

Case Report Form Design and Implementation

Document No.:	CR013 v6.0
Author:	Elizabeth Craig
Issue Date:	28 APR 2026
Effective Date:	28 APR 2026

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 The case report form (CRF) is a data acquisition tool used to capture the required data, as defined by the protocol, for each individual participant during their participation in the trial.
- 1.3 Source data is defined as all information, in original records and certified copies of original records or clinical findings, observations, or other activities in a clinical trial, necessary for the reconstruction and evaluation of the trial. Source records are where source data are recorded for the first time. These can be paper or electronic.
- 1.4 The design of the CRF and its completion has a direct impact on the quality of the data collected during a clinical trial. A well designed CRF will ensure that; no essential data is missed, data queries are kept to a minimum, aid data management and assist with statistical analysis and reporting.

2 Purpose

- 2.1 The purpose of this SOP is to describe the procedure to be followed when designing and developing CRFs for use within a clinical trial sponsored by UoE and/or NHSL.

3 Scope

- 3.1 This SOP applies to all research staff involved in the development and implementation of CRFs and any other data acquisition tool as applicable in trials sponsored by the UoE and/or NHSL.

- 3.2 This SOP also applies to ACCORD Clinical Trials Monitors and any other member of staff involved in the development or review of CRFs.
- 3.3 Section 5.4 (CRF Review Process) and 5.5 (Amending the CRF) apply only to trials which have undergone combined risk assessment (GS002).

4 Responsibilities

- 4.1 CRF design is the responsibility of the CI, or designee. Input should also be sought from other members of the research team including but not limited to the person responsible for the final statistical analysis (normally the trial statistician).
- 4.2 Review of the final CRF, and any subsequent updates, is the responsibility of the ACCORD Clinical Trials Monitor, or designee, for trials which have undergone combined risk assessment (GS002). Implementation of the CRF and any subsequent updates is the responsibility of the CI, or designee.

5 Procedure

5.1 General Principles

- 5.1.1 The CI, or designee, will design the CRF to ensure that only data defined in the protocol are captured.
- 5.1.2 The design of the CRF should ensure that;
- Data will be captured and entered into the CRF in a chronological order, reflective of the protocol.
 - The order of trial visits and procedures will be taken into account, in order to make data entry as easy as possible for users and minimise the risk of missing data capture.
 - Where data will be transcribed into the CRF from source records, the layout and content of the CRF will be structured to minimise transcription errors e.g. terminology across source records and the CRF should be consistent.
 - Raw data will be collected, where this is practical, to minimise unnecessary calculations and reduce risk of error.
- 5.1.3 Free text is not easily analysed and therefore where possible should not be used to complete data fields.

- 5.1.4 Listing definitive options with check boxes will limit ambiguity. Where appropriate, a combination of definitive answers and an option to enter 'other' and specify will allow for the collection of additional information.
- 5.1.5 If free text is essential, a comments box can be added. However, this should be used to collect relevant additional information only and not protocol defined outcomes, unless these are free text based e.g. qualitative research.
- 5.1.6 Changes or corrections in the reported data will be traceable, will be explained (if necessary) and will not obscure the original entry (if paper based).
- 5.1.7 Any data for which the CRF will act as the source record will be explicit in the study protocol and/or source data plan (CR004-T01).
- 5.1.8 Where the CRF is in paper form and an electronic database exists, the CI, or designee, will ensure the data captured in the CRF matches the data fields in the electronic database.
- 5.1.9 Any fields contained within the paper CRF which will not be entered into the electronic database will be clearly identified. For example an annotated master copy of the CRF could be held highlighting any data points captured in the CRF only.
- 5.1.10 The Principal Investigator (PI) must maintain a complete and independent copy of the data collected for their location's participants in a way that ensures that the data remains complete, readable and readily available and are directly accessible upon request by regulatory authorities, monitors and auditors.
- 5.1.11 Where data will be collected centrally (e.g. patient reported outcomes sent directly to the trial management office/database by questionnaire or text message) a process must be in place to ensure PIs have access to this data for participants at their location during the course of the trial and a copy of this data is provided to the PI for archiving at the end of the trial. This is also the case where source data is entered directly into an eCRF and access to the eCRF is removed at the end of trial. A complete copy of the data held in the eCRF must be provided to the PI for archiving.

