UNIVERSITY of CALIFORNIA





Annual Report on Compliance OFFICE OF ETHICS AND COMPLIANCE SERVICES

2009-2010

Office of Ethics and Compliance Services

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CHIEF COMPLIANCE AND AUDIT OFFICER OVERVIEW

It is with great pleasure that I present the second Annual Report on the activities of the Ethics and Compliance Services (ECS) Department covering Fiscal Year (FY) 2009-2010. ECS is responsible for coordinating, supporting, and promoting an effective systemwide Ethics and Compliance Program, as well as providing assurance to the Regents and the President that controls and mechanisms are in place to prevent, detect and/or mitigate compliance risk. In fulfilling these responsibilities, one of the primary objectives of ECS is to provide direction, guidance, and resources to each University of California (UC) location on fostering ethical and compliant behavior through an effective Systemwide and Campus Ethics and Compliance Risk Program. ECS bases the program on a framework that includes the Seven Elements of an Effective Ethics and Compliance Program, factors that help to prevent, detect and deter potential compliance risks across the University. The seven elements are:

- 1. Standards and Procedures
- 2. Oversight
- 3. Education and Training
- 4. Monitoring and Auditing
- 5. Reporting
- 6. Enforcement and Discipline
- 7. Response and Prevention

In FY 2009-2010, ECS leveraged the elements outlined above to focus on several key systemwide compliance risks. Achievements over this past year include hiring the first fulltime Systemwide Privacy Officer to assist with addressing a key compliance priority—data privacy and security. ECS also supported systemwide research compliance efforts through various activities which included facilitating training and working with campus research leaders and operations in recommending solutions to complex research compliance problems in areas such as export controls, effort reporting, etc. In the health sciences compliance arena, ECS focused on strengthening the systemwide health sciences compliance program structure through direct and significant leadership roles (due to vacancies in the Health Sciences Compliance Officer Role at UCLA and UCSF) by myself and my deputy, respectively. We promoted campus participation and benchmarking of health sciences compliance risks through development of systemwide metrics and reinstituting/developing formal and informal mechanisms of communication.

Federal enforcement efforts have increased to assure that organizations in receipt of federal funding are complying with their contractual obligations. Requirements issued by the National Institutes of Health (NIH), the Office of Inspector General for the Department of Health and Human Services (HHS/OIG), and the Federal Acquisition Regulations (FAR) to name a few and which all apply to our university communities, stipulate that compliance programs be in place with certain common elements. Chapter 8 of the United States Sentencing Commission's (USSC's) Federal Sentencing Guidelines (1991) identifies the seven elements of an effective compliance program, which contribute to the USSC's considerations when sentencing organizations by reducing culpability for elements that are in place and effective, or increasing culpability when such elements are lacking. These guidelines have been adopted in the establishment and development of ethics and compliance programs in numerous industries, including higher education, and therefore form the basic framework of our ethics and compliance program.

In the same vein of increased enforcement by regulatory agencies, this year the USSC wanted to promote increased ownership and accountability by organizations of their compliance program efforts, which resulted in modifications to Chapter 8 (Appendix A) of the Federal Sentencing Guidelines, that will take effect November 1, 2010, barring any Congressional action against them. These modifications include four new requirements that must be met for organizations to reduce their culpability: (1) those with operational responsibility of the compliance and ethics program must report directly to the governing authority or its subgroup, such as an audit committee of the board of directors; (2) the compliance and ethics program must detect the offense before its

discovery outside the organization, or before such discovery was reasonably likely; (3) the organization must promptly report the offense to the proper governmental authorities; and (4) no person with operational responsibility in the compliance program may have participated in, condoned, or remained willfully ignorant of the offense. If these requirements are met, along with having the seven elements of an effective compliance program in place, organizations may receive credit for their compliance and ethics program, and therefore reduce their culpability score.

The new requirements promise increased scrutiny and increased emphasis on known risks, or those that should have been known, within our UC communities. These are coupled with additional regulatory compliance challenges for the University in FY 2010-2011, for example, new and proposed laws with respect to transparency and reporting to government agencies and the public. High-visibility topics, such as privacy breaches, financial conflicts of interest in research, and management of federal contracts and grants, are under regulatory scrutiny. The new health care reform laws (Patient Protection and Affordable Care Act – PPACA), the Red Flags Rule, the Higher Education Opportunity Act, and new training requirements by federal funding agencies are also areas of focus for ECS in FY 2010-2011.

Despite the programmatic and regulatory compliance challenges faced by the University System, I am confident that ECS and campus ethics and compliance risk programs will continue to work closely together to identify, prevent, detect and/or mitigate priority compliance risks. In so doing, ECS will work closely with the campus ethics and compliance risk programs to ensure that these compliance priorities are addressed in a timely fashion, are managed on an enterprise-wide scale under the auspices of the established Campus Ethics and Compliance Risk Committees (CECRCs), and that mitigation plans are developed and executed for these priorities. The effectiveness of the systemwide ethics and compliance program will be measured not only by the achievements of the systemwide Office of Ethics and Compliance Services, but more importantly, by the effectiveness of the ethics and compliance risk programs at all of our University locations. ECS is looking forward to providing the necessary leadership and assistance to further develop and document effective enterprise-wide ethics and compliance risk programs at all University locations which will ultimately demonstrate systems and mechanisms are in place to mitigate our risks to resolution or to a minimal level.

Sheryl Vacca, Senior Vice President Chief Compliance and Audit Officer University of California

FY 2009-2010 IDENTIFIED KEY COMPLIANCE RISK PRIORITIES

The FY 2009-2010 ECS Annual Plan was developed using a process that prioritized potential compliance risks identified through review of federal/state/local regulatory and industry communications, University-location-specific communications and processes, and management communications including internal audit risk assessment results. The potential compliance priorities that were originally identified for focus during FY 2009-2010 are provided below. Details of ECS activities aimed at mitigation and prevention of these potential risks are included in Section III of this Report.

It is important to note that the FY 2009-2010 Annual Plan was a dynamic document, which allowed for reassessments and strategic changes during the fiscal year as unforeseen higher compliance priorities were identified that could negatively impact the University. As would be expected, additional compliance priorities arose and were addressed during FY 2009-2010, and these areas are included and described in Sections III and IV of this Annual Report.

Definition of Compliance Risk Priorities as stated in FY 2009 – 2010 Annual Plan:

Data Security and Privacy

A number of highly-publicized personal information breaches at University locations in the past several years have prompted additional focus on systemwide data security and privacy issues. All of these incidents received national media coverage. Naturally, these incidences caused reputational harm, while also posing potential financial repercussions for the University. Due to the increasing risk in this area, in FY 2009-2010 a systemwide Privacy Officer was hired as part of the systemwide Office of Ethics and Compliance Services. This Officer works closely with University locations to identify, prevent and reduce risk in the area of data security and privacy.

American Recovery and Reinvestment Act

On February 17, 2009, the American Recovery and Reinvestment Act (ARRA) was signed into law by President Obama. The expressed purpose of this Act was to create new jobs and retain existing ones, spur economic activity, and invest in long-term growth over a two-year period.

As of May 2010, the University of California had received approximately \$977 million from more than 1,600 award transactions from federal agencies including the Department of Energy, National Institutes of Health, and the National Science Foundation (data obtained from http://www.ucop.edu/newsroom/newswire/img/35/3548937444bf568f463c37.pdf). While the additional funding for basic science research has been a boost to the University during a time of diminished and uncertain funding for higher education in California, acceptance of ARRA funding came with additional compliance responsibilities. In addition to the traditional federal awards' reporting requirements, new reporting requirements were associated with the acceptance of ARRA funding. The nature and frequency of these new reports have posed serious compliance challenges for University locations in FY 2009-2010.

ARRA also included the Health Information Technology for Economic and Clinical Health (HITECH) Act, which entails the first modifications to the Privacy and Security Rules promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) since those Rules took effect in 2003 and 2005, respectively, and enhanced compliance responsibilities and potential breach consequences for the University system. As a result, more challenges are ahead related to compliance with these rules with respect to data privacy and security.

