University College London Hospitals
NHS Foundation Trust

Title: UCLH Standard Operating Procedure for Research Monitor Access to UCLH EHRS (EpicCare Link UCLH)

SOP Number and Version: UCLH SOP 12, Version 1	**Effective Date:** 01/05/2019 **Review Date**: 01/05/2021

For Trust-wide SOPs, please check this is the **latest version of the SOP** on the Joint Research Office website: https://www.ucl.ac.uk/joint-research-office/.

For Departmental SOPs, please check this is the **latest version of the SOP** with the Research Unit QA Manager.

Author:
Name: Mona Hassan
Position: JRO Research Quality & Safety Manager

_____

Signature Date

Approved by:
Name: Rajinder Sidhu
Position: Deputy Director, Research Support

_____

Signature Date

Authorised by:
Name: Nick McNally
Position: Managing Director, UCLH/UCL Research

_____

Signature Date

Revision Chronology:			
Version Number:	**Effective date:**	**Reason for change:**	**Author:**
1	01/05/2019	Initial release of SOP, for standardised use across UCLH (research).	Mona Hassan, JRO Research Quality & Safety Manager ***Contributors and reviewers:*** Israel Serralvo-Caballero, EHRS Clinical Systems Designer – Research (Module Coordinator) Nausheen Saleem, EHRS Clinical Systems Designer – Research (Module Coordinator) Arti Kara, JRO Research Audit & Quality Officer Rajinder Sidhu, Deputy Director of Research Support Celia St Clair, Quality Assurance Manager, Cancer Clinical Trials Unit Kirsty Adams, Quality Assurance Manager, Clinical Research Facility Matthew Hall, UCLH Head of Information Governance and UCLH Data Protection Officer

ACRONYMS

AE	Adverse Events
ATOS	UCLH IT Service Providers
ATIMP	Advanced Therapy Investigational Medicinal Product
CRO	Contract Research Organisation
CRF	Clinical Research Facility
CRFs	Case Report Forms
CTIMP	Clinical Trial of Investigational Medicinal Product
EHRS	Electronic Health Records System
Epic	EHRS Software
GCP	Good Clinical Practice
ISF	Investigator Site File
JRO	UCLH/UCL Joint Research Office
PI	Principal Investigator
SAE	Serious Adverse Events
SOPs	Standard Operating Procedures
CCTU	Cancer Clinical Trial Unit
CRF	Clinical Research Facility
RN	Research Nurse
R&D	Research and Development Department
QA	Quality Assurance

1. BACKGROUND

All regulated clinical trials (e.g. CTIMPs, ATIMPs, regulated device trials) ongoing monitoring, throughout the duration of the trial. It is the responsibility of the sponsor to ensure that trials are adequately monitored, either directly, or via a contracted vendor (e.g. a CRO, external monitoring services, etc.).

Monitoring is defined as the act of overseeing the progress of a clinical trial, and of ensuring it is conducted, recorded and reported in accordance with the protocol and any amendments, Sponsor and UCLH SOPs and Policies, the principles of ICH Good Clinical Practice (GCP), and the applicable regulatory requirements.

The purposes of trial monitoring are to verify that:

a) The rights and well-being of research participants are protected.
b) The reported trial data are accurate, complete, and verifiable from source documents.
c) The conduct of the trial is in compliance with the currently approved protocol, with the principles of ICH GCP, and with the applicable regulatory requirements[1] (e.g. HRA Approval, REC Favourable Opinion, and MHRA Notice of No Objection/Acceptance).
d) All trial documentation required to reconstruct the trial are filed in the ISF, and retained within source documentation.
e) The UCLH study team are appropriately trained before and during the trial.
f) Research staff undertaking trial duties have been appropriately delegated by the PI.
g) Research participants are eligible, and any non-compliances or breaches are appropriately reported to the sponsor.

