UC Riverside, School of Medicine Policies and Procedures
Policy Title: Compliance Auditing and Monitoring
Policy Number: 950-02-020

Responsible Officer:	Chief Compliance and Privacy Officer
Responsible Office:	Compliance Advisory Services
Origination Date:	11/2020
Date of Revision:	
Scope:	UCR School of Medicine

I. Policy Summary

The procedure outlined in this document is a guide for audits conducted by or on behalf of UCR School of Medicine Compliance and Advisory Services.

II. Definitions

A. Ad Hoc Audits: Any audits that occur in the regular course of business. Conditions that may trigger an ad hoc audit includes:
1. Processes that are inconsistent with policies and procedures
2. Unexpected financial or statistical results
3. A request from Senior Leadership, a department's manager or director

B. Chief Compliance and Privacy Officer (CCPO): The individual in charge of overseeing and managing compliance issues within UCR SOM, ensuring that it is complying with regulatory requirements, and that UCR SOM and its employees are complying with internal policies and procedures.

C. External Audits: Audits that are initiated by an external party, including commercial and government payers or their representatives (ex: OIG, CMS).

D. Internal Audits ("IA"): Audits/reviews designed to determine a department's or staff member's level of compliance with legal and regulatory guidelines and/or compliance with an internal policy or standard operating objective.

E. Identified: An overpayment is considered identified when the nature and basis for the overpayment are known to the UCR SOM and the patient accounts that are out of compliance resulting in the overpayment have been recognized.

F. Monitoring: On-going statistical or other reporting to promote and review compliance after the audit process has been completed.

G. Planned Audits: Any audit that is planned with assigned resources. These audits may include audits that result from performing a Risk Assessment.

H. Research Audits: A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

I. **Risk Assessment:** Analysis and prioritization of risk areas. Usually, the highest risk areas will be assigned resources to conduct an audit. A risk assessment is generally performed separately for Research vs. General Compliance issues.

III. Policy Text

A. The School of Medicine (SOM) Compliance and Advisory Services takes reasonable steps to achieve compliance with applicable laws and with the University's compliance standards by utilizing auditing and monitoring practices. The Chief Compliance and Privacy Officer (CCPO) is responsible for overseeing that auditing and monitoring are properly executed, documented, and evidenced to ensure effective training and quality review of work performed.

B. Legal counsel will be consulted, as necessary, with respect to audit and monitoring activities.

C. All audit and monitoring activities are conducted in such a manner as to maintain any appropriate legal privileges.

D. The results of all audit and monitoring functions are provided to the Chief Compliance and Privacy Officer, who shall report such results to the Compliance Committee.

E. In the event any audit or review reveals potential violations or areas for improvement, the CCPO will take any appropriate action in accordance with policy, including without limitation, conducting an investigation, advising enforcement and discipline if warranted, development of a corrective action plan, modification of the SOM's standards and policies if necessary, and to the extent feasible, reporting to applicable government agencies, including submission of any overpayments made to UCR SOM within 60 days of being identified.

IV. Responsibilities

Compliance Advisory Services

V. Procedures

A. Oversight

1. **The Chief Compliance and Privacy Officer**
   a. Recommends and facilitates auditing and monitoring of identified risk areas related to compliance with laws and regulations, as well as organizational policies, procedures, and the Code of Conduct.
   b. Verifies completion of compliance audits and any corrective action measures arising from them.

2. **The members of the Compliance Department:**
   a. Have unrestricted access to all system records relevant to the audit with which they are involved.

b. Conduct auditing and monitoring of identified risk areas related to compliance on and ongoing or as needed basis and may review the following (including but not limited to):
   - Policies and procedures
   - Internal controls
   - Data integrity
   - Financial statements
   - Contract & Grants
   - Patient records in all systems
   - Research applications and documentation

c. Provide management with analyses, recommendations, counsel and information concerning the activities reviewed.

d. Do not develop or install procedures, prepare records, make management decisions, manage or oversee implementation of the action plan, or engage in any other activity that could be reasonably construed to compromise the Auditor's independence.

e. The internal audit plan will be presented to the Compliance Committee on an annual basis and all Ad Hoc audits will be presented at the next scheduled quarterly Compliance Committee upon completion.

