Entering Research Information to the Electronic Patient Record

Document No.:	AD001 v5.0
Author:	Carol Mackenzie
Issue Date:	28 JUL 2025
Effective Date:	11 AUG 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 TrakCare (also known as TRAK) is the electronic patient management system used across NHSL.

1.3 eCasenotes are electronic patient case notes that have been scanned to the web-based application Scottish Care Information (SCI Store) and are viewable online through TRAK. Once paper case notes are digitised the paper is securely destroyed by NHSL Digital Health Records.

2 Purpose

2.1 To describe the procedure for entering research information to the electronic patient record (EPR) for research studies which are actively running in NHSL.

3 Scope

3.1 This SOP applies to Investigators and study teams entering information to the EPR for research participants.

4 Responsibilities

4.1 It is the responsibility of the Investigator, or designee, to;

- Document information pertinent to a patient's clinical care in the patient's EPR (agreeing the location within the EPR with the wider research team) either via direct entry into TRAK, or scanning of paper notes,

- Verify copies of paper notes as a true copy of the original,
- Send paper notes to Digital Health Records for scanning or ensure authorisation has been granted by NHSL Digital for self-scanning of paper notes,
- Check the eCasenote to ensure the scanned records are viewable online through TRAK.

4.2 It is the responsibility of the Research Team to obtain authorisation from NHSL Digital prior to scanning any documents directly into SCI Store and maintain a record in the Investigator Site File (ISF), verifying that documents have been uploaded correctly and are a true copy.

5 Procedure

5.1 Required research information in the EPR

5.1.1 The Investigator, or designee, will add an alert/research episode, as required, to the patient's EPR to show they are taking part in a research study.

5.1.2 Information documented throughout a research study which is pertinent to a patient's clinical care will be documented in their EPR by the Investigator, or designee.

5.1.3 Information will be recorded by the Investigator, or designee, in compliance with the study protocol and applicable regulatory requirements.

5.1.4 Unless otherwise agreed with the trial Sponsor, information to be retained in the EPR should include the following where applicable to the study design;

- Copy of the signed consent form
- Details of consent process e.g. documenting the consent discussion
- Documentation of ongoing participant consent
- Copy of Participant Information Sheet (PIS)
- Copy of GP letter/any correspondence to medical professionals
- Contact details for the Principal Investigator (PI)/research team
- Confirmation of participant eligibility
- Details of co-enrolment requirements for trial
- Details of IMP(s)/intervention(s) given (including batch numbers, date of dosing and dose received where applicable)
- Details required for emergency unblinding
- Details of any adverse events relating to that patient.

- Details of concomitant medication
- Results and dates of any research specific procedures/tests
- Details of participant withdrawal or study discontinuation
- Date of participant study completion
- Any other information deemed relevant to clinical care by the Investigator

5.1.5 The points on the above list which are required and the location that information is documented within the EPR will depend on many factors e.g., study design, specialty, and patient status at the time of the study (e.g. inpatient or outpatient). The Investigator should agree a consistent approach with the research team on where the information will be documented for each participant within that study and capture this record in the ISF (e.g., source data plan).

5.1.6 This information listed in section 5.1.4 can be entered in the EPR in two ways:

1. Scanning of paper records to the EPR i.e. eCasenotes
    - By dedicated Digital Health Records scanning team (see section 5.2)
    - Directly by research team after agreement with NHSL Digital (see section 5.3)
2. Direct entry of data into TRAK e.g. as a clinical note (see section 5.4)

5.2 Scanning by Digital Health Records

5.2.1 For any piece of information listed (section 5.1.4) for which the source data is a paper record (e.g. patient consent document), the Investigator, or designee, will send a verified true copy (indicated by a dated signature following a visual check of the copy against the original) of the paper record to the Digital Health Records department, in accordance with the NHSL Healthcare Records Scanning Policy (HRECS/PP/36).

5.2.2 All documents sent for scanning must have a label placed on them containing the patient's Community Health Index (CHI)/Unique Hospital Patient Identifier (UHPI). If no labels are available, the patient's name, date of birth and CHI/UHPI should be clearly written on the document. The original source data must be filed in the ISF or patient study folder by the Investigator, or designee. Where copies are taken from the original source data and retained in the ISF, these will also be marked as a verified true copy.

