UC ETHICS AND COMPLIANCE SERVICES

The University of California Ethics and Compliance Services Office completed its fifth year of operations serving its systemwide colleagues to maintain regulatory compliance and enhance the reputation of the most respected public university system in the United States.

EXECUTIVE SUMMARY

The Office of Ethics and Compliance Services (ECS)[1] completed its fifth year of operations in June 2013, maturing from a fledgling communication structure into a robust program that assists the campuses and other University of California (University) locations in identifying and mitigating compliance risks across the system. With the support of the Regents and systemwide senior academic and administrative leadership, Senior Vice President/Chief Compliance and Audit Officer (SVP/CCAO) Sheryl Vacca has established a program that effectively addresses identified issues in a timely and comprehensive manner.

The success of an effectual ethics and compliance program is validated by evidence of an organizational philosophy that actively promotes a transparent, ethical culture encouraging stakeholder responsibility for corporate compliance. Increased reporting through the University whistleblower hotline demonstrates employee awareness of the ECS program and the University's commitment to its mission and values, as well as a commitment to uncovering and resolving potentially non-compliant activities. During this past year, ECS undertook a self-assessment process to rate its progress, and identify areas of improvement, by asking campuses to assess their ethics and compliance program against the federally recognized seven elements of an effective compliance program. Following the aggregation of that information, two external compliance experts were engaged to review system program documentation, individual and aggregate results of the location self-assessments, and interview select campuses, Office of the President (OP) and system employees on their understanding of the ethics and compliance program and the value it provides to the University. The results of the assessment are currently under review but the general theme is that the University of California has an established framework for compliance and is working towards evolving to an outcomes "risk intelligent" focused model through the system.

Key Initiatives

Over the past five years, ECS has worked collaboratively with system leadership to identify and assist in developing mitigation strategies to remain compliant with highly complex standards and regulations. The prime focus of the department for its first two years was to assist the campuses, Agriculture and Natural Resources (ANR), OP, and Lawrence Berkeley National Laboratory (LBNL) in developing or enhancing their operational structures to accommodate compliance communication and reporting channels. This required operationalizing their compliance-focused committees to address campus or systemwide priority compliance risk areas, such as international issues, safety of minors on campus, or clinical research billing processes. During that same time period, ECS was instrumental in providing campus/locations with access to low-cost or free compliance-specific education and training through three systemwide symposiums, multiple on-site trainings, and numerous webinars covering a variety of compliance risk areas. In addition, ECS's oversight of systemwide investigations and assistance with complicated or conflicted investigations at the campus/locations has resulted in systemwide savings through reduction in external consulting/legal fees for investigations. Finally, ECS assumed responsibility for systemwide/presidential policies and delegations of authority by reviewing and updating processes around the development, review and rescission of policies and delegations of authority.

Key Potential Compliance Risks Facing University of California

Key compliance risks facing the UC system over the past five years, including FY 2012-13, continue to be: 1) data privacy and security; 2) research compliance; 3) government reimbursement accuracy; 4) campus culture of compliance; and 5) campus safety. The following report outlines ECS sponsored activities over the past five years that were developed to assist University locations in identifying and mitigating their unique compliance risks related to the five categories noted above.

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[1] For a complete list of all acronyms and their related definitions used in this report, refer to Appendix C.

UC Ethics and Compliance Services

2008-2013 – FIVE YEARS AND GROWING

OVERVIEW

The Ethics and Compliance Services Office (ECS) was established in the fall of 2007 as directed by the UC Board of Regents. In her new position as Senior Vice President and Chief Compliance and Audit Officer (SVP/CCAO), Sheryl Vacca worked quickly to design and implement a comprehensive ethics and compliance program – one that would assist University management in the identification and mitigation of regulatory compliance risks across the system. By the end of its first five years, the University's Ethics and Compliance Program (Program) is considered a best practice among institutions of higher education compliance programs across the United States – one that other universities, striving to establish strong compliance programs look to for guidance.

Following the Regents' approval of the Program in July 2008, ECS focused its efforts over the next several years on laying a strong, compliance oversight foundation for the ten campuses, Lawrence Berkeley National Laboratory (LBNL), Agriculture and Natural Resources (ANR) and the Office of the President (OP). For the purpose of this report, the term "campus" will be used to denote all locations as referenced above. In addition to assisting the campuses when potential compliance risks were identified, ECS worked collaboratively with campus leadership to establish clearly defined processes for the identification, discussion, resolution and reporting of potential regulatory compliance risks by campus and System leadership to the Board of Regents. Campus Ethics and Compliance Risk Committees (Committees) are co-chaired by the location-specific Campus Ethics and Compliance Officer (Officer) who is typically the Provost/Executive Vice Chancellor, Vice President or the Director. Several campus Chancellors attend these

Figure 1: Campus Ethics and Compliance Risk Structures

meetings on a regular basis which are typically scheduled on a quarterly, if not monthly basis.
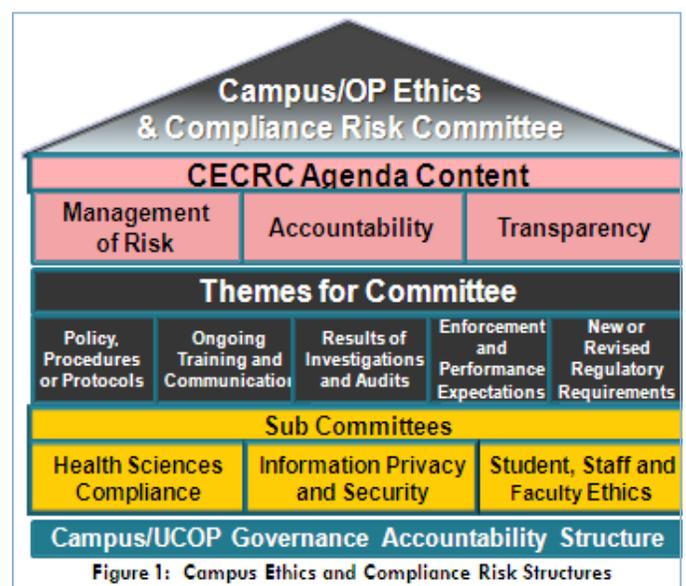
Over the past five years, a number of major regulatory compliance risks were identified that required campus interventions, while major economic issues were also impacting the University, for example student safety on campuses, managing youth activities and others. The crippling loss of State revenues resulted in budget cuts and the downsizing of administrative support to faculty that has had lasting effects. It was a testament to the University's exemplary academic and administrative leadership, who continued to invest in functions such as ethics and compliance, to recognize the benefits that a strong culture of compliance could bring to their locations during such a challenging time.

The value of the Program has been actualized in a number of initiatives that are detailed in this report, but more importantly is reflected in the increased awareness of ethical behavior and compliance to regulatory and policy requirements. Changes in attitudes and behaviors related to ethical behavior, albeit more difficult to measure, are the key indicators of ECS's contribution to the University as it strives to more efficiently and effectively meet its commitment of research, education and public service to the citizens of California.

GAUGING PROGRESS

Board approval of a program and dissemination across an organization does not deem it effective. Understanding the value of a compliance program and how it works collaboratively with management to improve quality of services provided, assure compliance with applicable regulations and organizational policy, and decrease cost is essential for a comprehensive, enterprise approach to achieving strategic success in mitigating risk.

ECS has typically measured its progress in meeting its annual goals and objectives through the aggregation of internal data and data from the campuses. This data determines the extent to which elements of the Program have been integrated into operations and whether there have been any quantifiable measurements that proves the value of the Program. Quantifying success in a compliance program is a conundrum that plagues the industry – how can we objectively measure what did not happen as a direct result of our activities or prove that it was a result of our activities alone? It is not as quantifiable as measuring dollars saved when premiums are decreased because of decreased claims; however, industry agrees that we can begin to correlate changes in behavior to improvements in certain indicators or metrics of compliance.
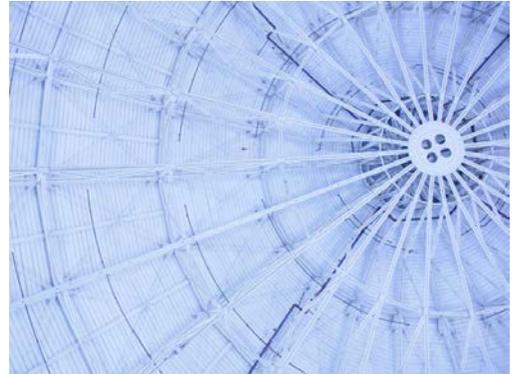
LAWRENCE BERKELEY NATIONAL LAB

ECS has used a number of indicators to measure whether the Program continues to hold value to its internal client base, specifically the Regents and the campuses. The indicators used include:

UC LOS ANGELES

- External review of the Program to assess its compliance with accepted nationally-based standards;
- Review of several agreed upon systemwide metrics that document progress towards a more consistent response to key compliance risks;
- Measurement of a work place culture that has a direct impact on ethical and compliant decision-making; and finally,
- Review of key accomplishments achieved during the past year.

A high-level overview of the past five years will be discussed in this report. For more detail on certain accomplishments, refer to the Program Annual Reports (FY 2008-09 through FY 2011-12) which can be found on the ECAS website: http://www.ucop.edu/ethics-compliance-audit-services/compliance/ecas-plans-reports-summaries.html

INDEPENDENT PROGRAM REVIEW

FEDERAL SENTENCING GUIDELINES – A FOUNDATION

It is industry practice and a recommendation from key government regulators that compliance programs are periodically reviewed to determine the effectiveness of the program in meeting its mission and goals, while adhering to Section 8 of the United States Sentencing Commission's Federal Sentencing Guidelines (FSG). The FSG outline the seven elements of an effective compliance program[2] which are typically the foundation of most compliance programs within the United States. Figure 2 shown below outlines the seven elements that are the foundation of the University's Program.