Conflict of Interest

Conflict of interest (COI) issues in healthcare and academic research contexts continue to be a priority risk for the University. With passage of the provisions of the Physicians Payment Sunshine Act on March 23, 2010 (as part of the Health Reform Laws-H.R. 3590: Patient Protection and Affordable Care Act of 2009), drug and device manufacturers are required to disclose gifts and payments made to physicians on a Department of Health and Human Services-maintained website that will be made public by September 30, 2013. Increasing attention with respect to UC policies and procedures aimed at mitigating the negative impact of conflicts of interest in the delivery of academic healthcare and the conduct of research has occurred over the past year, with attention from Senator Grassley and others. Additional requirements have been proposed by the National Institutes of Health in 2010 that lower the monetary threshold for reporting of significant financial interests related to a research proposal, and shift the burden of identifying when such an interest is a true conflict from the investigator to the institution. Like other American universities, UC supports innovative entrepreneurial initiatives, but at the same time, has an obligation to minimize risk related to conflicts of interests by fully disclosing and appropriately eliminating or managing COI.

Effort Reporting

Compliance with federal effort reporting requirements is an ongoing risk for the University, since over 50% of total University expenditures come from federal sponsorship. In the research environment several high profile cases have shown that the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS), and the Department of Justice (DOJ), continue to be aggressive in bringing charges for noncompliance with time and effort reporting requirements. Moreover, the Inspectors General of various federal agencies continue to perform target audits of cost sharing tracking systems and certifications, effort reporting processes, cost allocations, administrative and clerical salaries, and sub-recipient monitoring. Findings from the labor and effort reporting audits conducted over the past five years by the National Science Foundation's OIG at institutions of higher learning have focused national attention on problem areas such as cost transfers, summer salary, accurate certifications (suitable means of verification), and training, among other issues. In response to non-compliance with effort reporting regulations, in 2008 Yale University signed a settlement with the federal government to return approximately \$7.6 million. Yale is not alone as other Universities have also signed settlements related to this area and paid monies back to the enforcement agencies.

Even though the above priority areas were a focus for our ethics and compliance risk activities, they were integrated into a larger group of compliance activities to assure they were not singly addressed, but became part of an overall focus to mitigate risks. As reported in Section III, ECS became involved with several different compliance functional groups to assist in the risk mitigation efforts.

COMPLIANCE FUNCTIONAL GROUPS

A. Research Compliance

Compliance with ARRA Reporting Requirements

As mentioned in Section IIB, recipients of ARRA funding incur mandatory federal reporting requirements. On April 6, 2010, President Obama issued a memorandum ("Combating Noncompliance with Recovery Act Reporting Requirements") directing federal agencies to use every means available to identify any prime recipient required to file a report on FederalReporting.gov that has failed to do so, and hold such recipients accountable to the fullest extent permitted by law, including terminating awards, pursuing measures such as suspension and debarment, reclaiming funds, and considering, initiating, and implementing punitive actions.

In an effort to mitigate risk in this area, ECS initiated a systemwide monitoring effort in March 2010 after two formal ARRA-reporting quarters had passed. While the new requirements for ARRA-funded projects have posed significant compliance challenges for University locations, ECS found that the campuses had worked diligently to establish processes, systems, training and internal controls to ensure timely and accurate quarterly reports for these projects. University locations developed and maintained ARRA reporting tools, worked closely with investigators to obtain quarterly progress information, worked with the UC Office of the President to develop systemwide approaches for identification of ARRA-funded awards, and expended significant resources on ongoing ARRA-related compliance activities. Some practices among the University locations that appear likely to facilitate sustainable compliance in this area include: hiring of ARRA coordinators, using independent reviewers for quality assurance of data prior to submission of ARRA reports, using a locally developed "jobs calculator," and incentivizing research coordinators to collect and compile information that leads to accurate and timely ARRA reports.

Compliance with Conflict of Interest Policies and Regulations

A systemwide COI Workgroup has been formed to address policies and guidance to improve systemwide controls in reporting of conflicts of commitment in the medical enterprise, and to facilitate systemwide efforts to support COI management tools. ECS will play an active role in this workgroup and continue to assist with identifying ways in which compliance can be integrated into current practices effectively, with ease and transparency.

The Kuali-Coeus (KC) COI Module, a COI disclosure and management e-solution that is being developed via a national consortium, with UCSD leading the effort, has been discussed as a possible technology solution for reporting COIs. ECS will continue to assist these efforts to assure risk-mitigating controls and mechanisms are effective. Additionally, ECS will help provide input on new proposed regulations such as the National Institutes of Health and the financial COI requirements proposed for later this year.

Effort Reporting Compliance

Compliance with federal effort reporting requirements set out in the Office of Management and Budget (OMB) Circular A-21 and University policy remains a high risk area for the University. In FY 2009-2010 many activities occurred in this area that included identifying areas for improvement in educational opportunities, and effort reporting system enhancements. These areas were discussed with systemwide senior leadership, and the Effort Reporting System (ERS) Management Workgroup was charged with development of metrics to be used in evaluating the University's effort reporting compliance, while the Provost's Office was charged with leading a Faculty/Researcher Workgroup to develop systemwide effort reporting training for investigators. ECS was charged with facilitating both of these efforts.

In FY 2009-2010, ECS worked with the ERS Management Workgroup to develop measurable metrics that serve as indicators of timely and accurate effort reporting. Beginning in FY 2010-2011, each University location will report on the identified metrics to systemwide senior leadership, through ECS. ECS also worked with the Provost's Office to identify a chair for a Faculty/Researcher Workgroup to lead the development of systemwide effort reporting training content. Once the group was formed, ECS facilitated calls and webinars, and provided background information to help the group develop an outline of key effort reporting training concepts. For

detailed training content development, ECS provided funding support for an outside consulting group to develop the module, and provided project management. The online course has been developed, and is currently being reviewed by the Provost's Office. The online effort reporting course will be ready for campus distribution in FY 2010-2011.

ECS also provided advocacy support for a Payroll Certification System pilot project initiated under the Federal Demonstration Partnership that would replace the traditional interpretation of OMB A-21 as requiring effort certifications with a mechanism whereby investigators would certify that the payroll paid on a project is reasonable in relation to the work that was performed. ECS is supporting and participating in activities to gain regulatory support for a pilot program with UCI and UCR related to payroll certification versus time and effort reporting. The pilot proposal information is currently under review by DHHS. If approved, faculty could meet compliance reporting requirements in this area in a more efficient and more effective manner.

Intellectual Property (IP) Compliance

Royalty Audits

Earned royalties due to universities from the licensing of university intellectual property are often underreported by licensees. In collaboration with the campus Technology Transfer Officers and the systemwide office of Innovation Alliances and Services, a focused compliance audit was done in this area. Outside expertise was obtained for the audit and ECS managed communication, work flow, consultant deliverables and assuring campus follow up occurred on the audit observations.

Themes for improvement that were identified in this audit included early detection of underpaid royalties, and early and ongoing review of compliance with contract language that needs to occur. Ongoing monitoring in this area will continue in FY 2010-2011.

Monitoring for Proper Intellectual Property Assignment

Active monitoring of proper assignment of University intellectual property (IP) to The Regents is an important element of an effective IP compliance program. Historically, there has been no systemwide effort in this area, in large part due to the difficulty in identifying IP that may be improperly assigned. In an effort to minimize this hurdle, ECS in coordination with the Office of Research and Graduate Studies, conducted a pilot project in FY 2009-2010 to provide campuses with data that identifies IP that may be associated with UC researchers, and that may be improperly assigned either to the inventor, personally, or to a non-University entity, and asked them to analyze the data. Preliminary results suggest that the data have identified IP created by University researchers that may need to be properly assigned to The Regents – IP that was not previously known to the campuses. This is a difficult area in which to obtain accurate and current data, but ongoing efforts will continue to be utilized to monitor appropriate assignment of IP.

Compliance with New Regulations: Responsible Conduct of Research

A new regulation effective for National Science Foundation (NSF) applications submitted on or after January 4, 2010, requires the proposing institution to certify that it has a plan to provide training in the responsible conduct of research (RCR), and to provide oversight for students (undergraduate and graduate) and postdoctoral scholars who will be supported by NSF to conduct research. Institutions are also required to verify that the students and postdoctoral scholars have received the required training.

In FY 2009-2010, ECS coordinated with all University locations to develop a systemwide implementation plan for the new NSF RCR requirement. A faculty-led workgroup at UCLA set out to develop an online RCR course for UCLA that they are making available for systemwide use. ECS supported this effort by negotiating a systemwide copyright license to the National Academy of Sciences content they needed, for unlimited systemwide user access, worked with the systemwide Learning Management System (LMS) administrator to identify resources for authoring the UCLA-developed content in the LMS format, paid for LMS authoring, and worked with the LMS administrator to achieve systemwide programming changes to the payroll system to add a special training code for identification of NSF-funded students and postdoctoral scholars.

