

## UCLH Research & Development

### COVID-19 - UCLH Remote Monitoring arrangements - EpicCare Link UCLH

Please read in conjunction with UCLH R&D COVID-19 Research guidance, available at [www.ucl.ac.uk/joint-research-office](http://www.ucl.ac.uk/joint-research-office).

The below arrangements have been put in place for remote monitoring during the COVID-19 pandemic, as per [HRA](#) and [MHRA](#) guidance.

Interim arrangements have been put in place for remote monitoring via EpicCare Link UCLH; monitors may conduct monitoring activities remotely, however **all** of the below conditions must be put in place:

#### Regulatory requirements for remote monitoring:

- Remote monitoring is in reference to the review of electronic patient records via **EpicCare Link UCLH only**. It is **not** permissible to send scanned paper medical notes/work sheets containing patient identifiable information externally, as this is in breach of GDPR and UCLH Information Governance requirements.
- **Anonymised scanned/electronic patient documents:** this is the decision of the Principal Investigator (and sponsor, where applicable); it is anticipated that scanning of source documentation will create a significant administrative burden to UCLH study teams, therefore it is the Principal Investigator's decision as to whether the anonymising and scanning of source documents for monitoring purposes is appropriate, and to communicate this to the sponsor.
- Monitors must take adequate measures to ensure patient confidentiality is maintained at all times, and reviewing of patient records is not conducted in public spaces or other locations where others who are not authorised could view sensitive information. If these assurances cannot be provided, remote monitoring should not be conducted.
- Any personal devices (e.g. laptops) used to access EpicCare Link must have adequate security and firewalls installed, as well as antivirus, internet security protection, secure log-in and passwords, and must not be left unattended and accessible.
- Any protocol deviations, violations or breaches must continue to be reported as per standard processes (refer to the UCLH [SOP for Reporting and Managing Incidents and Events in Research](#) and sponsor SOPs).

#### Actions for requesting EpicCare Link remote monitoring access:

- Monitors must complete the '*Remote Monitoring – UCLH Research Monitors Code of Conduct*' (Version 3, 28/10/2020) document (available on myUCLH Research page: <https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=10586>). Submission of the 'on-site' template will **not** be accepted for this purpose, and will be rejected.

- Where possible, UCLH study teams should indicate in their IT ticket that the account request is for remote monitoring only, and not on-site monitoring.
- Monitor accounts will last for the duration of the monitoring visit (currently maximum 4 days), however access remains restricted to the hours of 8.30am – 5.30pm (GMT/BST), Monday to Friday. UCLH study teams are permitted to release patient records for the duration of the monitoring visit, rather than on a day-to-day basis.
- Otherwise, the guidance for requesting/extending a monitor EpicCare Link account as per the *UCLH Standard Operating Procedure for Research Monitor Access to UCLH EHRS (EpicCare Link UCLH)* (available on myUCLH or request from JRO) should continue to be followed.

Practical requirements for remote monitoring:

- EpicCare Link UCLH web address is:  
[https://epiccare.uclh.nhs.uk/Carelink/common/epic\\_login.asp](https://epiccare.uclh.nhs.uk/Carelink/common/epic_login.asp).
- Monitors are encouraged to use the latest version of the **Mozilla Firefox** browser, to avoid any login issues (Internet Explorer is known to have compatibility issues with EpicCare Link).
- Monitors should liaise with their UCLH study team contact if they have any issues with using EpicCare Link UCLH.
- **Under no circumstances** should monitors attempt to request accounts themselves via UCLH IT Services. These will be rejected and referred back to the UCLH study team contact.

Please note these are **interim** arrangements in response to the impact of COVID-19 on research at UCLH. **If remote monitoring is not pragmatic and the above conditions cannot be guaranteed, the JRO recommends that monitoring activities are postponed until an on-site visit is allowed.** The upcoming *SOP for on-site External Research Visits during COVID-19* should be followed when live within the Trust (will be made available on the SOP pages on myUCLH Research when safe to resume, and national lockdown restrictions are lifted).

As the situation is constantly evolving, UCLH research staff and sponsors are encouraged to frequently refer to the JRO website and myUCLH Research pages for current guidance.

If you have any questions or issues, please email [research-incident@ucl.ac.uk](mailto:research-incident@ucl.ac.uk). If you have any questions specific to your EpicCare Link monitor accounts (e.g. login/password issues, access restrictions, etc.), please email: [uclh.ehrs.researchstudies@nhs.net](mailto:uclh.ehrs.researchstudies@nhs.net).