Use of Electronic Patient Records (EPR) for Research
Research & Innovation SOP J-5016

University Hospitals of Leicester NHS
NHS Trust

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1. Introduction and Who Guideline Applies to

This SOP sets out the procedures for accessing and using Electronic Patient Records (EPR) for the purpose of clinical research at the University Hospitals of Leicester NHS Trust (UHL). The EPR is a digital system that consolidates all patient medical information - including medical history, test results and prescribed medications - into a single, unified platform. UHL has replaced its 35-year-old legacy system with a new Patient Administration System (PAS) - a digital platform designed to support and streamline clinical and administrative workflows across the Trust. The PAS has been fully integrated with the Nervecentre EPR.

With the increasing transition from paper-based to electronic medical records, it is essential that procedures for use of EPR to support the conduct of clinical trials are clearly defined and consistently implemented. In line with participant consent, clinical research teams require access to identifiable medical records for the purposes of recording research activity and collecting data. Study sponsors must also be granted appropriate access to patient records to facilitate effective data verification.

Clinical staff must be able to identify patients who are actively participating in clinical trials, as this may involve the administration of investigational medicines or other treatment that could potentially affect their clinical care. This is particularly critical during emergency admissions, where prompt access to information regarding trial participation may be essential to informing safe and appropriate treatment decisions.

Additionally, standardised procedures are necessary for ensuring that clinical staff providing care to trial participants can promptly notify investigators and trial teams whenever a participant receives healthcare outside the confines of a study. Such communication helps investigators to determine whether the event has implications for the participant's ongoing trial involvement or requires further reporting in accordance with applicable regulatory and protocol requirements.

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued guidance outlining the requirements that electronic medical records must meet in order to be deemed suitable for capturing and retaining source data in clinical trials. The retention of, and controlled access to, such data is pivotal for verifying the integrity and reliability of study results.

This SOP applies to all sponsored and hosted clinical research conducted at UHL.

2. Guideline Standards and Procedures

2.1. Definitions

EPR	Electronic Patient Record(s) – a digital system that consolidates electronic patient medical information into a single, unified platform (e.g. Nervecentre, CITO, SystmOne, Chemocare, BadgerNet)
Essential records	The documents, data and meta data – regardless of format – that are linked to a clinical trial and collectively allow verification that the trial was performed in accordance with Good Clinical Practice (GCP) and all applicable regulatory requirements, and that the trial results are reliable

PAS	Patient Administration System - a digital platform designed to support and streamline clinical and administrative workflows within the hospital
Downtime records	Any temporary, paper-based or offline electronic records used to capture essential clinical or research-related information when the EPR (or other digital research platform) is unavailable due to planned or unplanned downtime
Study Monitor	For the purposes of this SOP, the term 'Monitor' describes any authorised individual who requires access to a participants' medical record for regulatory or quality oversight of a clinical trial. This includes, but is not limited to, clinical trial sponsor representatives (e.g. CRA's, monitors, auditors) and representatives of regulatory authorities. Study monitors can be internal or external to UHL.
Source Data	The initial, original records in which clinical observations, findings, or activities related to a trial participant are first recorded (e.g. blood results, clinical charts, radiology reports, pharmacy records, medical consultations etc). Source data is collected to inform clinical study endpoints.

2.2. Access to Electronic Patient Records

When agreeing to participate in clinical research, participants will usually grant research staff, the study Sponsor and regulatory authorities access to identifiable medical records for the purposes of recording research activity, data collection, audit and monitoring (copies of consent forms and participant information sheets must be kept with the medical record).

To comply with data protection regulations and UHL governance requirements, access to the EPR is strictly controlled and limited to authorised staff. Access will be granted only where it is necessary for an individual's clinical or operational responsibilities, and only after the required training has been completed. When accessing and updating the EPR, staff must comply with Trust standards for record-keeping and information governance. Investigators must ensure that study monitors are aware of all EPR systems that contain source data relevant to the research.