[1] ICH GCP (R2)

h) Research participants have given their initial informed consent prior to trial participation and ongoing consent for any amendments.
i) Adequate safety information is recorded.
j) IMP Management: checks on receipt, storage area and conditions, accountability and destruction.
k) CRF and source data are consistent and accurate.
l) Facilities and equipment are and remain suitable for conducting the trial.
m) Processes are consistently followed and activities are consistently documented to ensure high-quality trial conduct and protocol compliance.

The level of monitoring will vary significantly, depending on the risk and complexity of the clinical trial being conducted. Monitors will follow Sponsor and/or trial specific SOPs for their monitoring activities, and will follow a Monitoring Plan and schedule.

Research and UCLH EHRS

On-site monitoring activities involving patient medical records are traditionally paper-based. However, on 31st March 2019, UCLH launched Epic, a single UCLH electronic health medical records system, to replace the use of paper medical records and existing electronic systems within the Trust[2]. Epic UCLH includes the functionality to support clinical research activity. All research procedures, consenting activities, and adverse events are recorded within the electronic record for each participating UCLH patient. It is mandatory for all researchers at UCLH to ensure patient records are updated to reflect research activity.

- All UCLH research studies approved by the UCLH/UCL joint Research Office (JRO) are registered onto Epic as part of the R&D approval process; the UCLH study team are responsible for associating ('tagging') patients and research appointments to the study record on Epic, and recording patient research activity throughout the trial/study.
- A patient's record within UCLH EHRS will therefore contain a research icon to indicate that they are involved in a research study, with a research banner link to further details about the study.
- Researchers can order research related procedures (e.g. prescriptions, lab tests, scans, etc.), record AEs and SAEs, upload signed consent forms, etc., within the patient's record. UCLH researcher access is restricted to their job role, i.e. the ability to order drugs and procedures is restricted to staff with the appropriate authorisations.
- All UCLH staff with an Employee Staff Record (ESR) can access Epic, provided they have completed appropriate Epic training. All research staff must complete research-specific training and assessments, prior to access. Staff can only log in via their unique UCLH user ID and password. Access levels are determined by job role.
- All information entered into the EHRS is supported by audit trails which include when the entry (or a change to an entry) was made (date and time) and by whom. Changes can be made to data within EHRS by those who have the access to do so - these changes will be evident within the audit trails. Audit trails are secure, and locked from being edited.

[2] Paper medical records will continue to be stored with UCLH Medical Records locally, for active/active in follow up studies, at the time of Epic's launch, throughout the duration of the trial. These can be retrieved as per Trust Medical Record Policy, provided they are tagged as 'research-related'. Further details available via the JRO.

Research Monitor access via EpicCare Link UCLH

External research monitors will be able to view a patient's electronic medical record via their own user account in **EpicCare Link UCLH**. EpicCare Link UCLH is an external, secure digital portal that will connect the research monitor with the Epic system at UCLH. Monitors will be able to securely view information about research patients, including conditions, tests, procedures, results, treatments, clinical letters, and scanned research documentation, e.g. consent forms. EpicCare Link UCLH is a live feed of data that can be refreshed at any point. Patient information in EpicCare Link UCLH is set to ***View Only*** mode for monitors; no edits can be made, and monitor actions are auditable. Access is web-based; therefore monitors can use their own devices (e.g. laptops) to complete monitoring activities on UCLH EHRS, provided they adhere to the '*EpicCare Link UCLH – Research Monitor code of conduct'* (Section 6), which sets out R&D, UCLH Information Governance and Epic conditions of use, per study/trial. Monitors must additionally complete their EpicCare Link UCLH monitoring activities on UCLH premises, within the same location as the UCLH study team. No remote access is permitted by the Trust.

Additional external research personnel access requirements to EpicCare Link UCLH

Sponsor audits and regulatory inspections are likely to occur throughout the duration of a clinical trial. Auditors and Inspectors may be granted access to EpicCare Link UCLH via the process outlined within this SOP.

