

Office of the President

TO MEMBERS OF THE COMMITTEE ON COMPLIANCE AND AUDIT:

ACTION ITEM

For Meeting of July 17, 2013

APPROVAL OF ETHICS AND COMPLIANCE PROGRAM PLAN FOR 2013-14

RECOMMENDATION

The Senior Vice President – Chief Compliance and Audit Officer recommends that the Committee on Compliance and Audit approve the Ethics and Compliance Program Plan for 2013-14, as shown in Attachment 1.

BACKGROUND

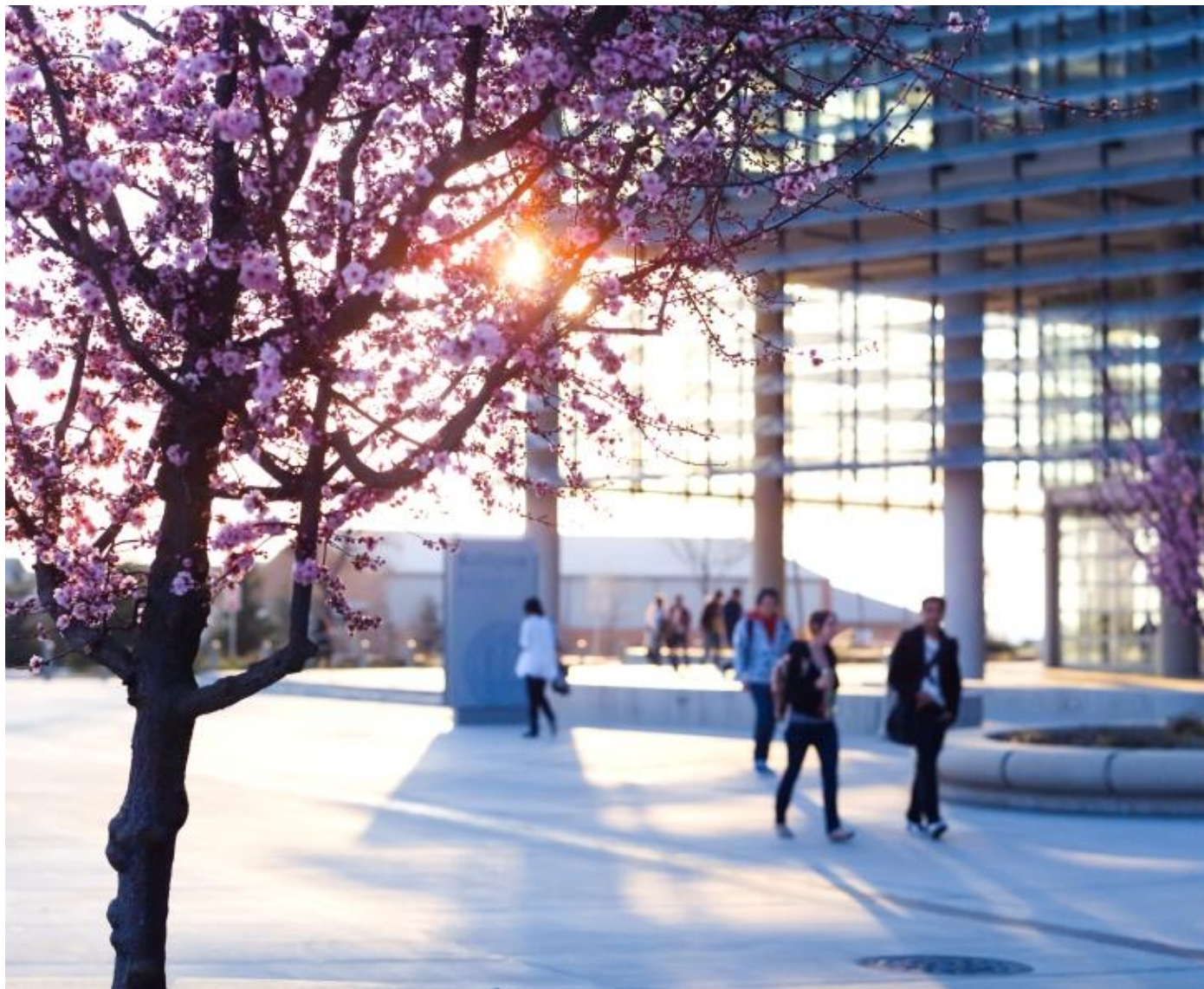
The Ethics and Compliance annual work plan for Fiscal Year 2013-14 (Plan) has been designed to reflect the ongoing maturation of the University of California Ethics and Compliance Program which is going into its sixth year of operation. Like other industries, higher education continues to value a comprehensive, integrated ethics and compliance program, designed to positively impact the culture of the organization in its efforts to meet its mission and maintain its value. The University of California Ethics and Compliance Program is recognized as a national leader in ethics and compliance program development and implementation by colleagues from other leading academic institutions who recognize the innovative and effective methodologies used by the Compliance Program to assist the individual campuses in their overall compliance efforts.