Authorised staff must only view elements of the patient record that are required to fulfil their role. Investigators, research managers and delegated staff are responsible for ensuring that EPR access is removed promptly when no longer required.

2.2.1. EPR Access for UHL Research Staff

Only authorised members of the clinical research team (including substantive staff, holders of honorary contracts, or approved collaborators) may access the EPR for research purposes. Research staff must have documented approval to work on the study (i.e. delegation log) and have a legitimate research role that necessitates EPR access. Access must be role-appropriate and limited to the minimum necessary for the approved role.

Before accessing the EPR, UHL research staff must have completed UHL-mandated Information Governance and data protection training, GCP training (where applicable) and any EPR-specific training required to enable them to safely and appropriately navigate patient records.

Research staff must promptly report any suspected or actual data breach, inappropriate access, or error in record handling through the UHL incident reporting process, and take immediate steps to mitigate risk where safe and appropriate.

2.2.2. EPR Access for Research Monitoring and Audit

Where required, read-only access to the EPR can be granted to research Monitors. External staff must first obtain a UHL Active Directory account (through IAMWEB), after which the required EPR access can be

requested through Neurons. Access requests must be completed by a designated UHL member of staff. The person requesting access is responsible for verifying the identity of the Monitor and the purpose and scope of their access to UHL systems.

Monitors must complete all necessary EPR training relevant to their role. Systems access must only take place using a UHL terminal or through e-Desktop.

EPR systems should be configured to restrict research Monitor access to the records of participants enroled in the specific trial being reviewed, and to ensure such access is fully auditable. Where this is not technically possible (e.g. Nervecentre PAS), Monitors should be reminded of their responsibilities for information governance, including only accessing records of patients on the trial that is being monitored, and handling all data securely. As per MHRA, the monitors' employment contract already establishes personal accountability and sanctions for any breach of confidentiality or misuse of data, it is neither appropriate or necessary for trial locations to require additional non-disclosure agreements.

Where it is not possible for a Monitor to be given direct access to the EPR, the Monitor may view records accessed by a member of the study team. So-called 'over the shoulder' observation is only permissible with personal supervision of the member of the study team accessing the electronic record.

In cases where monitoring of source data needs to take place via a remote monitoring visit, sharing of medical records with an authorised Monitor is permitted, but only via the MS Teams platform. Use of any other platform, software or system will require prior agreement from the UHL R&I Office with clear indication as to the reasons that MS Teams is not suitable to meet requirements.

Records may be shared via a webcam or screen share, but the Monitor must not record or retain screen shots of medical records viewed in this way.

Electronic copies of source documents may also be uploaded to a secure portal (such as EDGE or Florence) for remote monitoring. The R&I Admin team can grant Monitors temporary access to these systems. The individual requesting access must accept responsibility for granting the external monitor access to UHL systems. The same conditions of use will apply as for other EPR (e.g. Nervecentre PAS).

Identifiable electronic patient records must never be transferred directly to a Monitor (via email, MS Teams or any other means), except where explicit and specific consent to do so has been provided by the patient within the terms of the ethical approval, or where CAG approval for such transfer of identifiable data is in place.

2.2.3. EPR Access for Regulatory Oversight

There is a statutory requirement to provide direct access to patient records for regulatory inspection (e.g. MHRA). In such an event, research teams must ensure that regulatory Monitors are granted timely, direct, and unhindered access to relevant parts of the EPR, where required. This access will be provided strictly for the purposes of compliance verification, and must be managed in line with all applicable data protection, confidentiality, and information governance requirements.

Access to the EPR can be requested via the UHL Neurons system. Access requests must be completed by a designated UHL staff member. The person requesting access is responsible for verifying the identity of the Monitor and the purpose and scope of their access to the EPR. Monitors must only access the specific elements of the health record necessary to fulfil their statutory, regulatory, or audit functions.

2.3. Use of Research Alerts in Nervecentre PAS

The Nervecentre PAS system includes an alert function specifically designed to indicate that a patient is participating in a clinical trial. Instructions for accessing the alert can be found in R&I Template T-1060.

