Office of the President

TO MEMBERS OF THE COMMITTEE ON COMPLIANCE AND AUDIT:

ACTION ITEM

For Meeting of July 12, 2011

ETHICS AND COMPLIANCE PROGRAM PLAN FOR 2011-12

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 2011-12, as shown in Attachment 1.

(Attachment below)

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



Ethics and Compliance Program Plan for 2011-12

July 2011

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Overview

The University of California's (UC) Systemwide Ethics and Compliance Program (ECP) was originally driven by The UC Board of Regents in 2006 in response to several high profile compliance issues. Sheryl Vacca, Senior Vice President and Chief Compliance and Audit Officer (CCAO), was recruited for the development and implementation of the ECP and presented the proposed plan for Regental approval at their July 2008 meeting. The UC Ethics and Compliance Program was approved and adopted by the Board through a resolution at that time, and currently all UC locations have operationalized a campus-specific ECP that is evolving through the different levels of maturity and is very dynamic.

Obtaining input from key leadership at the campuses, Lawrence Berkeley National Lab (LBNL), Agriculture and Natural Resources (ANR) and University of California Office of the President (UCOP), was critical for ensuring the initiation of systemwide ethics and compliance efforts. It was important for leadership to understand that the model developed would be instrumental in assisting each location to facilitate compliance risk-based communications, identify compliance risks and assure mitigation of compliance risks across and between campuses and reported to the Regents. The identification and commitment of a Campus Ethics and Compliance Officer (CECO), receipt of senior commitment and ownership, and collaboration with each location on compliance risk identification and mitigation efforts, were recognized as key concepts that would ultimately lead to a positive impact to the University. In addition, the Health Science Compliance Program had been established several years ago and its integration into the systemwide compliance program was also important in considering overall risks.

Current Environment

UC faces FY 2011-12 with a financial crisis of exceptional proportions. Initial state budget cuts of \$500 million may be augmented with additional hundreds of millions of dollars of state cuts if increased income taxes are not extended beyond July 1, 2011. Without alternative resources to meet this budget gap, the President has directed campus Chancellors to make necessary budget cuts which will negatively impact campus operations and the delivery of core services. This may entail the elimination of academic as well as other programs and include the reprioritization and redistribution of job duties as personnel downsizing will be necessary to meet the new budget limits. Administrative services will bear the brunt of budgetary constraints as the campuses strive to maintain commitments to the mission of UC: education, research and public service.

As the federal government also weathers its own budgetary crisis, federal agencies have increased their surveillance of allocated dollars to higher education and research functions to ensure the accurate usage and reporting of those funds, as per contract language. Thus, as institutions of higher education compete for limited dollars, there is an increased focus on greater transparency and accountability that accompanies the acceptance of research grants and other federal funding. To continue our eminence in research and education, UC must maintain a competitive advantage in attracting more federal funding. In supporting this goal, UC remains committed to ensuring campuses comply with applicable federal rules and regulations governing funding allocations to avoid the requirement to repay spent funds and/or incur fines for usage or reporting inaccuracies.

The UC System and Campus Ethics and Compliance Programs' ability to focus limited resources on monitoring and mitigating key compliance risks is more imperative in this tumultuous environment. Campuses may be forced to cut programs or administrative services adversely impacting compliance oversight and monitoring, while ensuring there is no reduction of the compliance risks associated with the flow of federal funding. As a result, it becomes even more important for Ethics and Compliance Services (ECS) to continue its focus on supporting the campuses in their efforts to operationalize and track and report on campus-specific compliance work plan activities to mitigate identified risks. ECS will continue to collaboratively leverage system and campus level resources to provide efficient and timely responses to identified needs for improved operational processes and/or oversight. Preventing non compliant behavior, or lack of management controls or mechanisms in compliance, is a focus which is difficult to establish in an environment that is forced to react due to changes in economy, scalability of resources and increased regulatory constraints.

