University of California

Office of Ethics, Compliance and Audit Services

Compliance Annual Report
Fiscal Year 2008/2009

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

Table of Contents

Chief Compliance & Audit Officer Overview

The Board of Regents of the University of California formally approved a resolution establishing the Ethics and Compliance Program (the "Plan") in July 2008, and this Program completed its first full year in FY 2008/2009. While addressing some key compliance risk matters during the year, the Office of Ethics, Compliance and Audit Services (ECAS) also focused its efforts in developing the Ethics and Compliance Program in two main areas: (1) program and office infrastructure development and (2) activities and initiatives that demonstrated collaboration and integration within the fabric of the University of California (UC) system.

The following seven elements of an effective compliance program were utilized to organize ECAS work priorities and activities:

1. Standard of Conduct and Policies and Procedures
2. Governing Body, Compliance Structure and Compliance Officer
3. Education and Training
4. Communication/Anonymous Reporting
5. Enforcement and Screening
6. Audit and Monitoring Activities
7. Response and Prevention

This report will outline accomplishments of the Program and the Office of Ethics, Compliance and Audit Services during the past year and will demonstrate the value of the Program to the campuses as the University faces unparalleled challenges resulting from the global recession, state budget cuts, system-wide re-structuring activities, and reduced financial resources, including the impacts of furloughs. These challenges are fertile breeding grounds for an increase in compliance-related risks.

During the past year, the focus of the ECAS Office has been to:

Program
- Complete office infrastructure development
- Oversee development and implementation of mitigation activities to address key compliance risks identified across the system
- Initiate processes to identify potential compliance risks
- Establish processes for the development of comprehensive compliance auditing and monitoring plans, both from a campus/laboratory and system-wide basis
- Provide compliance program assessment and management services to medical center campuses

Campus
- Assist campuses in establishing their Ethics and Compliance Risk Committees (ECRCs)
- Actively engage the ECRCs in the assessment and review of compliance risks
- Assist the medical center campuses in recruitment of key compliance leadership
- Assist two medical center campuses with interim coverage for key compliance leadership positions

Communication and Training
- Develop and implement appropriate general and specific education and training based upon potential compliance-related risks
- Refine UC anonymous and other compliance-related communication systems

The ECAS Program has matched and exceeded the typical phases of a maturation process for compliance programs in a number of areas. First year goals were generally focused on the development of infrastructure: compliance office structure, policies, procedures, committees, understanding of organizational operational and cultural systems and development and implementation of general compliance training around the institution's standards of conduct.
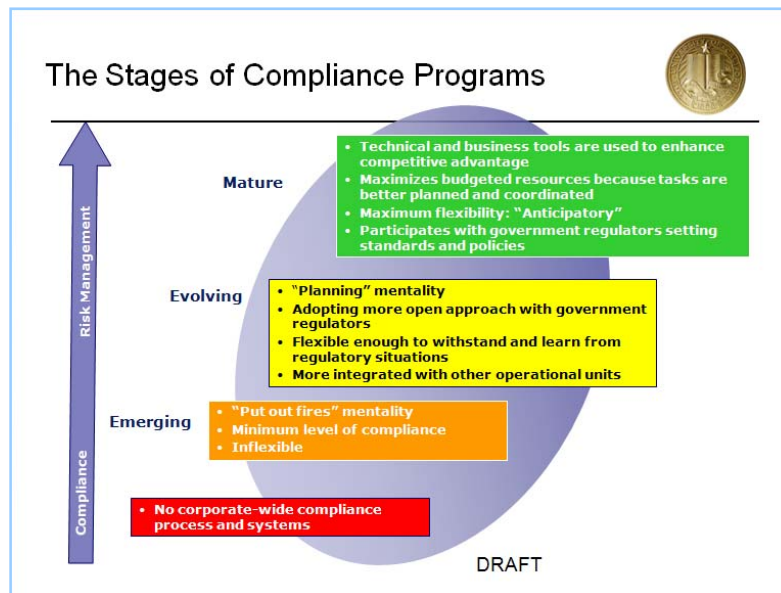
While achieving its infrastructure development goals, ECAS has also demonstrated its value by leading and/or participating in a number of substantive compliance risk initiatives. A sampling of initiatives includes:
– Effort Reporting
- Export Control
- Privacy Breaches
- Identify Theft Prevention/Red Flags Rule
- Anonymous Hotline/New Vendor Implementation