ETHICS AND COMPLIANCE PROGRAM SELF ASSESSMENT AND INDEPENDENT REVIEW

The systemwide ECS Program is in the final stages of an external review by an independent compliance program expert and a peer, academic chief compliance officer, to determine where the University program is in its maturation, and what recommendations or improvements would move the University's ECS Program to a higher level of effectiveness. The first step of this review process was the completion of an ethics and compliance program self assessment form by each campus Officer with approval by its Committee. The self-assessment tool was developed based upon the FSG's seven elements of an effective compliance program and other compliance industry tools to gauge the comprehensiveness of a program. The external consultants are finalizing their report that will be presented to the President's Compliance and Audit Committee (PCAC) in the fall of 2013.
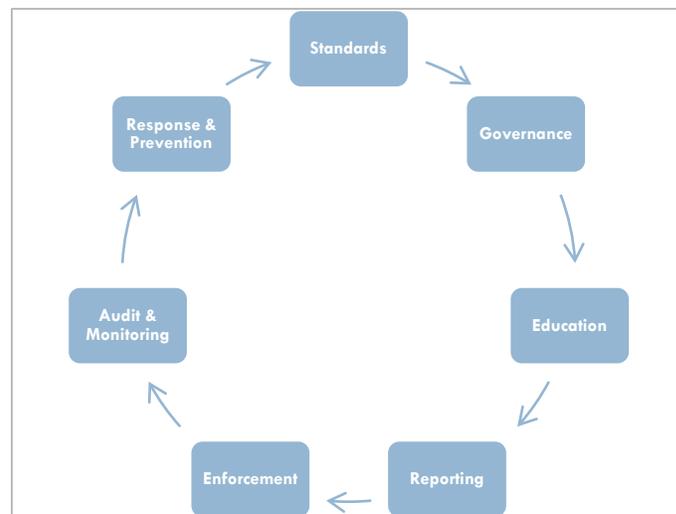

FIGURE 2: THE SEVEN ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

PROGRAM METRICS

Measuring progress in meeting the objectives of a key strategic goal is paramount to effective management. Understanding what indicators document movement towards a goal and making sure those indicators, or metrics, are actionable and can be acted upon establishes a strong foundation for change.

COMPLIANCE PROGRAM OBJECTIVES AND/OR METRICS – FIVE YEAR COMPILATION

Over the past five years, ECS worked collaboratively with campus officers to develop consistent metrics that can be measured across all locations, are valuable to leadership at all campuses, and are easily aggregated within current systems. The number of metrics selected is limited to two or three and focuses on key risks that are found at all campuses. At the onset of the Program, ECS reviewed programmatic or structure metrics in an effort to document the foundation of a strong Program. As it has matured, ECS continues to move the campuses forward to a more outcomes-focused metric system – one that quantifies the impact of the Program on University operations.

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[2] The United States Sentencing Commission – Federal Sentencing Guidelines, Section 8.
http://www.ussc.gov/Guidelines/2012_Guidelines/Manual_PDF/2012_Guidelines_Manual_Full.pdf

The following categories outline the key compliance risk areas where metrics were developed and measured over the past five years:

1. Systemwide and campus ethics and compliance program elements in place and operational;
2. Data privacy and security awareness;
3. Government reimbursement reporting and claims accuracy;
4. Research compliance (conflicts of interest disclosure and education, export controls, others);
5. Campus safety;
6. Culture of ethics and compliance;
7. Compliance risk topic education and training; and
8. Trending of confidential hotline reporting.

CAMPUS COMPLIANCE METRICS – FY 2012-13

The top three systemwide compliance areas of concern for this past fiscal year: 1) data privacy and security; 2) research compliance; and 3) culture of compliance and their related risk mitigation activities, were monitored through metrics agreed upon by the Officers. The metrics included:

Data Privacy and Security
- The three metrics monitored measured progress in identifying breach responses, reporting of fines/penalties for confirmed breaches and implementation of the President's Systemwide Privacy and Information Security Steering Committee (PSPISSC) recommendations. However, reporting on the PSPISSC was postponed due to final stages of feedback being received from the Academic Council.

Research Compliance
- The research compliance metrics focused on processes to identify and report potential research conflicts of interest and implementation of enhanced Public Health Service reporting and training requirements.

Culture of Compliance
- Knowledge and implementation of processes to comply with the stricter California Child Abuse and Neglect Reporting Act (CANRA) was monitored in addition to reporting and trending data on reported allegations of non-compliance with the UC *Statement of Ethical Values and Standards of Ethical Conduct* (Standards of Conduct).

UC BERKELEY

UC MERCED

THE VALUE PROPOSITION: ENHANCING THE UNIVERSITY ETHICAL CULTURE

It is universally agreed within the compliance industry, and espoused by government regulators, that evidence of a workplace culture with a strong commitment to ethics and compliance is the backbone of an effective compliance program. Having faculty, administrative management and staff who embrace "doing the right thing", and incorporate it into their daily jobs provides a fertile environment for continuously improving quality and potentially decreasing the cost of providing education.

Improving a culture of compliance requires commitment from the Regents, President and Chancellors/Laboratory Directors, to the University community to reinforce the University's Standards of Conduct. This requires ongoing education on the availability of a confidential reporting system to capture alleged improper government activities or non-compliance with University

OFFICE OF THE PRESIDENT

policies, affirmation that issues raised will be investigated and resolved expeditiously, and assertion that retaliation will not be tolerated. As evidenced by a number of factors explained in more detail later in this section, the Program appears to have made a positive impact on enhancing the University's culture of ethics and compliance.

CULTURAL DIMENSIONS

Norms, values and attitudes, job-related behaviors, and management control systems and processes work together to produce a culture of ethics and compliance. For the purposes of this report, ECS defines the culture of ethics and compliance as a product of those components, as outlined below:

1. *Climate* (personal dimension) Employees' perceptions and attitudes toward the University's goal of ethics and compliance;
2. *Behavior* (behavioral dimension) Employees' day to day actions toward this outcome; and
3. *Systems* (Systems and processes dimension) Presence and quality of management controls and processes in support of stated values and appropriate behaviors.

The following section details the above three dimensions providing overview of the evolution of the University's ethics and compliance culture since the inception of the Program.

I. CLIMATE

Based on the results of a variety of measures, such as program assessments, surveys and interviews (collectively termed 'results' for this report) summarized in Figure 3, ECS has concluded there has generally been a positive impact on employees' perceptions of the University's goal of ethics and compliance over the tenure of the Program. Active leadership engagement and employee commitment, two components of an ethical culture, appear to have strengthened over this timeframe.

University of California Employee Surveys	
CUCSA Staff Engagement Survey (UCOP, UCB, UCD, UCR, UCSD, LBNL)	2012
LBNL Employee Survey	2010
UCSD Work Survey Analysis	2006-2009
UCB Workplace Climate and Care/Life Issue	2009
UCOP Staff Opinion Survey	2007
UCR Employee Opinion Survey	2006
UCD Climate Survey	2004

Figure 3: List of UC Employee Surveys (2004-2012)

ACTIVE LEADERSHIP ENGAGEMENT OR 'TONE AT THE TOP'

REGENTS	Regents' Compliance & Audit Committee
SYSTEM	President's Compliance & Audit Committee
ANR	Ethics, Compliance and Enterprise Risk Committee*
LBNL	UC Contract Assurance Council
OP	Ethics & Compliance Risk Committee*
UCB	Committee on Compliance, Accountability, Risk and Ethics Committee*
UCD	Ethics and Compliance Risk Committee*
UCI	Ethics and Compliance Risk Committee
UCLA	Oversight Committee on Audit, IT Governance, Compliance and Controls*
UCM	Executive Compliance and Risk Committee*
UCR	Ethics and Compliance Risk and Audit Controls Committee
UCSD	Compliance, Audit, Risk and Ethics Committee
UCSF	Ethics and Compliance Board*
UCSB	Joint Ethics and Compliance and Audit Risk Committee
UCSC	Ethics and Compliance Risk Committee

*Chancellors Regularly Attend Meetings

Figure 4: UC System & Campus Ethics & Compliance Risk Committees

Active leadership engagement or *'tone at the top'* is a key performance indicator of an effective enterprise compliance program in maintaining a culture of ethics and compliance. Results from several surveys (as noted above) indicate that University employees perceive leadership as actively engaged in the promotion of the Program, including adherence to the University's Standards of Conduct.

Active leadership engagement is evidenced across the University through senior leadership involvement in their location-specific Committees, as well as in their endorsement of the University of California Whistleblower Hotline and its related systemwide non-retaliation policy. A majority of Chancellors, Directors or Vice Presidents regularly attends their campus Committee meetings as shown in *Figure 4: Campus Ethics and Compliance Risk Committees.* This commitment communicates a strong message to location faculty and staff on the importance of the Program.

EMPLOYEE COMMITMENT

University employees perceived themselves to be committed to the University's goal of a culture of ethics and compliance. A strong indicator of employee commitment is the extent to which employees are willing to report potentially unethical conduct. As noted later in this report, there has been a steady increase in the number of employees who have accessed and utilized the University's Whistleblower Hotline over the past five years to report alleged workplace misconduct. This fact is consistent with the noted surveys and interviews where employees have consistently stated they would report misconduct, even though there may be a perceived fear of retaliation.

II. BEHAVIOR

While ethical climate speaks to employee perceptions, changes in behavior are objective indicators of the presence of a culture of ethics and compliance. Over the course of the last five years, there have been noticeable changes in systemwide employee behavior from an enterprise compliance and risk intelligence perspective. Enterprise compliance is a coordinated approach to compliance that spans multiple organizational units in diverse geographic locations. Risk intelligence measures the extent to which employees communicate, collaborate and coordinate on the implementation of enterprise compliance across organizational units. ECS has helped to consolidate efforts in enterprise compliance at the University by enhancing and/or augmenting risk intelligence efforts at each location.
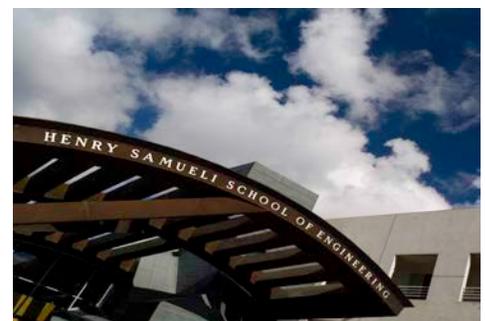
UC IRVINE

INTEGRATION INTO OPERATIONS

The campuses, working collaboratively with ECS, successfully implemented their Program infrastructure by the end of FY 2009-10. The focus during the next three fiscal years (FY 2010-11, FY 2011-12 and FY 2012-13) was to assist the campuses in identifying and implementing a comprehensive risk profile for each location. Prior to Program initiation, there was scant documentation at the system or campus level that supported consistent collaboration between the various risk disciplines on identifying, or working on developing strategies to mitigate compliance or other types of risk. It appeared that departments typically worked in isolation within their divisional silos and did not regularly communicate, collaborate or coordinate their activities. Their efforts were fragmented in terms of leveraging opportunities for other departments/divisions with similar risk opportunities, and were not well distributed beyond division and/or campus borders.

COMPREHENSIVE RISK PROFILE

UC DAVIS

This lack of coordination described above produced independent risk management activities with the potential for limiting focus on the linkage between risks. The lack of coordination also had the potential for disparate monitoring and reporting which could have increased the likelihood of duplication of effort. Through implementation of a comprehensive risk profile, as shown in Figure 5, the campuses impacted behavior by establishing a common framework for coordination among risk disciplines in their risk assessment and risk mitigation activities. In short, a comprehensive risk profile at each location helped to promote behavior consistent with risk intelligence across the System. As examples of behavioral change, campuses provided evidence of increased communication, collaboration and coordination across silos as the ethics and compliance functions worked in tandem with internal audit and risk services to conduct risk assessments and manage risk mitigation activities. Coordination of risk management activities resulted in the recognition of the connection between risks and risk prioritization, as well as collaboration in monitoring and reporting functions. This resulted in the campuses behaving in ways that reduced duplication of effort and better management of resources.