Plan Objectives

As in the past, the FY 2011-12 ECS Plan integrates the **UC Statement of Ethical Values and Standards of Ethical Conduct (Statement)**¹ as a foundation for ensuring compliance with rules and regulations that govern all aspects of UC operations. The Statement provides a roadmap for faculty, management and staff on how to work on the mission of UC in a responsible and ethical manner. The Plan objectives include:

¹ See Addendum A: University of California Statement of Ethical Values and Standards of Ethical Conduct

- A framework based on the "Seven Elements of an Effective Compliance Program" as provided by the United States Sentencing Commission's Guidelines for Organizations (FSG) to proactively plan for the efficient use of limited resources to address prioritized potential compliance risks. The seven elements include:
 - 1) Written Standards of Conduct/Policies and Procedures;
 - 2) Governing Body Oversight and Designation of Compliance Officer;
 - 3) Employee Education and Training;
 - 4) Communication Systems (Confidential Hotline);
 - 5) Screening and Enforcement;
 - 6) Auditing and Monitoring; and
 - 7) Response and Prevention.

This framework is also consistently being utilized by federal funding agencies where they are requiring compliance efforts, for example, Department of Education (DOE), National Institutes of Health (NIH) or National Science Foundation (NSF), etc.

- Assistance to CECOs in their campus efforts to identify, prioritize, develop and evaluate work activities to address risks.
- A high level outline of the work steps necessary to effectively address the scope of potential compliance risks; and
- Documentation of action plans to assist campuses/UCOP/LBNL to mitigate the risks outlined below.

Potential Compliance Risks

The FY 2011-12 ECS Plan has been developed in collaboration with the ten campuses, LBNL and the five academic medical centers. To achieve greater efficiencies in senior leadership time and staff productivity, CECOs were requested to collaborate with Internal Audit (IA) and Risk Services, as applicable, on a combined risk assessment process – see the below graphic for combined IA and CECO/ECS work efforts in conducting campus risk assessments.

FY11/12 Risk Assessment Timeline



Campus/location-specific compliance work plans were developed with associated compliance risks, mitigation activities and by developing outcomes oriented performance metrics. Based on the analysis of campus risks submitted by each campus, trending of data available and nationally recognized industry areas of compliance concern, ECS grouped identified campus compliance risk areas into compliance risk categories. The ECS work plan below summarizes those trended key work plan areas or the system priorities.² The risk categories are not presented in priority order, but are randomly listed and warrant equal attention with a due date of fiscal year end - June 30, 2012.

The risks listed are a compilation of key risks from all locations; however, not all risks are found at each campus. Detailed campus work plans which are scalable to the campus culture and resource limitations will outline the specific key risk(s) within the risk category that each location will address. Further detail on planned mitigation activities by the campuses will be provided as periodic updates on the metrics are made available. These plans are dynamic and will be reassessed periodically by campus leadership to assure risk priorities are appropriate to campus needs.

² See Addendum B – FY11-12 Compliance Work Plan – Major Risk Issues

1. **Campus Safety & Climate** — this category includes issues related to safety, diversity, and acts of violence or disruption to campus activities.

Campus Safety & Climate remain major areas of concern for this next fiscal year as each location continues in their efforts to review and enhance campus-wide processes and systems to identify and respond to a variety of concerns.

Goal:

Campus processes are in place to assure a safe, diverse and tolerant environment; and monitoring for trends to indicate a need for additional process improvements.

Metric(s):

Location documentation shows evidence of campus process implementation and evaluation with appropriate mitigation plans to address significant identified trends.

11. **Government Funds Reporting Requirements Accuracy** — this category includes the accurate reporting of the use of funds received by the University from the federal government per contractual or reimbursement regulation, such as time and effort reporting per NSF, NIH, American Recovery and Reinvestment Act (ARRA) grant monies, and Centers for Medicare/Medicaid Services (CMS – primarily Medicare and MediCal) billing and coding accuracy.

