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.

<table>
<thead>
<tr>
<th>Function</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIM Analyst</td>
<td>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.</td>
</tr>
<tr>
<td>The Enterprise Security System Analyst</td>
<td>Grant EPIC (EMR) restricted access template to NetIDs listed in HR database as “Research Monitor”</td>
</tr>
<tr>
<td>MUSC Research Personnel</td>
<td>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.</td>
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</tbody>
</table>
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 logs in 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). 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

**Approved By:**

Kathleen T. Brady, M.D., Ph.D.
Associate Provost, Clinical and Translational Science
Interim Associate Provost for Research

**Information Contact**

South Carolina Clinical and Translational Research Center (SCTR) SUCCESS Center

**Effective On:**

Version 1: January 15, 2015
Version 2: April 7, 2015
Version 3: October 21, 2015
External Research Monitor/Sponsor Auditor Agreement

<table>
<thead>
<tr>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Monitor Name</td>
<td></td>
</tr>
<tr>
<td>Monitor Address</td>
<td></td>
</tr>
<tr>
<td>Monitor Phone</td>
<td></td>
</tr>
<tr>
<td>Monitor Email</td>
<td></td>
</tr>
<tr>
<td>Monitor Day/Month of Birth</td>
<td></td>
</tr>
<tr>
<td>Position/Title</td>
<td></td>
</tr>
<tr>
<td>Company/Employer</td>
<td></td>
</tr>
<tr>
<td>Approximate Length of Commitment (not to exceed one year)</td>
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Justification for Need: The above requester requires an MUSC non-employee NetID in order to monitor the study and data management for a research study being conducted at MUSC.

1. Research Monitor acknowledges that MUSC paper files and electronic medical records systems contain protected health information for all of its patients. Research Monitor agrees to only access the information deemed necessary by Research Monitor in those medical records of patients who are patients participating in an authorized study ("Study") in which MUSC participates. The study coordinator will place records of identified Study participants into a queue for access by the Research Monitor. Study Monitor may not access information of patients other than those included in the above referenced Study.

2. Information contained in the MUSC record may be disclosed only as set forth in the Clinical Trials Agreement pertaining to the applicable Study.

3. If, in connection with this Study, the Research Monitor comes into contact with individually identifiable health information relating to patients who are not Study patients or information of Study patients deemed by authorized Sponsor and Research Monitor as not necessary for the Study, Research Monitor will maintain the confidentiality of such information and not knowingly use it for any purpose. Research Monitor will also alert the MUSC Study Coordinator associated with the Study.

4. Research Monitor acknowledges that MUSC may audit access to and use of patient information by Research Monitor at any time or on an ongoing basis.

5. Research Monitor understands that the log on ID and computer password (Credentials) assigned to Research Monitor are to be used solely by Research Monitor in connection with the Study and sharing the Credentials is prohibited. Research Monitor understands that the access is temporary for the limited time of the review.
6. Research Monitor may not share or misuse assigned Credentials. Sharing or misuse of Credentials may result in termination of access to all Study patient information by Research Monitor. Research Monitor further understands that violation of this External Research Monitor/Sponsor Auditor Agreement ("Agreement") may result in Research Monitor being barred from accessing MUSC information and prosecution to the fullest extent of state or federal law.

7. If a Research Monitor permanently stops working on the Study for any reason or no longer needs access to Study information, then Research Monitor shall have the Sponsor immediately report this to the Principal Investigator.

I understand that the Medical University of South Carolina reserves the right to accept or reject my application for Credentials in its sole discretion.

I release the Medical University of South Carolina for any and all damages I may incur as a result of this Agreement.

I hereby certify that the above statements made in this application are true and accurate. I further agree to indemnify and hold harmless MUSC and its affiliates for any and all claims which may arise as a result of this Agreement.

Signature: ___________________________ Date ___________________________

The information below is to be completed by MUSC Research Personnel:

<table>
<thead>
<tr>
<th>MUSC Sponsor's Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(MUSC Sponsor is the research team member responsible for endorsing the Net ID)</td>
<td></td>
</tr>
<tr>
<td>MUSC Sponsor Phone Number</td>
<td></td>
</tr>
<tr>
<td>MUSC Sponsor Email</td>
<td></td>
</tr>
<tr>
<td>MUSC Sponsor Department Name/Phone Number</td>
<td></td>
</tr>
</tbody>
</table>

The External Research Monitor named above is a representative of an external company or organization that is currently under contract with MUSC or with a Sponsor of a study in which MUSC participates. I agree to oversee Study Monitor’s access to the medical records of Study Participant’s in accordance with the above agreement.

MUSC Sponsor’s Signature: ___________________________ Date ___________________________
Process for Providing Research Monitors with Epic Access

1) Upon notification that a research monitor will be visiting campus, have the research monitor complete the “External Research Monitor/Sponsor Auditor Agreement”

2) An MUSC research personnel assigned to the study being monitored, will sign the “External Research Monitor/Sponsor Auditor Agreement”, thereby sponsoring the external NetID request.