The Plan has been developed using prioritized risk assessment observations and work plan activities from each of the campus ethics and compliance risk committees which includes all ten campuses, Lawrence Berkeley National Laboratory, Agriculture and Natural Resources and Office of the President. Additionally, campus compliance staff worked collaboratively with internal audit, and as possible, the risk management functions at each campus to more fully capture identified compliance risks for inclusion in the campus work plan. Prioritization of the risks was discussed and agreed upon by the campus ethics and compliance officers and is reflected in this systemwide Plan. The following systemwide compliance risk areas, listed in no specific order of priority, will be focused on in this Plan and include key mitigation activities. Outcomes will be measured in the review of management risk mitigation activities and resolution of identified risks.

1. **Research Compliance:** Specifically focusing on the complexities of research in areas of government enforcement action, e.g., documentation, conflicts of interest and export controls.
2. **Government Reporting:** Focus on external regulatory activities, e.g., agency audits, and key risk areas where supporting documentation is needed for federal and/or state funding.
3. **Culture of Ethics and Compliance:** Continual emphasis across the system on supporting the cultural tone of accountability and “doing the right thing.”
4. **Data Privacy and Information Security:** Continual monitoring and training on protection of data across the UC landscape.
5. **Health Sciences:** Focus on the increased regulatory complexities associated with the Affordable Care Act, clinical research and related billing, and other regulatory enforcement areas.
6. **General Compliance:** International activities, complex business system initiatives such as UC Path, policy and procedure management, investigations and overall tracking of emerging themes.

(Attachment below)

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
OFFICE OF ETHICS, COMPLIANCE AND AUDIT SERVICES



ETHICS AND COMPLIANCE PROGRAM PLAN
2013 – 14

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I. Executive Summary

Background and Overview

The Office of Ethics, Compliance and Audit Services (ECAS) is a Regental Office of the University of California (University) that provides direction, guidance and resource references on how to optimize ethical and compliant behavior through effective ethics and compliance programs. Our goal is to help the University fulfill its responsibilities to the people of California in an ethical environment that is compliant with applicable laws, rules and regulations, and in which the public trust is maintained. Consistent with the Ethics and Compliance Program charter, the Ethics and Compliance Services (ECS) program develops an annual work plan to help mitigate non-compliance in high risk areas and assure the Regents that compliance controls supporting the University's strategic goals are in place, and evaluated on a regular basis.

This ECS Annual Compliance Workplan (Plan) for FY2013-2014 (FY14) has been developed in collaboration with the ten campuses, Lawrence Berkeley National Laboratory, Office of the President, Division of Agriculture and Natural Resources and the five medical centers, and strives to address key risks facing the University system as a whole. The Plan has been developed using prioritized risk assessment observations and work plan activities from each of the locations' campus ethics and compliance risk committee function (CECRC). ECS and campus compliance staff, including the CECRC members and the Campus Ethics and Compliance Officers (CECOs) worked collaboratively with the internal audit function and the risk management functions at each location to more fully capture identified compliance risks for inclusion in the campus work plan, and then prioritized for this system-wide Plan.