In their campus compliance work plans, government funds reporting accuracy as a key compliance risk was identified by some due to the complexity of the rules and regulations. The potential gaps in consistent processes across campuses in the accurate and timely collection and reporting of required data was also noted as a key risk.

The following list highlights areas of focus which may have been included in campus workplans:

- ARRA Reporting
- Billing & Coding (Medical Centers/Student Health Centers)
- Electronic Medical/Health Records (EMR/EHR)
- Federal Funding Accountability and Transparency Act (FFATA)
- ICD-10 (International Classification of Diseases 10)
- Payroll Certification Demonstration Project at UCI/UCR
- Records Management and Policies
- Time & Effort Reporting

Goal:

Adequate site-specific protocols and processes are in place to assure accurate and timely submission of reports/claims to government to support expenditures of funds and/or reimbursement of claims.

Metric(s):

Education, training, and audit and monitoring activities occur per work plan with appropriate management action plans documented with timely response to actions.

- III. Data Privacy and Security this category includes the privacy and security of personal financial and/or health information for patients, faculty, students and administrative staff. Like industry, there was agreement among the CECOs that data privacy and security will continue to be a key risk area well into the future across all campuses due to the challenges of the UC environment which has open access and autonomous operations. In their compliance work plans, they identified the following specific areas of compliance risk as part of their plans:
 - Data Security Information Technology (IT) Systems
 - Encryption of Mobile Devices
 - Personal Health Information (PHI)
 - Personal Identifiable Information (PII)
 - Records Management (refer to II)
 - Access issues

Goal:

Data privacy and security efforts on systemwide and campus-specific initiatives have the management mechanisms and controls in place to help meet regulatory requirements. Staff compliance to established protocols is improved and enhanced through education and enforcement activities.

Metric(s):

Audits occur per plan and recommendations and management responses for process improvements are monitored for timely resolution. Education and training occurs per campus-specific and systemwide plans.

IV. Research-related Compliance Risks – this category includes risks related to research operations. Examples include:

- Clinical Trials Research Billing
- Conflicts of Interest individual and institutional
- Contracts & Grants compliance with terms
- Export Controls
- International Activities
- Intellectual Property
- Independent Review Board (IRB) Approval Processes
- Responsible Conduct of Research

Goal:

Research-related compliance policies, procedures and applicable implementation steps are in place to assure compliance with applicable government or other contractual rules or regulations.

Metric(s):

Key research compliance risk process reviews completed, recommendations provided to locations, and education and training occurs as needed. Audits conducted per plan with resultant observations, recommendations and management action plans monitored for timely resolution/reduction of risks. Systemwide export controls program is implemented.

V. **Culture of Ethics and Compliance** — this category incorporates the University's Statement of Ethical Values and Standards of Ethical Conduct that is accepted systemwide as the "right thing to do" and continues to need reinforcement in developing a strong ethical culture during these challenging economic times.

Culture was identified by the campuses as a key risk area. The CECOs noted in their compliance work plans that they are concerned with the impact of budgetary reductions on their campus cultures, particularly on the ethics and compliance function. To this end, they identified the following specific areas within this category:

- Fraud Management
- Management accountability for compliance risk mitigation
- Policies/Delegation

Goal:

UC maintains a current level of processes and systems to demonstrate commitment to its *Statement of Ethical Values and Standards of Ethical Conduct.*

Metric(s):

ECS communication and educational efforts will be provided on the elements of a culture of compliance.

Appropriate controls surrounding compliance-related activities, including administrative and faculty compliance-related enforcement guidelines for non-compliance to training and other compliance-related mandates, are reviewed for applicability within the UC environment.

