I. 8.7.12 Industry Auditor and Monitor Visitations

Chapter 8 - Health & Safety	Original Effective Date: November 2013
Section: 8.7 University Policy	Date Last Reviewed: December 2024
Responsible Entity: Chief, University Police	Date Last Revised: December 2024

II. Purpose

The purpose of this policy is to establish general requirements for hosting industry auditors and monitor visitations to the UT Health San Antonio campus or any of its controlled affiliated sites.

III. Scope

This policy applies to all UT Health San Antonio departments, centers, or organizational units and hosted visits by industry auditors and monitors.

IV. Policy

UT Health San Antonio clinicians and staff shall interact with industry auditors and monitors in a manner that meets regulatory and UT Health San Antonio policy standards, protects patient confidentiality, and does not interfere with education, research, or patient care.

Industry auditors and monitors who conduct business at or with UT Health San Antonio must do so in accordance with this policy and procedure. Industry auditors and monitors may not be on UT Health San Antonio premises without prior permission from authorized personnel. If an auditor/monitor is conducting auditing/monitoring activities that relate to UT Health San Antonio business at a non-UT Health San Antonio location or entity, the auditor/monitor must follow policy regarding visitations that are in place at that location or entity.

A. Requirements

1. Registration

   a. 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 University or meet with any other staff.

    b. Industry auditors/monitors must sign-in and obtain a "One Day" identification badge. The identification badge must be visible while at a UT Health San Antonio site. This badge may be obtained at the check-in or registration area of each respective UT Health San Antonio site and may be produced by the site. It must comply with the requirements of the Institutional Handbook of Operating Policies (IHOP) Policy 8.7.9 Keys, Identification Cards and Access Requests.

    c. Each UT Health San Antonio 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:

        i. Obtain and validate industry auditor/monitor identity;

        ii. Record the date, time of arrival, auditor/monitor name, company name;

        iii. Contact number, and area of assignment;

        iv. Ensure the auditor/monitor has an appointment, and;

        v. Record the UT Health San Antonio representative to whom the auditor/monitor will be assigned.

2. Industry auditors/monitors must be accompanied by a UT Health San Antonio 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

3. "Piggybacking" (where one visitor officially registers but is accompanied by another individual who has not registered) is strictly prohibited.

4. Visitors will only be permitted to have access and review protected health information that pertains to the specific purpose of their visit. See IHOP Policy 13.1.2 Access to Patient Electronic Medical Records by Research Sponsor Monitors.

5. Industry auditors/monitors must obtain a "person of interest" (POI) designation and criminal background check if they will be at a UT Health San Antonio site four (4) or more consecutive days. If an industry auditor/monitor will be at a UT Health San Antonio site for three (3) days or less, they must obtain the "One Day" identification badge and sign-in for each separate day.

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

B. Violations

1. This policy and related procedures must be closely followed by industry auditors/monitors and UT Health San Antonio personnel. Violations of this policy will be subject to intervention by UT Police.

2. All UT Health San Antonio 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, they should do the following:

   a. Ask the industry auditor/monitor if they are aware of this 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.

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

V. Definitions

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

Industry Auditor/Monitor – 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 – faculty members and trainees at all levels in any patient care or clinical trial discipline; staff, volunteers, or persons hired by UT Health San Antonio to perform work at or on behalf of UT Health San Antonio.

VI. Related References

There are no related documents associated with this Policy.

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	Policy Origination		
09/2021	Policy Review/Discretionary Edit	UTPD/ICPO	09/15/2021
12/2024	Policy Review/Discretionary Edit	UTPD	12/17/2024