Alerts should be activated upon randomisation or enrolment of a patient into a relevant clinical trial. Alerts should be deactivated only after the patient has completed the trial, including any required follow-up.

Given the resources required by research delivery teams to administer these alerts, alerts should only be used for interventional trials from one of the three categories selectable in the alert:

- Interventional (Drug)
- Interventional (Medical Device)
- Interventional (Other)

Although it is rare for a patient to be on more than one interventional trial, multiple trials can be listed under the 'Clinical Trial Reference (IRAS)' section. However, due to technical limitations only one Principal Investigator (PI) can be listed in the 'Principal Investigator' section. PI's for additional trials should be added as 'Key Research Contacts', which is a searchable text field based on the UHL directory. If used, it must be stated in the 'Clinical Trial Notes' section which trial each PI is responsible for.

When a clinical trial alert is logged on the Nervecentre, the UHL Medical Records team will also add a research alert label to the cover of any paper medical notes retrieved for that patient. Research staff should also label paper medical records themselves where this has not already been done.

If a patient with an active Nervecentre Research Alert is admitted for urgent care, the admitting clinical team must promptly notify the Principal Investigator or research team using the contact details stated in the Alert. Early notification allows investigators to assess any impact on the participant's trial involvement and requirements for further regulatory or protocol-specific reporting. Investigators may also be able to provide guidance on the continuation of trial interventions, such as study medication or procedures.

Research teams should periodically review active research alerts to ensure they remain accurate and are removed when no longer required.

2.4. Use of EPR for Managing and Reporting Clinical Trial Activity

Research activity should be recorded contemporaneously. Any information which could impact patient care, even if collected solely for a clinical trial, must be included in the medical record, or clearly referenced and readily accessible to the caregiver.

Where findings are of clinical relevance or otherwise require clinical interpretation, the filed record should also state who has reviewed the findings, when this review took place and an assessment of the clinical significance of any findings. Likewise, records generated during delivery of routine patient care may also be used as primary evidence for supporting clinical trial endpoints.

Where entries made within the EPR represent the first point of documentation for clinical or trial-related information, these will be considered 'source data'. In case of discrepancies, the original EPR entry will constitute the primary record, unless otherwise stated in the protocol

Where copies of source data are required (e.g. monitoring, inspection or audit), printouts or PDF extracts from the EPR may be provided, subject to UHL confidentiality and data protection requirements. Certified copies must include:

- Patient identifier
- Date and time of extraction
- Identity of the individual producing the copy
- Confirmation that the copy is accurate and complete

Certified copies become part of the trial's essential record. No alteration of the EPR is permitted to create a certified copy.

For studies involving volunteers, a participant may not have existing Trust medical records. Where this is the case medical records should be created if the study requires creation of a medical alert, or if the participants' involvement in the study will create records of relevance to their medical care outside of the research.

Certain trial-specific activities may not be fully supported within the EPR, such as:

- Blinded treatment allocation
- Detailed IMP accountability records
- Protocol-specific assessments not part of routine clinical care
- Research-specific questionnaires or diaries

In these cases, study-approved paper or electronic source records must be maintained alongside the EPR. Essential documents that support trial conduct and data quality must be maintained in the Trial Master File (TMF) or Investigator Site File (ISF).

2.5. Use of Nervecentre PAS for prescribing Investigational Medicinal Products (IMP)

Prescribing via the UHL Electronic Prescribing and Medicines Administration (ePMA) system is a requirement for inpatient studies running in an area where electronic prescribing has been set up and where IMPs have to be administered. During the initial protocol review, the clinical trials pharmacist should identify which trial IMPs need prescribing on ePMA.

A member of the Digital Medicines Team will set up the prescribing template for the study with the appropriate information provided by the Clinical Trials Team.