VI. Health Reform — this category takes account of the ongoing changes occurring as the federal government continues to negotiate portions of the Patient Protection and Affordable Care Act (ACA). These changes may impact certain elements of the Act recently passed by Congress. The new rules and regulations associated with ACA which implicate Medicaid/Medicare billing and coding, the False Claims Act, Stark anti-kickback laws, medical information privacy, and quality of care. As a consequence, ACA has the potential for increased compliance risks to the University as terms are interpreted and mandated across the nation for ACA.

Goal:

Determination of impact of ACA sections on University operations and development of an ECS monitoring tool to track implementation effort to ensure compliance to Act timelines.

Metric(s):

Awareness of the regulations and their impact on our organization increased through mechanisms such as training, use of tools and communication.

The above risks will be outlined in detail with specific ECS and campus/location objectives and quantifiable performance metrics assigned. Periodic status reports on the agreed upon metrics will be provided to the President's Compliance and Audit Committee (PCAC) and the Board of Regent's Compliance and Audit Committee.

Addendum A

University of California Standards of Ethical Conduct

Purpose

Pursuit of the University of California mission of teaching, research and public service requires a shared commitment to the core values of the University as well as a commitment to the ethical conduct of all University activities. In that spirit, *the Standards of Ethical Conduct* are a statement of our belief in ethical, legal and professional behavior in all of our dealings inside and outside the University.

Applicability

The Standards of Ethical Conduct apply to all members of the University community, including the Regents, Officers of the Regents, faculty and other academic personnel, staff, students, volunteers, contractors, agents and others associated with the University. Organizationally, the *Standards* apply to campuses, the National Laboratories, the Office of the President, the Division of Agriculture and Natural Resources, campus organizations, foundations, alumni associations and support groups.

1. Fair Dealing

Members of the University community are expected to conduct themselves ethically, honestly and with integrity in all dealings. This means principles of fairness, good faith and respect consistent with laws, regulations and University policies govern our conduct with others both inside and outside the community. Each situation needs to be examined in accordance with the *Standards of Ethical Conduct*. No unlawful practice or a practice at odds with these standards can be justified on the basis of customary practice, expediency, or achieving a "higher" purpose.

2. Individual Responsibility and Accountability

Members of the University community are expected to exercise responsibility appropriate to their position and delegated authorities. They are responsible to each other, the University and the University's stakeholders both for their actions and their decisions not to act. Each individual is expected to conduct the business of the University in accordance with the *Core Values* and the *Standards of Ethical Conduct*, exercising sound judgment and serving the best interests of the institution and the community.

3. Respect for Others

The University is committed to the principle of treating each community member with respect and dignity. The University prohibits discrimination and harassment and provides equal opportunities for all community members and applicants regardless of race, color, national origin, religion, sex, gender identity, pregnancy, physical or mental disability, medical condition (cancer-related or genetic characteristics), ancestry, marital status, age, sexual orientation, citizenship, or status as a covered veteran. Further, romantic or sexual relationships between faculty responsible for academic supervision, evaluation or instruction and their students are prohibited. The University is committed to creating a safe and drug free workplace. Following is a list of the principal policies and reference materials available in support of this standard:

- The Faculty Code of Conduct
- Academic Personnel Policy Manual
- The Faculty Handbook
- Personnel Policies for Staff Members
- Policies Applying to Campus Activities, Organizations and Students
- Policy on Sexual Harassment and Procedures for Responding to Reports of Sexual Harassment
- University policies on nondiscrimination and affirmative action
- Campus, laboratory and Office of the President Principles of Community

The University's health sciences enterprises are committed to the ethical and compassionate treatment of patients and have established policies and statements of patient rights in support of this principle.

4. Compliance with Applicable Laws and Regulations

Institutions of higher education are subject to many of the same laws and regulations as other enterprises, as well as those particular to public entities. There are also additional requirements unique to higher education. Members of the University community are expected to become familiar with the laws and regulations bearing on their areas of responsibility. Many but not all legal requirements are embodied in University policies. Failure to comply can have serious adverse consequences both for individuals and for the University, in terms of reputation, finances and the health and safety of the community. University business is to be conducted in conformance with legal requirements, including contractual commitments undertaken by individuals authorized to bind the University to such commitments.