Key Compliance Areas

The key systemwide compliance risk areas to be focused on in FY14 include, in no order of importance, the following:

1. **Research Compliance** –*complexities of research in areas of government enforcement actions, e.g. documentation, conflicts of interest and export controls.*
2. **Government Reporting** –*external regulatory agency activities, e.g., agency audits, and key risk areas where supporting documentation is needed for federal and/or state funding.*
3. **Culture of Ethics and Compliance** –*cultural tone of accountability and “doing the right thing”.*
4. **Data Privacy and Information Security** –*protection of data across the University landscape.*
5. **Health Sciences** –*regulatory complexities associated with the Affordable Care Act, clinical research and related billing, and other regulatory enforcement areas.*
6. **General Compliance** – *international activities, complex business system initiatives such as UC Path, policy and procedure management, investigations and overall tracking of emerging themes.*

These key risk areas are discussed in more detail in Section III of this Plan.

II. Plan Background and Development

Higher Education Ethics and Compliance Program – State of the Industry

These are challenging times. Evolving burdens are being placed on higher education institutions that require a need for well-defined governance structures, clear and well-articulated policies and procedures, targeted training addressing ‘top risks’, real transparency and optimal communication practices. Our higher education compliance environment is also faced with increased regulatory focus on myriad rules and regulations that govern our work and emerging, but often unpredictable issues, such as youth activities and violence on campus.

Legal and regulatory requirements affecting higher education are constantly in flux, and colleges and universities need to have reliable and consistent processes in place for identifying and complying with applicable laws and regulations. In addition to regulatory burdens, budget constraints often increase compliance risks as we continue to increase efficiencies and strive to meet expectations to become more cost effective. Areas such as social media, online education, international activities, conflict of interest and the need to improve governance and accountability remain a high priority for colleges and universities. For example, universities are being challenged by the need to globalize the student experience and internationalize faculty and student bodies. While many colleges and universities have worked to establish compliance governance structures and communication frameworks, high regulatory risk areas remain, and there is often a gap between policy and behavior.

Compliance Program Self Assessment

As promulgated by regulatory guidelines, ‘effectiveness’ is one of the key criteria of a strong ethics and compliance program. Regulators consider the level of effectiveness of an organization’s ethics and compliance program in assessing penalties for noncompliance. As an industry best practice the effectiveness of a program should be assessed on a regular basis. While the ECS program continuously benchmarks itself to a number of ethics and compliance programs across the nation and is widely regarded as one of the leaders in the higher education industry, ECS also formally initiated a program self-assessment during this fiscal year to identify opportunities for improvement. In FY14, ECS will assess the results of this review and incorporate applicable actions into the Plan.

Risk Assessment and Plan Development

Risk intelligence is an organization’s ability to think holistically about risk by utilizing a common framework to help senior leadership make better decisions to achieve strategic goals. Mature risk programs promote coordination between areas and/or departments that are more actively involved in risk assessments, including compliance, internal audit and risk management. ECS has worked at both the system and campus levels to move the University towards a model of risk intelligence. During FY14, ECS will continue to work with the CECRCs and the campus mid-management compliance risk committees to help implement a more comprehensive risk intelligent approach. This approach will use system and campus strategic goals to identify and prioritize related compliance risks with the objective of developing a manageable risk mitigation plan. As the University ethics and compliance program moves towards a more mature risk intelligent model, cross functional risk owners will more likely

coordinate their efforts to share different perspectives, reduce duplication of effort, and conserve scarce resources.

