

## HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 13	Clinical Policies and Procedures	Effective:	November 2013
Section 13.1	Clinical Policies	Revised:	
<b>Policy 13.1.2</b>	<b>Access to Patient Electronic Medical Records by Monitors and Auditors</b>	Responsible Party:	Vice President for Medical Affairs

# ACCESS TO PATIENT ELECTRONIC MEDICAL RECORDS BY MONITORS AND AUDITORS

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## Policy

It is the policy of the Health Science Center that monitors and auditors will be allowed view-only access to electronic medical records (EMR) for:

- a. Patients participating in research studies sponsored by the monitor's organization; or
- b. Patients enrolled in a third-party payor plan offered or administered by the auditor's organization.

Monitors/auditors may not view patient records for any patient not authorized in this policy. Monitors/auditors must sign a [Confidentiality/Security Acknowledgement](#) and request temporary system access in accordance with Health Science Center policy. For monitors/auditors requesting EpicCare access, they must complete the online Chart Review class prior to receiving access to EpicCare. Monitors/auditors will receive login instructions and will be directed to the Knowledge Center for completion of the online Chart Review class, which can be found at <https://kc.uthscsa.edu/kc/login.asp>. Once a monitor/auditor has obtained access to the Knowledge Center, the following directions shall be followed to complete training:

- a. Select the Course Catalog tab;
- b. Select the Information Technology Center icon; and
- c. Scroll down the list and select "EpicCare Chart Review" to take the training.

For monitors/auditors requesting access to EMR's other than EpicCare, contact the Clinical Investigations to arrange for access. Monitors/auditors must provide Clinical Investigations (CI) or the Health Information Management (HIM) department a list of patients to review prior to arrival on site and must have an appointment. See the *Handbook of Operating Procedures* (HOP) policy for additional information at [Section 8.7.12](#), "Industry Auditor and Monitor Visitation".

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Access for monitors/auditors will be managed in accordance with this policy.

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**Definitions**

Clinical Investigations (CI): Research team that conducts human subject research.

Clinical Research Associate (CRA): Research personnel involved in human subject research at the Health Science Center.

Cancer Therapy & Research Center (CTRC): Cancer treatment center at the Health Science Center.

Electronic Medical Record (EMR): Digital version of a paper chart that contains all of a patient’s medical history from one provider or facility.

EpicCare: An EMR software application.

Data Coordinator (DC): Research technician intermediate

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**Procedure**

The following procedure will be adhered to provide monitors/auditors with view only access to patients records in EpicCare.

1. The EpicCare team will create the security class and roles necessary to maintain List Views for Clinical Investigations (CI) and the HIM department.
  2. The List Views will be managed and maintained by the CI team or the HIM department.
    - a. The DC or HIM department will confirm that the patients have signed consent forms allowing their records to be reviewed by a sponsor’s monitors or industry auditors.
    - b. The monitors/auditors will be granted access to EpicCare by the Epic team. The DC or HIM department will add the patients to the appropriate List Views in EpicCare for the monitor/auditor to view. Each List View will contain only the patients for a given study or audit.
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- c. The DC or HIM department will remove patients from the List View when the study is officially closed or an audit is concluded.
  - d. Permissions for the monitors/auditors will be revoked at the completion of the record review by the DC or HIM department
3. Prior to arrival on site, monitors/auditors shall do the following:
- a. Sign a [Confidentiality/Security Acknowledgement](#) per CI or HIM department policy.
  - b. Provide a list of patients for chart review (submit 30 days prior to site visit).
  - c. Request temporary network credentials (submit 30 days prior to site visit). For research study reviews, the DC will submit a domain account request to Information Management Services (IMS) through SupportWorks. For industry chart audits, the HIM department will submit a domain account request to IMS through SupportWorks. To submit a request for a domain account, access <http://supportworks.uthscsa.edu/sw/selfservice/>. From the link, select "My Services". Select the "Accounts and Access Management" category, followed by the sub-category "Network Account" and continue to follow the step-by-step instructions to request a domain account.
  - d. Complete the online Chart Review course and test (prior to site visit). This is required for login permissions to the EpicCare EMR.
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