Key Partnerships

The Research Compliance unit of ECS maintains important relationships with research compliance professionals across all University locations through organization of and participation in systemwide groups including the Research Compliance Advisory Committee (RCAC), the Health Sciences Research Compliance (HSRC) group, the Institutional Animal Care and Use Committee (IACUC) Directors and the Attending Veterinarians. ECS supports these groups by organizing regular conference calls, meetings and listservs. Importantly, ECS communicates about new and existing compliance policy/regulations, and monitors campus implementation through these venues. In addition, the Research Compliance unit of ECS participates in standing workgroups such as the Enterprise Risk Management (ERM) Panel, the Effort Reporting System (ERS) Workgroup, and in adhoc policy-making groups such as the Subject Injury Policy Workgroup, and the Conflict of Interest Workgroup.

B. Health Care Compliance

FY 2009-2010 has been a tumultuous year for health care across the nation, as well as at the University of California's five Academic Medical Centers (AMCs): Davis, Irvine, Los Angeles, San Diego, and San Francisco. UC organizations were not unique with regard to scrutiny of health care claims reimbursement by governmental regulators. UC also endured cost-cutting measures during this fiscal year due to the state financial crisis, which increased the risk of weakened compliance controls and risk mitigation systems. In efforts to prevent fraud, waste, and abuse, the federal government has ramped up oversight activities, resulting in more frequent audit requests and less time for audit responses by the University. These activities have a negative impact on productivity across several University functions, including compliance, quality review, care/case management, HIMS (health information management services), and patient financial services, as these departments spend increasingly more time meeting Centers for Medicare and Medicaid Services (CMS) Office of the Inspector General (OIG) deadlines for submitting requested records, rather than conducting operational duties.

Program Structure Updates

Compliance Program Leadership

Health Sciences (HS) Compliance program leadership remained stable at three of the five AMCs in FY 2009-2010, with UCLA and UCSF continuing their search for HS Compliance Officers. The UCLA HS Compliance Office is now staffed with a full-time Chief Compliance Officer. Systemwide support to UCLA for their compliance efforts continues, and was also provided during their recruiting. UCSF has been recruiting for their clinical enterprise compliance director position for some months as of this writing, but, led by the systemwide Deputy Compliance Officer, has restructured their program during the interim. The director will report to a fulltime UCSF campus-wide ethics and compliance officer, a position that is unique within the University system, and is currently under active recruitment.

Committees

Health Sciences Compliance Committee

In FY 2009-2010 the need for increased communication related to common compliance risks and successful mitigation strategies became evident. Government activity increased, underscoring the importance of sharing best practices in preparation for enhanced scrutiny. The HS Compliance Officers and Privacy Officers continue to meet regularly, in collaboration with representatives from the Office of General Counsel and other functional areas, as needed. This group also focuses on ways to increase education on compliance risks, and strategies for risk mitigation, especially in the clinical reimbursement areas of billing and coding.

Medical Billing Advisory Committee

With respect to improving collaboration between compliance and the faculty practices to achieve a more proactive and consistent approach to dealing with potential billing and coding concerns for health care billing and coding, it was decided to form a new committee that could formally focus on these issues. The Medical Billing Advisory Group (MBAG) was established with membership including the HS Compliance Officers, the Chief Compliance and Audit Officer, the Deputy Compliance Officer, the Deputy General Counsel for Health Law, reimbursement counsel and three physician faculty leader representing three campuses. This forum

provides for in-depth discussions on new or changed coding regulations, with the goal of providing consistent guidance to the Medical Center/ProFee compliance office coders with recommended position statements on the appropriate interpretation of complex or vague coding regulations.

Health Sciences Compliance Committee

As an adjunct to the Health Sciences Compliance Committee, the health sciences research compliance professionals expressed the desire to form a subgroup to meet and discuss their specific issues and needs as they span two different functional areas: health sciences compliance and research compliance. The group identifies areas for improvement, and shares best practices. The group discussed the complexity and lack of consistency between clinical trials billing processes at the various campuses. Several recommendations have been identified for improving these processes, and will be a focus area for FY 2010-2011.

Health Sciences Compliance Program Performance Metrics

The HS Compliance Officers have been active in developing performance metrics for FY 2010-2011.

Provider training/orientation on current coding documentation standards for professional fees remains a high priority for the HS Compliance Officer group as the intensity of federal audits increases. The five AMCs engage in different practices to code services and claims, ranging from providers coding their own encounters to outsourced coding to professional coders in external agencies. Discussions are ongoing and ECS is assisting the AMCs in developing a common software tool to enable completing these federal audits in a timely manner.

Regulatory Update

Government Audit Activities

The operational impact of increased government audit activities on health-related claims submitted to programs within the Centers for Medicare and Medicaid (CMS) such as Medicare, Medicaid (MediCal), Veterans Health, and the like continued to be one of the key priority areas for the Health Sciences. Compliance Officers grappled with developing internal processes to more efficiently meet the increased demand for documentation for paid claims, and planned and unplanned audits. The fuel feeding this audit activity was the November 2009 announcement by the United States Department of Justice (DOJ) of its successful recovery of \$2.4 billion under the False Claims Act for the fiscal year ending June 30, 2009. Violation of the False Claims Act is the primary criminal offense charged by the federal government to recover inappropriately received health care funding, for example, from the Medicare or Medicaid programs. For FY 2008-2009, the bulk of the recovery came from the healthcare industry (66%, or approximately \$1.6 billion), with roughly half of that amount coming from provider organizations (data obtained from http://www.prnewswire.com/news-releases/justice-department-recovers-24-billion-in-false-claims-cases-in-fiscal-year-2009-more-than-24-billion-since-1986-70521362.html). The other half was recovered from pharmaceutical and medical device companies.

As the prospect of a health care reform package potentially passing both Congressional chambers emerged in the first quarter of 2010, the need to identify its financial underpinnings became more urgent. It was widely reported that President Obama believed the majority of funding for the Patient Protection and Affordable Care Act (PPACA) would derive from the Office of Inspector General (OIG) more widely reviewing payments and the appropriateness of reimbursements. This administration's intent to prevent fraud, waste and abuse in government spending is validated by identifying programs in which the greatest number or dollar volume of improper payments are occurring. PPACA incorporates several requirements including naming the accountable senior official responsible for, and various mechanisms to track and calculate, overpayments in the designated program. Agencies must report their specific actions taken to reduce overpayments and meet specific overpayment reduction targets within 2 years.

OIG Letters

Industry has received letters from the Department of Health and Human Services (DHHS) OIG requesting detailed information about claim submission and collection processes. UC has also received these letters and each HS Compliance Officer has worked internally to resolve any identified issues and make repayments as indicated

Recovery Audit Contractors (RAC)

Established by the Tax Relief and Health Care Act of 2006 (Section 302), recovery audits successfully returned over \$900 million in overpayments to the Medicare Trust Fund between 2005 and 2008 during an initial demonstration phase in California, Florida, New York, Massachusetts, South Carolina and Arizona. At the same time, approximately \$38 million in underpayments have been returned to health care providers through these audits. Recovery audit contractors have been identified for all Medicare providers and the program has now officially been instituted across the nation. The audits include claims submitted and paid by hospitals, physician practices, nursing homes, home health agencies, durable medical equipment suppliers and any other provider or supplier that bills Medicare Parts A and B.

California healthcare providers have been receiving a number of Recovery Audit Contractors (RACs) letters which have focused primarily on select diagnosis-related groups (DRGs) and pharmacy charges, indicating an inpatient focus at this time. UC has also received these letters and each AMC has established work groups and related processes to internally address RAC audit requests, as well as any other significant external audit request, such as MediCal Integrity Contractor (MIC) audits. These efforts require multi-disciplinary teams, as well as effective technology solutions. This will be an ongoing focus for the healthcare industry and specifically our AMC's.

MediCal Integrity Program and MediCal Integrity Contractors (MIC)

The Deficit Reduction Act (DRA) of 2005 created the Medicaid Integrity Program (MIP) under section 1936 of the Social Security Act. This was the first comprehensive federal strategy to prevent and reduce provider fraud, waste, and abuse in the \$300-billion-per-year Medicaid program. Several of our organizations have received MIC audit letters with a focus on a payment code area.

Other Regulatory Focus Areas

Based on the DHHS OIG's Annual Work Plan, other governmental announcements or enhancements to regulations, and industry trends, other regulatory issues surfaced this past year that may impact the AMCs and Faculty Medical Groups. Typically, each University HS Compliance Officer reviews their respective organization's sensitivity to the identified issue to determine if process improvements to achieve more comprehensive compliance and/or potential payback are required. Key focus areas for FY 2009-2010 included:

- Physician supervision in the outpatient setting;
- The 72-hour rule;
- Charity care processes development and implementation; and
- Impact of health care reform (Patient Protection and Affordable Care Act).

