



# Electronic Medical Record Access for Research Monitors/Sponsor Auditors

**Established:** 1/15/2015  
**Responsible Office:** SCTR SUCCESS Center (842-792-8300, success@musc.edu)  
**Latest Version:** 10/21/15

## 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 Health Information Management (HIM) Analyst, the Enterprise Security System Analyst, and MUSC Research Personnel are responsible for ensuring compliance with and implementation of this policy.

Function	Responsibilities
HIM Analyst	Review request for Non-MUSC NetID and, when applicable, grant restricted NetID and temporary password and notify study team that the NetID has been issued.
The Enterprise Security System Analyst	Grant EPIC (EMR) restricted access template to NetIDs listed in HR database as "Research Monitor"
MUSC Research Personnel	Coordinate completion of Non-MUSC NetID application, submission of the application to HIM analyst. Create and share the appropriate patient list in the EMR with the research monitor/sponsor auditor. Notify University Compliance of names and dates of each study monitor visit to initiate HIPAA access audit and, post-monitoring visit, review/verify audit report from compliance.

## **POLICY:**

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

1. Research monitors/sponsor auditors, visiting campus with advance 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) provides monitor with the "External Research Monitor/Sponsor Auditor Agreement"

- a. MUSC research personnel completes applicable portions of the form before passing the form off for completion and signature by the monitor. (see form)

2: Research personnel (e.g. coordinator) sends "External Research Monitor/Sponsor Auditor Agreement" form to HIM analyst to request unique NetID and temporary password for each external research monitor.

3: HIM Analyst reviews the form and, if appropriate, assigns a restricted NetID account ("UNIV Sponsorship: Contractor – Research Monitor, No CATTs training, no email) to the research monitor, recording the NetID with the title "Clinical Trial Monitor" (to be cross-checked by EPIC security in Step 6) in the RA portal. The RA portal automatically generates and sends two secured, encrypted emails directly to research monitor (one containing the NetID and one containing the temporary password)

- a. Maximum account duration without an approved extension will be one year.

4: HIM analyst emails the study coordinator with the reach monitor's assigned NetID and emails the research monitor directly with instructions on how to change their temporary password.

5: HIM analyst calls IT help desk and notifies them to submit a remedy ticket for an Epic Security account request for the monitor's NetID to be assigned the MUSC RESTRICTED ACCESS USER (30482100) template.

6: When the Epic security team receives the remedy ticket, an Enterprise Security team system analyst verifies that access role requested is the role that is assigned to that NetID in the HR database. Upon confirmation, the system analyst will create the monitor/sponsor's EPIC account assigning the following template MUSC RESTRICTED ACCESS USER (30482100).

7: The MUSC research personnel (e.g. coordinator) logs into his/her EPIC account and creates patient list to be shared with the research monitor/sponsor auditor by assigning the monitor (by NetID) as a "VIEW ONLY" user of the list (see "Instructions for Creating and Sharing Patient Lists In EPIC").

8: Upon arriving to campus, monitor/auditor reviews the "View-Only Restricted Access Template EPIC Training for External Users".

9: Monitor/auditor joins the "MUSC guest" wireless network, and accesses WebApps using their NetID and password, and clicks on the EPIC icon on the WebApps dashboard to enter the EMR.

10: Monitor/auditor will have access ONLY to patient charts in pre-created list that have been shared with the monitor by the study coordinator.

**DURATION AND TERMINATION OF ACCESS:**

**A. NetIDs will be issued for the length of commitment indicated on the “External Research Monitor/Sponsor Auditor Agreement”, to a maximum length of 1 year, at which point the MUSC research personnel sponsoring the monitor/auditor will need to file for an extension of the NetID or the NetID account will become inactive and HIM will have to be notified to reset the account and issue a new temporary password.**

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

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

**C. Procedure**

HIM will be notified by MUSC research staff, legal, compliance, OCIO, or other MUSC personnel as appropriate for timely termination of the monitor/auditor NetID.

---

**Contact Information**

---

For information regarding the overall policy and related documents, please contact the SCTR SUCCESS center, (843-792-8300, [success@musc.edu](mailto:success@musc.edu)). For questions related to specific department roles/responsibilities, please contact the applicable department directly.

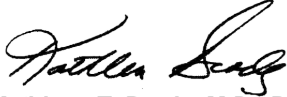
---

**Related Information**

---

**Other Documents:**

- “External Research Monitor/Sponsor Auditor Agreement”
- “Instructions for Creating and Sharing Patient Lists in EPIC”
- “View-Only Restricted Access Template EPIC Training for External Users”
- “Monitor Pre-Visit” Email Template

<b>Approved By</b>	<b>Information Contact</b>	<b>Effective On:</b>
 Kathleen T. Brady, M.D., Ph.D. Associate Provost, Clinical and Translational Science Interim Associate Provost for Research	South Carolina Clinical and Translational Research Center (SCTR) SUCCESS Center	Version 1: January 15, 2015 Version 2: April 7, 2015 Version 3: October 21, 2015