The *Ethics and Compliance Program Activity Summary* (see Appendix A) outlines key activities, categorized by each of the seven elements, which have been undertaken and accomplished by ECAS during the past fiscal year. Other key activities undertaken by ECAS during FY 2008/2009 will be detailed in this report.

The services that this office has provided in the past year have conformed to the Regent's Resolution from July, 2008 to adopt a voluntary ethics and compliance program and began the initial efforts of developing a "best in business practice" model.

Future efforts will focus on enhancing effective communications and processes in the reporting of compliance matters; further development and maintenance of compliance systems and controls that can be objectively assessed, monitoring and auditing for effectiveness and compliance to University policies, procedures or applicable legal requirements; and providing assurance that management is taking appropriate corrective action and remedial measures when problems are identified to resolve and prevent reoccurrence of those problems. A more comprehensive description of ECAS priorities for FY 2009/2010 can be found in the Ethics and Compliance Plan.

We are committed to conducting these efforts while meeting the University's mission to enhance public trust and demonstrate commitment to good stewardship of federal, state and private resources.

Sheryl Vacca
SVP/Chief Compliance and Audit Officer
October 2009

Background

As part of the Office's annual cycle, a system-wide Ethics and Compliance Plan is developed to guide the compliance priorities and efforts for the fiscal year. In FY 2008/2009, the Ethics and Compliance Annual Plan was developed through review and analysis of a number of focus areas including:

- Prioritization of potential compliance risk areas identified through industry peers and location-specific processes
- Collaboration with campus executive management and compliance personnel
- Analysis of communications of priority (defined as high risk in industry) focus areas in federal, state or other regulatory agency oversight activities from the higher education and health care industry professional organizations, research related professional organizations, and specific government agencies
- Integration of applicable topics from the Office of Inspector Generals (OIG) Work Plans from federal departments that have regulatory oversight for elements of higher education activities (i.e. Departments of Energy, Education, Health and Human Services)

The UC Compliance Program allows for revision of the Plan during the fiscal year, in the event of unforeseen compliance matters that could negatively impact the University.

The Compliance Annual Report tracks performance against the Plan in addition to highlighting accomplishments beyond the scope of the Ethics and Compliance Annual Plan.

ECAS Program Structure and Organization

The UC Ethics and Compliance Program has established a compliance communication structure under which information flows from key compliance risk areas within the campus to the campus ECRC. Each campus ECRC is comprised of senior leadership responsible for the compliance efforts across the campus and is chaired by the Executive Vice Chancellor/Provost and the campus Ethics and Compliance Officer (CECO). The ECRC assures that high risk compliance priorities for the campus are addressed.

Information from the campus ECRCs flows to the system-wide Ethics and Compliance Risk Council (SECRC) which is comprised of campus leadership representatives, as well as university-wide leadership and faculty representatives. Communication to and from the ECRCs and the SECRC is facilitated through the CECO and the SVP/Chief Compliance and Audit Officer. The SECRC is co-chaired by the President and the SVP/Chief Compliance and Audit Officer. The President's Compliance Committee (PCC), which is comprised of the President and the Senior Leadership Cabinet, also advised on compliance activities for the system.