The following Plan is based upon the nationally accepted compliance plan structure: the United States Sentencing Commission's (USSC) seven elements of an effective compliance program as outlined in Section 8 of the Federal Sentencing Guidelines. Key compliance risks were identified at each campus and then aggregated across the system and prioritized by the CECOs (*Appendix A: Compilation of Common Compliance Risk Areas*). The list reflects a quantifiable prioritization of the aggregated campus regulatory risks which established the systemwide compliance risk pool for the FY14 Plan. The methodology for scoring is noted on the Appendix A legend, but generally the scoring determination for risk *likelihood* and *severity* was 1-4, with 1 reflecting a low risk to 4 reflecting a strong likelihood and high severity of that risk. The *level of control* score, also 1-4, valued 1 as having no control, to 4 reflecting a high level of control, which would mitigate the seriousness of the first two categories. The resulting *residual risk exposure* score provides a basis for prioritizing and acting upon those risks.

For the purpose of this Plan, all risks with scores greater than 3.5 will be addressed. Section III will outline key goals and related activities that will be undertaken by ECS to assist the locations in mitigating their specific risks as identified in Appendix A, related to the systemwide prioritized risk areas.¹

III. Key Compliance Risk Focus Areas

1. Safety

Laboratory Safety

This potential risk continues to be ranked as a compliance focus area for the campuses due to relevant CalOSHA laboratory safety requirements; as well as the Regents/Los Angeles District Attorney's Office agreement and its related requirements which went into effect during the past fiscal year. Due to the comprehensive operational oversight and follow-up by the Risk Services department, this risk will not be addressed directly by ECS, other than to monitor progress towards compliance with the agreement in collaboration with Risk Services and Internal Audit.

2. Research Compliance Risk

Export Controls

Compliance with the evolving export control regulatory and operational landscape remains a key compliance risk for University in FY14 as evidenced by its systemwide, residual risk exposure score of 3.84. During President Barack Obama's 2013 State of the Union Address the President noted that, "we cannot look back years from now and wonder why we did nothing in the face of real threats to our security and our economy". Immediately following that address was the release of the "White House Strategy on Mitigating the Theft of Trade Secrets" which demonstrated a blurring of "cybercrime," "theft of trade secrets" and "export control violations", all reflecting academic institution involvement.

¹ Due to the dynamic nature of risks, the goals may be revised during the fiscal year to meet additional priority or other business risks identified by the organization.

As export control reform continues to evolve in unexpected ways, both opportunities and challenges are created for academia. Recent enforcement actions shed light on the need to remain vigilant, especially in the realm of international collaborations involving foreign travel and the shipping of tangible research materials as well as traditional UC concerns regarding fundamental research and academic freedom.

Goal

Systemwide open access principles are reviewed with location leadership and revised accordingly to develop formal systemwide policy. Training and education related to federal export control laws delivered in-person and online, with focus on in-person training for researchers.

3. Government Reporting

Regulatory Activities

The onsite audit focus of government agencies, such as the National Sciences Foundation (NSF), the Center for Medicare/Medicaid Services (CMS) Office of Inspector General (OIG), and the Office of Federal Contract Compliance Programs (OFCCP), across a number of campuses and medical centers has increased the resource burden on the locations as evidenced by the increase in the residual risk exposure ranking of this risk to 4.00. Locations are tasked with assisting these agencies in their audit efforts to ensure the accuracy of the audited information, as well as assure that appropriate controls are in place and well communicated to administrative staff and faculty. Cost disallowances, paybacks and fines can be a result of negative audit observations which may negatively impact the system's financial resources and national reputation.

Goal

ECS will monitor external agency audit activities and facilitate systemwide response, as appropriate, to external agency audit activities and responses. Summary reports of trended observations and/or recommendations will be shared with campus leadership to enhance local controls on high risk reporting requirements. ECS will also conduct audits in the health sciences and/or research compliance risk areas.

4. Culture of Ethics and Compliance

Managing Youth Activities

Even though the residual risk exposure ranking of this ongoing risk area has improved to 3.33 during this past year, ECS continues to focus on activities related to maintaining compliance with relevant state laws and regulations as well as University policy on this important area.

Goal

The new University Policy on Reporting Child Abuse and Neglect to assure system-wide compliance with the revised California Child Abuse and Neglect Reporting Act (CANRA) as referenced in California Penal Code Section 11164-11174.3 will be disseminated to campuses.

