



Electronic Medical Record Access for Research Monitors/Sponsor Auditors

Established: 1/15/2015

Responsible Office: Epic Research, epicresearch@smtp.musc.edu

Latest Version: 1/15/2020

Summary

This policy describes the process approved at the Medical University of South Carolina (MUSC) for requesting and obtaining access to Epic, the electronic medical record (EMR), for external research monitors/sponsor auditors.

Policy

POLICY STATEMENT

The purpose of this policy is to:

- a) to define those individuals, by role, who require access to the patient EMR at MUSC
- b) to define the restricted access that will be granted for the purpose of research monitor/sponsor audit visits; and
- c) to define how the process of determining eligibility for access and for granting access will be implemented.

RESPONSIBILITIES:

The Epic Research team and MUSC Research Personnel are responsible for ensuring compliance with and implementation of this policy.

Function

Responsibilities

Epic Research Team

Builds patient group in Epic and links research study to that patient group. Monitors and reviews requests for research monitor access and, when applicable, creates a Research Monitor User ID in Epic and assigns the appropriate patient group(s) to the monitor. Sends research monitor notice of their user account and temporary password along with instructions regarding their access. Notifies study team that research monitor set up has been completed. Inactivates accounts when necessary.

MUSC Research Personnel

Requests research monitor access through Epic Carelink. Completes requests for additional studies to be linked to the research monitor's Epic account. Releases study participant records to research monitor.

MUSC University Compliance

In conjunction with the Epic Research team reviews monitor access in Epic Carelink for inappropriate use.

POLICY:

A. Individuals by job function or title who require access to the EMR at MUSC are as follows:

1. Research monitors/sponsor auditors, performing remote or in-person visits with advanced notice, who are employed or contracted by an entity under contract with MUSC to ensure that the data being recorded and submitted to the entity by MUSC research staff is complete and accurate.

B. Research monitors/sponsor auditors will be granted limited access to the EMR, with access to only the records of patients that signed consent for the specific trial being monitored/audited. Although the research monitors/sponsor auditors are limited to which patient charts they can access, once inside a patient chart they will have access to that patient's entire chart for the purposes of conducting their job duties.

PROCEDURE

The process of determining eligibility for access and for granting access will be implemented as follows:

1: Upon receiving notification that a monitor will require EMR access, MUSC research personnel (e.g. coordinator) requests monitor account access at <http://muschealthcarelink.com>, and agree to the MUSC Study Team Terms and Conditions making them the institutional sponsor for the monitor.

A. Upon visiting the link above, MUSC research personnel clicks "Request New Account" link and selects "Research Monitor – Request access for a Research Monitor" completing the research monitor request form.

2: Epic Research team receives request and confirms that all required information has been provided.

3: Epic Research team, upon confirmation of required information, creates a User ID for the research monitor

A. Naming convention = RM+number

a. If the user had previous Epic Access, they will still need to have a new user created since the old user is tied to a netID and the Epic Research Team cannot make changes to that system.

4: Epic Research team adds the appropriate patient group to the research monitor, completes set up and confirms the correct user template was assigned

A. The patient group name (created with STUDY + SPARCRequest number) should match the site information that was added by the study team in the research monitor request form. If it does not, then the Epic Research Team will deny the request and contact the study team to resubmit with the correct information.

5: Epic Research team assigns temporary password and requires research monitor to change password upon first logging into Carelink.

6: Epic Research Team emails the research monitor the user name and password that was created for them, as well as the Research Monitor Tip-sheet that will walk them through how to use the MUSC Carelink portal to complete their review.

A. The Epic Research Team will also notify the Point of Contact for the study team to let them know that the research monitor access has been set up and the research monitor was contacted with login information and instructions.

7: MUSC Research Personnel will release study participant records to an external research monitor.
(see "Releasing study participant records to an external monitor").

8: Monitor/auditor will log into the MUSC Carelink system using the login information that was sent to them by the Epic Research Team.

- A. The first time the monitor logs in, they will be asked to:
- Agree to the research user/monitor terms and conditions.
 - Change their password to be one that only they know – and not the one created for them by the Epic Research Team.

10: Once they are completely logged into the system, the research monitor can review all participants' charts that have been released to them by clicking on either the Patient Lists tab or the clinical review tab at the top of their Carelink window. Monitor/auditor will have access ONLY to patient charts in pre-created list that have been shared with the monitor by the study coordinator.

11: Both the MUSC University Compliance office and the Epic Research team will be reviewing the research monitor activity in the MUSC Epic Carelink system. If a monitor prints records or violates the terms and conditions, their access will be withdrawn.

DURATION AND TERMINATION OF ACCESS:

Once the date passes set by the research study team (step 3 of Releasing study participant records to an external monitor) the external research monitor will no longer have access to the records. If all records have expired, the monitor will still be able to log into Carelink, however there will be no patients or data for them to view. Monitors who do not access the MUSC Epic Carelink system for more than 6 months will have their accounts inactivated by the Epic Research Team. Monitors who do not have access reactivated for them 6 months past inactivation will be deleted from the system.

- A. Should access need to re-instated, the research study team would have to request new access for the monitor and new log in credentials would be generated by the Epic Research Team.

B. All access to the MUSC EMR will be terminated if an individual:

- is no longer employed or contracted by the entity under contract with MUSC;
- completes all monitoring/auditing duties on assigned trials under contract with the sponsor; or
- violates MUSC policy or otherwise accesses, uses or discloses MUSC protected health information inappropriately;
- prints records or violates the terms and conditions
- MUSC may terminate access at any time at its own discretion.

C. Procedure

Epic Research Team will be notified by MUSC research staff, Legal, Compliance, OCIO, or other MUSC personnel as appropriate for timely termination of the monitor/auditor access.

Contact Information

For information regarding the overall policy and related documents, please contact Epic Research team.

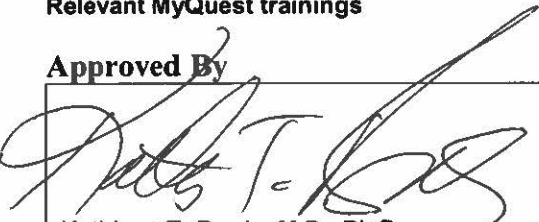
Related Information

Relevant MyQuest trainings

Approved By

Information Contact

Effective On:

 Kathleen T. Brady, M.D., Ph.D. Vice President for Research	Epic Research Team	Version 1: January 15, 2015 Version 2: April 7, 2015 Version 3: October 21, 2015 Version 4: December 28, 2017 Version 5: January 15, 2020
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