Management of Complaints

Document No.:	CR018 v2.0
Author:	Heather Charles
Issue Date:	09 JUL 2025
Effective Date:	23 JUL 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 ACCORD may receive complaints from a variety of sources, including research study participants, their relatives or representative (e.g. solicitor), study teams or from ACCORD service users.

1.3 The Participant Information Sheet (PIS) for a research study should detail how research study specific complaints can be made.

1.4 Service user complaints should be submitted in writing to the ACCORD office at enquiries@accord.scot.

1.5 For the purpose of this SOP, types of complaints that may be received by the ACCORD office have been categorised in the table below.

Type of Complaint	Definition
Participant Complaint	An expression of dissatisfaction made by a research study participant (or on their behalf) about the conduct of a research study or their participation in a research study, which required investigation and a formal response from the Chief Investigator (CI) or from the site Principal Investigator (PI), respectively.
Serious Service User Complaint	Any written report of dissatisfaction which expresses significant concern with the service provided by the ACCORD office, made either by an Investigator or a member of a research team, which requires investigation and a formal response from ACCORD Quality Assurance (QA) and/or the ACCORD senior management team (SMT).
Serious Participant Complaint	A complaint that has not been satisfactorily resolved by the study team and therefore requires Sponsor/R&D/QA involvement. This should always include instances where the subject matter concerns: harm to participants (other than where it can be readily demonstrated that the harm complained of was an expected progression of the disease, unconnected with the trial); any breach of confidentiality; initial complainant dissatisfaction following first response or any other matter where the possibility of legal action is intimated.

2 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the process for handling complaints received from ACCORD service users, and complaints related to clinical research studies sponsored by the UoE and/or NHSL, and studies hosted by NHSL.

3 Scope

3.1 This SOP is applicable to all ACCORD personnel, ACCORD service users and research teams working on research studies sponsored by UoE/NHSL or hosted by NHSL.

4 Responsibilities

4.1 When a complaint is received by an ACCORD member of staff or a member of a research team, the individual in receipt of the complaint is responsible for assessing the information provided to determine if it may be considered a complaint as defined in section 1.5. They are responsible for seeking advice from their line manager to help make the assessment if required.

4.2 The complaint recipient, or their line manager, is responsible for informing the appropriate Investigator and/or ACCORD personnel of the complaint within 24 h of receipt/reading the complaint e.g. Sponsor or host representative.

4.3 The Chief Investigator (CI), Principal Investigator (PI), or designee, is responsible for;

- Contacting the complainant to confirm receipt of the complaint within 3 working days of receipt of the complaint,
- Assessing, investigating and resolving a participant complaint within 5 working days of receipt, (where appropriate),
- Informing the Sponsor(s) of a participant complaint deemed to be serious,
- Implementing agreed actions to address the complaint and communicating these to the complainant,
- Ensuring that communication and documentation around a complaint is retained in the Trial Master File (TMF) or Investigator Site File (ISF) and informing ACCORD when a complaint has been resolved/closed.

4.4 The UoE and/or NHSL Sponsor or host representative is responsible for;

- Contacting the complainant to confirm receipt of the complaint within 3 working days of receipt of the complaint,
- Assessing, investigating and resolving a complaint within 5 working days (where appropriate),
- Notifying the CI and/or PI, QA and the ACCORD SMT of a complaint (if applicable),
- Implementing agreed actions to address the complaint and communicating these to the complainant,
- Seeking guidance from senior colleagues in NHSL/UoE and independent clinicians, where appropriate.

4.5 Ensuring that communication and documentation around a complaint is retained in the relevant study TMF, Sponsor file or study specific R&D file (if applicable).

4.6 The QA Manager, or designee, is responsible for logging the complaint and agreed actions, timelines and outcome in the ACCORD Quality Management System (QMS) on the ACCORD SharePoint. The QA Manager, or designee, may also provide regulatory advice to the CI/PI, Sponsor/host representative, SMT. The Sponsor or host representative (section 4.4) may be the QA Manager.

4.7 The ACCORD SMT is responsible for oversight of all serious service user complaints and serious participant complaints, ensuring that a response is issued within 5 working days of receipt. Where this is not possible, the timeline can be extended to a maximum of 20 working days with the rationale for this documented in the ACCORD QMS. The Sponsor or host representative (section 4.4) may be someone from the ACCORD SMT.

4.8 The ACCORD R&D administration team and the UoE research governance team is responsible for forwarding complaints receipted in the enquiries@accord.scot/resgov@accord.scot e-mail inbox, respectively e.g. to the NHSL and/or UoE Sponsor/host representative(s) and/or Heads of Research Governance (NHSL and/or UoE).

5 Procedure

5.1 Initial Receipt of Information

5.1.1 On receipt of a verbal service user complaint to an ACCORD member of staff, the complainant will be asked to refer to this process, document their complaint in writing and to submit this to ACCORD (enquiries@accord.scot). CR018-F01 Service User Complaint Form can be used for this purpose.