Key Risks	Current Status	Mitigation/Control Measures	Responsibility					Control Evaluation
			Mgmt	Internal Audit[i]	Ethics & Compliance[ii]	Risk Services[iii]	OGC/HR	
Adherence to Laboratory Safety (CAL OSHA requirements)	Potentially under-controlled	Development and approval of systemwide PPE and Safety Training Policy;	x	x	x	x	x	Risk Services leads system wide efforts for management activities related to compliance to settlement.
		Implementation of lab inspection tool;	x	x		x		Compliance to assist with monitoring of compliance to settlement.
		Development of research lab-specific, chemical standard operating procedures (SOPs).	x	x		x		Internal Audit to conduct audit to determine adherence to settlement requirements.
Adherence to research sponsoring agency regulations and agreement terms and conditions	Potentially under-controlled	Regular training sessions in grant administration for appropriate staff.	x		x			ECS webinars and internal education on best practices conducted;
		Ongoing best practice meetings in place.	x		x			Internal monitoring could occur through campus compliance work plan.
Campus Safety – Workplace Violence	Potentially under-controlled	Ongoing assessments by threat management team – follow-up on issues completed	x			x		Risk Services assists in development of training materials.
		Police Department leads workplace violence trainings.	x					
		Development of consistent workplace violence training materials.			x	x		Monitoring plan established by IA or ECS to assure training and follow up has occurred.
		Institute pre-employment background checks.	x	x			x	

FIGURE 5: EXAMPLE OF CAMPUS-WIDE POTENTIAL RISK WORK PLAN- FY 2013-14

TONE IN THE MIDDLE

The most striking evidence of change in campus and systemwide behavior came through campus mid-management committees tasked with compliance and enterprise risk identification and mitigation. Not all campuses have formal mid-management committees for this function, but all have similar processes to collaborate at the mid-management level to identify, aggregate, prioritize and recommend key risks to the Committees for inclusion in the Ethics and Compliance Annual Work Plan. As mentioned earlier in this report, 'tone at the top' is a key performance indicator of an effective enterprise compliance program supporting a culture of ethics and compliance; however, 'tone in the middle' is equally as important. Mid-management involvement in compliance risk assessment and mitigation activities serves as evidence of integration of front line management in the resolution of identified risks by senior leadership. This evidence has a cascade effect, the involvement and communication upwards and downwards within the organization to enhance process improvement activities is a definite indicator of a positive compliance culture.

III. SYSTEMS

Management control systems and processes are essential to an effective and comprehensive systemwide program to maintain a culture of ethics and compliance. Systems and processes reinforce appropriate behavior and operationalize organizational values.

RESOURCE ALLOCATION AND STATUS

Resource allocation to an organization's compliance function is a key performance indicator of the quality and status of compliance risk-related

UC RIVERSIDE

management control systems and processes. ECS conducted systemwide internal benchmarking to determine if the Program has adequate resources to address compliance risks. This campus-specific information was shared with campus leadership as an integral element of each location's risk intelligence profile in order to gain a better understanding of how resources are leveraged at the campus level to address identified issues.

RISK MITIGATION

The campuses have implemented and enhanced their management control systems and processes of compliance risk assessment and risk prioritization activities due to the shift in behavior towards a more integrated approach to solve campus issues. The campuses continue to distinguish between strategic and reputational, systemic, and unit level risks.
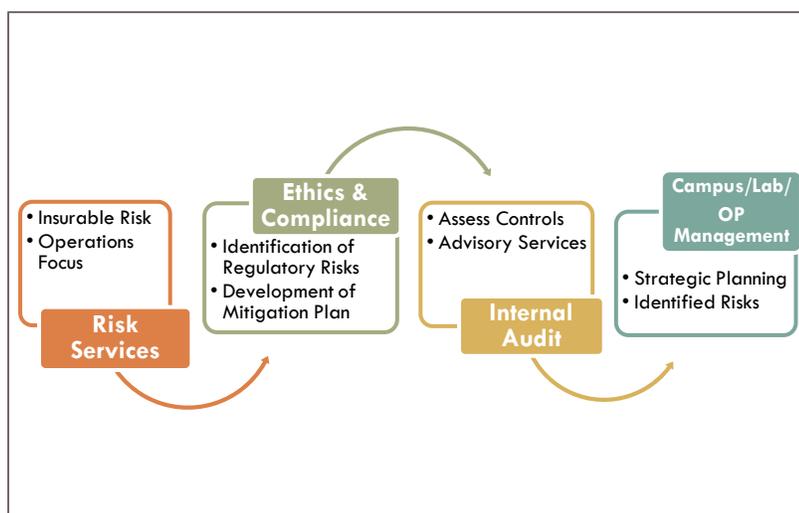

FIGURE 6: COORDINATION BETWEEN THE RISK DISCIPLINES: AN EFFICIENT APPROACH

Risk mitigation activities are now more formally managed, with the Committees providing guidance and oversight to risk identification and mitigation activities, and the mid-management committees providing operational management of campus systemic risks supporting unit-level management resolution activities. The mid-management group typically reports progress of risk mitigation activities to the Committee, which then summarizes its progress to ECS for inclusion in reports to the PCAC and to the Regents' Committee on Compliance and Audit.

A combined Systemwide Workplan is drafted and approved by the Regents with resultant progress reports summarized in the Ethics and Compliance Program Office Annual Report.

KEY ACCOMPLISHMENTS

With the support of System and campus leadership, ECS worked collaboratively with campus colleagues to lead and/or assist the campuses in the following three main categories of compliance-related activities:

- *General Regulatory Compliance* that includes systemwide compliance and audit education and training, investigations, auditing and monitoring, trending and resolution of confidential hotline reports; and review and maintenance of Presidential Delegations of Authority and the Presidential Policy Administration System;
- *Research Compliance* including systemwide programs related to government grant oversight and export controls regulatory activities;
- *Health Sciences Compliance* reflecting the diverse compliance activities occurring at the Health Sciences campuses.

The following sections detail both the systemwide and campus progress in goals to mitigate compliance risks. The initiatives are both short-term as well as long-term in nature and activities may span several fiscal years. This five-year reflection will provide a synopsis of the progress made in the above compliance areas over that timeframe.

I.   General Regulatory Compliance

"ECS provides the campuses with a wealth of training resources on a variety of topics…"
Wendi Delmendo, UC Davis Chief Compliance Officer

Ethics and Compliance Education and Training

UC SAN FRANCISO

ECS has established an ongoing education program that consists of both web-based and on-site, instructor-led trainings on key compliance and internal audit-related topics that assist the locations in meeting the job-specific, compliance education needs for their staff. ECS has continued to advance its webinar program over the past five years with over 120 webinars and trainings presented to University faculty and staff during FY 2012-13 (See Appendix A). The in-person trainings are held at a northern and a southern California centrally located campus to keep travel costs low and leverage the costs of subject matter instructors. As noted in the quote from UC Davis' Chief Compliance Officer Wendi Delmendo in the box above, the ECS education program is well-respected and campuses rely on ECS to provide the necessary orientation to new and/or changing regulatory risk areas with expert information on how to meet the resulting compliance challenges. As a collegial and professional courtesy, ECS has provided California State University, Stanford University, University of Southern California, California Institute of Technology, University of Washington and University of Texas compliance professionals access to the education sessions.

COMPLIANCE AND AUDIT SYMPOSIUMS – A BIENNIAL EVENT

Three systemwide Compliance and Audit Symposiums have been held since the inception of the Program. The first was held in 2009 in San Francisco with approximately 200 attendees. In response to campus requests to build on the program and to provide low-cost training to campuses in northern and southern California, the following two Symposiums (2011 and 2013) were held both in Irvine and in San Francisco to lower attendee travel expenses. The 2011 Symposium had approximately 400 attendees (north and south) while the 2013 Symposium had the highest attendee rate to date of over 500 attendees (north and south).

REGENT CHARLENE ZETTEL AND EVP NATHAN BROSTROM PRESENTING AT THE 3RD COMPLIANCE AND AUDIT SYMPOSIUM

Continuing education credits have been offered each year, with up to 33 credit hours available for compliance, audit, legal and human resources certification at the most recent Symposium at a nominal charge. Campus leadership has realized the value of these low-cost, high quality education and networking alternatives to external conferences and seminars, resulting in higher campus attendance rates. In addition to external experts, speakers were selected from cross-disciplines across the University System in an effort to provide participants with examples of best practice solutions to the complex regulatory issues facing all campuses.

INVESTIGATIONS

The ECS Investigations Unit focuses on two primary areas of the compliance program:
- Management of the independently operated *hotline system* for anonymous reporting, and
- Coordination, management and *investigation* of suspected improper governmental activity, complaints of retaliation, work place misconduct and breaches of ethical conduct.

WHISTLEBLOWER HOTLINE REPORTING SYSTEM

The *University of California Policy on Reporting and Investigating Allegations of Suspected Improper Governmental Activities* (Whistleblower Policy) governs the reporting and investigating of potential employee misconduct at all University locations. The processes identified in the Whistleblower Policy help ensure the University is in compliance with federal and state whistleblower laws and if violations of policy or law occur, they are effectively, efficiently and fairly addressed. The University established a systemwide independently operated whistleblower hotline in 2003 to provide a twenty-four hours per day/seven days per week reporting system with a provision for anonymous reporting. The hotline system did not replace other avenues for reporting concerns as employees are encouraged to report in their supervisory chain or to other appropriate University offices or officials.

UC SANTA BARBARA

In 2008, Ethics Compliance and Audit Services (ECAS) expanded the toll free telephone hotline system with the addition of web-based reporting (*universityofcalifornia.edu/hotline*). Complaints reported through the hotline system are automatically entered into a case management database for reporting, managing, investigating and tracking by the campus and OP personnel. These same personnel are responsible for recording in the case management database complaints received through a variety of other intake points at the campuses and OP.

Over the past three years (FY 2010-11, FY 2011-12 and FY 2012-13), following the change from a reporting system with insufficient capabilities to case manage the hotline reports to a more comprehensive case management system, the rate of reports by location (normalized by number of full time equivalents: 1000 FTEs per case) has increased approximately 40%. Of the cases tracked in the case management system, 1.2 cases per 1,000 FTEs were substantiated. The representative charts are found in Appendix B.