The Office of the General Counsel has responsibility for interpretation of legal requirements.

5. Compliance with Applicable University Policies, Procedures and Other Forms of Guidance

University policies and procedures are designed to inform our everyday responsibilities, to set minimum standards and to give University community members notice of expectations. Members of the University community are expected to transact all University business in conformance with policies and procedures and accordingly have an obligation to become familiar with those that bear on their areas of responsibility. Each member is expected to seek clarification on a policy or other University directive he or she finds to be unclear, outdated or at odds with University objectives. It is not acceptable to ignore or disobey policies if one is not in agreement with them, or to avoid compliance by deliberately seeking loopholes.

In some cases, University employees are also governed by ethical codes or standards of their professions or disciplines—some examples are attorneys, auditors, physicians and counseling staff. It is expected that those employees will comply with applicable professional standards in addition to laws and regulations.

6. Conflicts of Interest or Commitment

Employee members of the University community are expected to devote primary professional allegiance to the University and to the mission of teaching, research and public service. Outside employment must not interfere with University duties. Outside professional activities, personal financial interests, or acceptance of benefits from third parties can create actual or perceived conflicts between the University's mission and an individual's private interests. University community members who have certain professional or financial interests are expected to disclose them in compliance with applicable conflict of interest/conflict of commitment policies. In all matters, community members are expected to take appropriate steps, including consultation if issues are unclear, to avoid both conflicts of interest and the appearance of such conflicts.

7. Ethical Conduct of Research

All members of the University community engaged in research are expected to conduct their research with integrity and intellectual honesty at all times and with appropriate regard for human and animal subjects. To protect the rights of human subjects, all research involving human subjects is to be reviewed by institutional review boards. Similarly, to protect the welfare of animal subjects, all research involving animal subjects is to be reviewed by institutional animal care and use committees. The University prohibits research misconduct. Members of the University community engaged in research are not to: fabricate data or results; change or knowingly omit data or results to misrepresent results in the research record; or intentionally misappropriate the ideas, writings, research, or findings of others. All those engaged in research are expected to pursue the advancement of knowledge while meeting the highest standards of honesty, accuracy, and objectivity. They are also expected to demonstrate accountability for sponsors' funds and to comply with specific terms and conditions of contracts and grants.

8. Records: Confidentiality/Privacy and Access

The University is the custodian of many types of information, including that which is confidential, proprietary and private. Individuals who have access to such information are expected to be familiar and to comply with applicable laws, University policies, directives and agreements pertaining to access, use, protection and disclosure of such information. Computer security and privacy are also subject to law and University policy.

Information on the University's principles of privacy or on specific privacy laws may be obtained from the respective campus or laboratory information privacy office.

The public right to information access and the individual's right to privacy are both governed by state and federal law, as well as by University policies and procedures. The legal provisions and the policies are based upon the principle that access to *University of California* information concerning the conduct of the people's business is a fundamental and necessary right of every person, as is the right of individuals to privacy.

9. Internal Controls

Internal controls are the processes employed to help ensure that the University's business is carried out in accordance with these *Standards*, University policies and procedures, applicable laws and regulations and sound business practices. They help to promote efficient operations, accurate financial reporting, protection of assets and responsible fiscal management. All members of the University community are responsible for internal controls. Each business unit or department head is specifically responsible for ensuring that internal controls are established, properly documented and maintained for activities within their jurisdiction. Any individual entrusted with funds, including principal investigators, is responsible for ensuring that adequate internal controls exist over the use and accountability of such funds. The University has adopted the principles of internal controls published by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission.

