The Newcastle upon Tyne Hospitals NHS Foundation Trust

Newcastle University

Paperlite: Recording and Auditing Research Activity in eRecord

DLV-GEN-SOP-003

1. Background/Introduction

In October 2019, Newcastle Hospitals stopped using physical health records in almost all clinical areas. In addition, almost all paper-based diagnostic request forms were replaced with electronic request forms. This large-scale change programme aimed to make the organisation 'Paperlite' and in line with that objective, the Directorate of Clinical Research is also working towards becoming 'Paperlite' in its research activities.

For the Directorate to be compliant with Good Clinical Practice (GCP), its use of electronic health records must be reliable, allow for standard workflows and be easily accessible to clinical teams. Each record must also provide a comprehensive picture of a patient's clinical pathway and all their research interventions, as per the International Conference on Harmonisation of Good Clinical Practice (ICH-GCP) Principle 2.10:

"All clinical trial information should be recorded, handled, and stored in a way that allows accurate recording, interpretation and verification."

The Medicines and Healthcare products Regulatory Agency (MHRA) define "raw data" (also known as source data) as the original recorded data that was previously recorded on paper and filed in the health record. With the implementation of an electronic health record, source data will be input directly into the system or recorded as a true copy. To qualify as source data, an entry must be the first entry and permit reconstruction of the activities.

The document serves to outline how research delivery teams should use the electronic health record to record activity previously recorded in the physical care record.

2. Purpose

This Standard Operating Procedure (SOP) defines the Trust's research procedures for recording study-related data in the Trust's electronic health record, in particular the recording of research source data.

The document clarifies the requirements for maintaining accurate and thorough records as described in ICH-GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected'.

The document also aims to provide clear guidance as to how research data should be collected and stored so as to comply with the Trust's Information Governance Policy.

It is important that the Trust has a system in place to identify a research participant in their health record in order to enable treating physicians to be aware of the patient's participation

in a trial. Documentation of participation in the participant's health record is required for all patients recruited into all studies being conducted in the Trust. This takes the form of an electronic 'flag' in the health record.

Several Works Instructions (WIs) underpin this SOP, setting out - how to add a research flag to an existing electronic health record; how to create a new electronic health record; how to add a 'research note' and how to upload scanned documentation. There is also a WI that sets out how scanned information will be audited for quality assurance of the documentation and scanning process.

3. Scope of Document

This SOP applies to all employees within the Trust who have a need to record research information in the health record, including administrative information such as appointment details.

The information contained in this document should be used for all research studies conducted by the Trust. Where electronic health records are not in use, in a small number of areas, the appropriate alternative action is outlined.

This document does not cover access to the electronic health record for external parties. Instead, please refer to DLV-GEN-SOP-001 (Physical On-site Access to EHR for Monitors, Auditors and Regulatory Inspections).

This document does not cover the principles of data management. Instead, please refer to NJRO-REG-SOP-012 (Data Management).

4. Definitions

- Paperlite: A Trust-wide change programme to digitise health records and processes such as requests for imaging and bloods.
- EHR: Electronic health record.
- eRecord: The EHR used by the Trust.
- Source data: All information contained 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) and are specific to each study.
- Source documents: Original documents, data and records such as hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments,

copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medicotechnical departments involved in the clinical trial. Case Report Forms (CRFs) may be used as source documents only if specified in protocol.

- CRFs: Case Report Forms. The data collection tool used by a study sponsor of a clinical trial to collect data from each trial participant. All data on each participant in a clinical trial are held and/or documented in the CRF, including adverse events. The data is normally held in a pseudonymised format i.e. a name is replaced with a unique participant study number.
- PI: Principal Investigators
- CI: Chief Investigator
- CTA: Clinical Trials Associate
- CTIMP: Clinical Trial of an Investigational Medicinal Product
- GCP: Good Clinical Practice
- ECG: Electrocardiogram
- GP: General Practitioner
- HCA: Health Care Assistants
- HRA: Health Research Authority
- MHRA: Medicines and Healthcare products Regulatory Agency
- REC: Research Ethics Committee
- SOP: Standard Operating Procedure
- WI: Works Instruction

5. Roles & Responsibilities

It is the responsibility of all employees conducting or supporting research activity requiring use of the electronic health record to ensure they familiarise themselves with and follow the relevant policies, procedures and works instructions. Email notifications about amendments to existing SOPs and WIs or the publication of new SOPs and WIs will be sent via Q-Pulse; employees must ensure they are compliant, e.g. with relevant reading and document acknowledgements.