Of the 946 cases tracked in the case management database during the last fiscal year (see Appendix B), the following characteristics were identified:

- Overall increase of 30% from the prior fiscal year (FY 2011-12).
- Hotline reporting system accounted for 69% of complaints reported to the University during this fiscal year.
- Seventy-seven percent (77%) of reporters this fiscal year used toll free and web-based reporting electing to report their matter anonymously.
- The hotline system provided an opportunity for investigators to engage the reporter in a question-and-answer dialog by giving them a secure log-on identification code allowing them to return and review their submitted report. Last fiscal year, 17% of anonymous reporters took advantage of the opportunity to follow-up on their initial report.

INVESTIGATION FUNCTION

"…the support provided by the ECS Investigations Unit has been invaluable in investigating complicated and often lengthy compliance concerns. Their systemwide knowledge and diverse backgrounds leverage their outstanding expertise in a cost effective and expeditious manner."

Gary Mathews, UCSD, Vice Chancellor, LDO & CECO

The ECS Investigations Unit serves as the principal point of contact at OP for the campus, LBNL and ANR Locally Designated Official (LDO) on all matters involving the hotline system and for cases investigated under the University's Whistleblower Policies. The LDO is the University location official with primary responsibility to receive reports of allegations of suspected improper governmental activity and to manage the investigation process. When the allegation of improper governmental activity involves the Chancellor, the Laboratory Director, Vice President of ANR, the LDO or LDO's supervisor, the matter is referred to the Systemwide LDO at OP to ensure the independence and neutrality of the investigation process. In addition to these matters, some cases are referred to the systemwide LDO at OP or to ECS for investigation of sensitive, complicated and complex whistleblower complaints and compliance concerns. The Investigations Unit conducts these investigations itself or manages an outside subject matter expert investigator. In addition, ECS provides administrative support for the OP and systemwide LDO and OP Investigations Work Group.

Due to the increase in numbers of investigations handled centrally, and in an effort to efficiently manage these cases, the ECS Investigations Unit was expanded in 2011with the addition of two principal investigators to assist the Director of Investigations in conducting systemwide investigations (3 FTE's total).

Average Cost of External Investigator per Case
$50,000

Average Cost of In House Investigators per Case
$15,200

(Including salary and estimated benefits)
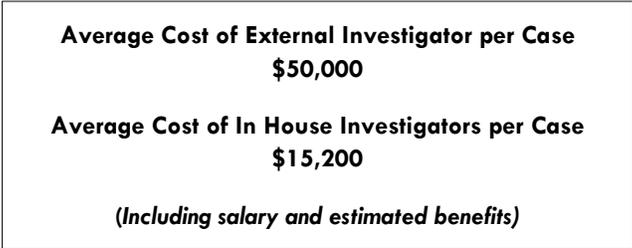
Figure 7: Budget Savings Realized by Internal Investigators

The goal of expanding the ECS Investigation Unit was to reduce the number of investigations that required the engagement of outside (third party) investigators. The hourly rate of outside investigators ranged from $225 to $275 per hour while the hours involved in a case typically were in excess of 200 hours. The ECS investigators have been involved in a wide range of investigations to include retaliation, discrimination, hostile work environment, conflict of interest, theft of property, policy violation, work place misconduct and employee grievance complaints. During FY 2012-13, the Unit investigated and closed 19 workplace investigations. Additionally, the Unit began working on 18 new cases in the same period. Overall, 37 cases were handled within the Investigation Unit during the last fiscal year.

Number of cases handled within the ECS Investigation Group in FY 2012- 13			
Closed cases investigated by ECS Investigator	Cases triaged and/ or managed by the ECS Investigation group	In Progress (case started in FY 2012-13)	Total
19	64	18	101

The use of independent investigators for employee misconduct has become more compelling with the increasing trend by regulators and court decisions towards objectivity in workplace investigations. Campus resources have been stretched with budget concerns and subject matter expertise has not been as readily available as in the past. ECS Investigations Unit has been a valuable resource to ensure the University responds to the duty of the employer for a full, prompt and fair investigation when serious allegations of workplace misconduct arise. As noted by Vice Chancellor Gary Mathews at UCSD, the ECS Investigations Unit has been instrumental in assisting their campus in investigations.

INVESTIGATION TRAINING – ENHANCING CONSISTENCY

Conducting an effective investigation requires personnel with not just knowledge of University policy, laws, regulations and the investigation process but also having appropriate interpersonal skills to conduct interviews with the complaining party, subject and witnesses. ECS recognized the importance of training for University workplace investigators particularly when as many as 22 different campus organizations have some type of investigation responsibility.

In 2010, ECS worked with an outside provider to develop a three day training program on conducting workplace investigations. From 2010 to 2012, four training seminars (3 days length) were held in northern and southern California for over 200 University workplace investigators. ECS facilitated Sexual Assault Investigations Training in northern and southern locations in 2012 for 89 University investigators. Sessions on investigations training was provided at the annual Compliance and Audit Symposiums in2009, 2011 and 2013. In June 2013, ECS completed development of a one day basic investigators' training program to be conducted by the ECS Investigations Unit at each participating campus.

PRESIDENTIAL DELEGATIONS OF AUTHORITY (DoAs)

For the past several years, ECS has worked collaboratively with the President's Cabinet to review all Presidential DoAs for appropriateness, timeliness and applicability to the current leadership structure. The existence of outdated or expired DoAs with responsible positions/titles listed that are no longer in the management structure have posed a challenge for assuring compliance to applicable UC policy, at both the System and campus levels. Nationally the trend is to consolidate roles and responsibilities outlined in DoAs in specific leadership role descriptions and allow for management oversight of related functions stemming from a position description versus a task-specific DoA.

UC SANTA CRUZ

This review process continued during this fiscal year with identification of all DoAs and assignment to the appropriate senior leader position. Expired or outdated DoAs are slated for official rescission through the Policy Steering Committee after a period of stakeholder review. DoAs that are specific in nature, and not directly related to a role description, will be updated and maintained in the electronic DoA system.

The outcome of this project will be a streamlined Presidential DoA process that will enhance systemwide compliance to applicable Presidential directives.

PRESIDENTIAL POLICY MANAGEMENT

The cornerstone of an effective compliance program includes clearly written and disseminated policies and procedures. These documents assist faculty and staff in understanding and complying with applicable University requirements and regulations embedded in institutional policies. In 2008, ECS initiated a comprehensive inventory of current policies, working with stakeholders to ensure the policies were current and rescinding policies that were no longer relevant to the University mission. A new Policy Administrative System was created to move policies from a paper format into a standard template, moved into an electronic library, and conveyed to users in a more transparent and easily accessible website.

Of 425 policies in place during FY 2011-12, forty-one (41) were determined to be redundant and officially rescinded, and to date 139 have been transferred to the new template. The ECS Policy Office continues to work with business unit management to review and update the remainder of policies and retire those that are no longer appropriate and update regulatory language as needed.

II.   Research Compliance

As one of the primary missions of the University, and comprising approximately twenty percent (20%) of the University's revenue base, research activities and compliance with research-related regulations and policies has been a key compliance risk focus over the five years of the Program, and it continued to be a high priority for the University in FY 2012-13. As noted earlier, a number of compliance risks are so complex and span such a large segment of the University that their mitigation activities overlap several years. Key risks included in that category that will be discussed in the following section include research-related conflicts of interest, intellectual property, effort reporting activities and export controls.

CONFLICT OF INTEREST

Conflict of interest (COI) continues to be a high priority compliance risk for the University due to our large research enterprise and continued public and regulatory focus as noted in Figure 8 on the right. New COI regulations, found at the website listed in the box to the right, were issued by the Public Health Services (PHS), which includes the National Institutes of Medicine (NIH) - the University's top funding agency. These regulations went into effect on August 24, 2012 and significantly increase regulatory requirements for PHS-funded investigators, including increased reporting frequency, reduced threshold amount for reporting financial interests, mandatory training, and more.

Figure 8: A Note from the NIH -- Compliance Oversight
(NOT-OD-12-159 released September 21, 2012)

The Proactive FCOI Compliance Oversight Program (FCOI Compliance Program) is a component of NIH's oversight responsibilities to assure grantee compliance with FCOI requirements. The objective of this initial phase of the FCOI Compliance Program is to obtain and evaluate publicly accessible FCOI policies for a sample of NIH grantee institutions. As with other compliance programs, if deficient areas are noted, institutions will be expected to formally address and resolve all identified issues. NIH plans to continue and expand the FCOI Compliance Program during FY 2013. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-159.html

Efforts by the University to prepare for the new regulations over the last two fiscal years (FY 2011-12 and FY 2012-13) included revision of System and local policies, procedures and reporting forms, implementation of new electronic COI reporting and management tools and development of systemwide training.

In FY 2012-13, ECS supported implementation of new COI regulations by overseeing delivery and tracking of systemwide training to approximately 22,000 University researchers. Delivery of the training took place in early August 2012 and met both the new PHS training requirement and the University's mandated general compliance training requirement. Delivery and tracking of the training was managed centrally by the Learning Management System to reduce burden on the campuses. Of note, as of June 2013 there is an 84% compliance rate for completion of the Compliance and Conflict of Interest (COI) for Researchers across all University locations. The campuses continue to track those relevant researchers who have not completed the training and processes have been established to monitor for completion of training occurs prior to the issuance of new federal grant monies.

COI is also a focused area of risk for our health science arena. The Affordable Care Act (ACA) has provided increase focus on health care providers and disclosure of their relationships with drug manufacturers and medical device companies which has been heightened with the expanding federal requirements. This has been an area where our AMC campuses have been trying to assist with easier reporting solutions around COI for our health care providers.

Intellectual Property – Royalty Audit Program

To address concerns among the higher education community that earned royalties owed to universities from licensing of intellectual property are typically underreported by licensees, and to recover potentially underpaid royalty income due the Regents, ECS has been conducting and funding systemwide royalty audits using an outside consultant since July 2009.

ECS conducted 19 audits since FY 2010-11 under the Royalty Audit Program, identifying nearly $3 million dollars in underreported royalties across 13 audits (68%). To date, ECS has facilitated the collection of $1,298,640 in underpayments. As shown at the right, the total cost incurred by ECS in professional fees over the life of the program is $316,511, for a **return on investment of 310%** (actual recoveries/total audit fees).
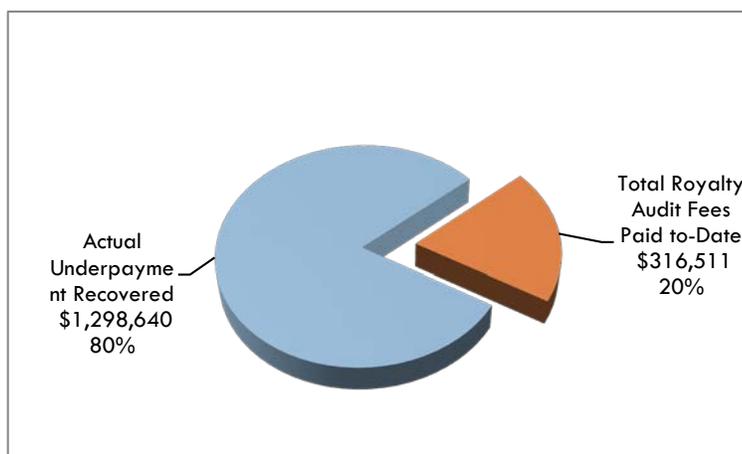
FIGURE 9: ROYALTY AUDIT PROGRAM REPORT FY 2010 THROUGH FY2013

Effort Reporting on Federal Research Projects

Research grant and contract funds reporting requirements continue to be a strong focus of the federal government. Concerns with the complexity and lack of clarity around federal effort reporting regulations was addressed, along with a myriad of other grants accounting regulations in FY 2011-12 in federal proposed rulemaking, the outcome of which is still pending.

