Study Records

Document No.:	CR007 v8.0
Author:	Marise Bucukoglu
Issue Date:	20 NOV 2025
Effective Date:	04 DEC 2025

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 Essential records are defined as all documents and data, including meta data, associated with a clinical trial that facilitate its ongoing management and collectively allow the evaluation of the trial's methods, affecting factors and outcomes, ensuring that participants are protected, and trial data is reliable.

1.3 Study records demonstrate compliance with regulations and Good Clinical Practice (GCP), help manage the study and confirm that data and conduct are valid.

2 Purpose

2.1 This SOP explains how to prepare and complete study records in line with ICH-GCP E6 (R3) principles and applicable regulatory requirements.

3 Scope

3.1 Applies to:

- Chief Investigators (CIs), Principal Investigators (PIs), and study teams designing and participating in NHSL/UoE-co-sponsored or singly sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs), Clinical Investigations of Medical Devices (CIMDs) and non-CTIMPs.
- ACCORD staff supporting researchers with the development or review of study records and monitoring completion of study records.

3.2 Responsibilities

3.3 CI, PI and Sponsor Representative responsibilities are outlined below:

- CI (or delegate): Create and maintain study records, ensuring compliance with applicable regulatory requirements and principles of GCP. Complete submission to the Health Research Authority (HRA)/Research Ethics Committee (REC), relevant competent authorities (e.g. Medicines and Healthcare Regulatory products Agency (MHRA)), and NHS Boards/Trusts as required.
- PI: Train the research team on the protocol and other study records and ensure all study records are complete at each study location.
- ACCORD Sponsor Representative: Advise on content of study records before Sponsor approval (SOP GS003 Sponsorship Approval).
- Clinical Trials Monitor: Monitor the Trial Master Files (TMF/Sponsor File and location Investigator Site Files (ISFs) for completeness of study records.

4 Procedures for Study Set Up

4.1 Protocol

4.1.1 The design and how the study will be conducted will be detailed in a protocol, written in line with principles of GCP. It will outline objectives, design, methodology, statistics, and organisation of the study, ensuring participant safety and addressing the research questions.

4.1.2 The appropriate protocol template will be used depending on the type of study, unless otherwise agreed with the Sponsor Representative:

- Clinical Trial of Investigational Medicinal Product (CTIMP): CTIMP protocol template CR007-T01.
- Non-CTIMP: Recommended to use Protocol template CR007-T02 (general), CR007-T19 (data only), CR007-T20 and T21 (qualitative research).
- Clinical Investigation of Medical Device (CIMD): Clinical Investigation Plan or Clinical Performance Study Protocol template CR007-T23.

4.2 Participant Information Sheet and Consent Form

4.2.1 The study will be explained to participants in lay language via a Participant Information Sheet (PIS), and their consent recorded on an informed consent form (CF), where appropriate. If the participant agrees, their GP will be informed of their participation in the study by the PI in the form of a letter.

4.2.2 The following templates will be used, unless otherwise agreed with the Sponsor Representative:

- PIS and Consent: Template CR007-T03 (general), CR007-T04 (adults with incapacity), CR007-T05 (recovered capacity), CR007-T22 (qualitative research)
- GP Letter: If the participant agrees, template CR007-T06.

4.2.3 The HRA website (https://www.hra.nhs.uk/) offers guidance, aligned with ICH-GCP, on topics to include in a PIS and CF, covering adults with incapacity, children and young people, emergency research, deceased participants, tissue samples, research databases and tissue banks, genetic research, and ionising radiation.

4.3 Version Control and Approval

4.3.1 All records must be version controlled with the version number and date on the title page and all subsequent pages (SOP QA008 Document Version Control).

4.3.2 Once authorised by the Sponsor Representative, the protocol, PIS(s), CF(s), and GP letter must be submitted to the HRA/Research Ethics Committee (REC), relevant competent authorities (e.g. Medicines and Healthcare Regulatory products Agency (MHRA)), and NHS Boards/Trusts as required.

4.3.3 The CI or delegate will provide the latest approved records to all PIs. PIs will ensure their study location teams are fully informed and working with current versions of essential records.

4.3.4 CTIMP and CIMD protocols: All versions of the protocol must be signed by the Sponsor Representative and CI to confirm agreement to conduct the study according to the protocol. If involved in protocol development, the lead statistician or delegate should sign to verify the statistical plan detailed in the protocol. PIs at study locations must also sign the protocol. The fully signed protocol will be retained in the TMF, ISF and/or Sponsor File.

4.3.5 Non-CTIMP protocols involving a clinical investigational agent: It is recommended that the CI, Sponsor Representative, lead statistician (if appointed) and PIs at each study location sign the protocol.

5 Procedure for Study Conduct

5.1 Study Records

5.1.1 The Sponsor Representative will review all study records for REC or regulatory submission, including the protocol, PIS, Consent Form and GP Letter. Members of the ACCORD team will also review related records such as Case Report Forms (CRFs), study specific Standard Operating Procedures (SOPs), Data Management Plans, and any other records demonstrating compliance with trial procedures or ethical and regulatory requirements. The scope and frequency of reviews will be discussed with the Sponsor Representative during study set-up.

5.1.2 The PI or delegate will maintain study location records throughout the study (SOP CR001 Establishing and Maintaining Trial Files; Investigator Site Files, Trial Master Files and Sponsor Files).

5.1.3 For monitored studies, the Clinical Trials Monitor will check the ISF for completeness as per the study monitoring plan (SOP CM002 Monitoring of Active Studies).