- ECS will facilitate delivery of online training for mandatory reporters and work with the campuses to identify current compliance activities related to managing youth activities.
- ECS will monitor compliance to policy on a quarterly.

5. Data Privacy and Security

Privacy and Information Security Steering Committee Recommendations

Even though data privacy and information security residual risk rankings reflected improved scores of 2.38 and 2.22 respectively, the publication of the University of California Privacy and Information Security Steering Committee (Committee) recommendations has brought data privacy and information security to the forefront for this next fiscal year. The information technology conversions that campuses are undertaking to update or replace aging business systems entail significant risk to privacy and information security management. With the recommendations of the Committee delivered in late FY13, a focus for ECS in FY14 will be to support the approved recommendations and enhance privacy and security of personal financial and/or health information across the system.

Goal

The goal of this risk mitigation includes several areas:

- Collaboration occurs with respective functions to review and revise policies as appropriate.
- Privacy training will be provided in collaboration to all campus locations.
- Assistance with development and dissemination of Information Security training, as requested.
- Assistance to campus locations on assuring leadership that privacy and information security risks are being addressed.
- Collaboration will occur with the Chief Information Officer (CIO) to report to the President and the Regents on the overall status of Privacy and Information Security

6. Health Sciences Compliance

Clinical Research Billing

Accurate and timely submission of billing and coding data to government reimbursement agencies continues to be a key compliance program risk that requires continual and focused vigilance. Due to a change in the Medicare payer for the health sciences, many requirements must be addressed and put into place by the end of the year. The consequences of non-compliance with clinical research billing rules may be disastrous in terms of negative publicity for the University and resultant lack of sponsorship, increased paybacks of inaccurately billed services to insurers, potential monetary (civil) fines for billing errors to the CMS, undercharging or overcharging study accounts.

Goal

Clinical research billing reviews are completed and relevant observations and recommendations are presented to health sciences leadership for review and appropriate remediation.

Health Sciences Coding

Even though the residual risk ranking of this area is 3.15, below the risk threshold for this report, the potential for increasing compliance risk over the next several years increases due to the overall lack of qualified coding resources. This lack of resources impacts the timeliness and accuracy of appropriate claims submission to all payers from the health sciences functions, as it does to other institutions across the nation.

Goal

Availability of skilled resources will be increased by developing and implementing a systemwide industry-sponsored, coding certification program that will focus on two main areas at this time: physician coding and diagnosis coding. In addition, ongoing training will be provided for current coding professionals and a monitoring program will be initiated to track and trend retention of UC coding professionals, and coding accuracy rates.

7. General Compliance

International Activities

The University has international activities that span faculty/student exchange programs, intercollegiate consortia, sponsored research, research collaborations, international alumni associations, foundations, trusts, and more. The proliferation of the establishment of foreign operations and affiliates by the campuses/LBNL increases risk of non-compliance in a variety of areas that are tied to the rules, regulations and practices of foreign governments and cultures. ECS is currently revamping a policy to devolve much of the responsibilities for engaging in international activities to the campuses, but providing a library of high-level risks associated with international activities for consideration of risk-mitigation.

Goal

Compliance risks associated with international activities will be mitigated through early implementation of controls around high-risk areas.

Changes in Data and Financial Systems

The human resources, financial and health sciences areas across the University will continue to be impacted by major changes in their information technology systems, adding to the complexity of completing daily transactions. From instituting or enhancing electronic health/medical records (EMR) in the health science entities which will impact clinical documentation and claim submission processes, to revising current processes to align to the new UCPath financial systems, these major initiatives have the potential for a number of compliance risks to emerge.

Goal

Collaboration with key business functions leading the above initiatives to determine, as appropriate, at what point audit or monitoring assistance can be provided by ECS working collaboratively with Internal Audit.