In addition to the campus ECRCs and SECRC, ECAS utilizes strong partnerships built with functional discipline working committees and groups to identify compliance issues and develop strategies and tactics to mitigate those issues through education and training, process enhancement and implementation of best practices, and development of monitoring plans. Active working committees and groups exist in the Research Compliance, Health Science, Privacy, and Investigations of Improper Governmental Activities areas and are detailed further in the ECAS Program Efforts section of this report.
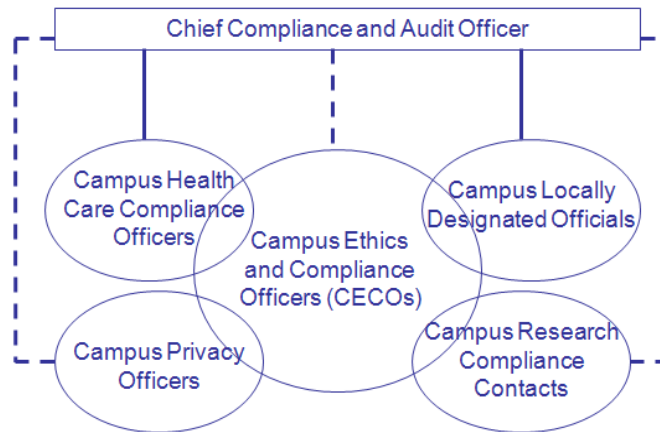
ECAS is comprised of a small group of subject matter experts with significant experience in a wide variety of functional disciplines.

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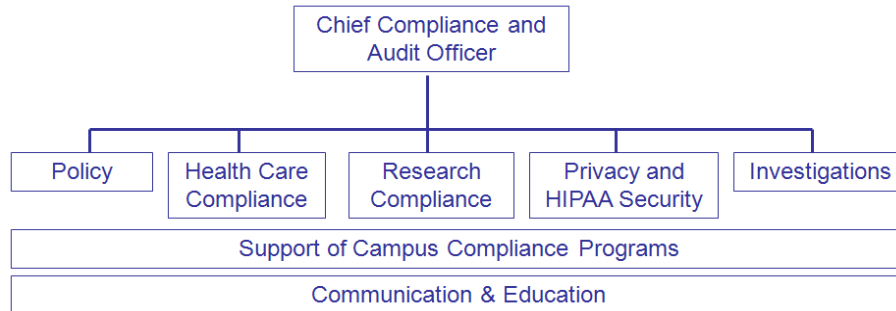
The UC Ethics and Compliance Program and the priorities of ECAS have been designed to promote adherence to standards of conduct and to ensure compliance with legal, regulatory, Regental and UC policies that govern all aspects of UC operations *including but not limited to* the following:

- Assisting campuses in the development of policies, procedures and internal controls that help reduce compliance risks in all aspects of its operations.
- Establishment of communication methodologies to effectively disseminate compliance policies to administrative and academic employees.
- Development and implementation of a comprehensive reporting and compliance tracking mechanism for academic and administrative employees to report suspected violations of UC policies or regulatory obligations without fear of reprisal. This mechanism ensures the prompt investigation of all appropriate reports of alleged violations.
- Development and implementation of training programs, including mandatory training, utilizing the most appropriate methodologies to reach all constituent audiences to ensure that UC policies are clearly understood and faculty and staff are able to carry them out effectively.
- Ensuring the development and implementation of ongoing audit and monitoring activities in an effort to assess the effectiveness of internal controls and monitor compliance with applicable UC policies and applicable standards of practice and regulatory obligations.
- Development and implementation of an effective system to reinforce individual accountability and responsibility for ensuring compliance to UC policies and/or regulatory obligations by the administration of equitable disciplinary actions commensurate with the severity of the infraction.

ECAS Program Efforts

Campus Ethics & Compliance Risk Committees (ECRCs)

ECAS outreach to the campuses is performed by two Directors of Ethics and Compliance. Both are new to their positions in FY 2008/2009 and have worked diligently to establish effective working relationships with the CECO and key compliance points of contacts on campus.

The campus ECRCs are an integral component of the UC Ethics and Compliance Program. Most campuses were successful in achieving the goals set for establishment of a campus compliance committee during the fiscal year including the establishment of: meeting frequency, administrative procedures, and committee leadership and membership. The development of campus ECRCs is an evolutionary process and as the overall Compliance Program matures, it is the expectation that the campus ECRCs will also progress within the maturity model.

