University of California

Ethics and Compliance Plan

Report to the

Compliance and Audit Committee of the Regents

July 14, 2009

INTRODUCTION

The Ethics and Compliance Services (ECS) function of the Ethics, Compliance and Audit Services (ECAS) Office has been operating under the guidance of The Board of Regents' approved Ethics and Compliance Program Plan since July, 2008. UC's voluntary implementation of an ethics and compliance program continues to provide a foundation for UC to proactively demonstrate its adherence to its mission, as well as its commitment to ensure good stewardship of federal, state and private resources, especially during these challenging financial times.

The following ECS Annual Plan for 2009-2010 has been developed based on compliance areas as identified by the Regents of the University of California (Compliance and Audit Committee), University of California Office of the President (UCOP), the ten campuses, Agriculture and Natural Resources (ANR) and Lawrence Berkeley National Laboratory (LBNL). In addition to the specific campus areas noted above, an overall review of industry higher education compliance risks and federal and state regulatory requirements that are the particular focus of government enforcement were identified, reviewed, prioritized and incorporated into the Plan. An integral part of this plan includes the "value-add" role that ECS plays in assisting UC locations in continuing to enhance their compliance efforts.

The Plan includes a detailed work strategy that outlines key monitoring elements and project management by the ECS Office.

ETHICS & COMPLIANCE PLAN

I. Plan Objectives

The 2009-2010 ECS Plan continues to integrate the UC Statement of Ethical Values and Standards of Ethical Conduct as a foundation for ensuring compliance with applicable rules and regulations that govern all aspects of UC operations. The Plan objectives include:

1. Providing a framework based on the Seven Elements of an Effective Compliance Program (Federal Sentencing Guidelines (FSG)) to proactively plan for the efficient use of limited resources to address prioritized potential compliance risks.
   a. ECS Office to effectively assist the Chief Ethics and Compliance Officers (CECOs) in their campus efforts to identify, prioritize, develop and evaluate work activities to address risks.

2. Outline at a high level the work steps necessary to effectively:
   a. Address the scope of the potential compliance risks;
   b. Document action plans to assist the campuses/UCOP/LBNL to mitigate those risks;

    c. Validate/establish audit management controls to detect and/or prevent compliance risk; and

    d. Provide a formal mechanism to measure progress to achieve plan objectives and overall systemwide program goals.

II. Plan Development

As noted in the Introduction, the ECS Annual Plan for 2009-2010 was developed through review and analysis of a number of focus areas including:

- Prioritization of potential compliance risk areas identified through industry peers, location-specific processes, and confidential communications including internal audit risk assessment results.

- Collaboration with UC Health Sciences Compliance Officers, UC Privacy Officers and UCOP Human Resources Quality Assurance & Compliance leadership.

- Analysis of communications of priority (defined as high risk in industry) focus areas in federal, state or other regulatory agency oversight activities from the higher education and health care industry professional organizations, research related professional organizations, and specific government agencies.

- Integration of applicable topics from the Office of Inspector Generals (OIG) Work Plans from federal departments that have regulatory oversight for elements of higher education activities (i.e. Departments of Energy, Education, Health and Human Services).

The Plan is developed to allow for its revision during the fiscal year in the event of unforeseen compliance matters that could negatively impact the University.

III. Potential Compliance Risks

A comprehensive list that includes, but may not be limited to, the potential compliance risks that have been identified and prioritized for focus during 2009-2010 are the following:

- Data Security and Privacy (including Health Insurance Portability & Accountability Act (HIPAA)) Issues

- American Recovery and Reinvestment Act (ARRA) Funds Mandated Reporting and HITECH ACT Requirements

- Conflicts of Interest

- Research Compliance/Effort Reporting

There are other potential risks in the Annual Work Plan that are being scheduled for review (refer to **FY 2009-2010 Ethics and Compliance Work Plan-Exhibit A**). Metrics will be provided on a periodic basis to the Regent's Compliance and Audit Committee on the focused areas and work plan activities (refer to **FY 2009-2010 Focused Compliance Risks Performance Metrics Dashboard-Exhibit B**).

IV. Plan Outline

ECS utilizes the elements of an effective compliance program to organize the department's work activities. These include the following categories which are addressed in the workplan:

Standard of Conduct and Policies and Procedures

Governing Body, Compliance Structure and Compliance Officer

Education and Training

Communication/Anonymous Reporting

Enforcement and Screening

Audit and Monitoring Activities

Response and Prevention

Summary

Budget year 2009-2010 will be a challenging one for all administrative and academic personnel of the University of California as we meet the demand of a national and international monetary crisis as well as a state-wide budget meltdown. The federal government demand for transparency and institution of unfunded increased compliance requirements, coupled with decreased funding support for our mission, complicates our planning processes. The ability to remain focused on our core values and target areas to further support the campuses and LBNL in meeting their primary objectives will be the test of the ECS program's effectiveness.