B. Confidentiality

1. Confidential information acquired by SOM Compliance Department is privileged and must be held in strictest confidence. It is to be used solely for SOM defined purposes.
2. Confidential information is transmitted only to those persons who need the information to discharge their duties as staff or governmental and contracted Auditors.
3. All reports are filed in the Compliance Department with limited access control.

C. Records Retention

1. Auditing and Monitoring reports are maintained in compliance following UCR SOM's records retention policy.

D. Audit Selection

1. The Compliance Department develops a schedule of activities and departments to be audited annually and presents it to the Compliance Committee. This schedule includes both risk assessment audits and known ad hoc audits.
2. The Compliance Department evaluates the scope of an unscheduled audit request or requirement, including the availability of resources. The audits with regulatory risk will have the highest priority.

E. Risk Assessment

1. An annual compliance risk assessment will be conducted, incorporating any issues identified through the regular course of business, external alerts (e.g., annual OIG work plan), and internal surveys and interviews, soliciting input form administrative leaders.
2. The Compliance Department evaluates the scope of an audit request, availability of resources, and timing of the next regularly scheduled audit. The audits with regulatory risk have the highest priority.

F. Annual Audit Work Plan

1. Once the list of risks has been developed, they will be ranked according to probability of occurrence and potential impact or consequences. The Compliance Department will develop an annual audit work plan that places the greatest emphasis on addressing areas of highest risk.
2. The plan includes specific areas of UCR SOM operations which will be audited or reviewed during the year in the specific area.
3. Internal audits may be performed with approval and under direction of the CCPO.

G. Audit Process

1. Audit Planning: An Audit outline will be prepared (See attachment 1) Preliminary communication with key stakeholders, regarding the audit scope and timing, will take place prior to the initiation of the audit.
2. Opening Conference: As needed, the CCPO will direct an opening conference which provides the Auditor(s) with the opportunity to work with all key players and department management to further define the scope of the upcoming audit, learn where to find pertinent information for the audit, and in general explain the specific audit program to the stakeholders.
3. The CCPO will invite to the audit opening meeting the audit requestor, any appropriate staff members, and the appropriate department manager or director. The SOM Dean will also be notified of the audit.
4. The anticipated duration of the audit will be discussed in this meeting.
5. For Audit preparation the Auditor(s):
   a. Gathers information and conducts interviews as necessary to gain an understanding of the operation or system under review.
   b. Research pertinent policies, procedures, guidelines, regulations, or industry standards to assess the level of compliance of the processes being reviewed.
   c. Prepare an audit program which outlines the objectives, scope, procedures, and staff involved.
   d. Create work papers, which effectively document the fieldwork performed and serve as the connecting link between the audit assignment, the Auditor's fieldwork, and the final report.
6. The Auditor will provide evidence to support the findings.

7. Turn-around time for directors to comply with audit requests for data should be as follows:
   a. Urgent regulatory requirement: immediately to 5 business days.
   b. Monitoring audit: 5-15 business days.
   c. The director of their area will be notified if information requested from the department under review is not delivered to Compliance within 10 business days.
   d. In extenuating circumstances, the director may request, and the CCPO may grant a reasonable extension on an exception basis.
8. Reporting:
   a. After the data has been analyzed the Auditor completes a report (See Attachment 2) that clearly express the objectives, scope, sampling methodology, procedures, and findings of the audit.
   b. The report will identify areas of non-compliance and improvement opportunities and be delivered to the department manager and/or director responsible for that area.
   c. Any findings requiring immediate action will be shared with the management team as they are found. This report may be verbal and does not remove the obligation of a final written report for the audited process or department.
   d. The Auditor will communicate milestone reports to the department management throughout the review process.
9. Audit Close Meeting and Action Plan Generation
   a. After all the data has been analyzed and a report has been generated, the Auditor will present the findings and recommendations expressed in the report to:
      - The audit requestor
      - Any appropriate staff members
      - Appropriate department manager or director
   b. The department leaders will be responsible for documenting management response for any recommendation for improvement.
   c. The Auditor will negotiate a reasonable timeframe for completion of the action plan.
   d. The Auditor will continue his/her review of audit recommendations noted in the action plan until satisfactory solutions have been found for reported deficiencies.
   e. The audit will be considered closed when the final report has been issued and an agreed upon action plan has been created by the department.
   f. It is the responsibility of the department to execute the action plan and notify the CCPO upon completion.

H. Overpayments

1. If an internal audit determines that there was an overpayment, the Auditor will immediately notify the CCPO who will work, as practicable, to refund the overpayment within 60 days of the date it was identified.