Research Compliance

The Research Compliance unit of ECAS underwent a leadership change this past year and the new Director of Research Compliance has facilitated inter-campus compliance communication through hosting conference calls and workgroup/taskforce meetings including the following:
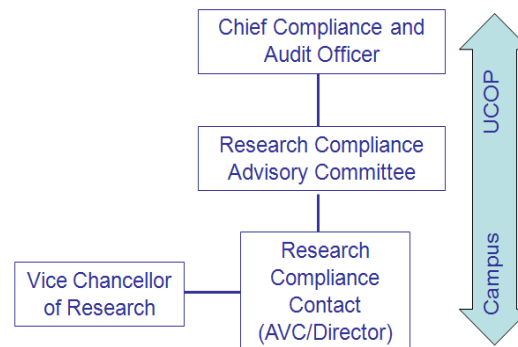
- Research Compliance Advisory Committee (RCAC)
- Institutional Animal Care & Use Committee (IACUC)
- Institutional Review Board (IRB) Directors
- Conflict of Interest Coordinators
- Attending Veterinarians
- Animal Records Workgroup
- Environmental Health and Safety Leadership Council
- Effort Reporting System (ERS) Management Working Group

The Research Compliance unit is tasked with updating UC system-wide leadership on regulatory compliance and programmatic compliance issues during periodic meetings. In addition, the unit also provides education, assistance and resources to the UC research compliance community, including compliance information as it relates to research in specific areas (i.e., Export Control, Conflict of Interest) and facilitating and developing educational offerings related to research compliance (i.e., development of the integrated "Compliance Briefing: UC Ethical Values and Conduct, and Conflict of Interest for Researchers" module mandated for completion by all University researchers).

In FY 2008/2009, the Director of Research Compliance participated on the steering committee of the UCLA Research Administration Organizational Assessment performed by an outside consultant engaged by UCLA leadership. The Research Compliance unit closely coordinates efforts and responses to system-wide issues with OP, and meets regularly with other OP units including the Office of General Counsel (OGC) and the Office of Research and Graduate Studies to ensure appropriate communication on research compliance issues.

Health Sciences

The Health Sciences Compliance group of ECAS is responsible for interfacing with the Compliance Officers at the five Academic Medical Center campuses on important health sciences compliance issues, and provides system-wide communication infrastructure (i.e., calls, meetings, website, listserv) to enable sharing of relevant compliance information and best practices.
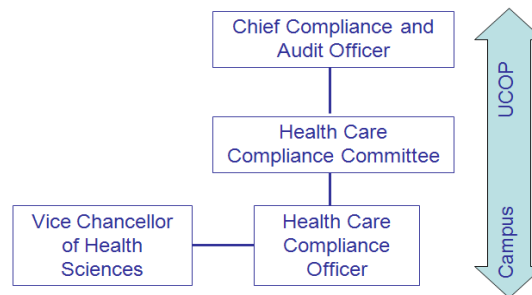
In FY 2008/2009 the Health Sciences Compliance group of ECAS facilitated communication with campus Health Sciences Compliance Officers, provided system-wide education on various health sciences compliance topics, and developed reporting tools to gather campus compliance program information.

Topics and issues that were addressed by the Health Sciences Compliance Group during FY 2008/2009 included:

Structural Discussions
- Current campus compliance interactions/communication practices (i.e., Internal Audit (IA), OGC, Risk Management, Senior Leadership)
- Integration of campus Health Sciences Compliance Programs
- Health Science Compliance Program development and design
- Health Science Compliance Officer recruitment and interim assistance in filling open leadership positions
- Benchmarking various processes internally and externally
- Interaction with outside regulatory agencies
- Processes for development of individual annual work plans
- Reporting practices
- System-wide Compliance Program performance metrics