In spite of pending federal reform to effort reporting requirements, locations continued to improve compliance in this area. Several campuses improved effort reporting compliance through implementation of oversight structures, policy revisions, tools, resources and training. For the third year in a row, ECS collected systemwide effort reporting compliance metrics from all ten campuses. The federal government expects all effort reports submitted by the University to be timely and accurate. Our overall results demonstrate continued improvement.

- *ECS collected systemwide effort reporting metrics for the 3rd year in a row for tracking and trending – identified a 14% increase in average timeliness of effort/payroll reports from FY 2009-10 to FY 2011-12*

In April 2010, the University was approved by the Department of Health and Human Services (DHHS) to conduct an 18-month Payroll Certification Demonstration Project. Two campuses, UC Riverside and UC Irvine are serving as pilot sites for this project to test whether payroll certification is a less burdensome and more meaningful alternative to the current process of effort reporting. As part of the requirements under the approved pilot, ECS developed and delivered a survey to end-users of payroll certification at both pilot campuses to gather feedback about preferences of using the new *payroll certification* approach versus *effort reporting* to comply with federal cost accounting rules for grants and contracts.

Export Control

The export control function is one of the most complex regulatory compliance risks facing major research universities across the country, due to the need for adequate alignment of federal trade and security regulations to an academic culture of open access to research. Open access to research includes campus-based research, as well as the growing movement toward conducting research abroad in a variety of countries, including those with politically-charged environments.

FIGURE 10: SYSTEMWIDE EXPORT CONTROL INQUIRIES BY CATEGORY FY 2012-13

Key:
OFAC – Office of Foreign Asset Controls
ITAR – International Traffic in Arms Regulations
EAR – Export Administration Regulations
RPS- Restricted Party Screening
TCP – Technology Control Plan
Classification – Identifying regulatory categories governing an item
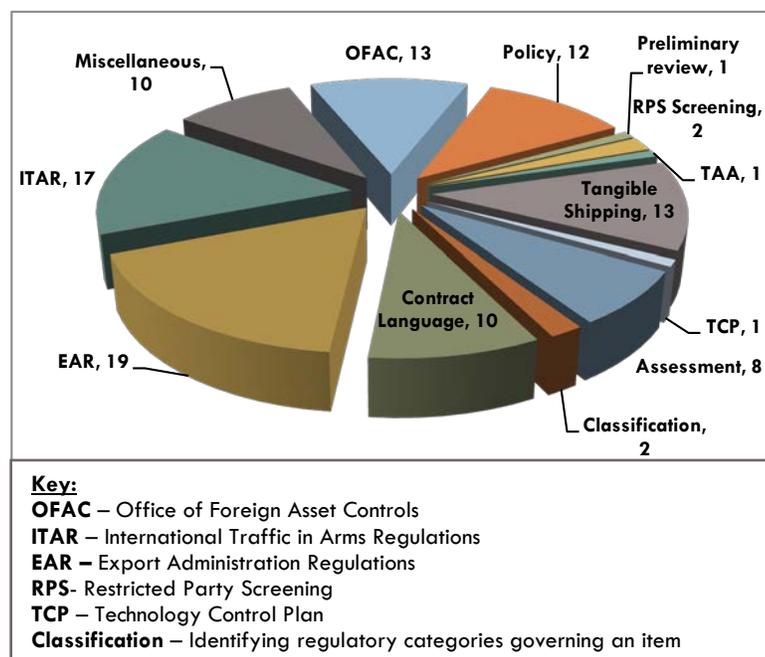
The export control function has typically been decentralized across the campuses and the ability to identify research activities requiring export licensing has been limited, primarily due to the lack of campus subject matter expertise in this specialized risk area. Combined with the lack of expert resources, the lack of an organized process to aggregate, track and trend rising export control issues across the System highlighted the need for a different approach to mitigate a number of risks related to this function.

In FY 2010-11, ECS developed a systemwide Export Control Compliance Program that initially focused on providing a subject matter expert resource (System Export Control Officer) and convening the first Systemwide Export Control Workgroup with representation from all University locations to discuss key compliance issues and share best practices. Working collaboratively with the campus representatives and relevant OP offices, ECS is now able to identify, track and address pertinent export control issues. Campuses have realized an average savings of $4,000 per license application when completed by the System Export Control Officer, in addition to the savings realized by not retaining external support for application completion.

As the campuses have become more knowledgeable about ECS export control function support, requests for assistance have increased. During FY 2012-13, ECS responded to 235 diverse export control related inquiries, an increase of 161% from FY 2011-12. For example, support was provided to obtain appropriate classification and licensing approvals from the federal government to allow the export of controlled research-related items as well as developing technology control plans to enable researchers to proceed with their research without the need for obtaining licenses. ECS applied for all five of the International Traffic in Arms Regulations (ITAR) licenses, enabling the export of defense articles critical to research programs at two University locations.

In addition to advice and support to campuses on ITAR and Office of Foreign Assets Control (OFAC) licensure, key accomplishments by ECS during this past fiscal year include:

- Provided export control training to University stakeholders, including in-person training and webinars.
- Hosted the *West Coast Best Practices Forum on Export Controls in Higher Education* attracting participants from across the System as well out-of-state research institutions.
- Developed an export control document repository for use by all University locations to pool and share documents, presentations, and other related tools.
- Launched a policy review subgroup to the Export Control Workgroup to address concerns regarding University policies toward restrictive access and long-standing practices regarding open access.
- Compiled an international shipping profile of university shipping practices for research and non-research items.
- Initiated outreach with agency leadership in the State Department, Treasury Department's Office of Foreign Asset Controls, and the Commerce Department's Bureau of Industry and Security.

III.   Health Science Compliance

Each of the five Academic Medical Centers (AMCs) has a robust Health Sciences (HS) Compliance Program that focuses on identification and mitigation of specific key compliance risks. In FY 2012-13, AMCs focused on compliance issues related to implementation of new electronic systems including medical record and billing systems, new processes for clinical research billing compliance, preparation for ICD-10 coding, response to and monitoring of privacy breaches and government audits including a large number of Medicare Recovery Audit Contractor (RAC) audits, and a range of HS compliance inquiries and complaints, as well as other initiatives.

ECS and the HS Compliance Officers jointly developed a set of common systemwide metrics for FY 2012-13. Observation services (1-day stays) has been focused on by the Medicare Recovery Audit Contractors (RACs) as high risk for overpayment, the HS Compliance Programs measured observation services as a percent of overall Medicare admissions at each AMC. The results show the University AMCs during FY 2012-13 had admission rates comparable to the national average (University AMCs from 5-21% including transfers; the national average at approximately 15%, excluding transfers [reference PEPPER- Program for Evaluating Payment Pattern Electronic Reports]). In addition, the effectiveness of local policies governing outpatient facility billing (evaluation and management [E/M] coding) was reviewed, as that potential risk area continues to be a target for federal payers to audit. An additional systemwide metric included whether each AMC has policies and processes in place for processing the billing and coding of cardiac devices with any associated manufacture credits. Finally, each AMC accessed their readiness for a HIPAA (Health Insurance Portability and Accountability Act) privacy audit from the Office of Civil Rights (OCR). While the HS Compliance Programs have traditionally included our five AMCs, during this report period UC Riverside has actively become involved in the HS compliance function as it builds its School of Medicine and HS function and is developing a compliance work plan to address the program's stage of maturity.

A major initiative undertaken by four of the five HS compliance officers in collaboration with the SVP/CCAO and the ECS department over the past several years focused on implementing a compliance audit system for professional fees services billing. The fifth location is currently in the process of implementing the system. The ongoing audit capability for monitoring and assuring accurately coded professional fee claims has been so effective that, with the assistance of ECS, the HS functions are in the process of implementing a similar hospital-based compliance audit software system.

During this past fiscal year, it was announced by Centers for Medicare and Medicaid (CMS) that California's Medicare Administrative Contractor (MAC) will be changing from Palmetto to Noridian between August and September 2013. The MAC is responsible for reviewing and approving Medicare reimbursement to the medical center's for clinical care, including coverage for items and services provided in the course of certain clinical research studies. Noridian has a reputation of higher expectations and more stringent interpretations in the clinical research billing (CRB) area than Palmetto. It is expected that this will translate into an environment where CRB information and

documentation will need to be much more readily available, including the maintenance of a coverage analysis for each study. This process is explained in more detail in the section that follows.

Clinical Research Billing Process Review

The University conducts approximately $2 billion annually on clinical research activities between the five HS campuses. The complexity of the rules and regulations that govern the billing of clinical research activities between government health care programs, private payers, and research sponsors is overwhelming. Erroneous claims submission can result in large paybacks and potentially hefty fines and/or sanctions against participating state or federal health care programs.

In FY 2012-13 ECS initiated a systemwide focus on CRB activities that included external operational process reviews at each of the five HS functions by a nationally recognized CRB expert to determine whether established processes met industry standards for accurate and timely claim submission. Specific recommendations were provided to each location, many of which are included as progress notes in the attached Health Sciences Compliance Program Annual Reports.

SUMMARY

ECS leadership continues to review its operations in an effort to continually improve its processes; mature as an ethics and compliance program to provide a more efficient system to detect, deter and prevent instances of fraud, waste and abuse; and increase value to the University as it strives to meet its mission to the citizens of California.

