**Background**: Externally sponsored clinical trials at the University of Kentucky, per contractual relationship and terms, may be monitored periodically by the sponsor or specified third party (“research monitor”). The research monitor reviews study regulatory documents, source documents, and site study data to ensure the investigator is abiding by the study protocol requirements and adhering to good clinical practice (GCP) and regulatory requirements. Source documents include, but are not limited to, original or certified copies of clinical patient charts, pharmacy dispensing records, and imaging. At UK HealthCare (UKHC), patient clinical records are currently housed in electronic medical records (EMR), specifically Sunrise Clinical Manager (SCM) and Allscripts Electronic Health Records (AEHR).

**Purpose**: This process document outlines the UKHC institutional expectations for ensuring standardized procedures by which clinical research study teams request EMR access for research monitors, expectations for communication, and review and audit processes related to this access.

**Process**:

1. **Request Access:** At least two weeks prior to the need for remote EMR access to be available for the research monitor, the study team representative must submit the following forms to the Provider Portal team via email to Liz Robertson at **lizcolumbia@uky.edu****.**  See Appendix A.
	1. **UKHC Research Monitor Request Form for Remote View Access to Electronic Medical Record via Provider Portal;** and
	2. **UKHC Research Monitor Confidentiality Agreement for Remote Access**
2. **Linkblue ID:** Per current University of Kentucky duo authentication procedures, EMR access will require a linkblue ID for each individual receiving EMR access. The Provider Portal team will coordinate with the UKHC Identity and Access Management team (IAM) to determine if a linkblue ID has already been issued to the individual for which access is being created. If no existing linkblue ID is located, a new one will be created.
3. When a temporary UK ID# is created, Provider Portal team will notify the study team representative and the Office of Corporate Compliance Privacy team via email.
4. It is the responsibility of the study team representative to contact the research monitor with instructions for [activation of the linkblue ID](file:///%5C%5Cukhcdata%5Cdept%5CEVPHA%20Administration%5COfficeofCorpComp%5C%40Corporate%20Compliance%5CAnne%5CClinical%20Research%5CRemote%20Monitor%20Access%5Cactivation%20of%20the%20linkblue%20ID) (<https://newemployee.uky.edu/Account/NewEmployee>). An example memo is included as Appendix B.
5. **Training Requirements:** The research monitor must complete the [Provider Portal 2.0 training](https://ukhealthcare.uky.edu/medical-professionals/physician-portal) before gaining access to the EMR.
6. UKHC Office of Corporate Compliance Privacy Team may generate an audit report of the research monitor access upon request of the study team or as a matter of a routine audit. If a research monitor is found to violate appropriate access of permitted patient records, the Privacy Team will take any further action necessary per audit findings, including but not limited to revocation of research monitor access.

**Provider Portal Access Exceptions:**

The below listed areas are not currently accessible via the Provider Portal.

* Ophthalmology
* Dentistry
* Cath Lab
* Imaging (reports are available in the medical record while images are not)
* Manometry

If research monitor access is needed for these areas, the study team may utilize the following methods to assist with remote monitor access to review applicable patient medical records on a case-by-case basis via one of the following approved methods:

* **Zoom meeting** (either UKHC HIPAA compliant platform or UK campus platform)
	+ Must create unique meeting ID for each session
	+ Must utilize unique password for each session
* **Secure email** (You must type #Secure or #Encrypt at the beginning of the subject line)
* **Microsoft Teams**: create a private site with guest access for the research monitor

**APPENDIX A**

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**APPENDIX B**

**Example communication from study team representative to research monitor:**

Date: Month Day, Year

To: Name, Research Monitor Title

From: Name, Study Team Representative Title

**RE: Your Individual Remote Access to UK HealthCare Electronic Medical Records**

Please find below your individually assigned UK ID# and user name. This information is necessary to set up access to our electronic medical record systems: Sunrise Clinical Manager (SCM) and Allscripts Electronic Health Records (AEHR) via the Provider Portal.

12345678 UKID

Jzr230-username

You will need to complete the setup of your linkblue ID and password at <https://newemployee.uky.edu/Account/NewEmployee> or call our help desk at 859-323-8586 and they will assist you in completing that process. You will use the provided temporary passcode at initial login.

In order to be able to use the Provider Portal you will need to complete a training video that gives you a brief overview of the system and how to use it. The below link is to a YouTube video created for this purpose:

[Provider Portal 2.0](https://ukhealthcare.uky.edu/medical-professionals/physician-portal)

If you have technical questions regarding any of the above, please call our help desk at 859-323-8586. I may be reached at 859-XXX-XXXX for other issues.