

**HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES**

Chapter 8	Health and Safety	Effective:	November 2013
Section 8.7	University Police	Revised:	
<b>Policy 8.7.12</b>	<b>Industry Auditor and Monitor Visitation</b>	Responsibility:	Chief, University Police

## **INDUSTRY AUDITOR AND MONITOR VISITATION**

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### **Policy**

Health Science Center clinicians and staff shall interact with industry auditors and monitors in a manner that meets regulatory and Health Science Center policy standards, protects patient confidentiality, and does not interfere with the process of patient care. Industry auditors and monitors who conduct business at or with the Health Science Center must do so in accordance with this policy and procedure. Industry auditors and monitors may not be on Health Science Center premises without prior permission from authorized personnel. If an auditor/monitor is conducting auditing/monitoring activities that relate to Health Science Center business at a non-Health Science Center location or entity, the auditor/monitor must follow policy regarding visitations that are in place at that location or entity.

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### **Definitions**

**INDUSTRY AUDITOR/MONITOR:** Means any individual conducting audit or review activities on behalf of an industry sponsored clinical trial study or on behalf of a third party payor.

**CLINICIANS AND STAFF:** Means faculty members and trainees at all levels in any patient care or clinical trial discipline; staff, volunteers or persons hired by the Health Science Center to perform work at or on behalf of the Health Science Center.

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### **Procedure**

Industry Auditor and Monitor Registration:

1. Industry auditors/monitors must sign-in and obtain a "One Day" identification badge. The identification badge must be visible while at a Health Science Center site. This badge may be obtained at the check-in or registration area of each respective Health Science Center site and may be produced by the site. It must comply with the requirements of HOP Policy 8.7.10 Identification Badge Policy. Each Health Science Center site shall develop a sign-in procedure to be followed when an industry auditor/monitor arrives. The sign-in procedure should consist of the following, at a minimum:
    - a. Obtain and validate industry auditor/monitor identity.
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- b. Record the date, time of arrival, auditor/monitor name, company name, contact number, and area of assignment.
    - c. Ensure the auditor/monitor has an appointment.
    - d. Record the Health Science Center representative to whom the auditor/monitor will be assigned.
  2. Industry auditors/monitors must have an appointment prior to arrival on campus. Each authorized appointment is for that day's appointment only and does not provide authorization to visit any other area of the Health Science Center or meet with any staff.
  3. Industry auditors/monitors must be accompanied by a Health Science Center employee at all times if the visitation will include access to the following areas:
    - a. Patient care areas
    - b. Patient waiting areas
    - c. Supply and drug storage areas
    - d. Dispensing areas of the pharmacy
  4. "Piggybacking" (where one auditor/monitor officially registers, but is accompanied by another individual who has not registered) is strictly prohibited.
  5. Industry auditors/monitors will only be permitted to have access and review protected health information that pertains to a particular clinical trial study or audit that they are responsible for auditing or monitoring. Auditors/monitors must be accompanied at all times. See the *Handbook of Operating Procedures* (HOP) policy for obtaining access to electronic medical records at [Section 13.1.2](#), "Access to Electronic Medical Records by Auditors and Monitors".
  6. Industry auditors/monitors must obtain a POI "person of interest" designation and criminal background check if they will be at a

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Health Science Center site for four (4) or more consecutive days. If an industry auditor/monitor will be at a Health Science Center site for three (3) days or less, they must obtain the “One Day” identification badge and sign-in for each separate day. See the *Handbook of Operating Procedures* (HOP) policy for obtaining a POI designation and criminal background check at [Section 8.7.11](#), “Contractors and Vendors”.

7. Industry auditors/monitors that have an ongoing, frequent need to be on Health Science Center sites, but the duration of each visit is less than three (3) days, should obtain a POI designation and a criminal background check.

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**Violations**

This policy and procedure must be closely followed by Industry auditors/monitors and Health Science Center personnel.

All Health Science Center personnel responsible for industry auditor/monitor activity will assist in monitoring compliance. In the event that a faculty member or staff observes an industry auditor/monitor who is not in compliance with the requirements of this policy, the staff should do the following:

- a. Ask the industry auditor/monitor if they are aware of the “Industry Auditor and Monitor Visitation” policy. (If not, they should be asked to leave the area and directed to the registration or check-in area to obtain proper identification and sign-in.)

Any violations of the above procedures will subject the auditor, monitor and/or company to suspension of on-campus visitation privileges.

Violations of the policy will be subject to intervention by UT Police.

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