Appendix A: UC Ethics, Compliance and Audit Education Sessions – FY 2012-13

| Topic	Speaker	Date	Location
Identifying and Addressing Workplace Bullying: UC Challenges and Obligations	Jennifer Chin (UCOP), Sara Thacker (UCB)	7/11/2012	Webinar
Sexual Assault Investigations Training	**Jody Shipper (USC), Denise Oldham (UCB)**	**7/12-13/2012**	**Oakland, CA**
Sexual Assault Investigations Training	**Jody Shipper (USC), Denise Oldham (UCB)**	**10/2-3/2012**	**Irvine, CA**
University Workplace Investigators Training	**Deborah Allison, Sue Ann Van Dermyden**	**10/22/24/2012**	**Irvine, CA**
UC's Records Retention Schedule Update Project	Laurie Sletten (UCOP)	12/12/2012	Webinar
Cloud Computing: Export Controls, Security and Other Considerations	John Villasenor (UCLA)	1/9/2013	Webinar
2013 UC Compliance & Audit Symposium (North)	**Various**	**1/28-31/2013**	**San Francisco, CA**
2013 UC Compliance & Audit Symposium (South)	**Various**	**2/11-14-2013**	**Costa Mesa, CA**
CANRA and Application of UC Policy	Jennifer Chin, Rachel Nosowsky (UCOP)	2/21/2013	Webinar
UCSD Cash Loss Investigations: Ocean View Terrace Restaurant & Others	Christa Perkins, Aparna Handa (UCSD)	3/6/2013	Webinar
Expanding Conflict of Interest and Commitment Policies to Address Unique Business Risks	Bart Aoki, Julia Arno, Mary Croughan (UCOP)	4/9/2013	Webinar
Clery Act – Briefing and Challenges for CSAs	Pam Roskowski (UCSF)	5/7/2013	Webinar
Ten Things to Know Before Taking Your Laptop Overseas	Brian Warshawsky (UCOP)	5/15/2013	Webinar

Topic	Speaker	Date	Location
DOJ Training on Immigration-Related Practices (I-9)	UCOP HR, DOJ	5/22/2013	Webinar
IT Audit Training		6/6/2013	Oakland, CA
Visual Compliance Training Part 1	Brian Warshawsky (UCOP)	6/12/2013	Webinar
Emerging Healthcare Issues: How Will They Impact Hospital Reimbursement? *Part One*	Sharon Hartzel, Lori Laubach (Moss Adams LLP)	6/19/2013	Webinar
Emerging Healthcare Issues: How Will They Impact Hospital Reimbursement? *Part Two*	Sharon Hartzel, Lori Laubach (Moss Adams LLP)	6/26/2013	Webinar

Appendix B: Hotline Statistics

Systemwide total cases by report category between FY 2011-12 and FY 2012-13

Systemwide Total Cases

FY12 Total: 760 Cases
FY13 Total: 946 Cases
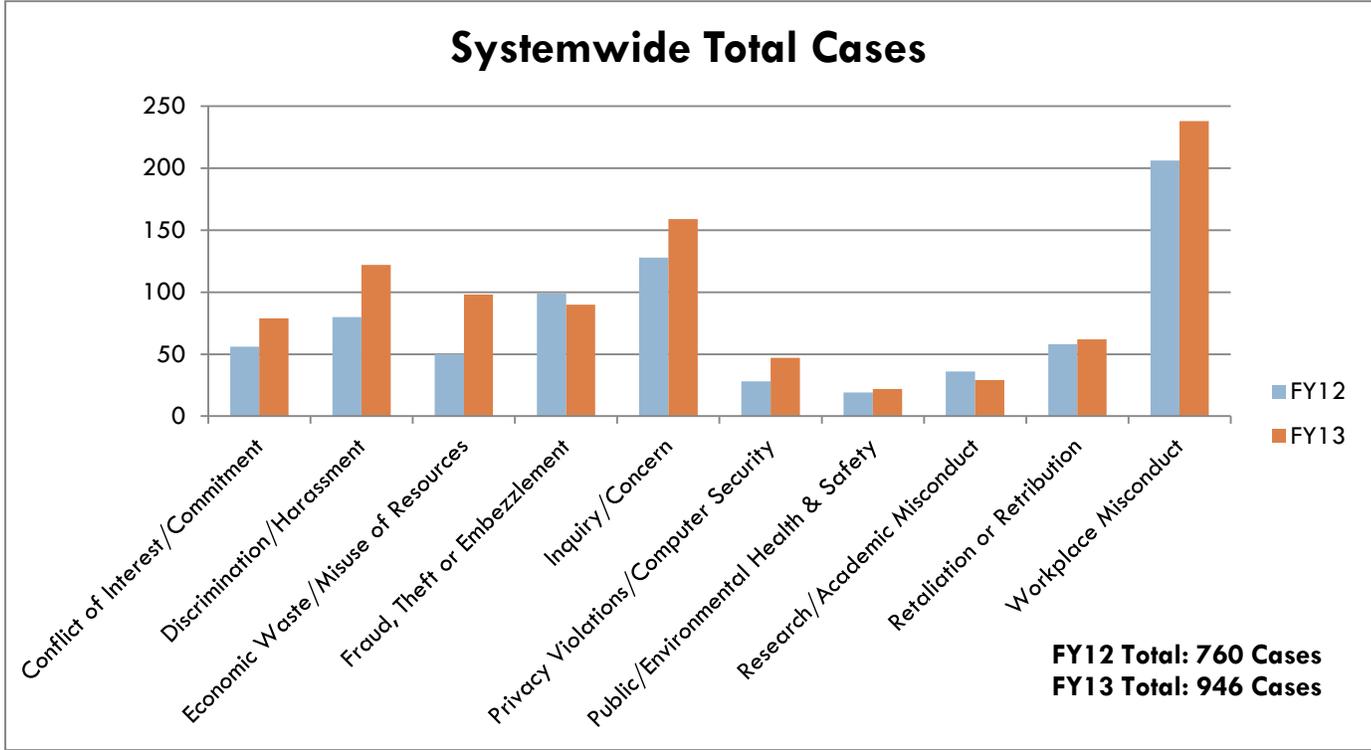
Systemwide Number of Substantiated Cases between FY 2011-12 and FY 2012-13

Systemwide Substantiated Cases


Systemwide Substantiated Cases per 1,000 FTE
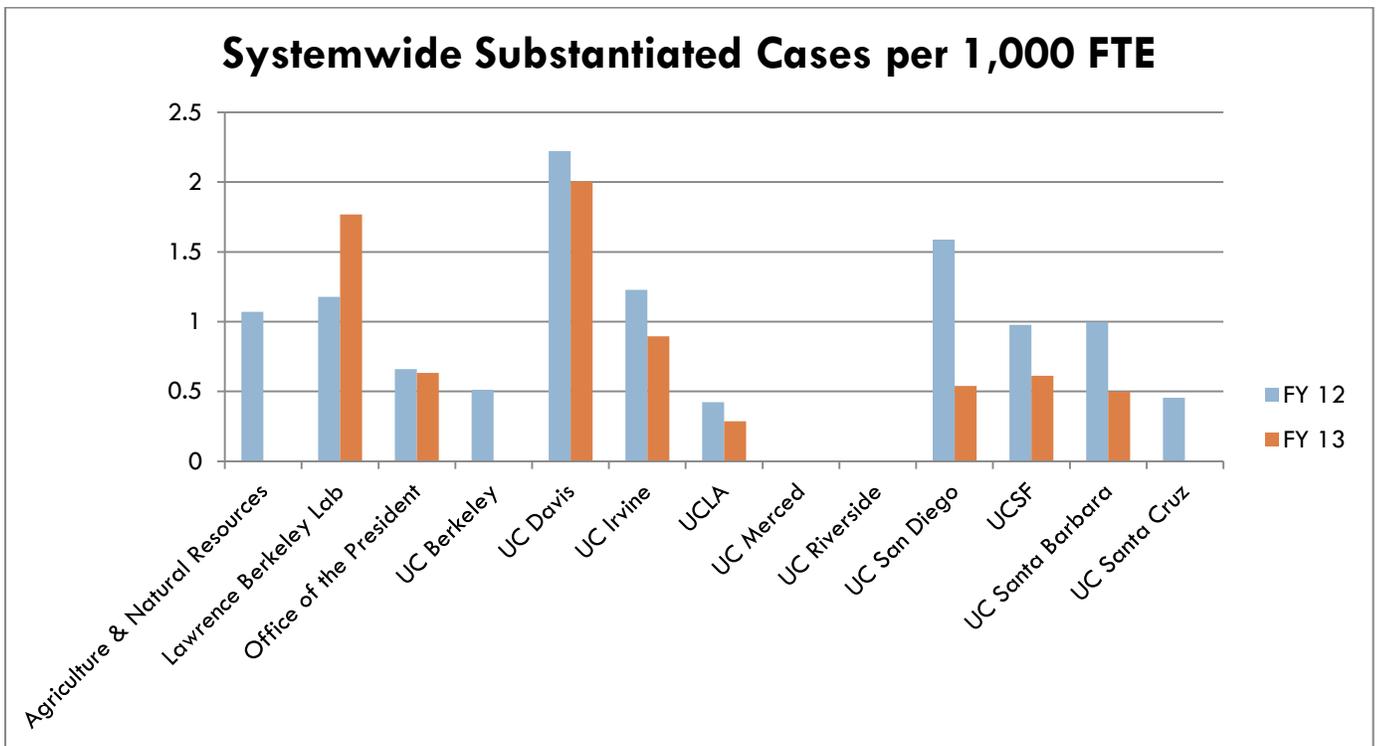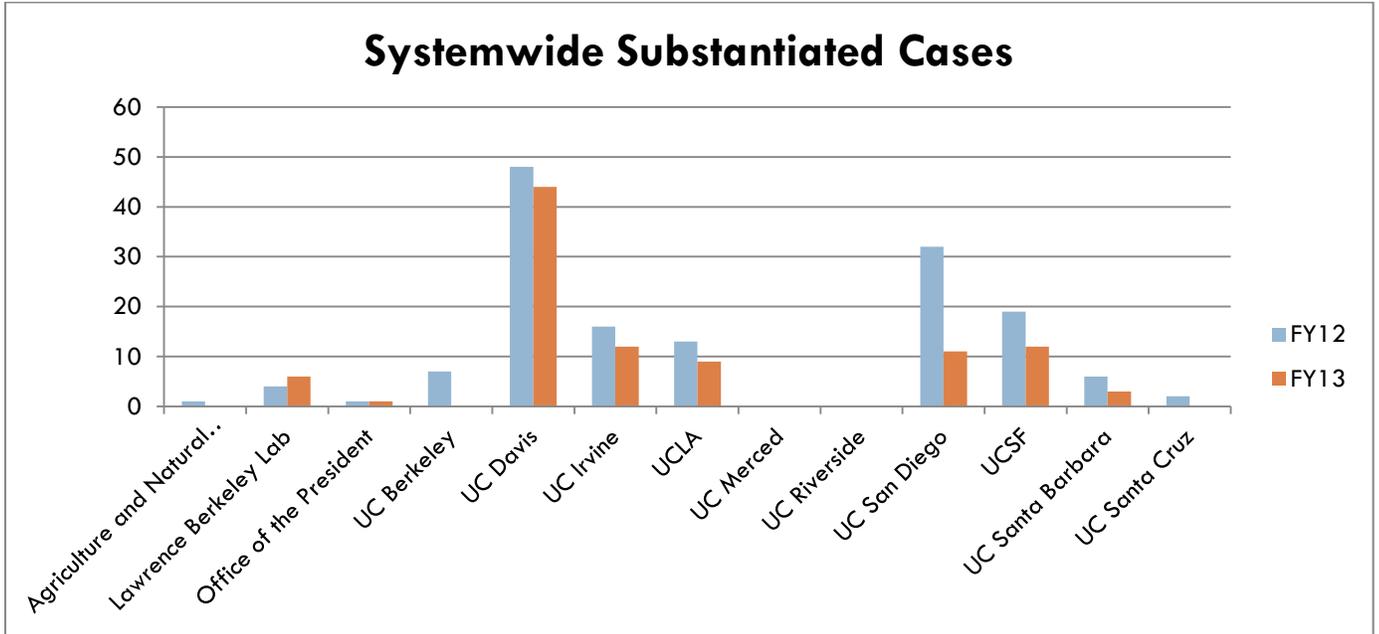
**Systemwide Total Cases by Campus between FY 2011-12 and FY 2012-13**

