Category: CoM- Office of Clinical Research (OCR) **Applicable for:** CoM Clinical Research Professional Faculty and Staff	**COLLEGE OF MEDICINE** **Operating Procedure/Guideline** **Access to Electronic Medical Records by Study Monitors, Auditors, and External Research Staff for the Purpose of Human Subjects Research (EpicCare Link)** **Effective Date: 06/01/2023** **Prior Effective Date: 06/01/2023**	**Document Owner:** CoM Office of Clinical Research Compliance Administrator **Responsible Office(s):** CoM Office of Clinical Research **Disseminated:** Office of Clinical Research 06/01/2023

Background

This document details the procedures by which requests are made for study monitors, auditors, and regulatory auditors, and access is granted to electronic medical records (EMR) and research study information of individuals enrolled in IRB approved research studies at UC Health. This is a system-wide standard operating procedure that applies to clinical research conducted in the facilities of University of Cincinnati (UC) and affiliated facilities (UC Health, LLC, University of Cincinnati Physicians Company {UCPC}, LLC) and all University of Cincinnati and UC Health Clinical Research Professional Staff that conduct clinical research in these facilities.

Guidelines

The purpose of this SOP is to define the process for study monitors and auditors, along with regulatory auditors to obtain appropriate access to EMR and research study information for the purpose of clinical research.

Definitions:

Study Monitors and Auditors: Individuals contracted by an external research Sponsor or Contract Research Organization (CRO) to oversee the progress of a clinical trial. Their responsibilities include the review of EMR and research study information to ensure the study is conducted and data are handled in accordance with the protocol, good clinical practice (GCP), and applicable ethical and regulatory requirements.

Regulatory Auditors: Auditors representing a federal, state, or other regulatory organization whose responsibility is to review and audit clinical research for compliance. Examples include but are not limited to the Food and Drug Administration (FDA), National Science Foundation (NSF), and the National Institutes of Health (NIH).

Epic: UC Health's electronic medical records (EMR) system.

Inspector's Key: A letter produced by the UC Health Medical Records Department containing a username and password to securely access specific record requests in Epic.

EpicCare Link: Epic's web-based application, which provides community and external users secure access

to select patient information. It is a read-only application and will deliver study participant information to Sponsors and CROs for the purpose of monitoring and auditing patient records and research study information.

Research Site Administrator: The University of Cincinnati or UC Health research individual with approval or requesting account setup approval to facilitate access to EpicCare Link for monitors, auditors or IRB approved external researchers. This individual can serve in the oversight role or as a backup administrator.

CWMS number and Icertis Agreement Code: A CWMS number is a unique identifier generated by CWMS that was assigned to any contract in CWMS, which remains with the contract throughout it's life cycle. Icertis is the new contract management system to which EpicCare Link agreements will be submitted as of April 24, 2023. An Icertis agreement code will be generated instead of a CWMS number moving forward.

Mandatory Site Verification: The process by which the Research Site Administrator verifies if auditors and monitors still require access to EpicCare Link. Once a quarter, this verification is required by accessing the EpicCare Link platform. If this process is not completed, access to Epic is terminated until the verification is finalized.

Process

Access Via UC Health Medical Records Department

- The Principal Investigator (PI) and/or designee will submit a written request on behalf of the monitor, auditor or an IRB approved external researcher per the Medical Record Research Request Form to the Medical Records department at least 10 business days prior to the anticipated need. Shorter time frames will be permitted in the case of regulatory auditors. This request will describe the specific records requested to be prepared for review.

- The request will be submitted to the following Medical Records department common mailbox for review and approval: Research-Record-Req@UCHealth.com

- The PI and/or designee will receive a response indicating the records have been prepared and set up under the Inspector's Key along with the username and password for access within 10 business days of the Medical Records Research Form submission.

- Requests for regulatory auditor access to medical records will be submitted to the Medical Records department utilizing the Medical Record Research Request Form. These specific requests will be fulfilled based on the period required by the regulatory auditor.