IV. ECS Program Focus Areas

In addition to the identified key compliance risks for the FY14 Plan, we will continue to focus on two important areas within ECS – the Office of Investigations and the University Policy Office. The Office of Investigations is responsible for coordinating, tracking, managing and/or conducting investigations at both systemwide and at the Office of the President. This Investigations Office is also responsible for oversight of an independent hotline to receive and investigate confidential reports of suspected misconduct. The overarching objective of the hotline is to help the University maintain its commitment to a culture based on the highest of ethical standards. The University Policy Office oversees the policy-making process in all areas for which the President has authority. The University of California systemwide policy process involves broad consultation with diverse University constituencies on the ten campuses, ANR, LBNL and the Office of the President; maintains all Delegations of Authority from the President to the Chancellors and senior managers; and is the official repository of historical and current documents.

Investigations Goals

The ECS Investigations Unit will introduce a new web-based intake form to assist Local Designated Officials (LDOs) in managing their workload by streamlining the process of reporting suspected misconduct initiated from sources other than the hotline reporting process. ECS will also continue to leverage internal investigation resources with the campus investigations teams to promote an investigation response that is prompt, thorough, fair, objective and properly documented. ECS will also deliver an introductory workshop for employees who are new to investigations and continue with ongoing training sessions for current investigators. The unit will continue to track and trend issues identified and report to leadership, as appropriate.

Policy Project Goals

ECS will continue to provide clear guidance on such issues as governance, policy framework, and writing “plain language” policy. ECS will also provide web-based tools to access policy review schedules and status.

V. Summary

In collaboration with the campuses, ECS will further quantify the goals and objectives related to this Plan which will then be aggregated periodically and reported to the Regents’ Compliance and Audit Committee. ECS also continues to co-lead an informal networking and benchmarking group, the InterUniversity Compliance Consortium (IUCC) that includes representatives from prominent group of western universities to share compliance program best practices. This external collaboration will continue to help provide a forum to discuss and review compliance program best practices and process improvements.

Compilation of Campus Identified Compliance Risk Areas Draft Campus Compliance Work Plans FY2013-14

Risk Area	Focus	Risk Likelihood	Risk Severity	Level of Control	Residual Risk Exposure
Safety	Laboratory Safety*	3.00	3.90	3.50	3.51
	Emergency Planning*	2.90	3.70	3.50	3.22
	Violence on Campus*	2.80	3.70	3.50	3.11
Research	Conflicts of Interest	3.40	2.80	3.60	2.67
	Intellectual Property	2.90	2.70	3.60	2.19
	Export Controls	3.00	3.20	3.00	3.84
Government Reporting	Billing/Coding-HS	2.90	2.60	3.70	1.96
	Fraud, Waste, and Abuse	3.10	3.00	3.50	2.79
	Regulatory Activity, i.e., external audit	3.70	3.00	3.20	4.00
Culture of Ethics and Compliance	ADA/EEOC	3.10	2.70	3.20	3.01
	Diversity-Awareness	2.70	2.60	3.60	1.97
	Managing Youth Activities	2.80	3.30	3.20	3.33
	Management Accountability	3.11	2.67	3.22	2.95
	Reputational	3.11	3.00	3.33	3.11
Data Privacy & Security	Privacy	3.00	3.60	3.90	2.38
	Information Security	3.00	3.70	4.00	2.22
General Areas	UCPATH	3.11	3.22	2.89	4.23
	Third Party Relationships	3.00	2.89	3.00	3.47
	International Activities	2.90	2.80	2.80	3.57
Health Care	Billing and Coding	3.33	2.83	3.33	3.15
	Regulatory Activity	3.33	2.83	3.17	3.46
	Clinical Research	3.14	3.43	3.14	4.00
	Conflict of Interest	3.50	2.50	3.00	3.50
	Third Party Relationships	2.80	2.60	3.00	2.91
	Privacy and Security	3.17	3.33	3.83	2.46
Risk Likelihood	Rare=1, Unlikely=2, Possible=3, Likely=4, Almost Certain=5				
Risk Severity	Negligible=1, Minor=2, Moderate=3, Serious=4, Critical=5				
Level of Control	None=1, Minimal=2, Moderate=3, Strong=4, High=5				