Systemwide Total Cases

Systemwide Total Cases per 1,000 FTE
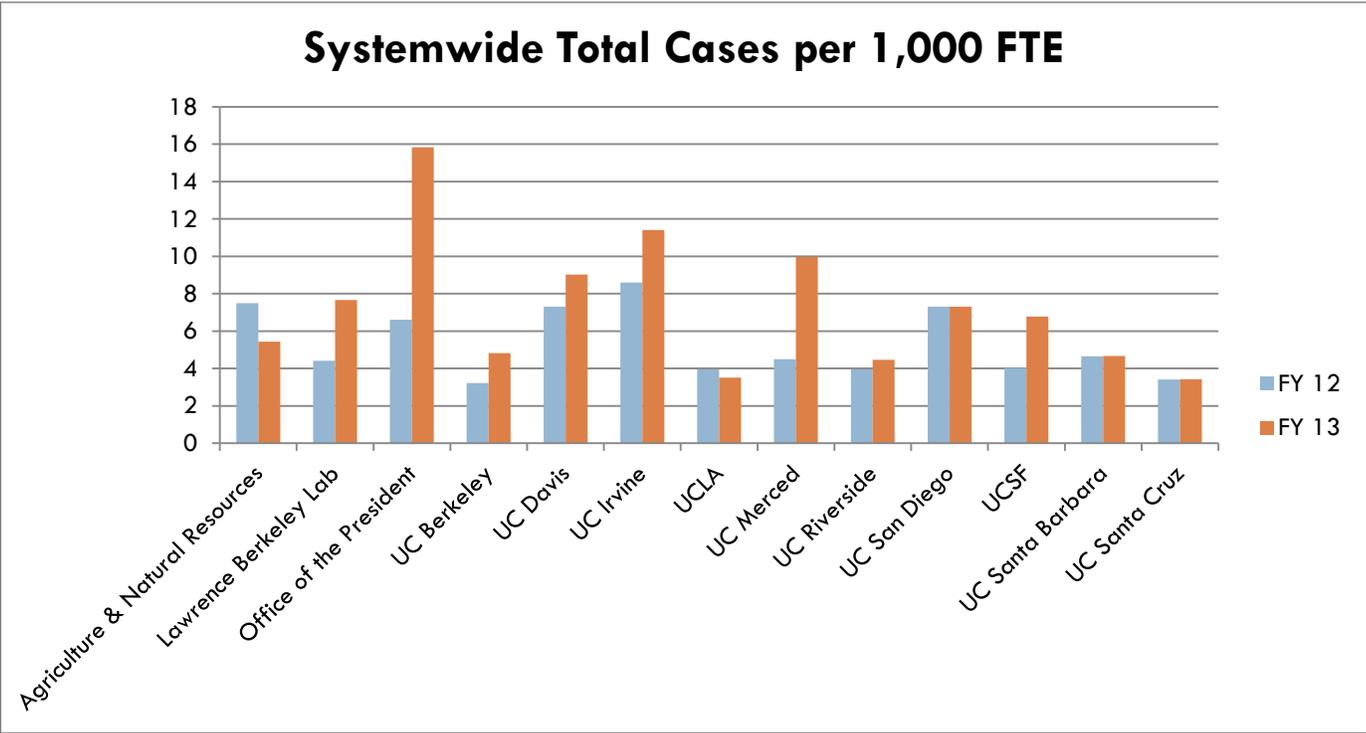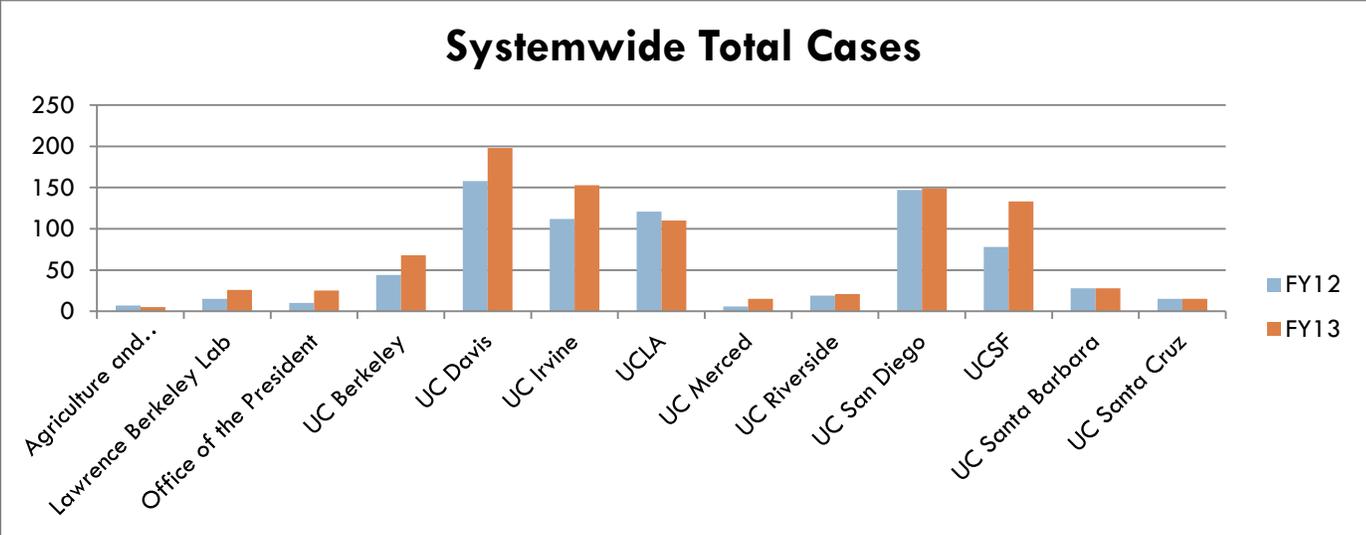
Systemwide Substantiated cases by Campus between FY 2011-12 to FY 2012-13

Systemwide Substantiated Cases

Systemwide Substantiated Cases per 1,000 FTE
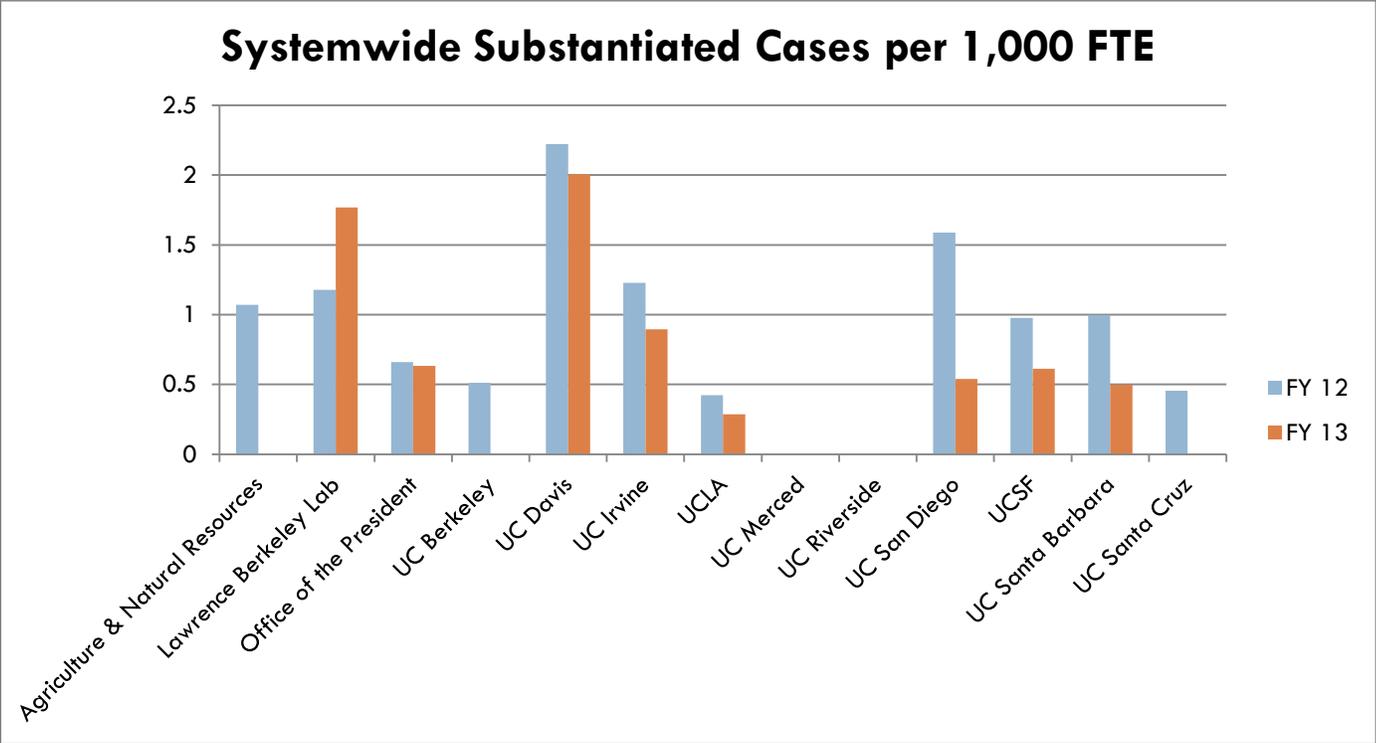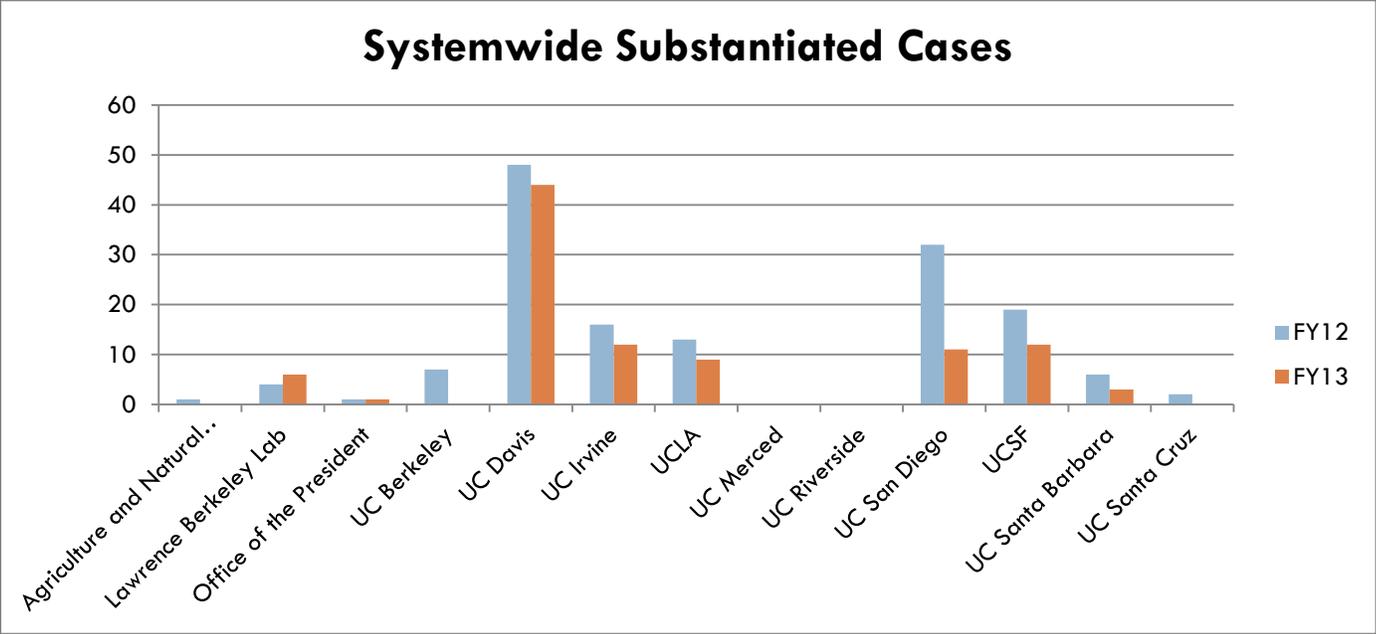
Medical Center Cases between FY 2011-12 and FY 2012-13