3) MUSC research personnel will submit signed and completed “External Research Monitor/Sponsor Auditor Agreement” to Health Information Management (HIM) Analyst (currently Lavarrick Townes, lavarric@musc.edu) by email

4) MUSC research personnel will send the monitor an email, notifying him/her that she will be receiving notification of their NetID/password from an automated email and include instructions on how to change the temporary password.
   a. Please see “Email template for Monitor Instructions”

5) After receiving notification from the HIM Analyst of the monitor’s assigned NetID, MUSC personnel will create the patient list in Epic and share the list with the monitor’s NetID, with “VIEW ONLY” permission
   a. Please see “Instructions for Creating and Sharing Patient Lists In Epic”

6) When the monitor arrives on campus, please ensure that they access the “MUSC guest” wireless network and WebApps using his/her own NetID

*Please note: University Compliance should be notified of each upcoming monitor visit prior to monitors arrival to trigger the HIPAA audit process and coordinator attestation at the conclusion of the visit.
Good Morning/Afternoon 

Your External Research Monitor/Sponsor Auditor Agreement form has been submitted to our Health Information Management (HIM) team. You should soon receive two automated emails, one containing your NetID and another containing your temporary password. The subject of these emails should read Subject: MUSC NetID Information and the sender should be From: MUSC NetID Manager. Please be sure that your email security settings will allow these emails to be received. Once these emails are received please note that the additional steps will also need to be completed to access Epic, the MUSC EMR.

1) You are required to change your temporary password to a personal password. To do so, please visit netid.musc.edu and click on “Change password”. You will be prompted to read the MUSC Computer Use Policy and indicate agreement by clicking the check-box at the bottom and entering your NetID. On the next screen, you will be asked to enter your temporary or “Current Password” and create and confirm a “New Password”.

2) When you arrive on campus, to access Epic you will have to first join the “MUSC guest” wireless network.

3) Once you have joined the “MUSC guest” wireless network, access WebApps at https://webapps.musc.edu/vpn/index.html.

4) Click the “Epic” icon on the WebApps dashboard to access the EMR.
Instructions for Creating and Sharing Patient List in Epic with Research Monitors

Step 1: Navigate to your Patient Lists activity (by the tab on your home screen or on the Epic button menu) and click on the Edit List icon (as seen below). To create a new list click the “Create My List.”

![Image of Epic Patient List interface]

Step 2: A pop-up box will open. The pop-up box will allow you to name the list as well as put in any columns that you want the Research Monitor to see to identify the patient. Note: The list shown in “Selected Columns” in the screenshot below are the only columns that will be available to view by the research monitor.

![Image of Patient List pop-up box]

**Tip:** “Available Columns” can quickly be searched by clicking within the “Available Columns” box and typing the first few letters of the desired column title.

3. To Share the list click on the “Advanced tab” at the top of the pop-up box.
Instructions for Creating and Sharing Patient List in Epic with Research Monitors

4. Set the Access Level to “View Only” for the user. **THIS STEP IS IMPERATIVE IN ENSURING THAT THE LIST IS NOT COMPROMISED IN ANY WAY.**

Click within the field under “User” and enter the name or net ID of the user you would like to share the list with. Please note the list can be shared with multiple users by repeating the aforementioned steps.

Click the magnifying glass in the field under “Access Level” to open a Category Select box. Choose “View Only” by double clicking the corresponding item title.

Once this is done hit “Accept” to create the list.

5. Add patients to the shared list.
Instructions for Creating and Sharing Patient List in Epic with Research Monitors

To add patients to the shared list click on the My List you want to share then click the “Add Patient” button at the top of the Patient Lists activity. This will open a search box in which you can search for a patient by name or MRN. Once you find the patient hit “Accept” and the patient will be added to the My List. Repeat this for all patients you want to share.

The user you have given permission to view the My List will now be able to see the patients that you have added.
View-Only Restricted Access Epic Template Training for External Users

Step 1: Login to Epic using your NetID and Password.

Step 2: Your Epic login department is “Medical Records.” If a stop sign appears in the department field click on the magnifying glass to open up a department search box where you can select “Medical Records.”
Step 3: Your screen will automatically open to patient lists where you can view only the patients that have been shared with you by the study team. If there are any patients you wish to see that have not been provided in the list please contact your study coordinator. To view a patient double click on their name.

Step 4: The patient’s chart will open and you will have access to the Patient Summary as well as the Chart Review activity.

Patient Summary:
# Chart Review

<table>
<thead>
<tr>
<th>Admit Date</th>
<th>Admit Time</th>
<th>Discharge Date</th>
<th>Discharge Time</th>
<th>diagnosis/condition</th>
<th>Unit</th>
<th>IME</th>
<th>Lab</th>
<th>Radiology</th>
<th>Other Notes</th>
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<tr>
<td>1984-01-03</td>
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</tr>
</tbody>
</table>

**Other Details**

- **Admit Date**: January 1, 1984
- **Admit Time**: 12:00 PM
- **Discharge Date**: January 5, 1984
- **Diagnosis/Condition**: Unknown
- **Unit**: Unknown
- **Lab**: Unknown
- **Radiology**: Unknown
- **Other Notes**: Unknown