Overall responsibility sits with the Associate Director of Operations to ensure staff are adequately trained and able to comply with the relevant policies, procedures and working instructions.

6. Procedures

6.1 Documenting Participation in a Trial; Adding a Research Flag.

The EHR must contain a flag to indicate that a patient is participating in a trial (DLV-GEN-GUIDE-002). Where clinical areas are still using physical health records, a flag should still be added to the electronic health record and also to the physical health record using the relevant alert form – Appendix A.

A copy of the signed consent form and current Patient Information Sheet must be uploaded to the EHR (or filed in the hard copy medical notes where in use).

Where a study protocol requires a letter to be sent to the GP, a copy of that letter should be uploaded to the EHR (and filed in the medical notes where in use).

6.2 Recording source and routine data.

It is mandated for CTIMPs and advisable for all studies that the following information be documented within the patient's health record at each visit:

- visit number
- study number
- which study procedures have been completed
- patient's agreement to continue as a participant.

This will be via the production of a research note in the electronic health record (DLV-GEN-WI-007 Adding a Research Note to eRecord) and also writing in the hard copy medical notes where in use.

Other source data must be recorded (in accordance with the study protocol) and added to the patients' health record at each study visit either by adding a research note (DLV-GEN-WI-007 Adding a Research Note to eRecord) or uploading the relevant documentation (DLV-GEN-WI-008 Uploading Documentation to eRecord) or filing in the physical health records where in use.

A quality control system/procedure is in place to enable paper documents to be scanned and classified as source data, as detailed in 6.5.

Source data 'Top Tips' can also be found in Appendix B.

6.3 Transcribing data into Case Report Forms (CRFs)

All CRFs must be completed in accordance with the standards described in GCP guidelines.

The transcription of data into the study CRFs must be completed in a timely fashion, i.e. during, or as soon as possible after the study visit has been completed.

Where physical health records are used or where documentation is on paper to be subsequently uploaded on to the electronic health record:

- Always use a ballpoint pen; black ink should be used.
- Ensure data entry is as complete as possible without omissions. If data are unavailable write, for example, 'unknown' (UK), 'missing', 'test not done', etc. as outlined in CRF completion guidelines, if applicable. Avoid using the ambiguous phrase, 'not available'. Where possible an explanation should be provided for the missing data. This should also be initialled and dated.
- Ensure all entries are accurate, legible and verifiable with the source data in the medical record.
- For studies that are governed by MHRA authorisation all test reports (e.g. blood results, radiology reports, ECGs) must be signed and dated by the PI or suitably qualified individual in accordance with GCP. Any abnormalities must be noted and marked as either clinically significant or insignificant. Abnormal results may need to be recorded as an adverse event, depending upon their nature, and the appropriate action taken.
- Certified copies (paper or electronic copy) of the original document must be verified by a dated signature. Copies of clinical findings should be verified by the PI or suitably qualified individual. Copies of all other documents may be verified by the PI or designee as indicated on the delegation log.
- Corrections should be made as follows:
    - Cross out the incorrect entry with a single line so that the incorrect entry is legible. Never use correction fluid or obliterate entries made on the CRF.
    - Enter the correct data.
    - Initial and date the correction and, if appropriate, give an explanation of the correction.
    - The procedure to be followed for the resolution of data queries should be agreed with the study sponsor and documented in the protocol.
    - Laboratory values should be entered as they are without conversion from printed reports, even if in multi-centre study units of measurement differ from centre to centre, unless otherwise agreed in writing.

6.4 Data Protection

During the process of data collection and management it is important that all source data and study related material are kept in a safe location in line with the Data Protection Act 2018.

Maintaining subject confidentiality is imperative and research records should contain subject trial identifiers such as codes rather than patient names and/or hospital numbers.

Records being used during the study period such as patient medical records and paper CRFs should be contained in a secure location accessible only by authorised individuals. Furthermore, CRFs should not contain elements of source data which use patient identifiable information.

Where specific source data sheets have been designed for use in the trial, the CI (or delegated individual) should ensure that these are retained separately from the CRF.

6.5 Uploading Documentation to eRecord

A list of items to be uploaded to the electronic health record (or filed in paper record if in use) is outlined in Appendix C.

There are two different methods to upload hard copy documentation into eRecord.

One method involves local upload of documentation (utilising the multi-functional devices that exist around the organisation) which allow verification of uploaded documentation at source. The upload is typically (but not always) instant but can be time consuming for the large-scale document uploads.