5.2 Format

- 5.2.1 The CRF can be one single form covering all aspects of the study or a collection of separate forms.
- 5.2.2 The CRF can be paper and/or electronic in format.
- 5.2.3 Example paper CRF templates are available (CR013-T03). These can be used as a guide for CRF design where required by research teams however, they are provided as an additional aid to CRF design and it is not a requirement to use them. Where used the templates will be made study specific to collect only the data required by the study protocol.
- 5.2.4 Where the CRF takes electronic form, access must be secure and attributable to an individual. The system must be validated prior to implementation according to the Computer System Validation Policy (POL007).
- 5.2.5 Regardless of the format, the CRF will be version controlled and dated (QA008 Document Version Control) and will also include page numbers in sequential order.
- 5.2.6 Sufficient information will be included in the CRF to attribute every page to a participant e.g. study identifier and participant number.
- 5.2.7 Hospital/Community Health Index (CHI) numbers are not suitable as participant identifiers. Where collection of CHI number is required in the CRF this must be done in accordance with ACCORD policy (POL003, Data Protection and Confidentiality).
- 5.2.8 Personal data/Information (e.g. name, CHI number, date of birth, initials or other characteristics relating to the physical or social identity of a participant) will not be captured in the CRF unless considered absolutely necessary, by the Chief Investigator/Trial Manager for study conduct or, by the Trial Statistician, for analysis. If necessary, the Clinical Trials Monitor can consult the Research Lead to determine if a combination of characteristics can be considered potentially identifiable. Where potentially identifiable personal data/information is considered absolutely necessary and will be included within the CRF, consent documents (e.g. PIS) must inform

participants that potentially identifiable data/information will be available to the relevant parties.

- 5.2.9 It will also be clear which time point during the study each page belongs to, clearly identifying the visit or data collection time point as defined in the protocol and the date this data was collected.
- 5.2.10 For multi-location studies the location at which the CRF was completed will also be identifiable.
- 5.2.11 The format of data entry will be specified in the CRF e.g. dates (DD-MMM-YYYY, DD-MM-YY) and times (12 hour, 24 hour).
- 5.2.12 Units will be specified in the CRF where appropriate, ensuring that these match those described in the protocol and source records.
- 5.2.13 The CRF should include, unless otherwise agreed and justified with the clinical trials monitor, appropriate sign off areas for:
- Confirmation of eligibility by the PI or designee.
 - Oversight of test results by the PI or designee.
 - Completion of each section of CRF.
 - Overall sign off of the CRF by the PI or designee.
- 5.2.14 PI, or designee, sign off of CRF data will be required at the end of the trial and may also be required at appropriate data review time points throughout the trial depending on trial design, for example interim analysis, dose escalation review or other protocol-specific milestones. The requirement for additional PI sign off of data during the trial will be considered and documented at combined risk assessment (GS002).

5.3 Use of Alternative Data Acquisition Methods

- 5.3.1 Where trial data are obtained through tools or systems other than direct entry into the eCRF front end (e.g. bulk data uploads, external data-capture platforms, device outputs, laboratory information systems), the following requirements apply:
- The process for acquiring, transferring, and uploading such data must be defined, validated, and documented.
 - An audit trail must capture the source of the data, the individual performing the upload, and the date/time of import.
 - Any data-mapping, transformation, or formatting steps must be specified and version-controlled.

- Responsibilities for data review, reconciliation, and PI sign-off of site level data must be clearly assigned, including how the PI will review and attest to data not manually entered into the eCRF where required.
- Requirements for bulk uploads—including file formats, quality checks, and error-handling procedures—must be defined prior to use.

5.3.2 Where alternative data acquisition methods are used, the applicable requirements will be documented in the trial specific data management plan, or equivalent, unless otherwise agreed with the ACCORD QA Manager or designee.

5.4 CRF Completion Guidelines and Training

5.4.1 Trial specific CRF completion guidelines may be generated by the CI, or designee, if required. These are recommended where the study is multicentre to facilitate consistency of data entry across locations or where the data collected is particularly complex.

5.4.2 Where required, training will be provided by the CI, or designee, to location staff on the use of the CRF or other data acquisition tools. This training will be documented and must be completed prior to CRF access being granted for electronic systems.

