

Subject:		Issued By:	
<b>AUDITOR/MONITOR SITE VISITS &amp; AUDITS</b>		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2018	November 1, 2006	August 20, 2007	September 30, 2007

Reference: Original Monitor Site Visits and Audits Policy dated 4-12-2006 and updated as of 11-1-2006.

**PURPOSE**

To ensure that IDS Staff handle Auditor/Monitor site visits professionally and consistently.

**POLICY**

1. **COMPLIANCE:** IDS Staff will comply with all reasonable requests for Auditor/Monitor site visits with regards to dates, times and retrieval of required information prior to the site visit;
2. **ATTENDED TO BY A PHARMACIST:** Auditors/Monitors will be attended to by a licensed pharmacist at all times while onsite at the IDS Pharmacy;

**GUIDELINES & PROCEDURES**

1. **THE PHARMACIST WILL PULL REQUIRED DOCUMENTS:** Any document, record, or Drug Inventory Accountability Log required by the Auditor/Monitor will be retrieved by IDS Staff;
2. **REPORTING REQUIREMENTS:** The Auditor/Monitor must report any problems to the pharmacist. If necessary, these problems should be communicated by the pharmacist to HRA's President & CEO as soon as is practically possible;
3. **STEP-BY-STEP INSTRUCTIONS:** For every Auditor/Monitor visit, IDS Staff will follow the specific procedures identified below:
  - a. **APPOINTMENTS MUST BE SCHEDULED AT LEAST THREE WEEKS IN ADVANCE:** Auditors/Monitors must make an appointment with the IDS Pharmacy for a site visit at least three weeks in advance;
  - b. **INTERNAL AUDIT PRIOR TO SITE VISIT:** No less than one week prior to the site visit, the Pharmacist-in-Charge must perform an internal audit of the projects to be audited by the Auditor/Monitor. If corrective actions are required, the Pharmacist-in-Charge must complete these corrective actions prior to the site visit. Dependent upon the severity of the corrective actions, the Auditor/Monitor may have to be notified. Consult with HRA's President & CEO for case-by-case guidance on such issues;

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- c. **RETRIEVE STUDY-SPECIFIC PROTOCOL BINDERS OF INTEREST:** Place all study-specific protocol binders and Drug Accountability Log Sheets of interest on the workstation desk prior to the arrival of the Auditor/Monitor;
- d. **ASSIST THE AUDITOR/MONITOR:** Assist the Auditor/Monitor to the best of the IDS Pharmacy Staff Member's ability by making copies, answering queries, etc. If the IDS Pharmacy Staff Member feels that unreasonable requests are being made, discuss them privately with HRA's President & CEO after the site visit;
- e. **DRUG STORAGE & INVENTORY:** Show the Auditor/Monitor any drug storage areas that pertain to their studies. If requested, place drugs on the workstation for them to inspect and count. If the Auditor's/Monitor's inventory count does not match either the inventory balance in the Panacea Rx software or on the individual Drug Accountability Log Sheets, notify HRA's President & CEO immediately. Attempt to reconcile any discrepancies in the presence of the Auditor/Monitor;
- f. **RETRIEVE TEMPERATURE LOGS:** Have all temperature logs that apply to the medication of interest available for inspection by the Auditor/Monitor;
- g. **COOPERATE FULLY AND BE EFFICIENT:** IDS Pharmacists & Staff will provide full cooperation and assistance to the Auditor/Monitor during the site visit in order to make the visit as time efficient as possible.

**RESPONSIBILITY**

Pharmacist-in-Charge  
All IDS Staff