The other method involves a central upload of documentation (via Medical Records) and involves research teams producing and attaching a QR label to documentation and sending it to Medical Records to be uploaded via one of several large-scale scanning machines. Unless flagged as urgent, upload via this method typically takes 1-3 days.

As both methods will upload information to produce an equivalent end result (which is the documentation in the DocStore app in eRecord) and both methods are used across the Trust, both methods can be used for the upload of research activity. This provides resilience should there be a problem with either method. It is important to note when uploading via Medical Records, the date attached to the document when viewed in Document Store is the upload date not the date of the activity. This is a known anomaly across the organisation which emphasises the need for the uploaded documentation to specify the relevant event date.

Quality assurance of both methods will also be sought via regular, planned audit of uploaded information across all teams. There are robust quality assurance methods in place in Medical Records which have been audited via the Quality Assurance team in the NJRO.

7. References

- DLV-GEN-WI-001 Creating a Research QR Code label
- DLV-GEN-WI-006 Adding a New Patient Record in eRecord
- DLV-GEN-WI-007 Adding a Research Note to eRecord
- DLV-GEN-WI-008 Uploading Documentation to eRecord
- DLV-GEN-WI-009 Auditing of research documentation uploaded to e-Record
- DLV-GEN-WI-010 Adding a Research Flag to a Patient Record
- ICH E6 Good Clinical Practice (GCP) and subsequent addendums. https://www.ich.org/page/efficacy-guidelines#6-2
- Information Governance Policy
- MHRA GxP Data Integrity Guidance and Definitions. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/687246/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf

8. Appendices

A. Method of flagging research participation in hard copy health records.

Area	Method of flagging research participation
Women's Services	Participation is recorded on the 'Obstetrics Case Notes Summary Sheet' [Form NUTH497] filed in the front of the record.
All other clinical services, including dental services.	Participation is recorded on 'Alert Recording Form' [Form NUTH93] filed in the front of the record.

B. Source Data Top Tips

1. Source data refers to where data are first captured in any situation, not just on trial documents. Location of source data should be clearly documented.

2. Ensure source data is accurate and clear. If visit templates are used in the health record to facilitate recording of visit assessments, make sure data is updated accurately for each visit.

3. Participant consent details, participation in the trial and allocated study number must be documented.

4. Review and outcome of participant eligibility should be documented (by the PI or appropriately delegated member of medical staff' for CTIMP trials). Ideally the review of each inclusion/ exclusion criteria should be documented, alternatively a conclusive statement of participant eligibility can be documented providing there is supporting evidence of the review of each criteria.

5. Document participant visits at the time of visit or immediately after. Avoid regular retrospective entries.

6. Trial visits and dates must be documented explicitly, including unscheduled visits.

7. Document all the assessments performed and the results, including labs, scans, ECGs etc

8. Document all findings pertinent to the participant's general medical well-being, e.g. medical history, physical exam, vital signs and lab results.

9. Ensure the review of investigations such as lab and ECG results are documented. This includes adding comments on the clinical significance of the results and grading where applicable, investigator's sign off and date of review.

10. Document that concomitant medications and AEs were assessed at the visit and list details, such as relationship to IMP. AEs which have been resolved must also be documented (lack of documentation of AE review does not mean there were no AEs to report; it suggests that AEs were not reviewed). If an AE is on-going across a number of visits but causality due to IMP changes, this should be confirmed by a clinician and noted in the patients' medical notes.

11. Record details of trial medication administration. In cases where participants are instructed to return unused oral medications, the returns should be checked and documented, and any discrepancy to expected dosage addressed. Participant diaries if used should also be copied and added to the source notes.

12. Document date of final study drug administration and when the participant completed the trial, including the reason for withdrawal if applicable

13. Document any communication with the participant pertinent to the trial (e.g.: Participant information sheet sent for consideration, follow up phone calls), even where it is outside of normal standard of care.

14. Document any other information the participant has provided or discussions that took place during the trial visit even if not immediately relevant to the trial (e.g.: pregnancy).

15. In case of CTIMP, ATIMP and Device trials the participant's willingness to continue in the trial should be documented. This is good practice for all studies.

C. Items to be uploaded to the electronic health record (or filed in paper record if in use).

Item	Mandatory	Optional
Study protocol summary / flow chart		✓
Planned drug schedule/regime		✓
Visit schedule/log		✓
Patient information sheet	✓	
Patient consent form (copy)	✓	

Study pro-forma / data collection form		✓
Notes section, for additional research contact made, but not documented elsewhere	✓	
SAE/SUSAR reports (copy)		✓