

## 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. Effective immediately, **no onsite monitoring or auditing visits should be conducted at UCLH until further notice**.

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 only permitted for current studies where patients have **consented for the sharing of their personal information outside of the research site**. If patients have not explicitly consented to this, and it is not transparent in the Participant Information Sheet(s), remote monitoring should **not** be conducted.
- 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. If these assurances cannot be provided, remote monitoring should not be conducted.
- 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 1, 16/03/2020) document (available on myUCLH Research page: <https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=10586>); any previously completed codes of conduct are **not** accepted for remote monitoring, and account requests will be rejected until this has been provided.

- 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), 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:

- 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.

Please note these are **interim** arrangements in response to the impact of COVID-19 on research in the coming months. **If remote monitoring is not pragmatic and the above conditions cannot be guaranteed, the JRO recommends that monitoring activities are postponed until on-site monitoring is allowed.** On-site monitoring (and requirements) will resume once appropriate; UCLH research staff and sponsors are encouraged to frequently refer to the JRO website for further guidance.

If you have any questions or issues, please email [research-incidents@ucl.ac.uk](mailto:research-incidents@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).