On the regulatory horizon is the changeover from ICD-9 (International Classification of Diseases version 9) to the more complex and comprehensive ICD-10, which will require significant operational changes, and education and training to applicable staff. The AMCs are in the process of identifying their goals and objectives to meet this requirement scheduled for implementation on October 1, 2013.

Next Steps

The health science compliance goals and objectives for FY 2010-2011 include more detailed reporting on monitoring of operational compliance and efficiency efforts, focusing on federal and state health services claims submissions and funds reporting in accordance with government rules and regulations, HIPAA privacy and security regulations, and health science research-related activities. The impact of the PPACA on University health sciences compliance activities will be analyzed, and work plans adjusted, as needed. In addition, education and other compliance-related planning activities will continue to focus on the value ECS can bring to the strategic and operational goals of the University.

C. Data Security and Privacy

Revision to the Systemwide HIPAA Policies

In part stimulated by the HITECH Act changes to the HIPAA Privacy and Security Rules described in Section II, above, ECS led an effort to revise and update the systemwide policies for compliance with the HIPAA Privacy and Security Rules. The policies were updated on the basis of the University's operational experiences with HIPAA Privacy and Security over the past seven years, incorporated the requirements of the Security Rule, and added the new provisions and modifications of the HITECH Act.

HIPAA Privacy and Security Training

The HIPAA Privacy Rule requires all covered entities to train the members of their workforces on their HIPAA policies and procedures, as it relates to their work function. Each AMC has developed and implemented such training, however some of the smaller, independent organizational units of the University that are subject to HIPAA have lacked the resources to develop or acquire online training materials, or establish access to a system that facilitates both the delivery and tracking of such training. ECS collaborated with representatives from the AMCs to develop a HIPAA Privacy and Security online training module, which has been deployed via the University Learning Management System (LMS) to affected UCOP personnel, and made available to other organizational units systemwide.

Revised Systemwide HIPAA Business Associates Agreement (BAA)

HIPAA requires contracts (known as BAAs) with vendors that perform functions for UC HIPAA-covered entities using UC's protected health information, such as transcription services. The UC BAA was re-formed as a standalone agreement that need only be executed once per vendor on a systemwide basis, instead of multiple times for each vendor contract and for each campus. A contracts database was made available by UCSF as a repository for systemwide BAAs. These changes should significantly reduce the number of BAAs being executed, and create workforce efficiencies by reducing the time to negotiate new contracts with existing vendors.

Development of Breach Response Tools

A flow chart to determine whether a breach is required to be reported under California law was developed, and approved by the Office of General Counsel (OGC). This tool has been identified by several of healthcare organizations in the State of California to be a "best practice" and other organizations have adopted this tool for their use. A checklist for determining whether a breach needs to be reported under the new HITECH Act provision was developed by OGC, in consultation with ECS, and distributed to campuses by ECS. ECS also led a multi-functional systemwide work group in developing a breach response plan that can be used by all University locations.

Key Partnerships

ECS has developed communications and partnerships with key functions, such as the Office of General Counsel, Human Resources, Finance, Institutional Advancement, Student Affairs, Information Resources and Computing, Risk Services, Research and Graduate Studies, and others to improve processes around mitigating privacy compliance risk areas and help to shape our future practices in this area. ECS facilitates communication and participates on various leadership and work group committees to assure consistency in the approach towards this risk area.

D. General Compliance

University Policies

Across the higher education community and in companies worldwide, executives are examining internal administrative policy-making processes. Central to GRC efforts are clearly articulated, regularly reviewed and consistently communicated institutional policies. The Office of the Inspector General (OIG) has identified high-

level oversight, written policies, effective communication of policies, and continuous improvement as four of the seven elements of a successful compliance program. This year, the systemwide Policy Office within ECS has made numerous contributions to the goal of streamlining bureaucracy, increasing workforce efficiency, and demonstrating transparency and accountability to stakeholders.

The goal of the ECS Policy Office is to assist the University community in developing and interpreting policies and disseminate policy information to manage the policy lifecycle (creation, communication, management, maintenance). The Policy website (http://www.ucop.edu/ucophome/coordrev/ucpolicies/welcome.html) is consistently the most frequently accessed website within the UCOP domain.

The University systemwide policy universe comprises business and administrative policies, finance policies, research policies, student admissions and fee policies, budget and construction policies, student policies, academic and staff human resources policies, and others. Over the past few years, in connection with the restructuring of senior management compensation policies, the University (with the approval of The Regents) developed and implemented a standard policy template.

In FY 2009-2010, the ECS Policy Office analyzed and inventoried over 400 policies. This compilation will in turn be reviewed by UC Office of the President (UCOP) policy owners. One of the resources that will be made available as this review proceeds is a web-based, automated policy workflow tool that will enable policy owners and policy users to approve and disseminate governance materials, and maintain permanent electronic records of the approval process. The policy workflow and management technology tool is a component of software used by ECS to manage workflow, conduct surveys, and perform risk assessments on various University operations. As stated in the report, *UC* 2010, a New Business Architecture (available online at: http://uc2010.ucsd.edu/):

Policy provides institutional guidance for effective decision-making and ensures that mechanisms for regulatory compliance are embedded into business practices of the University. The University can do much to improve the maze of complexity that staff must negotiate today in order to determine what is and is not acceptable.

Policy organization supports efficiencies in all enterprises. In concert with implementation of the workflow tool, the President has initiated a review of all policies issued by UCOP as the first step in conforming University policy to the standard systemwide template. The Policy project will develop a policy taxonomy to integrate information across functions. For example, research scientists will be able to "link" from fiscal and financial administrative rules on research administration to related conduct of research content. Information will be sequenced logically to assist researchers, students and research administrators alike in managing complex regulatory and administrative rules. To support the research, teaching, and service missions of UC, policies will be organized to support policy users' roles & responsibilities. Additionally, this integrated framework will assure stakeholders that regulatory requirements are being met, and identify areas where more advice is necessary.

The University recognizes its responsibility to provide easy access to policies, guidelines, rules and procedures that demonstrate how the University conducts business, admits and governs students, serves the State, and performs exemplary research, in addition to being a well-regarded institution within its communities and preserving the public trust.

In FY 2009-2010, the Policy Office worked closely with owners to assure comprehensive review and dissemination of senior management compensation policies. Other mission-critical policies coordinated with key stakeholders including the General Counsel, campuses, and UCOP subject matter experts included:

- the University policy governing acquisition and control of Drug Enforcement Administration scheduled drugs and precursor chemicals used in the University's teaching and research programs;
- identification of records management and retention policy needs;
- integration of student fee policies across student affairs, budget, finance and research environments;
- revisions to policies related to administration of the UC student housing system; and
- refinement and updating of the University's procurement policies.

"Decommissioning" policy is another important function of the ECS Policy Office. Empty, obsolete documents that are kept in circulation on account of one important statement obfuscate essential, mission-critical information. The Policy Office has (with the consent of subject matter experts) retired four such policies this year, and frequently contacts policy owners about other outdated material. Instigation of accountability measures (mandatory periodic review) will accelerate this process. Planned activities for FY 2010-2011 include:

- Annually setting executive priorities for policies to be created, reviewed or considered for rescission;
- Instituting an expedited review process for certain categories of policy or situations, with input from the Office of General Counsel; and
- Developing a centralized policy tracking calendar to set expectations and to measure accountability.

Governance and Delegated Authority

In January 2008, the WASC Report of the Working Group on the Roles of the Office of the President (presented to the Governance Committee of the Board of Regents, January 8, 2008; available online at: http://www.universityofcalifornia.edu/future/roleofOPrpt.pdf) called for:

...clarity about the fundamental roles and responsibilities in the administrative governance of the University of California [including] the role of the president, including high-level decision rights, responsibilities, and accountability; [and] the roles of the Regents and chancellors with respect to the president, including their high-level decision rights, responsibilities and accountabilities (January 8, 2008, available at: http://www.universityofcalifornia.edu/future/roleofOPrpt.pdf).

The ECS Policy Office during the past year catalogued over 2,500 current and historical formal Delegations of Authority from the President to executive officers, including the Chancellors and the Lawrence Berkeley Laboratory Director. Analyzing the patterns in this half-century historical inventory, the Policy Office has already identified many opportunities for streamlining. The Policy Office will also institute an annual review cycle for Delegations of Authority to ensure adherence to Regents Standing Orders and Bylaws and other statements they may issue from time to time. The Policy Office drafted and/or coordinated 25 Presidential Delegations of Authority during 2009-10.