5.5 CRF Review Process

5.5.1 CRF design is a multidisciplinary process. The person responsible for final statistical analysis should be consulted early in the design process, should have input to the final design and be provided with the final agreed version of the CRF to be implemented.

5.5.2 CRFs do not require approval from the Research Ethics Committee (REC) or local R&D office. However, where forms are self-completed by the participant (for example questionnaires or diary cards) and form part of the CRF, the relevant approvals for these records should be sought.

5.5.3 The ACCORD member of staff conducting the Sponsor review (GS003 Sponsorship Approval) should be alerted by the CI, or designee, to any parts of the CRF completed by the participant at the time of Sponsor review.

5.5.4 For trials subject to combined risk assessment (GS002 Combined Risk Assessment) the CI, or designee, will ensure that the CRF is reviewed and approved by an ACCORD Clinical Trials Monitor, or designee before implementation. This review will be

conducted using the CRF Review template (CR013-T01), unless otherwise agreed with the Senior Clinical Trials Monitor for review to be documented elsewhere.

- 5.5.5 Initial review of the CRF by the ACCORD Clinical Trials Monitor, or designee, is the completion of section 1-3 of CR013-T01 or equivalent. This must be completed prior to first Site Initiation Visit (SIV) according to CM001 (Site Initiation and Sponsor Authorisation).
- 5.5.6 Any issues identified during the review process will be fed back to the CI, or designee, by the ACCORD monitoring team. Input will be sought from the person responsible for final statistical analysis of the trial for issues which affect data collected.
- 5.5.7 Once the final version of the CRF has been agreed it will be approved by the CI, or designee, and ACCORD Clinical Trials Monitor or designee. This approval will be documented using the CRF Version Tracker (CR013-T02) unless otherwise agreed by the ACCORD Senior Clinical Trials Monitor, in which case the approval will be documented elsewhere.
- 5.5.8 Paper source data worksheets may be used in conjunction with an electronic CRF to aid data collection at site. Where these worksheets are produced centrally by the Trial Management team for use across trial sites they will be reviewed by the Monitor alongside the CRF. Where sites produce their own source data worksheet templates these will be a site responsibility and will not routinely be reviewed by the Monitor as part of the CRF review,
- 5.5.9 Where applicable, Sponsor Authorisation to Open (SATO) (CM001 Site Initiation and Sponsor Authorisation) cannot be given until this review and sign off process has been completed.
- 5.5.10 Once the CRF has been approved for use by both the monitor, or designee, and CI, or designee, the CRF can be implemented. The implementation date should be recorded on the CRF Version Tracker or equivalent document.
- 5.5.11 Some electronic CRF systems may have their own version tracking facility. This can be used in place of CR013-T02 with prior agreement from the Senior Clinical Trials Monitor, or designee. However, approval by the CI, or designee, and ACCORD Clinical Trials Monitor, or designee, must be documented for each version.

5.5.12 The version of the protocol the CRF is based on, and the date each version became live, must also be documented in the CRF Version Tracker (CR013-T02), or equivalent document.

5.6 Amending the CRF

5.6.1 For trials subjected to combined risk assessment (GS002), unapproved versions of the CRF must not be implemented. Any amendments required to the CRF after approval will be sent to an ACCORD Clinical Trials Monitor or designee, for review.

5.6.2 A review of changes to the data captured in the CRF will be completed using CR013-T01 (CRF Review), unless otherwise agreed with the Senior Clinical Trials Monitor for review to be documented elsewhere.

5.6.3 Any modification which affects the data collected will be communicated to the person responsible for final statistical analysis by the CI, or designee, and feedback sought where required. Any issues identified during review will be fed back to the CI, or designee, by the ACCORD monitoring team, or designee.

5.6.4 Once agreed, the amended version will be added to the CRF Version Tracker (CR013-T02) and approved by the ACCORD Clinical Trials Monitor and CI, or designee. Once CR013-T02 (or agreed equivalent) has been completed, the amended CRF can be implemented at location. The implementation date will be documented in CR013-T02 (or agreed equivalent).