Ethics and Compliance Program Workplan
FY 2009-2010

Focus Area	Project Summary	Timeframe for Completion	Status
center: **Standard of Conduct and Policies and Procedures**			
Privacy Policies	1. Health Insurance Portability & Accountability Act (HIPAA) Privacy and Security – hospital and non-hospital sites.	Q1	
	2. Privacy – general (not HIPAA).	Q1	
Conflicts of Interest (CoI) and Conflicts of Commitment (CoC)	**Health Sciences Conflict of Interest** 1. Identify processes which Health Sciences (HS) areas have adopted for CoI and CoC and assure policies in place.	Q1	
Enforcement Policy	1. Assist UC Office of General Counsel (OGC) and Provost in development of academic enforcement policy.	Q1	
Compliance Policies and Procedures	**Health Sciences** 1. Assist Medical Centers in review and revision of HS Code of Conduct (once approved by Academic Senate) and assist in distribution.	Q3	
Policy Management	**UCOP** 1. Implement "best practices" policy management procedure and disseminate template and associated tools to UCOP policy owners.	Q1	
	2. Automate policy review process through electronic project management system.	Q2	
	3. Schedule training of policy owners for adoption of automated review system.	Q2	

Ethics and Compliance Program Workplan
FY 2009-2010

Focus Area	Project Summary	Timeframe for Completion	Status
Oversight (Governing Body, Compliance Structure and Compliance Officer)			
Delegations of Authority (DoA)	1. Facilitate DoA review by Human Resources (HR) /management in regards to senior leadership roles and responsibilities with related job description revisions.	Q2	
	2. Provide DoA process and governance structure for leadership review.	Q2	
Campus Ethics and Compliance Risk Committees (CECRC)	1. Enhance campus/LBNL collaboration on campus compliance initiatives and CECRCs.	Ongoing	
	2. System/Campus/Program Office performance metrics annually established and aligned to President's Accountability measures.	Q1	
	3. Planned implementation of a compliance risk management and policy management and tracking system.	Q2	
	4. Develop, with Academic Leadership, a standard process for discussion related to compliance efforts and routine communication.	Q1	
Collaboration with Key Departments on Identification/Mitigation of Compliance Risk Areas	1. Legal, Finance, HR, Risk Management, Business Operations, Academic, etc.	Ongoing	
	2. Develop profiles for tracking and trending.	Q1	

Ethics and Compliance Program Workplan
FY 2009-2010

Focus Area	Project Summary	Timeframe for Completion	Status
	Education and Training		
Systemwide Training	1. Sexual Harassment Prevention Training – CA-AB1825.	Ongoing	
	2. Designated Official Conflict of Interest Training.	Ongoing	
	3. Development of Compliance/Privacy Newsletter (monthly with 1.0 continuing education credit).	Q3	
	4. Assist with Compliance training on Learning Management System (LMS), where necessary.	Ongoing	
	Specific Education – Compliance, IA, Others		
	1. Quarterly Compliance Education Days – north and south.	Q1	
	2. Webinars	Ongoing	
	3. New Employee Orientation at UCOP.	Ongoing	
	4. Risk-specific Training, i.e. export controls, etc.	Ongoing	
General Compliance	1. General Compliance module developed for use at all campuses.	Q2	
Clinical Research Billing	1. Provide focused research billing education, as applicable to findings of review.	Q4	
Privacy	1. Develop privacy training modules and make available to all locations through LMS and hard copy. HIPAA modules will also be made available.	Q1	

Ethics and Compliance Program Workplan
FY 2009-2010

Focus Area	Project Summary	Timeframe for Completion	Status
Conflicts of Interest for Researchers	1.　Provide CoI training modules (LMS and hard copy) for use at all campuses.	Q1	
Professional Fee Reimbursement	1.　Initial reimbursement rule training of School of Medicine (SOM) clinical providers conducted prior to submission of claims to government payors.	Ongoing	
<td colspan="4" align="center">**Communication/Anonymous Reporting**</td>
Communications	1.　Assist President in Systemwide communication of enforcement policy. 2.　Develop and disseminate Compliance Fact Sheets and Frequently Asked Questions (FAQs) on key regulatory issues. 3.　Develop formalized system for communication regarding compliance policy updates, conflict of interest topics, reporting concerns, and promoting a culture of compliance, including web site updates on an ongoing basis. 4.　Continue to facilitate systemwide meetings, calls, listservs to confer on risks with Locally Designated Officials (LDOs), Health Care Compliance, Research Compliance, and Privacy Committees.	Q1	