5.1.4 The following records will be maintained in the ISF by the PI:

- Delegation log (CR007-T12) listing appropriately qualified persons with delegated study-related responsibilities.
- Pre-screening log (CR007-T13) recording potential participants entering pre-study screening (unless otherwise agreed with the Senior Clinical Trials Monitor(s) or delegate).
- Consent and subject status log (CR007-T14) chronologically recording participants who consent and enrol in the study.
- Training record (CR007-T17) documenting study-specific training, confirming team members are qualified, informed of the protocol and procedures, and have completed GCP training in line with ACCORD GCP and SOP Training Policy (POL001).

5.1.5 The CI, or delegate, will update study records for new procedures and submit changes to the Sponsor Representative for approval (SOP GS011 Sponsor Approval of Amendments) before submission to the REC, R&D, and/or competent authorities, where applicable. The CI will ensure that new or modified records are not used until all approvals are received and that superseded records are retained in the TMF/ISF.

6 References and Related Documents/Records

- CR007-T01 CTIMP Protocol Template
- CR007-T02 Non-CTIMP Protocol Template
- CR007-T03 PIS & CF Template
- CR007-T04 PIS & CF AWI Template
- CR007-T05 PIS & CF Recovered Capacity Template
- CR007-T06 GP Letter Template
- CR007-T12 Staff Signature and Delegation Log of Responsibilities Template
- CR007-T13 Pre-Screening Log Template
- CR007-T14 Consent and Participant Status Log Template
- CR007-T17 Study Specific Training Record Template
- CR007-T19 Data Only Protocol Template
- CR007-T20 Qualitative UoE/NHS Protocol Template
- CR007-T21 Qualitative UoE Protocol Template
- CR007-T22 Qualitative UoE PIS and CF Template
- CR007-T23 Medical Device Protocol Template
- CR007-T24 Medical Device Investigator Brochure Template
- GL008 Guidance on Clinical Evaluation of Medical Devices and Clinical Performance of In Vitro Diagnostic Medical Devices
- GS003 Sponsorship Approval
- GS011 Sponsor Approval of Amendments
- QA008 Document Version Control
- CM002 Monitoring Active Studies
- CR001 Establishing and Maintaining Trial Files; Investigator Site Files, Trial Master Files and Sponsor Files
- POL001 GCP and SOP Training
- HRA Guidance: Consent and Participant Information
- ICH-GCP E6 (R3) Guidelines

7 Document History

Version Number	Effective Date	Reason for Change
1.0 - 5.0	22 MAR 2011 - 19 DEC 2018	Available on request via ACCORD QA (QA@accord.scot).
6.0	06 JAN 2021	CR007-T11 updated and moved to SOP GS013. CR007-T18 discontinued as detail now included in CR007-T03/04/05. Minor administrative changes throughout.

Version Number	Effective Date	Reason for Change
7.0	17 JUN 2022	Addition of protocol templates CR007-T19 and CR007-T20. Sections 5.1.3 and 5.1.4 to reflect their additions. Email address updated in section 5.1.6. Changes made throughout CR007-T01 (now v7.0), including a prompt for consideration of COVID-19 vaccine interactions, a Data Management Plan sub-section, additional risk adaption prompts, and removal of reporting SAEs/SARs/SUSARs and deviations/violations by fax.
8.0	04 DEC 2025	Refreshed content throughout. Addition of protocol templates CR007-T21, CR007-T23, PIS/CF template CR007 T22, and Medical Device IB template CR007-T24 (documents previously released)

8 Approvals

Sign	Date
Marise Bucukoglu (19-Nov-2025 12:51:55 GMT) AUTHOR: Marise Bucukoglu, Head of Research Governance, UoE, ACCORD	19-Nov-2025
Heather Charles Heather Charles (19-Nov-2025 12:52:23 GMT) APPROVED: Heather Charles, Head of Research Governance, NHSL, ACCORD	19-Nov-2025
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	19-Nov-2025

CR007 Study Records v8.0

Final Audit Report 2025-11-19

Created:	2025-11-19 (Greenwich Mean Time)
By:	Gavin Robertson (v1grobe9@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAA3ZgeH0IbnMhSY8x_S_iZhkN7AJRGHbGr

"CR007 Study Records v8.0" History

Document created by Gavin Robertson (v1grobe9@exseed.ed.ac.uk)
2025-11-19 - 12:40:41 GMT- IP address: 84.68.235.63

Document emailed to Marise Bucukoglu (marise.bucukoglu@ed.ac.uk) for signature
2025-11-19 - 12:43:21 GMT

Document emailed to heather.charles@nhslothian.scot.nhs.uk for signature
2025-11-19 - 12:43:21 GMT

Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2025-11-19 - 12:43:21 GMT

Email viewed by Marise Bucukoglu (marise.bucukoglu@ed.ac.uk)
2025-11-19 - 12:49:41 GMT- IP address: 104.47.11.62

Document e-signed by Marise Bucukoglu (marise.bucukoglu@ed.ac.uk)
Signature Date: 2025-11-19 - 12:51:55 GMT - Time Source: server- IP address: 192.41.114.230

Email viewed by heather.charles@nhslothian.scot.nhs.uk
2025-11-19 - 12:52:05 GMT- IP address: 52.102.18.53

Signer heather.charles@nhslothian.scot.nhs.uk entered name at signing as Heather Charles
2025-11-19 - 12:52:21 GMT- IP address: 62.253.82.243

Document e-signed by Heather Charles (heather.charles@nhslothian.scot.nhs.uk)
Signature Date: 2025-11-19 - 12:52:23 GMT - Time Source: server- IP address: 62.253.82.243

Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2025-11-19 - 13:11:23 GMT- IP address: 52.102.16.165

Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2025-11-19 - 13:12:17 GMT - Time Source: server- IP address: 77.97.224.249

Agreement completed.

2025-11-19 - 13:12:17 GMT