2. PURPOSE

This SOP is aimed at UCLH study teams, and outlines the process for initiating and managing monitor access to research patient records via EpicCare Link UCLH. Research monitors can be given access to research patient records provided that:

- the study/trial has received UCLH Confirmation of Capacity and Capability from the JRO
- the study/trial is registered on Epic
- there are patient records associated to the research study on Epic
- the local UCLH study team have been given **adequate** notice of the monitoring visit, and details of the monitor. In circumstances where urgent monitoring visits are required, or early database locks, shorter notice periods may be given. Shorter notice periods may also be given in first in human trials.
- UCLH IT have created an EpicCare Link UCLH user ID and login, unique to the monitor
- the 'EpicCare Link UCLH Research Monitor Code of Conduct' (Section 6) has been signed by the monitor, and stored within the ISF.

Monitors will be issued with an EpicCare Link UCLH user ID and password (unique to them; **under no circumstance should UCLH study teams share their Epic login information with external staff**); access to patient records will be restricted to 8.30am – 5.30pm, Monday to Friday. Monitors will be unable to log in outside of these times. Appropriate members of the UCLH study team (e.g. research coordinators, clinical trial practitioners, etc.) will be responsible for manually 'releasing' patient records to the monitor (via their EpicCare Link UCLH account); monitors will not be able to view any records that have not been released by a member of the UCLH study team. If a monitoring visit lasts for more than a day, then the patient records will need to be re-released to the monitor on a day-to-day basis.

The UCLH study team are responsible for ensuring the requirements of this SOP are fulfilled.

3. PROCEDURE

WHO? WHEN? HOW?

	Actions (When? How?)	Responsible persons (Who?)
1	*Studies/Trials in set up at UCLH:* UCLH study teams may follow this process in advance of the Site Initiation Visit (SIV) to initiate monitor access to EpicCare Link. 'Monitor code of conduct' may be signed at the SIV, then monitor login information provided. *Active studies/trials*: Sponsor informs UCLH study team of upcoming monitoring visit. UCLH study team require **adequate notice** (short notice periods are acceptable in reasonable circumstances, such as for first in human trials, early database locks, or urgent monitoring visits due to quality and safety issues). UCLH study teams will need to request monitor access via IT ahead of each monitoring visit (ideally 2 weeks in advance),	Sponsor/CRO/Monitor
2	UCLH study team obtain the following information for the monitor(s) (in some instances, more than one monitor may attend a monitoring visit): 1) Name 2) Occupation 3) Work email To facilitate monitoring visit preparations, UCLH study team should provide electronic copies of the *'EpicCare Link UCLH – Research Monitor code of conduct'* and *EpicCare Link guidance for RSH monitors* slides (Section 6).	UCLH study team
3	Monitor provides requested information to UCLH study team. Monitor may additionally provide a scanned copy of their signed 'code of conduct' (or later on site, prior to beginning their first monitoring visit). At this stage, if relevant, the study team should also request paper medical records for research participants (where applicable) via Epic Chart Tracking/UCLH Medical Records department, in order for these to be available for the first monitoring visit (retrieval time from UCLH Medical Records/Iron Mountain is maximum 7 working days).	Monitor
4	1) UCLH research coordinator raises a Ticket with UCLH IT Helpdesk, with clear indication that this is **Research** related, with the subject **'EpicCare Link Research Monitor Account request'.** 2) Provides the following **mandatory** information: - Monitor's name, occupation, work email address - Short study title (as registered on EDGE) - Study IRAS number - length of time access required - If you **urgently** require monitor accounts (e.g. first in human trials, early study database locks, safety monitoring visits, etc.), ensure this is made clear in your ticket request. IT will issue a service desk ticket number, which the UCLH study team	UCLH study team