5.2.3 Prior to sending the original/verified true copy of the record to the Digital Health Records department, the Investigator, or designee, will detail the items to be scanned in an inventory (AD001-F01 Research Document Scanning Inventory) and include this

inventory when sending paper records for scanning. The inventory will be used for all records relating to a research episode. Records included with inpatient or outpatient clinic notes will be sent according to local procedures (NHSL Healthcare Records Scanning Policy (HRECS/PP/36). The Investigator, or designee, will retain a copy of the inventory to track documents sent to Digital Health Records.

5.2.4 This inventory will be completed by a member of staff at the Scanning Bureau in Digital Health Records and returned to the Investigator, or designee, once all scanning is complete as per the NHSL Healthcare Records Scanning Policy (HRECS/PP/36).

5.2.5 On receipt of the completed inventory, the Investigator, or designee, will check the eCasenote to ensure all the records sent to Digital Health Records have been scanned and are viewable online through TRAK. This check will be documented on the inventory. For regulated studies only (e.g. Clinical Trial of an Investigational Medicinal Product (CTIMP) or Clinical Investigation of a Medical Device (CIMD)) the inventory must be maintained in the ISF as a record verifying that documents have been uploaded correctly and are confirmed as a true copy.

5.2.6 Information listed (section 5.1.4) which does not have a specific paper record (e.g. PI contact details) can be typed directly into TRAK by the Investigator, or designee.

5.2.7 When sending research documents to Digital Health Records, the Investigator or designee should ensure they are sent separately from other scanning. Research documents should be secured with a treasury tag, and placed in a poly pocket with the above inventory and sent to Health Records marked:

"For Scanning – [insert site] Health Records.
Category – Outpatient
Speciality – [insert main speciality associated with research]
Date of visit – [insert date of visit]"

5.3 Scanning by Research Staff

5.3.1 If a research team wishes to scan documents directly into SCI Store, they must first have received authorisation from NHSL Digital Department. The authorisation will be for named members of the team to upload any document type as specified in the initial request. e.g. any Consent Form, PIS or GP letter relating to the study. The team are not required to seek authorisation for each separate study, just the document type.

5.3.2 To request authorisation, the Investigator or the appropriate member of the research team must log a call with the Digital Service Desk. To do this, click the e85050 icon on an NHSL desktop/laptop and select Log a call, followed by SCI Store Document Upload from the TRAK section.

5.3.3 The Investigator or member of the research team must complete the Digital electronic request form and include details of the types of documents that they wish to scan (e.g. Consent forms, PIS, GP letter). Blank versions of each type of document must be attached to the call. These will be the only types of documents permitted to be scanned to patients' SCI Store records by the member of the team.

5.3.4 Once the request has been authorised, instructions will be sent by NHSL Digital Department on uploading the documents and how to correctly file them within SCI Store.

5.3.5 Where the Investigator or members of the research team are scanning documents directly into SCI Store, a record must be maintained in ISF by the person responsible, verifying that documents have been uploaded correctly and that they are a true copy. To verify that the primary and copy document(s) are identical, the Investigator or member of the research team will sign/date an inventory or equivalent file note listing the documents scanned.

5.3.6 If in future there are additional documents (of a different type) to be scanned, these must be sent directly to the Digital Health Records, or a separate SCI Store upload request made for authorisation.

5.4 Inputting information directly to TRAK

5.4.1 The Investigator, or designee, can add free text as a clinical note in the patient EPR tab on TRAK.

5.4.2 For participants who are seen as an 'inpatient' or in conjunction with a clinic visit, a clinical note will be added to that episode (EPR tab→ Overview/progress →Clinical note →add new) by the Investigator, or designee.

5.4.3 For participants seen out with normal hospital visits, an appropriate patient episode may be required to attach the notes for the visit. This can be done via the research icon in Trak to create a separate research episode, which will allow clinical notes to be created in relation to the visit. The speciality will be listed as the department the participant visited (e.g. Clinical Research Facility).

5.4.4 The Investigator, or designee, will create a new clinical note for each visit.

6 Key Information

6.1 For all studies, information collected which pertains only to the research study and has no relevance to clinical care should be held and archived by the research team in the ISF and will not be sent for scanning to the EPR.

6.2 Copies of case report forms will not be sent for scanning to the EPR. A summary of the visit will be captured either via direct entry into TRAK or on continuation sheets which can be scanned where clinically relevant.

