Guidelines 01: External Monitor Access to Sunrise EPR

Facilitating signing of agreement for new trials in set up

During site selection for a study access to medical records will be discussed; Sponsors or Sponsor representatives will be informed that viewing E-patient medical records on Sunrise EPR is permitted and will be provided with the following information. Access for external monitors will be *read only* but not restricted to research patients only. Sponsor representatives will need to sign an agreement to confirm they will only access records from trial patients. An audit trail will be used to ensure compliance with this.

Once we have been site selected, the Research Portfolio Manager responsible for the trial set up will ensure the e-patient medical records monitor access agreement is signed. The agreement will be found in the following location EPR Agreement for signing.docx

Facilitating signing of agreement for trials already open and being externally monitored

When the Research Nurse (RN)/Research Coordinator (RC) /Research Support Officer (RSO) is arranging a monitoring visit with an external monitor who has not previously had Sunrise EPR access granted, accessing e-patient medical records must be discussed. This may entail an update to the initial paperwork supplied regarding source data access. The RN/TC/RSO will ask the monitor the sign the agreement confirming they will only access records from trial patients.

On receipt of a signed agreement

Once the signed agreement is returned by the external monitor, this agreement will be stored in the following location on the RDSU drive [Signed External Monitor Agreements](#). The agreement will be listed using the external monitor's name and name of the trial, for example John Smith Watermelon.

Arranging and receiving access to Sunrise EPR system for external monitors

The EPR and IT teams require notice to set up this access, no later than 14 working days prior to the monitoring visit. Access currently can only be requested by Chris Ford, please email chris.ford1@nhs.net with the following details; please title the email external monitor access request for EPR. Once the process has embedded IT governance will allow more requestors.

New Starters First Name

New Starters Surname

New Starters Start Date

New Starters Site (e.g.CGH/GRH)

Organisation for example Pharmaceutical Company, Novartis

The Sunrise EPR team will liaise with IT Governance and IT new accounts team to organise access for the monitor. We will receive IT log-in information for the external monitor to use via email. This access will be active for 90 days; after this point the monitor with assistance from the delivery team will need to telephone the IT service desk, stating their username and ask for a password reset.

Once it is known the monitor will not be visiting again access rights will need to cease. Please inform the IT service desk using the email account ghn-tr.ITServiceDesk@nhs.net stating the username and that this access should be removed as it is no longer needed. Please inform the R&D generic email account ghn-tr.glos.rdsu@nhs.net when access is removed. This will be logged by the Research Support Officer in the EPR IT access table found in the following location [EPR IT access table.docx](#)

As part of the monitoring visit responsibilities please ensure the monitor is shown how to access Sunrise on first use. This will ensure the visit is conducted successfully and prevent accidental accessing of records. Please ensure all patients due to be monitored are recorded on the monitor access log at the time of the visit Monitor

access log.docx and emailed to the R&D generic email account at the same time as forwarding the monitoring report. The Research Support Officer will file the completed log in the completed monitor access log file Completed monitor access logs filing under trial name and date of monitoring visit. This will be a restricted access folder, as it will contain patient identifiable data.

If monitors inadvertently access the wrong patient this should also be recorded at the time of incident on the monitor access log. The incident should be reported within 24 hours to the R&D generic inbox ghn-tr.glos.rdsu@nhs.net and Chris Ford chris.ford1@nhs.net to ensure this highlighted prior to auditing. Please ensure all monitors are aware of the need to inform the research team if they have inadvertently accessed the wrong patient at the time of the incident.

Auditing external monitor access

Audits will occur every quarter and are requested currently by Chris Ford. A request for an audit will be made to the IT governance team and the quarterly report will be discussed at the SMT governance meeting the subsequent month.