5.1.2 The initial recipient of a written complaint (e.g. e-mail or CR018-F01) will assess the information provided to determine if it is a complaint in the first instance, with support from their line manager if appropriate. They, or their line manager, will then assess if the complaint is a participant complaint, serious service user complaint or serious participant complaint. If unsure, the recipient or line manager will seek guidance from a member of QA and/or SMT.

5.1.3 Where the initial recipient (i.e. not the CI/PI), in consultation with their line manager if appropriate, categorises the complaint as a participant complaint, they will e-mail the research study CI and/or PI within 24 h of receipt/reading the complaint. The e-mail will include the details of the complaint and request that they respond to the complainant within 3 working days of receipt of the complaint. This task may be undertaken by another member of the ACCORD team e.g. Sponsor/host

representative, QA Manager or member of SMT. QA will be copied into this correspondence (QA@accord.scot).

5.1.4 Where the initial recipient, in consultation with their line manager, categorise the complaint as a serious service user complaint or a serious participant complaint, they will e-mail the details of the complaint to the ACCORD QA Manager and the NHSL/UoE Heads of Research Governance within 24 h of receipt/reading the complaint. The Heads of Research Governance (NHSL & UoE) will communicate with the wider SMT where appropriate.

5.1.5 The QA Manager, or designee, will log the complaint in the QA folder on the ACCORD SharePoint and if deemed to be a serious service user complaint, will ask the complainant to complete form CR018-F01 Service User Complaint, and return this to QA@accord.scot. Completion of the form may not be required if the QA Manager, or designee, is satisfied that all the required information has been provided in an e-mail.

5.1.6 Where it is suspected that a complaint may be classified as a suspected serious breach or suspected research misconduct, SOP CR003 (Suspect Serious Breaches) or CR014 (Suspected Research Misconduct) will be followed, respectively.

5.2 Management of a Participant Complaint

5.2.1 Following receipt of a participant complaint (not deemed a serious participant complaint), the study CI/PI will acknowledge receipt within 3 working days of receipt of the complaint. This communication will indicate when the complainant can expect further communication i.e. a formal response should be issued within 5 working days of receipt of the complaint, which can be extended up to 20 working days with rationale for the extension documented.

5.2.2 The CI/PI will make every effort to resolve the issue following investigation (if necessary), ensuring that;

- Where the complaint involves an NHS patient or NHS member of staff, they refer to NHS Board/Trust procedure for handling complaints,
- Where a complaint involves a UoE member of staff, they refer to the UoE procedure for handling complaints,
- Communication with the complainant has oversight at a senior level (where deemed necessary),
- Details and outcomes are made available to relevant staff on a need-to-know basis,
- Staff are reminded of the need for confidentiality in communication and record keeping,
- Caution is exercised when using any form of written communication (e.g. e-mails) to the complainant,
- Participant identifiers are removed prior to complaint communication being forwarded from site or circulated internally,

- Details of the complaint, including outcomes, are recorded/retained in the TMF/ISF,
- The ACCORD QA team (QA@accord.scot) is informed when the complaint is considered resolved/closed.

5.2.3 Where the CI/PI has been unable to resolve a participant complaint to the satisfaction of all parties, the Sponsor/NHSL R&D will be notified. For studies sponsored by UoE/NHSL or hosted by NHSL, participant complaints deemed 'serious' will be e-mailed to the ACCORD office (enquiries@accord.scot) or the Sponsor/host representative. Emails should be titled 'Serious Participant Complaint' and include all relevant information (see section 5.3).

5.2.4 On receipt of a complaint to the ACCORD enquiries@accord.scot e-mail inbox, or to the resgov@accord.scot mailbox, the R&D administration team or UoE research governance team will forward the e-mail to the appropriate NHSL and/or UoE Sponsor/host representative(s) and/or Heads of Research Governance (NHSL and/or UoE) and the QA Manager for information.

5.2.5 The QA Manager, or designee, will log the complaint in the QA folder on the ACCORD SharePoint.

5.2.6 If required, the QA Manager, or designee, will contact the CI/PI by e-mail to confirm the complaint is closed and document the complaint outcome and closure date in the QA folder on the ACCORD SharePoint.

5.3 Management of a Serious Participant Complaint or Serious Service User Complaint

5.3.1 In the event that a complaint is assessed as serious, regardless of resolution status, it will be investigated by QA with oversight from SMT.

5.3.2 Following receipt of a serious participant complaint or a serious service user complaint, the QA Manager in consultation with SMT, will agree a plan for the management of the complaint, including who will respond to the complainant (e.g. CI/PI, Sponsor/host representative). An acknowledgement receipt will be issued within 3 working days, indicating when the complainant can expect further communication i.e. a formal response should be issued within 5 working days of receipt of the complaint, which can be extended up to 20 working days with rationale for the extension documented.