Substantive Discussions
- Anesthesia Billing and Coding
- Billing and Coding
  - Infrastructure/Processes
  - Tools
- CMS Never Events
- Health Sciences Code of Conduct
- HIPAA: Changes to CA law and HITECH Act
- Implementation of ICD10 Codes
- Pharmacy Licensing
- Research: Media Consent Forms

Privacy and Security

Due to the high risk of noncompliance with laws and policies that govern proper use, access and disclosure of health information and other individually identifiable information, data privacy and security continue to be high compliance priorities for UC. In light of this priority, and the highly publicized Health Insurance Portability and Accountability Act (HIPAA) breaches at two of the UC campuses in FY 2007/2008, ECAS gained approval to hire a combined system-wide Privacy Officer and HIPAA Security Officer (CPO/SO). During FY 2008/2009, interim staff filled the position of CPO/SO while recruitment efforts continued.
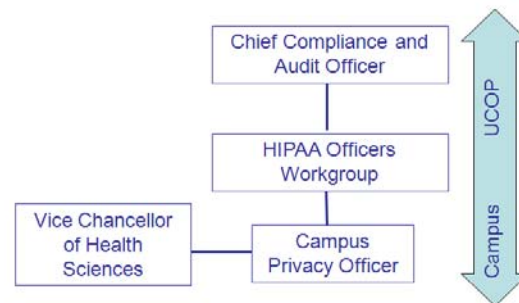
These interim roles functioned to establish key relationships among the campus HIPAA and other Privacy Officers. They provided organizational support for HIPAA Officer calls and meetings to discuss key compliance issues, and facilitated review and formation of workgroups to revise the following draft UC HIPAA policies for clarity and consistency with new state and federal law:
-    Policy on Managing Health Information Compliance
-    Health Information Glossary of Terms Policy
-    Group Health and Welfare Plans Policy on Use of Protected Health Information
-    HIPAA Business Associates Agreement (BAA) Policy
-    Mental Health
-    Policy on the Security of Electronic Health Information
-    Use and Disclosures (Patient Rights, Minimum Use, TPO)
-    HIPAA Research Policy
-    Breach Response Policy

The above policies are in various stages of development with a goal of having all policies vetted, finalized, and disseminated in FY 2009/2010.

A permanent system-wide Privacy Officer and HIPAA Security Officer joined ECAS in July 2009. This individual will focus on privacy issues beyond HIPAA Privacy, to include privacy associated with all individually identifiable information.   In addition, the role will include the HIPAA Security function, as is consistent with the federal enforcement trend of the HIPAA Privacy and HIPAA Security functions to be co-localized.

System-wide Compliance Training

ECAS efforts were mobilized this past fiscal year on developing and presenting a comprehensive education and training program across the UC system. The following provides a high level overview of the major content offered; however, for a detailed listing of all compliance-related education provided to OP, campuses, and LBNL, see Appendix B.

Audio/web-based conferences were provided both from internal experts as well as nationally known conference firms to educate UC staff on pending and ongoing compliance issues. Subjects included: indirect waivers and cost transfers for research, Clery Act implementation, and others.

In addition, the first Annual Compliance and Audit Symposium was held in February 2009 and provided both basic and advanced compliance-specific education to our UC colleagues.