- Access will be limited to only subjects enrolled in the IRB approved clinical research and for the maximum time frame required for completing the review.

- Access will be limited to individuals who have been assigned a temporary username and password via the Inspector's Key with the approval of the PI and/or designee.

- The username and password will be active for the duration of the monitoring/auditing visit.

- Documentation of access may be compared to the audit trail within the electronic medical record to verify what records have been reviewed.

Access Via UC Health EpicCare Link

- EpicCare Link is a feature of the UC Health EMR. Only IRB approved studies can be monitored through the use of EpicCare Link. Access to EMR for auditing and monitoring purposes is required and remote monitoring is an IRB and FDA approved method. EpicCare Link may be accessed for recruitment purposes as well and will follow the same process below.

- An EpicCare Link Agreement for Access to Protected Health Information must be executed prior to allowing external entity access to EpicCare Link. This agreement is at the company level between the external entity and UC Health for the sole purpose of the use of EpicCare Link regardless if the study contract is with UC Health or University of Cincinnati (UC).

    - Only one agreement is required at the company level, and can apply to remote monitoring using EpicCare Link for multiple studies the external entity may have open at UC Health or UC, regardless of those studies being housed in different departments. e.g.: An EpicCare Link UC Health Confidentiality Agreement is executed and finalized between "Company X" and UC Health. "Company X" has Study A with our Neurology department. "Company X" also has Study B with our Internal Medicine department. EpicCare Link Remote monitoring for both studies A and B, is able to be requested utilizing the same existing EpicCare Link UC Health Confidentiality Agreement between "Company X" and UC Health, and do not need separate agreements per study. Further information can be found at: Remote Monitoring (EpicCare Link)

        - Please send the agreement template to the outside entity for review and signature. If direct coordination between the OCR Contracts team and the outside entity is desired, please provide the OCR Contracts team with the contact information of the appropriate representative for the outside entity.

        - Once the outside entity has responded with the signed EpicCare Link UC Health Confidentiality Agreement, please contact the OCR Contracts team at UCP-ClinicalTrials@uchealth.com to have the executed agreement uploaded to CWMS or Icertis as of April 24th, 2023. The agreement will be assigned a CWMS number or an Icertis Agreement Code as of April 24th, 2023. Please keep record of this number or code, as it will be requested in the next steps of the process.

    - Once the agreement is executed or if a new agreement is not needed, the submitter will find additional information on next steps on the UC Office of Clinical Research College of Medicine Bearcats Landing Webpage

- The department research coordinator, Manager, Director or designee, will submit a request to serve as a Research Site Administrator and/or Research Coordinator by placing a footprints request, and attaching the EpicCare Link Research Site Administrator Access Request Form. This is required prior to allowing access for the monitor, auditor, or IRB approved external researcher, and can be one or two different researchers.

- The OCR will approve the request which notifies IS&T. The Research Site Administrator/Research Coordinator request will be completed by the UC Health IS&T security team, who will send notification to the OCR and requester when approved.

- The Research Site Administrator then contacts the external requester, collects the necessary information and then completes the online Research Study Monitor Access Request Form. Please see attached guidance document for more information.

- The Research Monitor will then be registered in the EpicCare Link system.

- The monitor will have access to study specific patient information for a designated time frame only.

- EpicCare Link requires Site Verification to be performed quarterly by Site Administrators during the months of February, May, August and November. The Site Verification begins on the 1st of the month and ends on the 28th of the month. Verification is required by the Site Administrator and is completed within the EpicCare Link online platform.

Key Words

- Medical Records
- EpicCare Link
- Investigator's Key
- Site Administrator
- Monitor
- Auditor
- External Researcher
- Agreement for Access to Protected Health Information

Related Documents / Appendix

- A1 Medical Record Research Request Form (to be sent to medical records)
- EpicCare Link Research Site Administrator Access Request Form (completed by Site Administrator)
- EpicCare Link Release of Information Instructions
- UCMC-HIM-SOP-001 Access to EMR By Study Monitor and Auditors