I. 13.1.2 Access to Patient Electronic Medical Records by Research Sponsor Monitors

Chapter 13 - Clinical	Original Effective Date: November 2013
Section: 13.1 Clinical Procedures	Date Last Reviewed: November 2020
Responsible Entity: Vice Dean for Clinical Affairs on behalf of Vice President for Medical Affairs	Date Last Revised: November 2020

II. Purpose

The purpose of this Policy is to facilitate appropriate and secured access to the Electronic Medical Records (EMR) of patients enrolled clinical studies for Research Sponsor Monitors (Monitors).

III. Scope

This Policy applies to all Monitors who are performing in an official capacity to review records of patients who are enrolled in clinical studies sponsored by the Monitor's organization.

IV. Policy

The University of Texas Health San Antonio (UTHSA) allows onsite and/or remote access to Monitors to access the EMR. Such access is granted within the framework of the following provisions:

A. Monitors are allowed temporary view-only access to EMRs of patients participating in research studies sponsored by the Monitor's organization.

B. Monitors may only view records for patients authorized in this policy. Extracting, copying, or capturing EMR data is not authorized.

C. Monitors must complete the following as part of the process of requesting system access, in accordance with UTHSA policy.

1. Review and sign the Confidentiality/Security Acknowledgment which is maintained by the sponsoring UTHSA department.
2. Monitors conducting monitoring activities on-site at UTHSA must obtain a "person of interest" (POI) designation and criminal background check if their on-site visit will be conducted for more than three (3) consecutive days per Institutional Handbook of Operating Policies (IHOP) policy 8.7.11 Contractors and Vendors.

D. Monitors may conduct remote access monitoring. Remote access to the EMR will be limited to no longer than five (5) calendar days; an extension will be considered upon written appeal.

E. Processes

1. Request Monitor Access to EMR

   Requests should be received at least thirty (30) days prior to the planned start date. Exceptions to the request deadline policy may be necessary (e.g., imminent FDA audit, unanticipated patient problem, change in Sponsor or CRO) and will be reviewed on an as needed basis by the Research Team.

   a. Monitors must provide the Research Team (RT) with a written request for access that includes:

      i. Official study title and study ID,

      ii. Study sponsor's name,

      iii. Monitor's name,

      iv. List of research subjects to be monitored,

      v. Declaration of whether review will be conducted onsite, remotely or both,

      vi. The monitoring time period (dates).

   b. Pursuant to IHOP policy 8.7.12 Industry Auditor and Monitor Visitation onsite Monitors must obtain permission for conducting business on UTHSA's premises (i.e., onsite access).

2. Configure EpicCare Link Access

   a. The EpicCare Team will create the security class and roles necessary to maintain a protocol specific List View.

   b. The List View will be managed and maintained by the RT.

      i. The RT will confirm that the patients contained in the Monitor's request have signed consent/authorization forms allowing their records to be reviewed by a sponsor's Monitors or industry auditors

      ii. The EpicCare Team will grant EpicCare Link access to the Monitor.

      iii. The RT will add verified patients to the appropriate List Views in EpicCare Link.

3. Monitoring Visit

   a. Prior to start of the monitoring visit, Monitors will submit a completed Confidentiality/Security Acknowledgement for On-line/Remote Monitoring (Form).

   b. Once the Form is received the RT will do the following:

      i. Forward the signed copy to the EpicCare team at utmsasupport@uthscsa.edu .

ii. Create a ticket to request access for the Monitor.

c. Once the RT creates the ticket, the following actions will take place:

i. The EpicTeam will enter the Monitor's visit dates in Epic and grant access to EpicCare Link for the those dates only. An extension of the ending Monitor visit access date will be considered upon written appeal.

i. The EpicTeam will send an email to the RT with the dates of Monitor access and confirm the ticket is completed.

ii. The RT will send an encrypted email informing Monitor of username, password, and dates of Monitor access.

d. Concluding the Visit

i. The RT will remove patients from the List View when the audit is concluded.

ii. Permissions for the Monitor will be revoked at the completion of the record review by the EpicCare Team.

V. Definitions

When used in this document, the following words have the meaning set forth below unless a different meaning is required by context.

Electronic Medical Record (EMR) – digital version of a medical chart that contains all a patient's medical history from one provider or facility.

Epic– the EMR software application.

EpicCare – the Epic EMR software application modules.

Epic Care Link – the web-based EMR portal that allows secure access to select patient information for designated users.

EpicCare Team – the Epic EMR and EpicCare Link support team.

List View – maintained protocol-specific list of patients accessible by a Research Monitor in EpicCare Link.

Monitor – an individual who acts as a liaison between a clinical trial site and the sponsor to oversee the progress of a clinical trial and ensure that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirements.

Onsite Access – refers to access of the EMR for the purpose of monitoring or auditing a study while on the UTHSA campus using a UT device.

Remote Access – refers to access of the EMR for the purpose of monitoring or auditing a study while physically not present on the UTHSA campus. Remote access is only possible using EpicCare Link.

Research Record – records, specific to patient's participation in a research study, that are not generally scanned into a patient's electronic medical record. Examples include, but are not limited to, a flowsheet of blood collections before or after drug infusion, a quality of life survey or a drug diary.

Research Team (RT) – the study staff responsible for the conduct of a specific research study (e.g., PI, AIs, Research Coordinators, Data Managers, Clinical Trials Office, or anyone appointed by the PI).

VI. Related References

Forms
Confidentiality/Security Acknowledgement for On-site/Remote Monitoring

Institutional Handbook of Operating Policies
8.7.11 Contractors and Vendors
8.7.12 Industry Auditor and Monitor Visitation

VII. Review and Approval History

The approving authority of this policy is the University Executive Committee.

Effective Date	Action Taken	Approved By	Approved Date
11/2013	New Policy/Approved	Executive Committee	
11/2020	Revised/Approved	Executive Committee	11/15/2020