The ECS Policy Office frequently advises campus offices and UCOP executive and Regental offices on appropriate authority to make contractual commitments on behalf of The Regents. In collaboration with the Office of the General Counsel (OGC) and senior leadership, ECS is leading an effort to prepare for management approval a "roles and responsibilities" summary for each UCOP executive officer. The summaries will incorporate appropriate delegations from the Standing Orders of the Regents and Regental and Presidential policies.

Key Partnerships

Ten years ago, the Policy Office instituted a monthly conference call to leverage the collective expertise of the University campus Policy Managers by sharing of best practices, problem-solving, and providing a forum for elevating policy concerns to a systemwide level.

The ECS Policy Office is a founding member of the Association of College and University Policy Administrators (http://www.acupa.org/) and continues to play an active role. This organization–now headquartered at the University of Minnesota – has over 60 members in over 20 states, including many public and private

universities, U.S. Immigration and Customs Enforcement, and one university in Australia. The ECS Policy Office also has begun collaborating with major U.S. corporations to share best practices on policy development and management.

In FY 2009-2010, the ECS Policy Office has presented several in-house policy and delegated authority workshops. The Policy Office has built relationships with Audit departments systemwide, both to assist in researching policy and delegated authority issues, and to support development of policy responses to audit findings.

The Policy Office is a first point of contact for campuses and campus community members searching for policies and policy interpretations, but also for members of the public and legislative staff. We collaborate with external relations and divisional offices to provide information on University policy to California legislators and citizens.

Timely communication of policies is a priority of the Policy Office, and in spite of attrition within UCOP last year, the Policy Office was able to distribute new policies and policy revisions to University location Policy Offices within one or two business days, leveraging their communication networks to broadcast important information to University location constituencies as soon as it is promulgated. The University of California Standards of Ethical Conduct are supported by a body of University policy that has stood the test of time, while at the same time adhering to regulatory and Regental prerogatives. Over 200 listserv subscribers receive timely updates each time new policies are issued, or policies are revised.

Also this year, on an interim basis the Policy Office has managed approvals and inquiries regarding the University's name and marks, and staffed the systemwide Committee on the Code of Conduct for Trademark Licensees. This activity supports the Regents' trademark rights and compliance with the University's policies safeguarding association of the University's reputation as one of the world's preeminent research, teaching, and public service institutions.

Education and Training

Mandatory Systemwide Training

In FY 2009-2010 ECS continued to develop and present comprehensive, timely, and resource-efficient compliance education and training programs across the University system to address identified compliance priorities. In collaboration with University locations and representatives from the Office of General Counsel and Academic Personnel, ECS oversaw the development and rollout of the following mandated compliance training programs through the University Learning Management System (LMS) which is operated by HR. They include:

- Compliance Briefing: UC Ethical Values and Conduct which was designed to reinforce UC's Statement
 of Ethical Values and Standards of Ethical Conduct and rolled out to all UC employees. The Regents
 also participate in this training through various presentations and education on compliance and legal
 concepts of our risk environment;
- Compliance Briefing: UC Ethical Values and Conduct, and Conflict of Interest for Researchers was
 designed to incorporate the UC Ethics information with conflict of interest training to satisfy granting
 agency requirements and applies to approximately 19,000 UC research employees;
- Sexual Harassment Prevention training is state-mandated for supervisors every 2 years and applies to approximately 22,405 supervisors across UC; and, lastly
- Conflict of Interest for Designated Officials which is required for certain University positions every 2 years and applies to approximately 1,412 persons.

Specific Issue-Related Training and Education

Due to the budgetary crisis that impacted the University, and the need for administrative and academic staff furloughs, all but necessary education and travel has been curtailed. In addition, the planned Second Annual Compliance and Audit Symposium was postponed this year due to budgetary concerns. As departments across the system adhere to furloughs and focus on "cutting costs," the need for education and maintenance of strong internal controls around new and existing regulations, UC Policy and legal requirements are even more critical, so that "cutting corners" does not become commonplace.

In collaboration with the systemwide Audit Department, ECS developed a quarterly training plan that allowed for on-site training that would include continuing education units (CEUs), and focused on pertinent compliance and audit issues. An effort was made to identify subjects and internal/external subject matter speakers that would span the audit and compliance world for more collaborative interactions and provide for in-depth cross-training on pertinent issues. Sessions were held in the north (Oakland and Berkeley), and the south (Irvine), which allowed for limited travel for most attendees, but provided free access to education programs.

ECS also made available up-to-date compliance training provided by external/internal subject matter experts through complimentary access to webinar presentations. Post-webinar evaluations demonstrated that these education opportunities provided pertinent, timely information, and are highly recommended by the campus community. In-person and webinar sessions were offered in a variety of functional areas, including export controls, research billing, information security & privacy, and Health Insurance Portability and Accountability Act (HIPAA).

In addition to ECS-organized quarterly on-site training/education sessions and webinars, audio conferences and webinars on pertinent high compliance-risk areas continued to be provided through arrangements with several external education sources, such as specialty consultants, HCCA (Health Care Compliance Association) and SCCE (Society of Corporate Compliance and Ethics).

ECS played a significant role in helping to develop critical training for campuses in the research compliance, and data privacy and security areas. For data privacy and security, ECS worked with the Academic Medical Centers to develop an online HIPAA training module for campuses and UCOP. ECS hosted an in-person half-day seminar on the new HITECH regulations.

In FY 2009-2010 ECS developed orientation for UCOP new employees based on the University of California Statement of Ethical Values and Standards of Ethical Conduct. The presentation includes information on the University's "whistleblower" program, and how to locate information on job-related policies and procedures as well.

Audit Services

Ethics and Compliance Services does not have its own auditing function. However, there are opportunities to leverage with the internal audit departments on campus and systemwide to help address auditing and monitoring areas for compliance. Additionally, ECS has utilized the services of outside subject matter experts, ie: export controls, royalties, etc. to assist with auditing and monitoring efforts, when needed.

Since the inception of ECS in 2008, there has been continuing emphasis on integration and collaboration between Audit Services and ECS to enhance risk monitoring and mitigation efforts across the University. In FY 2009-2010 internal audit risk assessment activities that support the development of the annual internal audit plan were recommended to be integrated with the annual compliance risk assessment process at the campus and systemwide-levels. These activities included interviews with local management, surveys, and analytical review of financial and non-financial data. In addition, annual audit and compliance plans were developed collaboratively to ensure the activities of each group were effectively complimented to maximize risk monitoring efforts. To facilitate information-sharing and coordination throughout the year, several systemwide and campus-level compliance committees were comprised of members of both Audit Services and ECS.

Investigations

The ECS Investigations Group is responsible for coordinating, tracking, investigating (where applicable), and managing complaints of suspected improper governmental activity, workplace misconduct, and other ethical breaches made under the University's Whistleblower Policy. This process is effectuated by a comprehensive program at all University locations to ensure compliance with federal and state whistleblower laws. Our robust reporting process, including an independently-operated hotline service, provides a communication mechanism to ensure that members of the University community, as well as the general public, can bring forward information of suspected improper governmental activity, or other non-compliant conduct, without fear of retaliation or retribution.

Process Improvement

During FY2009-2010, the Investigations Group initiated a process to identify, analyze, and improve operational effectiveness of the Whistleblower Program. Some of the process improvement activities that facilitated meeting new goals and objectives included: Investigator Training Program, Investigation Handbook, monthly Whistleblower Coordinator Webinar Series (Computer Forensics: Overview of the Process, Domestic Terrorism and Animal Rights Extremism, Metrics, Use of Reporting Case Management System), and OGC support in litigation and review of retaliation.

Campus and Laboratory Support

In FY 2009-2010 the University's Whistleblower Program received hundreds of complaints from various sources that required a determination as to whether an investigation was warranted or if the matter belonged in another University process. The type and quantity of complaints cannot be predicted in advance; however, the University's investigation protocol has established an efficient and fair method for determining the appropriate handling of every matter reported to the University. The Investigations Group collaborated with the campuses, the Division of Agriculture and Natural Resources (ANR) and Lawrence Berkeley National Laboratory (LBNL) to provide investigation support, including:

- Conducting sensitive investigations on behalf of the location;
- Supporting audit with public records searches;
- Supporting investigators with advice, referrals to external resources, report writing and editing, specialized metrics for local presentations; and
- Negotiating Professional Service Agreements (PSAs) with investigations & computer forensics firms.

Identification of Investigation Trends

Trend analysis assists the risk management process across the entire University system. While still in the early stages of compiling sufficient underlying data, the Investigations Group has observed an increase of reports of improper governmental activity or misconduct in the following complaint categories such as privacy/security violations; workplace misconduct/bullying; and, retaliation (Appendix A).

