves, Senior Clinical Trials Monitor, NHS Lothian, ACCORD	Jan 18, 2024
Gavin Robertson (Jan 18, 2024 14:01 GMT) AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	Jan 18, 2024

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