

DRAFT – For Discussion Purposes Only

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.
 - a. **UKHC Research Monitor Request Form for Remote View Access to Electronic Medical Record via Provider Portal;** and
 - b. **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.
 - a. 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.
 - b. It is the responsibility of the study team representative to contact the research monitor with instructions for [activation of the linkblue ID](#) (<https://newemployee.uky.edu/Account/NewEmployee>). An example memo is included as Appendix B.
3. **Training Requirements:** The research monitor must complete the [Provider Portal 2.0 training](#) before gaining access to the EMR.

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4. 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

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APPENDIX A



Complete and return: Fax: 859-257-4148 Email: lizcolumbia@uky.edu	Research Monitor Request Form Remote View Access to Electronic Medical Record via Physician Portal	Please Note: Information must be completed for processing. Please type or PRINT clearly.
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Date: _____ (mm/dd/yyyy) Your Date of Birth: ____ / ____ / ____

Previous UK Student or Employee: ☐ Yes ☐ No If yes – previous name: _____

Previous UK Portal Access: ☐ Yes ☐ No If yes – previous facility name: _____

Name: _____ ☐ M ☐ F

First M.I. Last

Email Address (REQUIRED) _____

IRB Number: _____	
Study Name: _____	
Department: _____	Building: _____
Phone: _____	Fax: _____
Study Team Contact Name: _____	
Study Team Contact Email: _____	Phone: _____

Remote View Access Services for Research Monitors via Physician Portal - Disclaimer

- The UK HealthCare Physician Portal is designed to provide a single point of access to information, tools and services specifically for the needs of referring providers. I will only look up information on patients for whom I have permission.
- The UK HealthCare Physician Portal is a private, secure network available only to authorized users. All users must register to receive a personal user ID and password, issued by UK HealthCare Information Technology Services.
- You assume full responsibility for using the information on the portal, and you understand and agree that UK HealthCare and its affiliates are not responsible or liable for any claim, loss, or damage resulting from its use by you or any user. UK HealthCare does not warrant that access to the portal will be error or virus-free.
- By choosing to use the UK HealthCare Physician Portal you acknowledge and agree to the terms of this Disclaimer. We reserve the right to modify these terms and policies at any time.

Your

Signature : _____

Approval is Required from Principal Investigator:

Principal Investigator Name (PRINT): _____

Principal Investigator Signature: _____

Principal Investigator Phone: _____

Principal Investigator Email: _____

**Complete both pages and return to Liz Robertson, lizcolumbia@uky.edu or fax to
859-257-4148. Please call 859-323-0736 with any questions.**



Research Monitor Remote View Access
for Electronic Medical Records via Provider Portal
Process Document

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Complete and return: Fax: 859-257-4148 Email: lizcolumbia@uky.edu		Please Note: Information must be completed for processing. . . Please PRINT clearly.
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Research Monitor Confidentiality Agreement

Name: _____
First M.I. Last

Date of Birth: ____/____/____ UKID: _____
mm /dd/yyyy To be completed by UKHC IT

I agree to keep UK HealthCare patient information confidential by observing the following:

1. I will protect my password from use or theft by others.
2. I will sign off the system when I leave my workstation and not allow others to use my access.
3. I will only look up information on patients for whom I have permission to view.
4. I will not look up my own medical information.
5. I will share patient information only with people who have a right to access the information in order to perform their job function.
6. When sharing information with people who have a right to access the information in order to perform their job function, I will ensure that I am in a private setting where others can not hear or see the confidential information.
7. I will password protect my personal digital assistant device that contains patient (or confidential) information.
8. I will not disseminate confidential information without appropriate authorization for release of information.
9. I will dispose of confidential information properly in accordance with all applicable policies.
10. I understand that audits will be performed on electronic medical record access to ensure compliance with this confidentiality agreement.
11. I understand that UK HealthCare has the right to take appropriate action up to and including termination of my access for breaches of misuse of Protected Health Information.

Please initial you have read and agree: _____ Date: _____

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UK HealthCare Information Security Research Monitor Portal Access Request Form

Guidelines for completing Research Access Request Form:

Date is the current date or the date form completed.

Date of Birth is your date of birth, month, day, year.

Name should be your full legal name, not a nickname.

Previous UK Student or Employee: Check yes or no appropriately.

If yes, previous name: any maiden name, if applicable.

Previous UK Provider Portal Access: Check yes or no appropriately.

Email is the email address of the Research Monitor requesting access. Email is required.

IRB Number is the unique number assigned to the study by the IRB of record.

Study Name is the name of the Study being monitored.

Department is the printed name of the department of the person signing the request.

Building is where department is located. (ie: HOSP = 4N, Wethington Bldg. Room 222.)

Phone is the number where Research Monitor can be reached.

Should be a direct line, preferably a cell phone - not the public number for the department.

Fax is the fax number where the user can be reached, if applicable.

Study Team Contact Name: Name of contact person on study team.

Study Team Contact Email: Email of contact person on study team.

Study Team Contact Phone: Direct line of contact person on study team.

Your Signature: **Your signature is required to obtain access.**

Principal Investigator Name is the printed name of the person who signed the request and authorized the user's access.

Principal Investigator Signature: **Principal Investigator Signature is required to obtain access.**

Principal Investigator Phone: Direct line of Principal Investigator.

Principal Investigator Email: Email of Principal Investigator.

Liz Robertson will email the user LogonID and password upon completion from UKHC IT Security & Identity Access Management.
If your request is urgent, please contact 859-323-0736.

Periodic reports of Research Monitor access will be created and passed to the Principal Investigator to verify appropriate access by the monitor. Inappropriate access must be reported to the UK HealthCare Privacy Officer at 859-323-8002.

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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](#)

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.