Industry Participation

The Investigations Group recognizes the importance of participation in industry groups for the purpose of sharing best practices. The Group believes that working in conjunction with industry organizations, associations, and University work groups contributes in positive ways to an effective compliance investigation protocol. During this fiscal year the Group's participation included new professional affiliations and representation on external boards and panels, as well as internal collaboration.

Whistleblower Program Awareness and Education

The ECS Investigations Group has continued to lead in Whistleblower Program Awareness and Education through the development of whistleblower training, and informational and educational material to promote awareness of this program. In doing so, the Group:

• Managed the mandated (CA Government Code) annual notice to all employees and posting of policy on/by July 1;

- Presented an interactive session at the annual Business Officer Institute (BOI) in December 2009 on the responsibilities of managers and supervisors when they are notified or learn of potential improper governmental activities; and,
- Presented an overview of the Whistleblower Program to departmental staff of various organizations at UCOP.

Key Partnerships

In FY 2009-2010 the Investigations Group maintained key partnerships with the campus and LBNL Locally Designated Officials (LDOs) and their coordinators and investigators. The LDO is the campus or lab official with the primary responsibility for managing reported allegations of suspected improper governmental activities. The Investigation Group's capability to coordinate, track and manage investigations system-wide has been enhanced with the implementation of an external case management Hotline Service and Issue & Event Manager (IEM) database.

Human Resources Compliance

ECS works closely with the Human Resources Department to facilitate compliance in this area (see Appendix B).

CAMPUS ETHICS, COMPLIANCE AND RISK PROGRAMS

ECS strives to effectively assist the Campus Ethics and Compliance Officers (CECOs) and Campus Ethics and Compliance Risk Committees (CECRCs) in their local efforts to identify, prioritize, develop, and evaluate work activities to address key risks, and to document action plans related to the mitigation of these risks. Highlighted below (Appendix C) are some of the FY 2009-2010 accomplishments of the CECRCs from across the system. Although the systemwide Ethics and Compliance Program is only a few years old, the locations have made great progress this year in contributing toward a strong and effective systemwide program.

The Campus Ethics & Compliance Officer (CECOs)

CECOs play a vital role on campus in the development and implementation of the campus ethics and compliance program. The CECO acts as a role model and a champion of ethical and compliant conduct for the campus community. To this end, each CECO provides on-campus leadership in the communication of compliance risks, as well as advice and counsel to the Chancellor and senior management on matters related to ethical and regulatory requirements. The CECO also serves as an essential link by coordinating program initiatives with ECS.

The Campus Ethics & Compliance Risk Committee (CECRC)

CECRCs maintain key oversight responsibilities for campus program development and implementation (including Lawrence Berkeley National Lab and Academic Medical Centers). An Executive Vice Chancellor/Provost co-chairs the committee along with a CECO. Members of the committee include senior leaders who are responsible for the various areas of campus compliance risk. In addition to program implementation, the committee members are responsible for the development and application of risk assessment tools for identifying and mitigating high risk compliance areas. Through the CECO, the CECRC then collaborates and coordinates with ECS on its compliance activities.

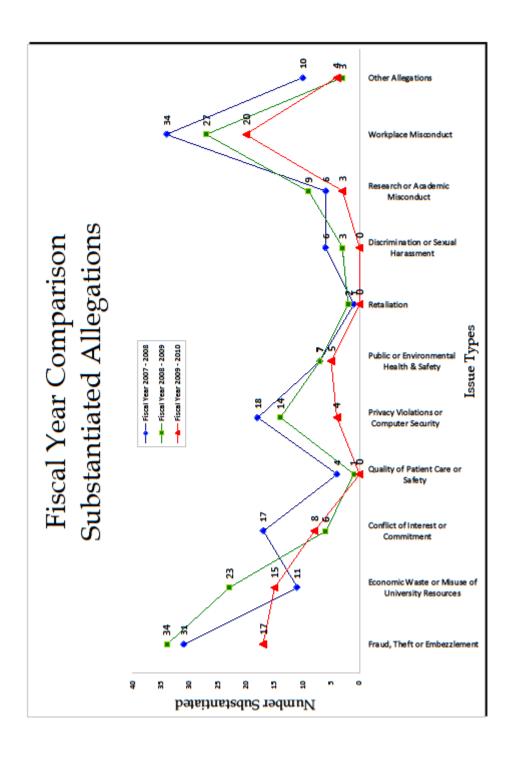
CONCLUSION

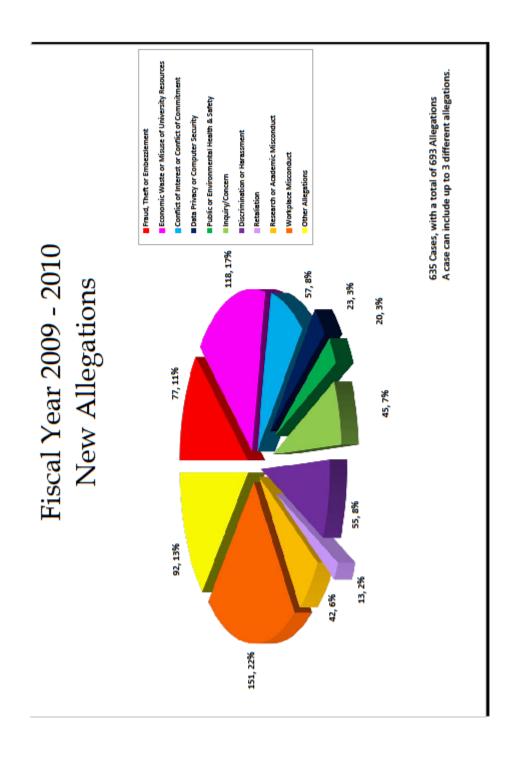
In these difficult economic times, organizations are under tremendous pressure to enhance operational performance. As a consequence, the critical link between ethics, compliance and organizational success becomes even more significant. Organizational leaders who believed their organizations were "in compliance" may suddenly find themselves facing regulatory or legal problems. These problems may arise as a result of lax internal controls or from aggressive risk-taking outside ethical or regulatory parameters in the attempt to "cut corners."

In October of 2007, the Board of Regents embarked on a course to establish a model ethics and compliance program for UC. Since the Board's approval, ECS has sought to implement a program that goes beyond mere legal compliance toward maintaining a strong, ethical organizational culture in which employees take personal responsibility for sustaining an ethical environment. In my professional opinion, the Board has succeeded to the extent that ECS continues to empower employees systemwide to bring forward potential ethics and compliance issues without the fear of retaliation.

In this second Annual Report, we have provided the reader with illustrations of the methodology ECS staff has used to effectuate sustainable change in organizational culture. The two key performance indicators of ethical organizational culture are (1) active leadership engagement and (2) management control systems and processes. As reported, University leadership continues to support the UC ethics and compliance program by clearly communicating and modeling the UC Statement of Ethical Values and Standards of Ethical Conduct for all employees. In this Report, we have also shown how the leadership has supported ECS in the implementation of management control systems and processes to support those values. The University's ethical culture starts with an appropriate 'tone at the top'; policies and internal controls then support the program by ensuring comprehensive reporting and clear accountability with full and effective oversight.

The UC ethics and compliance program is dynamic and evolving to include more substantive and broader coverage of compliance risk areas. The Regents, President and senior leadership have been instrumental in helping to make this happen by their responsive nature to issues and resolution of those issues. While our work is never done, we know that our relatively young program already meets and/or exceeds those of our peer organizations. Our focus in the next fiscal year will be on developing plans for sustainable education and auditing and monitoring activities to assist with our goal of prevention, detection and deterrence of noncompliant behavior in the University system.





Human Resources Compliance

The Human Resources (HR) Compliance group was established in 2008 to coordinate systemwide compliance efforts in the HR area. The group focuses on compliance with staff personnel policies (including Senior Management Group (SMG) Human Resources policies), the Group Insurance Regulations for the health and welfare benefit plans, and, in coordination with the Retirement Administration Service Center, the University of California Retirement Plan Regulations. The group works closely with Ethics and Compliance Services (ECS) to assist in supporting the overall systemwide Ethics and Compliance Plan. Key activities of the HR Compliance Group in FY 2009-10 include the following:

Monitoring of Rehired Retirees

Effective January 1, 2009, a new policy was issued on Reemployment of University Retired Employees Into Senior Management Group and Staff Positions. In FY 2009-2010 HR Compliance collected regular reports from locations on reemployment actions, validated the information against data in corporate systems, and provided summary information to University leadership for review of compliance with University policy.