7 Including research documents with Clinical Scanning

7.1 To ensure documents are effectively stored, the preferred approach for scanning is to use AD001-F01 (Research Document Scanning Inventory) following section 5.2. However, it is acknowledged that documents created as part of an outpatient/inpatient episode may be included with the clinical notes that are to be sent for scanning. Where including documents with other scanning, it is recommended all documents are clearly labelled as detailed in section 5.2 and inform other staff involved in processing the notes of the requirement for these documents to be sent for scanning before they are despatched to Digital Health Records

8 References and Related Documents

- HRECS/PP//36 NHSL Healthcare Records Scanning Policy
- AD001-F01 Research Document Scanning Inventory
- NHSL Digital Data Access Policy for Research

9 Document History

Version Number	Effective Date	Reason for Change
1.0	25 MAY 2017	New SOP
2.0	16 JULY 2018	Title of SOP updated. Addition of AD001-F01. Reference to HRECS/PP//36 NHSL Healthcare Records Scanning Policy
3.0	30 APR 2019	Addition of section 5.3 to allow staff to self-scan documents. Change of authorship from Elizabeth

		Craig (Senior Clinical Trials Monitor) to Carol Mackenzie (Digital Project Manager).
4.0	25 JUN 2021	Addition of new Research Team responsibility at 4.2. Section 5.1.1 specifies the need for an alert/research episode, as required, to be added to the patient's EPR to show they are taking part in a CTIMP. Section 5.1.5 added to detail the requirement for the research team to agree a consistent approach for where the information (specified in 5.1.4) will be documented, for each participant within that trial. Section 5.2.5 updated to outline that for regulated studies only, the inventory (AD001-F01) must be maintained in the ISF. Further clarifications throughout the SOP.
5.0	11 AUG 2025	NHSL eHealth renamed NHSL Digital. Broken links updated. Minor clarifications / edits made throughout. SOP and AD001-F01 (now v2.0) transferred to new ACCORD template.

10 Approvals

Sign	Date
Carol A MacKenzie Carol A MacKenzie (25-Jul-2025 10:05:01 GMT+1) AUTHOR: Carol Mackenzie, Digital Project Manager, NHSL	25-Jul-2025
Heather Charles Heather Charles (25-Jul-2025 09:53:17 GMT+1) APPROVED: Heather Charles, Head of Research Governance, NHSL, ACCORD	25-Jul-2025
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	25-Jul-2025

AD001 Entering Research Information to the eCasenote v5.0

Final Audit Report 2025-07-25

Created:	2025-07-25 (British Summer Time)
By:	Gavin Robertson (v1grobe9@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAQHke1NbKWAKLmsFdy5zUbk8dd0NYBfuZ

"AD001 Entering Research Information to the eCasenote v5.0" History

Document created by Gavin Robertson (v1grobe9@exseed.ed.ac.uk)
2025-07-25 - 09:38:12 GMT+1- IP address: 90.251.186.46

Document emailed to carol.a.mackenzie@nhslothian.scot.nhs.uk for signature
2025-07-25 - 09:47:30 GMT+1

Document emailed to heather.charles@nhslothian.scot.nhs.uk for signature
2025-07-25 - 09:47:30 GMT+1

Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2025-07-25 - 09:47:31 GMT+1

Email viewed by carol.a.mackenzie@nhslothian.scot.nhs.uk
2025-07-25 - 09:51:27 GMT+1- IP address: 62.253.82.244

Email viewed by heather.charles@nhslothian.scot.nhs.uk
2025-07-25 - 09:52:55 GMT+1- IP address: 52.102.16.181

Signer heather.charles@nhslothian.scot.nhs.uk entered name at signing as Heather Charles
2025-07-25 - 09:53:15 GMT+1- IP address: 62.253.82.244

Document e-signed by Heather Charles (heather.charles@nhslothian.scot.nhs.uk)
Signature Date: 2025-07-25 - 09:53:17 GMT+1 - Time Source: server- IP address: 62.253.82.244

Signer carol.a.mackenzie@nhslothian.scot.nhs.uk entered name at signing as Carol A MacKenzie
2025-07-25 - 10:04:59 GMT+1- IP address: 62.253.82.243

Document e-signed by Carol A MacKenzie (carol.a.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2025-07-25 - 10:05:01 GMT+1 - Time Source: server- IP address: 62.253.82.243

Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)

2025-07-25 - 10:09:21 GMT+1- IP address: 52.102.16.133

Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)

Signature Date: 2025-07-25 - 10:09:46 GMT+1 - Time Source: server- IP address: 62.253.82.242

Agreement completed.

2025-07-25 - 10:09:46 GMT+1