10. Use of University Resources

University resources may only be used for activities on behalf of the University. They may not be used for private gain or personal purposes except in limited circumstances permitted by existing policy where incidental personal use does not conflict with and is reasonable in relation to University duties (e.g. telephones). Members of the University community are expected to treat University property with care and to adhere to laws, policies and procedures for the acquisition, use, maintenance, record keeping and disposal of University property. For purposes of applying this policy, University resources is defined to include but not be limited to the following, whether owned by or under the management of the University (for example, property of the federal government at the National Laboratories):

- Cash, and other assets whether tangible or intangible; real or personal property;
- Receivables and other rights or claims against third parties;
- Intellectual property rights;
- Effort of University personnel and of any non-University entity billing the University for effort;
- Facilities and the rights to use University facilities;
- The University's name;
- University records, including student and patient records; and
- The University information technology infrastructure.

11. Financial Reporting

All University accounting and financial records, tax reports, expense reports, time sheets and effort reports, and other documents including those submitted to government agencies must be accurate, clear and complete. All published financial reports will make full, fair, accurate, timely and understandable disclosures as required under generally accepted accounting principles for government entities, bond covenant agreements and other requirements. Certain individuals with responsibility for the preparation of financial statements and disclosures, or elements thereof, may be required to make attestations in support of the *Standards*.

12. Reporting Violations and Protection from Retaliation

Members of the University community are strongly encouraged to report all known or suspected improper governmental activities (IGAs) under the provisions of the *Policy on Reporting and Investigating Allegations of Suspected Improper Governmental Activities* (Whistleblower Policy). Managers and persons in supervisory roles are required to report allegations presented to them and to report suspected IGAs that come to their attention in the ordinary course of performing their supervisory duties. Reporting parties, including managers and supervisors, will be protected from retaliation for making such a report under the *Policy for Protection of Whistleblowers from Retaliation and Guidelines for Reviewing Retaliation Complaints* (Whistleblower Retaliation Policy).

Adopted by the Regents of the University of California, May, 2005.

Addendum B

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



FY11-12 Compliance Plan - Major Risk Issues

Compliance Risk	Goal	Metric (s)
1. Campus Safety and Climate	Campus processes are in place to assure a safe, diverse and tolerant environment; and monitoring for trends occurs to indicate a need for additional process improvements.	Location documentation shows evidence of campus process implementation and evaluation with appropriate mitigation plans to address significant identified trends.
2. Government Reporting Accuracy	Adequate site-specific protocols and processes are in place to assure accurate and timely submission of reports/claims to government to support expenditures of funds and/or reimbursement of claims.	Education, training, and audit and monitoring activities occur per work plan with appropriate management action plans documented and timely response to actions.
3. Data Privacy and Security	Data privacy and security efforts on systemwide and campus-specific initiatives meet regulatory requirements and staff compliance to established protocols is improved and enhanced through education and enforcement activities.	Audits occur per plan and recommendations and management responses for process improvements are monitored for timely resolution. Education and training occurs per campus-specific and systemwide plans.
4. Research	Research-related compliance policies, procedures and applicable implementation steps are in place to assure compliance with applicable government or other contractual rules or regulations.	Key research compliance risk process reviews completed; recommendations provided to locations and education and training occurs as needed. Audits conducted per plan with resultant observations, recommendations and management action plans monitored for timely resolution of needs for improvement. Systemwide export controls program is implemented.
5. Culture of Ethics and Compliance	UC maintains systems and processes to demonstrate commitment to its Statement of Ethical Values and Standards of Ethical Conduct	ECS communication and educational efforts will be provided on the elements of a culture of ethics and compliance. Appropriate controls surrounding compliance-related activities, including administrative and faculty compliance- related enforcement guidelines for non- compliance to training and other compliance- related mandates are reviewed for applicability within the UC environment.
6. Health Care Reform	Determination of impact of ACA sections on University operations and development of ECS monitoring tool to track implementation effort to ensure compliance to Act timelines.	Awareness of the regulations and their impact on our organization increased through mechanisms such as training, use of tools and communication