In situations where an IMP needs to be administered to an inpatient on an ePMA ward but this was not part of the intended study design (e.g. IMP is usually given as an outpatient but the patient is admitted to hospital), a decision as to whether the IMP warrants addition to ePMA should be made on a case by case basis in discussion with the Digital Medicines Team as well as the research team. In the meantime, the IMP (if continuing) should be prescribed on ePMA as "IMP not in ePMA formulary" using the protocols under 'Speciality', 'Cinical Trials-Adult' or 'Clinical Trials-Childrens' with the full name, dose, strength and form of the prescribed medication documented within the qualifier. The route and dosing instructions should be amended on ePMA as clinically appropriate.

The EPR must be configured and used in a manner that prevents inadvertent unblinding of trial treatment allocation. Where the prescribing or documentation of IMP within the EPR could reveal treatment identity or allocation, appropriate safeguards must be implemented, such as restricted access screens, masking of product names, or segregation of blinded and unblinded roles. Only authorised unblinded personnel, such as designated pharmacy staff, may access unblinded IMP information. Clinical and research staff who are blinded to treatment allocation must not be exposed to EPR fields, prescription details, or medication lists that could reveal the investigational product. Where this is not possible, the PI is responsible for setting up appropriate safeguards to ensure accidental unblinding cannot take place.

Any accidental unblinding must be reported to the Sponsor in accordance with the study protocol, and assessed for impact on trial integrity and participant safety.

2.6. Handling, storage and retention of essential electronic research records

Electronic health records that are considered part of the essential record for a clinical study must be managed and retained in accordance with applicable regulatory requirements and UHL policy.

2.7. EPR downtime, contingency and business continuity

Where EPR is used for participant research visits, the PI is responsible for ensuring that:

- alternative arrangements are in place to enable clinical trial procedures to safely continue in the event of EPR system downtime (e.g. capture of trial activities, IMP prescribing, results reporting)
- monitors and Sponsors are notified if downtime may affect monitoring access, data entry timelines, or safety reporting

- downtime records are accurately transcribed or uploaded to the EPR once normal service resumes

All downtime records (clinical and study-related) will be considered source records and must be retained in accordance with UHL Records Management Policy, study protocol and regulatory requirements.

3. Education and Training

Before accessing the UHL EPR for research purposes, study personnel must be delegated by the Principal Investigator (PI) and have completed all relevant training for their role.

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Use of research alerts for eligible interventional trials	Review a sample of active interventional studies to confirm a Nervecentre research alert has been created where required and relevant clinical staff are aware of active study status	R&I Deputy Director of Operations	As per R&I audit schedule	Report to R&I Governance meeting
Recording of clinically relevant research information within the medical record	Review of participant records to confirm timely and accurate documentation of clinically relevant research information within the EPR, where required	R&I Deputy Director of Operations	As part of routine monitoring or audit	Report to R&I Governance meeting
Research monitor access to EPR systems	Review a random sample of monitor access requests to confirm authorisation, identity verification and appropriate access arrangements have been completed and documented	R&I Deputy Director of Operations	As per R&I audit schedule	Report to R&I Governance meeting

5. Equality Analysis Assessment

The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

As part of its development, an Equality Analysis on this policy have been undertaken and its impact on equality have been reviewed and no detriment was identified.

6. EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual

orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

7. Supporting References

SOP C-2028: Remote Monitoring for HOSTED studies

SOP J-5001: Managing Essential Research Documentation, the TMF and the ISF

SOP J-5014: Archiving of Essential Research Documentation

SOP S-1007: UHL Monitoring

SOP S-1015: Standard Operating Procedure for Management of Essential Documents and Trial Filing for Research sponsored by University Hospitals of Leicester NHS Trust

SOP S-1036: UHL Audit

T-1060: Creating a Research Alert in Nervecentre

8. Key Words

Research, Innovation, Electronic Patient Record, EPR, Good Clinical Practice, Monitor, Audit, Access, CI, PI, EDGE, FLORENCE, Nervecentre, PAS, Documentation, Clinical Trial

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CONTACT AND REVIEW DETAILS	
Policy Lead: Jen Boston R&I Deputy Director of Operations	**Executive Lead:** Nigel Brunskill R&I Director
Details of Changes made during review: N/A, New SOP	