6 References and Related Documents

- CR013 -T01 – CRF Review
- CR013 -T02 – CRF Version Tracker
- CR013-T03 – CRF template
- CR004 Recording and Reporting Study Data
- CM001 Site Initiation and Sponsor Authorisation
- GS002 Combined Risk Assessment
- GS003 Sponsorship Approval
- QA008 Document Version Control
- POL003 Data Protection and Confidentiality
- POL007 Computer System Validation

7 Document History

Version Number	Effective Date	Reason for Change
1.0	08 NOV 2016	New SOP.
2.0	31 OCT 2018	Scheduled review. Minor updates to 5.1.7 and 5.2.10
3.0	07 NOV 2019	Process for inclusion of personal data/information in the CRF added to 5.2.6. CR013-T01 updated to include a check for personal data/information.
4.0	30 JUN 2020	Addition of 5.4.5 defining initial review in relation to Site Initiation. Minor administrative update to add Section 4 to CR013-T01.
5.0	24 FEB 2022	Addition of 5.1.10 clarifying requirement for PI to hold complete and independent copy of site data. Reference to example paper CRF templates (5.2.3) and addition of templates (CR013-T03). Minor updates to 5.1.7 and 5.2.5.
6.0	28 APR 2026	Addition of 5.1.6 regarding changes in data being traceable, 5.1.10 clarifying that PI must maintain study data directly accessible and 5.1.11 regarding secure and attributable access to eCRF. Expectations for PI sign off of data clarified in 5.2.14. Addition of new section 5.3 Use of Alternative Data Acquisition Methods. Clarifications around training requirements in section 5.4 and clarifications throughout in relation to requirements for electronic systems and terminology changes in accordance with GCP E6 (R3).

8 Approvals

Sign	Date
<p><i>Elizabeth Craig</i></p> <p>Elizabeth Craig (27-Apr-2026 11:50:36 GMT+1)</p> <p>AUTHOR: Elizabeth Craig, Senior Clinical Trials Monitor, NHSL, ACCORD</p>	27-Apr-2026
<p><i>L. Mackenzie</i></p> <p>APPROVED: Lorn Mackenzie, QA Manager, NHSL, ACCORD</p>	28-Apr-2026
<p><i>Gavin Robertson</i></p> <p>Gavin Robertson (27-Apr-2026 11:59:01 GMT+1)</p> <p>AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD</p>	27-Apr-2026











CR013 CRF Design and Implementation v6.0

Final Audit Report

2026-04-28

Created:	2026-04-27 (British Summer Time)
By:	Roisin Ellis (v1relli8@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAANI9pSB5kB1HSh4XPK_Ty-s_ErxgTNGyW

"CR013 CRF Design and Implementation v6.0" History

-  Document created by Roisin Ellis (v1relli8@exseed.ed.ac.uk)
2026-04-27 - 11:19:49 AM GMT+1- IP address: 62.253.82.242
-  Document emailed to elizabeth.a.craig@nhslothian.scot.nhs.uk for signature
2026-04-27 - 11:20:48 AM GMT+1
-  Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2026-04-27 - 11:20:48 AM GMT+1
-  Document emailed to Gavin Robertson (gavin.robertson@nhslothian.scot.nhs.uk) for signature
2026-04-27 - 11:20:49 AM GMT+1
-  Email viewed by elizabeth.a.craig@nhslothian.scot.nhs.uk
2026-04-27 - 11:49:43 AM GMT+1- IP address: 52.102.16.165
-  Signer elizabeth.a.craig@nhslothian.scot.nhs.uk entered name at signing as Elizabeth Craig
2026-04-27 - 11:50:34 AM GMT+1- IP address: 62.253.82.243
-  Document e-signed by Elizabeth Craig (elizabeth.a.craig@nhslothian.scot.nhs.uk)
Signature Date: 2026-04-27 - 11:50:36 AM GMT+1 - Time Source: server- IP address: 62.253.82.243
-  Email viewed by Gavin Robertson (gavin.robertson@nhslothian.scot.nhs.uk)
2026-04-27 - 11:58:37 AM GMT+1- IP address: 90.240.128.160
-  Document e-signed by Gavin Robertson (gavin.robertson@nhslothian.scot.nhs.uk)
Signature Date: 2026-04-27 - 11:59:01 AM GMT+1 - Time Source: server- IP address: 90.240.128.160
-  Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2026-04-28 - 8:16:16 AM GMT+1- IP address: 52.102.16.165
-  Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2026-04-28 - 8:16:31 AM GMT+1 - Time Source: server- IP address: 77.97.224.249

✔ Agreement completed.

2026-04-28 - 8:16:31 AM GMT+1