Mandatory System-wide Training Efforts
The following mandatory courses were either provided or were in the process of development during the past fiscal year.
- AB1825 Sexual Harassment Prevention Training
- Conflict of Interest for Designated Officials - ECAS coordinated with Office of General Counsel to revise content of the briefing, and with system-wide Learning Management System (LMS) leadership developed rollout strategy and communications. Rollout of this briefing to approximately 1,500 designated officials occurred in August 2009.
- Compliance Briefing: UC Ethical Values and Conduct - ECAS revised the 2006 ethics training to include compliance information with new/revised illustrative scenarios. Briefing content was vetted system-wide among leadership, faculty and staff. In FY 2009/2010, ECAS will work with LMS leadership and the campuses/locations to develop the rollout strategy (October 2009) and communications for this training of over 190,000 University employees.
- Compliance Briefing: UC Ethical Values and Conduct, and Conflict of Interest for Researchers - ECAS combined the general ethics and compliance training with conflict of interest for researchers in an effort to consolidate the training into a single module. Content was revised to reflect changes in state law, and the content and proposed target audience was vetted widely among research administrators, the Vice Chancellors for Research at all 10 campuses and LBNL, and the system-wide Office of Research and Graduate Studies. In FY 2009/2010, ECAS will work with LMS leadership and campuses/locations to develop the rollout strategy (October 2009) and communications for this training of approximately 19,000 researchers.
- HIPAA Privacy and Security Training - ECAS facilitated efforts among the system-wide HIPAA Officers to develop a consolidated, comprehensive and updated HIPAA Privacy and Security Training module to be used by campuses as a model/template training for the HIPAA-covered workforce. It will be placed on the system-wide website as a training resource for the University and others. The training model/template will be finalized in FY 2009/2010 and further modified to meet the needs of a basic Privacy and Security educational resource for training non-HIPAA-covered workforce.

Investigations

UC's Whistleblower Program implements California Government Code Sections 8547 and 8548 through the system-wide Whistleblower Policy and Policy for Protection of Whistleblowers from Retaliation.

Working collaboratively with the Human Resources Department, the Investigation staff notifies the campuses, LBNL, and OP of their requirement to post flyers describing the Whistleblower Program and to send an electronic reminder about the program to all employees with e-mail accounts by July 1st of each year.
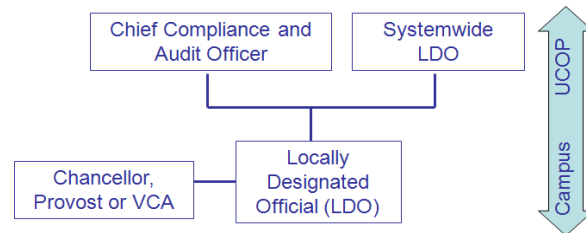
During the past year, the ECAS's Investigations unit accomplished the following.
- Conducted investigations within OP, LBNL, and the Berkeley, Davis, Irvine, Los Angeles and Santa Barbara campuses.
- Coordinated requests for investigations from the California Bureau of State Audits at OP and campus level.
- Participated in Investigations Work Group meetings at LBNL.
- Conducted a workshop for the campus and lab Locally Designated Officials (LDOs), Whistleblower Coordinators (WBCs) and Retaliation Complaint Officers (RCOs) in March 2009.
- Developed and delivered training in the Whistleblower Program to the supervisors and managers at the Merced campus and at the October 2008 session of the Business Officers Institute (BOI).
- Provided guidance to LDOs, Audit Directors and campus investigators on investigation strategy and the University's Whistleblower Policy.
- Developed a lending library of resources on investigations, ethics and compliance, to assist the LDOs and WBCs.
- Created a set of whistleblower awareness materials, including flyers and a brochure, for use by the campuses, medical centers, and LBNL.

Confidential Reporting

UC utilizes several confidential reporting mechanisms available to employees and the general public. Our independently operated hotline permits callers and web reporters to remain anonymous while simultaneously providing for future contact and follow-up. In addition to hotline complaints, reports of potential improper governmental activities (IGAs), violations of University policies and other compliance issues may be registered with the President, the Regents, Chief Compliance and Audit Officer (CCAO), LDO, or OGC; or locally at the campuses, medical centers and lab through LDO, various departments such as Human Resources, Internal Audit and the campus Police Department, or, in the case of an employee, directly to a supervisor or manager. Reports can also be filed with external agencies, such as the U.S. Department of Energy (DOE) or the California Bureau of State Audits (BSA). The Investigations function of ECAS is responsible for coordinating, tracking, managing and investigating (where applicable), regardless of the point of origin, all reports of suspected IGAs.