Voluntary Separation Programs

In April 2009, President Yudof issued guidelines for Local Voluntary Separation Programs (VSP). VSP programs were offered at University locations that included Berkeley, Davis Health System, Irvine, Santa Barbara, San Francisco, San Francisco Medical Center and Davis. In FY 2009-2010 HR Compliance monitored and provided proposed severance payments between \$50,000 and \$75,000 to the President for review. HR Compliance also collected data on program participation and savings during this time and reviewed corporate data to ensure that any VSP participants who return to University employment were identified. In this ongoing effort, HR Compliance will continue to monitor VSP severance payments and returning VSP employees to identify and mitigate possible systemwide financial, compliance and reputational risks.

Health & Welfare Eligibility

In FY 2009-2010 HR Compliance developed regular reports to ensure instances of duplicate health coverage, not allowed under the Group Insurance Regulations, were identified and corrected. At the commencement of this project, 135 families were identified with inappropriate duplicate coverage in January 2009. As of January 2010, only 6 families were so identified.

HR Compliance initiated a major project in FY 2009-2010 to review issues related to BELI (Benefits Eligibility Level Indicator) coding. As a result of this work, at least one location has now added BELI coding to its location training. Through continued review in this area, HR Compliance will work with University locations to mitigate systemwide financial risk associated with inappropriate BELI coding.

Key Partnerships

The HR Compliance group works closely with the location Chief Human Resource Officers (CHROs) who have created a CHRO Compliance Committee (with representatives from University locations including Irvine, Los Angeles, Davis Health System, Lawrence Berkeley National Laboratories, and Santa Cruz). HR Compliance also participates in ECS staff meetings to ensure that HR Compliance efforts are appropriately aligned with the systemwide Ethics and Compliance Plan.

UC Berkeley

In FY2009-2010, the Compliance, Accountability, Risks, and Ethics Committee (CARE) at UC Berkeley (UCB) conducted a campus-wide compliance risk assessment in order to identify their high-risk compliance areas. Based on the results of the risk assessment, CARE then sponsored three campus-wide compliance initiatives to mitigate the compliance risks: (1) Research; (2) Data Privacy and Security; and (3) Compliance Infrastructure. Based on an initiative methodology, CARE identified the objectives and assigned both a functional champion and performance metrics to measure outcomes.

Under the Data Privacy and Security initiative, CARE focused its efforts on compliance with the Payment Card Industry (PCI) Data Security Standard and the Federal Trade Commission's Red Flags Rule to great success. CARE facilitated in the creation of campus policies and procedures, sponsored education and communication, and provided oversight of monitoring and auditing activities to safeguard the privacy of personal information and the security of data.

For example, CARE worked with the UCB Campus Information Security and Privacy Committee (CISPC) to implement strong access control measures in order to protect credit cardholder data. Based on the new campus policies and controls, CARE and CISPC sponsored an education and communication plan to educate relevant stakeholders on PCI compliance. CARE/CISPC have continued to follow up on the rollout of the project by tracking campus monitoring activities of access to network resources and cardholder data.

With respect to the Red Flags Rule, CARE co-sponsored a comprehensive Identify Theft Prevention Program along with CISPC. Under the joint initiative, CARE provided oversight in the identification of red flags that fall into five categories: (1) warnings from consumer reporting agencies; (2) suspicious documents; (3) suspicious personally identifiable information; (4) suspicious activity related to a transaction account; and (5) notice of potential identity theft in connection with a transaction account.

Based on the identification of these red flags, CARE then facilitated with CISPC an education and communication plan to make sure that the relevant stakeholders understood what they should do in the event they detected a red flag. All relevant stakeholders are now engaging in education and training on how to prevent and mitigate identify theft on campus.

UC Davis

Participation in the systemwide Ethics and Compliance Program has provided the UC Davis (UCD) campus an opportunity to focus cabinet-level attention on important questions about compliance priorities. The Chancellor's Cabinet meets monthly as the Campus Ethics and Compliance Risk Committee (CECRC). On a quarterly basis, the CECRC convenes as the Internal Audit Services (IAS) Work Group. In FY2009-2010, the campus has seen multiple benefits from this consolidation of responsibilities. In particular, this arrangement has proven to be an efficient and effective means of focusing the attention of high level campus administrators on prioritizing campus risk management and compliance efforts.

At a recent meeting of the CECRC to consider the IAS FY 2010-2011 work plan, for example, consideration of the IAS risk assessment methodology triggered an important discussion among Chancellor, CECO, and Vice Chancellors about relaxing overly-restrictive policies and processes in order to free up resources for the campus's highest priorities—including its highest priority compliance activities. UCD believes that Chancellor Katehi's active interest in this matter and the availability of this monthly forum will ensure that campus risk management priorities will be addressed systematically in the coming months.

UC Irvine

The University of California, Irvine (UCI) Campus Ethics and Compliance Risk Committee (CECRC) facilitated the achievement of an outstanding rate of 97% compliance with the State of California's law mandating sexual harassment prevention education for supervisors.

The success has been the result of efforts from many individuals working to achieve compliance through many different routes. The campus' compliance with Assembly Bill (AB) 1825 originated with the administration's directive that supervisory responsibilities be removed from faculty and staff supervisors who failed to complete this legal obligation. In one instance, UCI administrators found it necessary to notify the relevant federal granting agencies that the individual was unable to supervise personnel on the grants due to his refusal to take the statemandated training.

In a different approach, the Dean of the School of Medicine recently exercised his authority to withhold a portion of the salary of health science compensation plan members who had not yet completed the Sexual Harassment Prevention education requirement.

The UCI CECRC has provided clear and frequent information about the AB1825 requirement via email, in newsletters, during meetings of all types, and even through an interview on UCI's campus radio station. To encourage assistance in each school or unit, the committee provided compliance lists on a regular basis.

The UCI program has benefited from providing a diverse range of training options. During the last fiscal year, the campus offered more than 30 workshops. UCI embedded sexual harassment prevention training in numerous other meetings and events, including department retreats, Chairs' meetings, their staff Effective Supervision course, and the Chancellor's cabinet meeting. UCI even utilized the availability of a renowned theater troupe for interactive theater productions in order to enliven the content of the training.

UC Los Angeles

A tragic laboratory fire in December 2008 helped catalyze a significant compliance effort relating to laboratory safety – an effort that is still underway. That fire took the life of a member of the UC Los Angeles (UCLA) staff and has prompted close scrutiny of UCLA's safety practices by regulatory agencies. Months before the California Occupational Safety and Health Administration (CalOSHA) had completed its investigation, Chancellor Block charged a Laboratory Safety Committee (LSC), chaired by the Vice Chancellor for Research with the following responsibilities:

- develop, recommend, update and maintain policies applicable to the health and safety of laboratory work;
- establish strategies to ensure ongoing and adequate hazard identification, surveillance and risk evaluation of laboratory activities;
- review findings of inspection and campus hazard surveillance programs; and
- communicate with the other campus Safety Committees to insure consistency and encourage collaboration.

The LSC has representation from across the laboratory sciences, Environment, Health and Safety office, unions and campus counsel. In addition to providing oversight and guidance, the LSC has the authority to modify, suspend, revoke and terminate any Laboratory activities that are deemed to pose an unacceptable risk to life or safety.

The LSC issued a report to the Chancellor in July 2009 that has served as a guide for further policy development in such critical areas as ensuring a comprehensive policy is in place requiring the use of Personal Protective Equipment (PPE) in all bench work. The LSC is just one example of how the campus has responded to a critical compliance area with a multidisciplinary approach that has had input and buy-in from faculty, staff, and the top leadership of the institution.

UC Merced

Funding requirements under the American Recovery and Reinvestment Act of 2009 (ARRA) include unprecedented levels of transparency and accountability. Recipients of federal funding are required to provide quarterly reports for each dollar allocated and spent. They must also provide metrics on job creation and retention as well as program, project, and sub-project performance. Recipients will need to provide this information both to federal auditors as well as on public websites. In short, oversight of federal awards reporting compliance will only continue to intensify as a consequence of the ARRA reporting requirements.

The nature and frequency of the information required by the new ARRA reporting regulations has posed serious compliance challenges for UC Merced (UCM). Under ARRA, in addition to traditional reporting requirements, UCM must also ensure compliance with, for example, enhanced whistleblower protections, the Davis Bacon Act, the National Environmental Policy Act, EEO rules and regulations, and the Federal Acquisition Regulations. UCM must also implement rigorous internal controls to ensure that the campus does not comingle ARRA funds.