I. Monitoring and Follow-up

1. The Compliance Department monitors risk areas when deemed necessary.
2. The follow-up may be informal observations, monitoring of specific data elements or in some instances, may take the form of a subsequent audit.
3. The nature of the follow-up is dictated by the seriousness and complexity of the deficiencies noted.
4. Monitoring may also include assessment of the compliance program. The CCPO and Compliance Committee may utilize, as necessary, any additional means of assessing the effectiveness of the UCR SOM compliance program, including the use of outside auditors and consultants.

VI. Forms/Instructions

Attachment 1 – Audit Plan Outline
Attachment 2 – Audit Finding Report

VII. Related Information

VIII. Revision History

New 11/2020

Approvals:

COMPLIANCE COMMITTEE: 01/27/2021

PAUL HACKMAN, J.D., L.LM.
CHIEF COMPLIANCE AND PRIVACY OFFICER,
SCHOOL OF MEDICINE

02-09-2021
DATE

Deborah Deas

DEBORAH DEAS, M.D., M.P.H
VICE CHANCELLOR, HEALTH SCIENCES
DEAN, SCHOOL OF MEDICINE

021021
DATE

Attachment 1

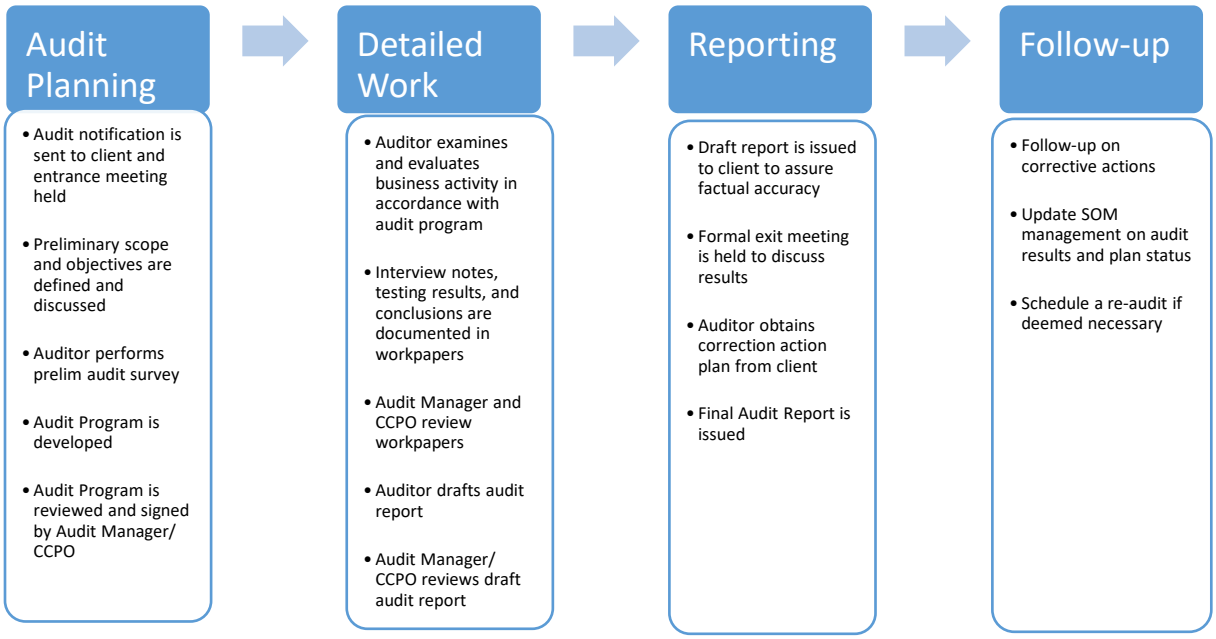
Compliance Advisory Services
Internal Audit

Meeting Start Date	
Meeting Start Time	

Present	**Name**	**Signature**	**Title**
Scope of Audit			
Audit Evidence			
Meeting End Time			
Anticipated Date of Closing Meeting			

Attachment 2

Audit Plan Outline



Attachment 3

Audit Findings

Audit Objective:	
Department Audited:	
Date of Audit:	
i-Sight Audit #:	

AUDIT FINDINGS	

AUDIT RECOMMENDATIONS	
ACTIONS TAKEN/ IMPLEMENTATION	

TIMELINE	