Ethics and Compliance Program Workplan
FY 2009-2010

Focus Area	Project Summary	Timeframe for Completion	Status
Confidential Reporting	**Hotline – EthicsPoint** 1. Aggregate, analyze and trend hotline call information for reporting.	Ongoing	
	2. Enhance consistent reporting capabilities at UC locations through location use of EthicsPoint case management system.	Ongoing	
	3. Maintain website to ensure accurate and timely information.	Ongoing	
Investigations	1. Provide support to systemwide LDO and campus/location LDOs.	Ongoing	
	2. Conduct independent investigations at various sites, where indicated.	Ongoing	
	3. Incident response will be timely according to policies.	Ongoing	
	4. Identify weaknesses in systems and controls through reporting and investigation mechanism.	Ongoing	
Enforcement and Screening			
Office of Inspector General (OIG) Department of Health & Human Services/ **General Services Administration (GSA) Exclusion & Sanction Checks Screening**	1. Assess systemwide overall process for OIG/GSA exclusion monitoring of employees.	Q2	
	2. Monitor discipline processes related to risk events.	Ongoing	

Ethics and Compliance Program Workplan
FY 2009-2010

Focus Area	Project Summary	Timeframe for Completion	Status
Audit and Monitoring Activities			

HIPAA Privacy	1. HIPAA Privacy Reviews
	
	   a. Assess overall compliance to policies.
	
	   b. Track and trend incidents (HIPAA).
		Q4
		
		Q3
		
		Ongoing	

Conflicts of Interest	<u>Health Sciences</u> 1. Conduct review of system HS areas to determine policy action follow through. 2. Monitor external activities related to CoI.	 Q1 Q1	
Accurate Academic Medical Center (AMC) Reimbursement	1. Billing and Coding Reimbursement Reviews. 2. Track & trend billing and coding observations in AMC.	Q2 Ongoing	
Cost Transfers	1. Internal Audit conducting audit.	Q1-2	
Effort Reporting	1. Collaboration with Internal Audit.	Q1-4	
Clinical Research	1. Billing: Review with OGC a sample of clinical research billing claims for each of the 5 Medical Centers. 2. Regulatory Compliance: Review systemwide prevalence of Principal Investigator (PI) sponsored Investigational New Drug Applications (INDs).	Q4	
Medicare Recovery Audit Contractors (RAC) Payments	<u>Health Sciences</u> 1. Medicare RAC audits are monitored and tracked for payment amounts and related trends for denial of reimbursement.	Ongoing	

Ethics and Compliance Program Workplan
FY 2009-2010

Focus Area	Project Summary	Timeframe for Completion	Status
Royalty Audits	1. Conduct systemwide royalty audits of selected licenses of UC intellectual property.	FY09/10, beginning Q1	
American Recovery & Reinvestment Act (ARRA)	1. Develop and conduct system monitoring plan to determine compliance with ARRA reporting requirements.	Ongoing	
Response and Prevention			
ARRA	1. Identify controls in place related to reporting requirements. 2. Review reporting requirement controls and that use of funds are compliant with funds received.	Q1-2 Q3	
Privacy	1. Privacy Review Follow-up. 2. Develop remediation plan for detected Systemwide vulnerabilities.	Q2	
Tool and Training Development	1. Develop tools, core training materials, etc for campuses/LBNL/UCOP or Medical Centers to utilize when assessing and preparing training for newly identified compliance risks.	Ongoing	
Research Compliance	1. Communication and facilitation of compliance activities around new regulations, i.e. National Science Foundation (NSF) America Competes Act.	Ongoing	

Exhibit B

Focused Compliance Risks Performance Metrics Dashboard
FY 2009/2010

Performance Metrics	System	Campus	Program	Risk Score	Met/Not Met	Comments
Conflicts of Interest (CoI) Campus efforts defined and established	x	x				
Other Metrics to be developed	x	x				
Privacy 100% of UC employees, as applicable, receive Health Insurance Portability and Accountability Act (HIPAA) privacy training in FY10	x	x				
Other Metrics to be developed	x	x				
Effort Reporting Campuses/LBNL have implemented systems to accurately report and track effort reporting, either web-based or manual (100%)	x	x				
Other Metrics to be developed	x	x				
American Recovery and Reinvestment Act (ARRA) Monitoring activities as mandated by the ARRA (for specified funds) are being conducted	x	x	x			
ARRA reporting requirements are met for each applicable campus/entity	x	x	x			
Other Metrics to be developed	x	x				