In order to meet the challenges posed by ARRA's transparency and accountability provisions, UCM hired an

ARRA compliance professional. Working with UCM's Campus Ethics and Compliance Risk Committee (CECRC) and the UCM Campus Ethics and Compliance Officer (CECO), the ARRA compliance professional will, for example, ensure the accuracy and publication of quarterly reports to a public website with the prescribed information.

UC Riverside

The Enterprise Risk Work Group (ERWG) Charter was created by the University of California, Riverside (UCR) Vice Chancellor (VC) of Finance and Business Operations (F&BO) in October 2009, in response to a new charge put forth by the UCR Ethics and Compliance Risk and Audit Committee (ECRAC). The ERWG, chaired by the UCR Director of Risk Management, meets quarterly and is comprised of individuals from the major functional units of UCR. Its primary focus is to assure that Enterprise Risk Management (ERM) decisions are aligned with the overall vision and goals of UCR. The progress of this ongoing initiative will be provided to the campus ECRAC through the UCR VCF&BO.

Under the direction of the ECRAC, UCR has embarked on a UC-developed Hazard Vulnerability Assessment (HVA) to effectively address safety, security, and anti-terrorism matters. Following the assessment, one of the strategies included the development and deployment of an on-line training module.

This Workplace Violence Prevention module was designed to provide core information, resources, and prevention strategies that are applicable to all UCR faculty, staff, and student employees. To ensure compliance with Title 8, California Code of Regulations, General Industry Safety Orders, the one-time training session will be mandatory.

The module is scheduled to be rolled out by the UCR Human Resources Department through the Learning Management System (LMS). Current employees will have six months to complete the two-hour module and will be sent email prompts. The 20% of UCR employees without access to a computer will be provided with a live class. The UCR Workplace Violence Prevention training module is highly adaptable and may well serve as a benchmark for other UC campuses.

UC San Diego

In response to ongoing campus concerns about data privacy and security, the UC San Diego (UCSD) Compliance, Audit, Risk and Ethics committee (CARE) constituted a new UCSD Information Security and Privacy Council (ISPC). In conjunction with this action, UCSD also named an interim Chief Information Security and Privacy Officer for both campus and health sciences operations.

As an example of issues under its charge, CARE has assigned the ISPC with the task of providing guidance on the appropriate application of state and federal privacy breach notification laws. ISPC will also assist CARE and the UCSD Campus Ethics and Compliance Officer (CECO) in achieving a cohesive organizational structure aligning responsibility, authority, and accountability for effective enterprise computer security and information privacy in a highly decentralized environment.

To this end, ISPC has already begun to monitor and audit to identify and correct root causes of security weaknesses in high-risk circumstances. Based on its monitoring and auditing efforts, ISPC has made specific recommendations on an optimal use of appropriate technical solutions to address security issues. In addition, CARE and ISPC have begun to develop campus policies to protect the privacy and security of confidential, personally identifiable information (PII) and protected health information (PHI) in all formats, e.g., paper, electronic, written, oral, transmitted, and/or stored.

CARE has also taken a number of other actions this year to assess and reduce information security risk, such as conducting a campus-wide survey to assess information security policy compliance, as well as conducting a number of internal audits in the various Vice Chancellor areas to address network security.

UC San Francisco

Over the course of the last several years, UC San Francisco (UCSF) has achieved a high compliance rate for federal effort certification. While the campus had consistently achieved a high rate of certification, UCSF had no way of verifying the quality of the certifications.

Upon reviewing some corrective action plans from other institutions in response to NSF effort certification audits, the UCSF Campus Ethics and Compliance Risk Committee (CECRC) discovered in a Cornell University report a mechanism that it could adapt in a practical way, with a limited and appropriate cost.

For two semi-annual cycles now under the direction of the CECRC, UCSF has matched the list of investigators certifying that 100% of their effort was expended on federal awards against the list of individuals submitting proposals during that time. Letters were sent by the campus controller to this population, explaining the rules, and asking them to confirm their certifications, or change the salaries previously charged.

The efforts of the CECRC and the controller sparked some excellent discussions with some of the investigators and their departments. As a consequence, for example, they made several changes to salary charges. In addition, UCSF Deans have since assumed primary responsibility for effort reporting compliance. Their actions have resulted in very rapid and complete compliance.

UC Santa Barbara

The UC Santa Barbara (UCSB) Campus Ethics and Compliance Risk Committee (CECRC) is comprised of the senior leadership on campus who meet on an ongoing basis in order to examine and evaluate risks that are prevalent throughout the campus, and develop comprehensive approaches to mitigating these risks. Gene Lucas, Executive Vice Chancellor, chairs this committee.

In order to bring a more comprehensive approach to mitigating these risks on campus, Executive Vice Chancellor Lucas has required that the Enterprise Risk Management Program and the Red Flags Program report to CECRC on an ongoing basis as well. This is to ensure that there is no duplication of effort among these groups and that there is a continuing and constant sharing of information regarding identification of risk and risk mitigation plans.

UC Santa Cruz

UC Santa Cruz (UCSC) began implementing its integrated Enterprise Risk Management and Compliance Program (ERMCP) in April 2010. The ERMCP is designed to leverage very limited campus resources in a way that effectively integrates compliance with management of other types of risk across the campus.

The UCSC approach is structured on the model that risk identification should be based on a campus-wide perspective, and lead to the development of procedural controls and standards designed to effectively manage the significant compliance risks and/or ensure compliance with laws, regulations, policies, and contractual requirements. This, combined with a solid accountability environment and ongoing compliance monitoring, provide the foundation for successful risk management and an effective compliance program.

An ERMCP Management Committee was formed consisting of primary process owners responsible for overseeing key campus functions, including emergency management, health and safety, research, financial and business, human resources, student affairs, information technology, conflict of interest, risk management, and data privacy and protection.

Its charge is to identify current and emerging campus-wide risk and compliance issues, analyze the issues from a campus-wide perspective, bring significant issues to the attention of the Campus Ethics and Compliance Risk Committee (CECRC) and support the CECRC's role in:

- Designing and implementing compliance and risk mitigation strategies;
- Supporting the campus community in managing risks and ensuring compliance; and
- Monitoring the effectiveness of ongoing risk management and compliance efforts.

The ERMCP Management Committee held its inaugural meeting in April 2010, and is in the process of developing data collection and reporting standards and protocols.

Lawrence Berkeley National Laboratory (LBNL)

Over the past year, LBNL has taken a number of steps to further integrate compliance into its operations. LBNL has incorporated Federal Acquisition Regulation (FAR) 52.203-13, Contractor Code of Business Ethics and Conduct (Dec 2008), which tracks with the basic elements of an effective compliance program per the Federal

Sentencing Guidelines. LBNL has conducted a gap analysis relative to the FAR requirements and is working to close those gaps.

As part of implementing the training element, LBNL produced an annual briefing for senior managers on conflict of interest, employee concerns, and research integrity.

Another step taken in the past year is the development of function-specific assurance plans for all the major operations areas. These plans describe how each of these areas/organizations provides assurance that LBNL is meeting its responsibilities under the UC/Department of Energy (DOE) contract, including compliance. These plans feed into an institutional contractor assurance system that provides assurance to UC and DOE. Furthermore, the Laboratory prepares an annual assurance letter for DOE regarding the state of its management control systems, and any material issues/corrective actions.

In response to heightened accountability provisions of the ARRA and the need to ensure that funds received are appropriately managed, LBNL established an ARRA Steering Committee to oversee implementation and reporting on ARRA funded projects. The early establishment of this committee and its diligent oversight has earned praises from the DOE. Progress on ARRA along with other assurance related issues is reported to the UC Contract Assurance Council on a monthly basis.

Division of Agriculture and Natural Resources (ANR)

With operations at fifty-eight county locations, three campuses, and nine Research and Extension Centers throughout California, implementation of a compliance, risk, and control program in ANR is unique in comparison to a campus.

To address these unique circumstances, ANR developed an on-site review program to address the geographical dispersion of ANR and this has evolved to become the cornerstone of its compliance program. The reviews consist of visits by a small multi-disciplinary team, with backgrounds in Environment, Health and Safety (EH&S), Risk Management, controls and accountability, to each of ANR's remote sites on a periodic basis.

While visits are "mock" inspections and audits for regulatory and compliance-related requirements, they are also a great opportunity to perform service-oriented training directed to the needs of the location, and to engage in risk assessment discussions with location personnel. All ANR locations are covered on a rotational basis over time; however, the program has become so successful that some locations are asking for the reviews sooner than resources and scheduling permit.