	must keep a record of. Must be initiated minimum 2 weeks in advance of monitoring visit. For **urgent** monitor account requests, the research coordinator may follow up directly with the Epic Research team by providing the IT ticket number. Please contact the JRO if you need support with this.	
5	Research coordinator receives notification from UCLH IT Service Desk when the monitor account has been created, with details of their unique User ID and password. As per Trust policy, this may take up to 2 weeks. During the account creation, IT will link the monitor's account to the study/trial being monitored, thereby enabling the UCLH study team to release patient records.	UCLH study team
6	At the beginning of the monitor's first visit, UCLH study team must ensure that the monitor's 'code of conduct' document has been signed by the monitor, and filed appropriately (e.g. within the ISF and department records). The monitor may send an electronic scanned copy in advance of the monitoring visit, or sign a paper copy at their first visit to site. Either option is permitted. **UCLH study teams are responsible for ensuring the monitor has signed their code of conduct prior to releasing their EpicCare Link login information.** Once confirmed, UCLH study team will pass on the Monitor's EpicCare Link User ID and password, with a web link to EpicCare Link UCLH (https://epiccare.uclh.nhs.uk/Carelink/common/epic_login.asp). UCLH study team must also ensure copies of the '*EpicCare Link guidance for RSH monitors'* slides are available to the monitor, if needed. These slides contain guidance on where to access areas such as research consent, AEs, lab results, research notes, etc. Any specific, technical questions regarding how to use Epic can be directed to the departmental research super users or the UCLH study team. UCLH study team should reiterate that monitor access is restricted to the hours between 8.30am – 5.30pm; personal devices may be used to access EpicCare Link UCLH, however this must be within sight of the UCLH study team.	UCLH study team
7	Following the above step, UCLH study team (i.e. research coordinator, research nurse, etc.) proceeds with 'releasing' electronic trial patient records to the monitor. Instructions on how to do this is detailed in the Epic tip sheet: '*Releasing Patients to Study Monitors'* (available on Insight). As monitor access is day to day only, research coordinators must run multiple reports to release their study patient records to the monitor.	UCLH study team
8	**Adding multiple studies/trials to Monitor's EpicCare Link account:** In certain circumstances, Monitors may conduct monitoring visits for more than one clinical trial, at any one time. When EpicCare Link accounts are set up, they are pre-linked to a specific study; the UCLH study team will therefore need to obtain a signed 'code of conduct' per trial, and raise a	UCLH study team

	ticket with IT to add additional studies to their account. UCLH study team should therefore follow the same process outlined in the 4th step, but indicate if an account has already been requested in the past. The UCLH study team will not be able to release patient records to the monitor until IT has completed this. **Monitor EpicCare Link Accounts: deactivations or password expirations** UCLH study teams will need to follow this SOP to raise a ticket with IT when monitors accounts have expired (e.g. since their last monitoring visit), with all the monitor details listed in the 4th step. IT will screen the monitor's details to check if duplicate accounts already exist, and reset their password accordingly.	

4. IMPLEMENTATION & TRAINING

Staff following this SOP shall confirm they have read and understood the procedures outlined above by completing their relevant training log as a record of acknowledgement.

5. PUBLICATION & COMMUNICATION

This SOP is authorised and published on the JRO website: http://www.ucl.ac.uk/joint-research-office. The latest version of the SOP will be made available on the JRO website and UCLH Insight page.

The original fully signed master copy is stored in a designated binder within the JRO and maintained by the JRO Research Quality & Safety Manager (or Research Unit QA Manager if a Departmental SOP).

6. TEMPLATES ASSOCIATED WITH THIS DOCUMENT

	Document	Stored
1.	EpicCare Link UCLH – Research Monitor code of conduct' template	*Research & Development Insight page*
2.	Epic tip sheet: 'Releasing Patients to Study Monitors'	*Research & Development Insight page*
3.	EpicCare Link guidance for RSH monitors	*Research & Development Insight page*

7. REFERENCES

Clinical Trials Directive 2001/20/EC: https://ec.europa.eu/health/human-use/clinical-trials/directive_en

Clinical Trials Regulation EU No 536/2014: https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

ICH GCP E6(R2): https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

JRO Website: http://www..ucl.ac.uk/joint-research-office

UCLH Insight (internal): http://insight/Pages/Home.aspx

8. APPENDICES