The investigation process is initiated by the LDO, who may be assisted by a convened Investigations Work Group in determining whether the allegation, if true, would constitute an IGA or a violation of University policy. If not, the complaint may be referred to management for resolution. The LDO monitors and tracks all investigations including notification of the whistleblower, subject(s) and management of the investigation's results. The LDO also follows through with any management corrective actions (MCAs) or personnel actions ensuing from the investigation. The LDO notifies the system-wide LDO of any significant matters. Periodically, case activity is reported.

Investigations Statistics

During the fiscal year, 491 new investigations were initiated and 436 investigations were completed (both new and ongoing). The majority were conducted by Internal Audit, Human Resources, LDOs or a Compliance Officer. However, a total of 22 different functional areas participated in investigations, including: University Police, Academic Personnel, the Title IX Office, the Institutional Review Board and Environmental Health and Safety.

The largest single type of complaint received this year related to workplace misconduct. Most of these allegations were reported through the hotline and often reflected management issues rather than substantive allegations of improper governmental activities (IGA). The prevalence of workplace misconduct complaints is consistent with industry-wide findings.

The importance of an anonymous reporting vehicle is illustrated by 75% of our hotline callers requesting anonymity. This percentage of anonymous hotline calls has remained consistent during the last three years (68%, 74% and 72%, respectively) and compares favorably to the higher education average of 81%.

Our hotline service provider has a significant higher education client base, including other university systems as well as Ivy League institutions. In one of their surveys, it was indicated that a combination of fear of retaliation and a sense of futility prevent employees from reporting observed violations of law and policy. Both of these factors are reported as prevalent in the government and non-profit sectors.

Workplace Misconduct comprises the majority of our allegations, at 21%. Fraud, Theft or Embezzlement and Economic Waste or Misuse of University Resources, both typically investigated by Internal Audit, reflect 25% of investigations.

Fiscal Year 2008 - 2009 Allegations

Fraud, Theft or Embezzlement 12%
Economic Waste or Misuse of University Resources 13%
Conflict of Interest or Commitment 8%
Quality of Patient Care or Safety 4%
Privacy Violations or Computer Security 7%
Public or Environmental Health & Safety 4%
Retaliation 4%
Discrimination or Sexual Harassment 9%
Research or Academic Misconduct 4%
Workplace Misconduct 21%
Other Allegations 14%

Complaints are received from a variety of sources, but the majority (52%) originates from University employees reporting suspected misconduct they encountered in the course of their daily work. The categor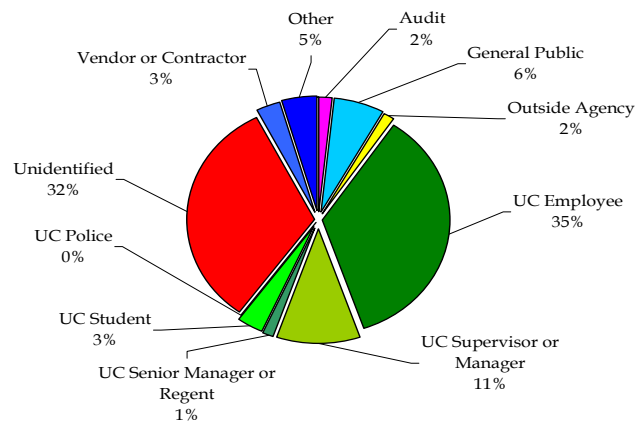ization of complaints was based on whether the complaining party used the hotline (43%) and whether they chose to remain anonymous (45%). While 75% of the hotline callers remained anonymous, only 23% of those who reported incidents through another means declined to disclose their identities.

Fiscal Year 2008 - 2009 Complaint Sources

Other 5%
Audit 2%
Vendor or Contractor 3%
General Public 6%
Outside Agency 2%
Unidentified 32%
UC Employee 35%
UC Police 0%
UC Student 3%
UC Senior Manager or Regent 1%
UC Supervisor or Manager 11%

Overall, approximately 30% of allegations are substantiated. Substantiation rates vary by type of allegation. Privacy Violations/Computer Security and Public/Environmental Health and Safety allegations are relatively rare, but their substantiation rates are high (49% and 41%, respectively). This year, 43% of Fraud, Theft or Embezzlement allegations and 42% of Economic Waste/Misuse of University Resources allegations were substantiated. When allegations are substantiated, administrative remedies may be necessary. Remedies may include personnel actions as well as procedural changes to mitigate risk of recurrence of that particular misconduct. In 24% of substantiated cases, the employee(s) responsible were immediately separated from the University.