Legend	
Documentation exists to support active mitigation of potential risk	(green)
Documentation not complete to support active mitigation of potential risk	(yellow)
No documentation to support active mitigation of potential risk	(red)

Ethics and Compliance Program Performance Metrics Dashboard
FY 2009/2010

Annual Ethics and Compliance Work Plan Performance Metrics	System	Campus	Program	Risk Score	Met/Not Met	Comments
Systemwide Ethics and Compliance Risk Council (SECRC) - quorum maintained for 90% of scheduled meetings	x	x				
Institutional Review Board (IRB) compliance with federal regulations governing board membership composition and quorum for voting	x	x				
Institutional Animal Care and Use Committees (IACUC) meeting federal regulations governing operations and documentation	x	x				
Ethics and Compliance Plan is developed from a risk assessment and shared with the Board			x			
Performance standards and evaluation metrics utilized in FY 2009-10 performance evaluations			x			
Ethics, Compliance & Audit Services (ECAS) web site is interactive and timely updates are provided at campus/OP			x			
Develop and execute a customer satisfaction survey with 70% satisfaction (includes Regents, system and campus senior leadership).			x			
Regental Board Committee receives regular compliance updates			x			
Regental Board Committee receives timely updates on critical compliance matters for system			x			
Mandatory Sexual Harassment Prevention (AB1825) training is completed by appropriate supervisors (100%) (2 year)	x	x				
General Compliance (Ethics) Training is completed by UC employees (100%)	x	x				
Health Sciences & Services Initial reimbursement rule training of School of Medicine (SOM) clinical providers conducted prior to submission of claims to government payors		x				
Education offered on appropriate and timely compliance and audit issues on quarterly basis			x			
Determine venue for annual compliance education that meets intent of budgetary constraints			x			
Completion of mandatory education offerings meet UC-wide timelines as established by the Regents			x			
Ethics and compliance-related education items presented at each CECRC meeting			x			

Ethics and Compliance Program Performance Metrics Dashboard
FY 2009/2010

Annual Ethics and Compliance Work Plan Performance Metrics	System	Campus	Program	Risk Score	Met/Not Met	Comments
Eminence building through presentations at national/regional associations and publications			x			
Effectiveness of training measured through decrease in risk areas related to training			x			
Identify compliance risks in a timely fashion and provide appropriate communication	x	x				
Investigations initiated and completed (tracked) in timely manner (100% of delays documented and submitted to ECS)	x	x				
Hotline or other Improper Governmental Activities (IGA) reports reviewed and triaged within 72 hours		x				
Investigations are initiated and followed up as per UC policy (100%).		x	x			
Implementation of system-wide guidance on the initiation, monitoring and completion of investigations			x			
Fact finding for investigations completed with appropriate level of subject matter expertise			x			
Develop process to distribute applicable regulatory information to campus stakeholders in a timely manner - "context sheets"			x			
Collaborate with Academic Senate Chair, President's Office and Compliance to establish consistent approach to non compliance related to training for academics	x					
100% submission of all applicable senior management group (SMG) compensation statements within established timeframes meeting accuracy and completion standards	x	x				
Health Sciences & Services (HS) Health Sciences billing and coding audits conducted (5 MCs)		x				
Health Sciences & Services HS billing and coding audit findings with appropriate mitigation plans and resolution		x				
Health Sciences & Services Clinical trials research billing errors		x				
Health Sciences & Services Recovery Audit Contractors (RAC) overpayments are monitored.		x				
Health Sciences & Services Exclusion and Sanctions Checks are conducted		x				

Ethics and Compliance Program Performance Metrics Dashboard
FY 2009/2010

Annual Ethics and Compliance Work Plan Performance Metrics	System	Campus	Program	Risk Score	Met/Not Met	Comments
Identified ARRA compliance issues are addressed timely and resolved	x	x				
Monitor remediation plans for resolution of identified risk	x	x				
Health Sciences & Services Privacy complaints are reported per regulation	x	x				
Quantification of value of UC Ethics and Compliance Program through prevention, early detection and deterrence of compliance risk event (return on investment (ROI) - will quantify, where and as appropriate)			x			
Demonstrated action plans are developed and implemented for critical compliance matters and are monitored for completion and resolution of the issues			x			

Legend	
Documentation exists to support active mitigation of potential risk	
Documentation not complete to support active mitigation of potential risk	
No documentation to support active mitigation of potential risk	