5.3.3 The assigned complaint respondent will ensure that;

- Where the complaint involves an NHS patient or NHS member of staff, they refer to NHS Board/Trust procedure for handling complaints,
- Where a complaint involves a UoE member of staff, they refer to the UoE procedure for handling complaints,
- Communication with the complainant has oversight at a senior level (where deemed necessary),
- Details and outcomes are made available to relevant staff on a need-to-know basis,
- Staff are reminded of the need for confidentiality in communication and record keeping,
- Caution is exercised when using any form of written communication (e.g. e-mails) to the complainant,
- Participant identifiers are removed prior to complaint communication being forwarded from site or circulated internally,
- The QA Manager is kept up to date with progress of the complaint.

5.3.4 The complaint investigation, actions, timelines and outcome will be documented in an investigation report by the QA Manager, or designee, (CR018-T01 Complaint Investigation Report template) and in an access-controlled QA folder on the ACCORD SharePoint. Where appropriate, documentation may also be filed in the TMF, Sponsor file or study specific R&D file.

5.3.5 Where QA/SMT has been unable to resolve a serious participant complaint or serious service user complaint, they may seek guidance from;

- Senior colleagues in NHSL e.g. Medical Director, Data Protection Officer, Central Legal Office,
- Senior colleagues in the UoE e.g. Dean of Research (College of Medicine and Veterinary Medicine – CMVM), Head of CMVM Research Office, UoE legal team,
- Independent clinicians, where appropriate.

5.3.6 QA/SMT will ensure that the outcome of a serious participant complaint or serious service user complaint is communicated to the Sponsor/CI/PI and/or complainant. This communication may be from a Sponsor or host representative.

5.3.7 The QA Manager, or designee, will close the complaint in the QMS once it has been confirmed that all actions are complete.

5.4 Freedom of Information (FOI) and Subject Access Requests (SAR)

5.4.1 Where an FOI or SAR is received, as part of the complaints procedure, the relevant procedures within NHSL and UoE will be followed.

6 References and Related Documents

- CR018-F01 Service User Complaint
- CR018-T01 Complaint Investigation Report
- SOP CR003 Suspected Serious Breaches
- SOP CR014 Suspected Research Misconduct
- NHS Lothian's Complaints Handling Procedure
- The University of Edinburgh Complaint Handling Procedure: Staff Roles and Responsibilities
- The University of Edinburgh Complaint Handling Procedure: The Complaint Handling Process
- NHS Lothian Subject Access Policy
- Freedom of Information (Scotland) Act 2002

7 Document History

Version Number	Effective Date	Reason for Change
1.0	11 AUG 2023	New SOP.
2.0	23 JUL 2025	Reference added to retention of documents in study specific R&D files in sections 4.4 and 5.3.4 i.e. specific to hosted trials.

8 Approvals

Sign	Date
Heather Charles Heather Charles (03-Jul-2025 16:25 GMT+1) AUTHOR: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	03-Jul-2025
MBS Marise Bucukoglu (10-Jul-2025 09:32 GMT+1) APPROVED: Marise Bucukoglu, Head of Research Governance, UoE, ACCORD	10-Jul-2025
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	03-Jul-2025

CR018 Management of Complaints v2.0

Final Audit Report 2025-07-10

Created:	2025-07-03 (British Summer Time)
By:	Gavin Robertson (v1grobe9@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAiKLabRtgWQrThnaJwtla7J4SzEpkisAr

"CR018 Management of Complaints v2.0" History

Document created by Gavin Robertson (v1grobe9@exseed.ed.ac.uk)
2025-07-03 - 15:58:59 GMT+1- IP address: 90.247.173.187

Document emailed to heather.charles@nhslothian.scot.nhs.uk for signature
2025-07-03 - 16:01:12 GMT+1

Document emailed to Marise Bucukoglu (marise.bucukoglu@ed.ac.uk) for signature
2025-07-03 - 16:01:12 GMT+1

Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2025-07-03 - 16:01:13 GMT+1

Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2025-07-03 - 16:08:14 GMT+1- IP address: 52.102.17.101

Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2025-07-03 - 16:08:27 GMT+1 - Time Source: server- IP address: 62.253.82.244

Email viewed by heather.charles@nhslothian.scot.nhs.uk
2025-07-03 - 16:24:53 GMT+1- IP address: 52.102.16.133

Signer heather.charles@nhslothian.scot.nhs.uk entered name at signing as Heather Charles
2025-07-03 - 16:25:14 GMT+1- IP address: 62.253.82.242

Document e-signed by Heather Charles (heather.charles@nhslothian.scot.nhs.uk)
Signature Date: 2025-07-03 - 16:25:16 GMT+1 - Time Source: server- IP address: 62.253.82.242

Email viewed by Marise Bucukoglu (marise.bucukoglu@ed.ac.uk)
2025-07-10 - 09:31:26 GMT+1- IP address: 104.47.11.254

Document e-signed by Marise Bucukoglu (marise.bucukoglu@ed.ac.uk)
Signature Date: 2025-07-10 - 09:32:16 GMT+1 - Time Source: server- IP address: 92.234.149.37

Agreement completed.

2025-07-10 - 09:32:16 GMT+1