Medical Center Substantiated Cases

Medical Center Total Cases

Medical Center Total Cases per 1,000 FTE
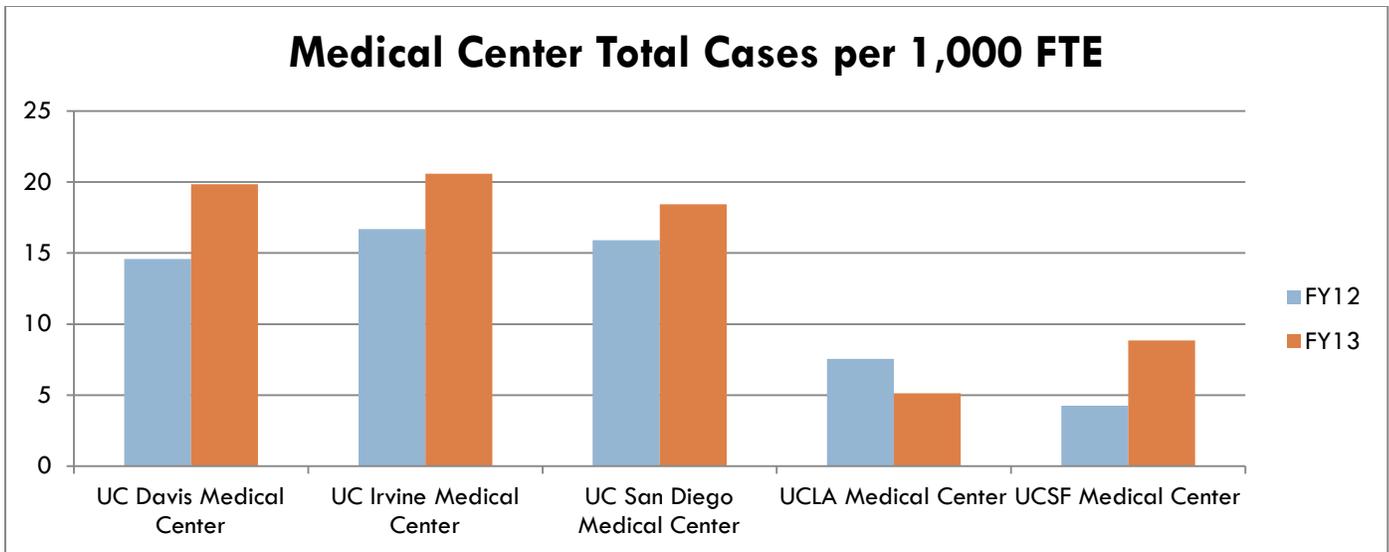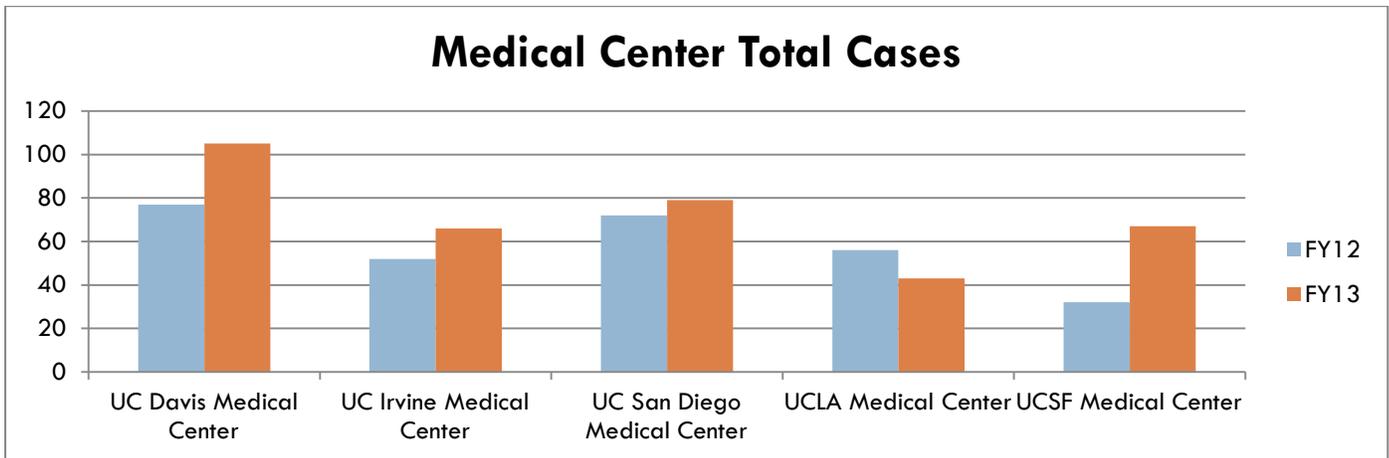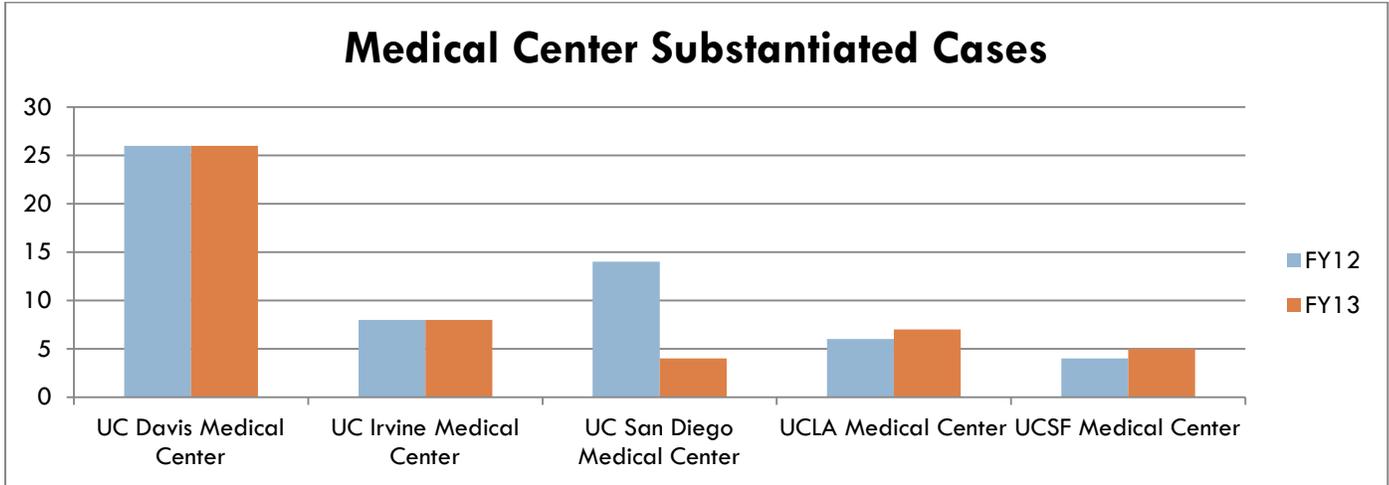
Appendix C: Annual Report on Ethics and Compliance- List of Acronyms

Academic Medical Centers	AMCs
Agriculture and Natural Resources	ANR
Campus Ethics and Compliance Committee	Committee
Campus Ethics and Compliance Officers	Officers
Centers for Medicare/Medicaid Services	CMS
Child Abuse and Neglect Reporting Act	CANRA
Clinical Research Billing	CRB
Ethics and Compliance Program	Program
Ethics, Compliance and Audit Services	ECAS
Evaluation and Management Codes	E&Ms
Federal Sentencing Guidelines	FSGs
Health Insurance Portability and Accountability Act	HIPAA
Health Sciences Compliance Officers	HSCO
Lawrence Berkeley National Laboratory	LBNL
Medicare Audit Contractors	MAC
Office of Civil Rights	OCR
Office of Ethics and Compliance Services	ECS
Office of the President	OP
President's Compliance and Audit Committee	PCAC
President's Systemwide Privacy and Information Security Steering Committee	PSPISSC
Program for Evaluating Payment Pattern Evaluation Reports	PEPPER
Senior Vice President/Chief Compliance and Audit Officer	SVP/CCAO
Statement of Ethical Values and Standards of Ethical Conduct	Standards of Conduct
University of California	University