The Association of Certified Fraud Examiners (ACFE) expects fraud and economic waste allegations will rise in coming years. Their finding relates to the intense awareness and compliance resulting from the financial scandals of 2000 and subsequent legislation in 2002. Participants in their annual survey indicated on average a 7% loss of revenues due to fraud. With the infusion of funding from the America Recovery and Reinvestment Act of 2009 (ARRA), we can expect more allegations of fraud and waste. Currently, our allegations of fraud and economic waste complaints combined exceed reports of workplace misconduct.

Auditing and Monitoring

Compliance has utilized internal audit and/or campus functions to perform auditing and monitoring for the first year of this program. The following areas were identified as system-wide, potential high risk compliance areas and the corresponding auditing responsibilities have been integrated into the overall internal audit plan at each campus. The general scopes of the reviews were developed with input from ECAS. Due to budget impacts on business processes and priorities, several of the planned auditing and monitoring activities were still in progress or deferred until FY 09/10. The following summarizes the status of auditing and monitoring as of June 30, 2009.

Health Care Vendor Relations Policy (In Progress)
The five medical center campuses reviewed compliance with the new Health Care (HC) Vendor Relations policy. The audit focused on policy training and education, policy monitoring and enforcement, interaction between health care vendors and University personnel, responsibilities of committees that oversee purchasing decisions, vendor preceptorships, publicity of industry support and the anti-kickback law. At June 30, the audits were still in progress and were expected to be completed by the first quarter of FY 2009/2010.

Health Information Portability & Accountability Act (HIPAA) Privacy/Security
This review will be further defined by the new system-wide Privacy Officer and will be conducted in FY 2009/2010.

Indirect Cost Waivers (In Progress)
The purpose of this audit was limited to reviewing the internal processes for requesting and granting indirect cost waivers on research grants. The audit reviewed whether the indirect cost exception/waiver process is in compliance with UC policy. The campuses have completed their reviews and a system-wide consolidated report is in draft form as of June 30, 2009.

Effort Reporting
The purpose of this audit was to evaluate whether key internal controls related to effort reporting processes were functioning in accordance with University policy and OMB Cost Principles to ensure salaries and wages charged to federal awards are allowable, allocable and reasonable. In addition, the audit staff evaluated the implementation of the new effort reporting system and its impact on the University's ability to comply with University policies and procedures as well as federal regulations governing effort reporting. The results of the audits were used as the starting point for the University's effort initiative, as described in the Key Initiatives section.

Royalties
In FY 2008/2009, criteria for a system-wide audit was co-developed with outside consultants to assess books and records of companies that have licensed University intellectual property. Earned royalty calculations and payments to the University for the sampled agreements selected will be the focus.

FY 2008/2009 Key Initiatives

Research Compliance

The following areas detail key potential compliance risks that have been identified nationally as areas of focus for academic research:

Effort Reporting

Federal sponsoring agencies continue to focus on compliance with time and effort reporting in federal grants and contracts pursuant to OMB A.21. For example, the National Science Foundation (NSF) has included labor and effort on their OIG work plan for the past several years. In FY 2008/2009, a prestigious research university was found to have violated the False Claims Act (FCA) and entered into a civil settlement with the government to pay in excess of $7 million dollars for findings related to inappropriate cost transfers and charging of summer salary. With such regulatory and financial risk at stake, effort reporting continues to be a high risk priority area for the University.

In FY 2008/2009, ECAS hosted a webinar to share information across the system about recent NSF labor and effort audits at UC Berkeley and UC San Diego. In addition, a system-wide internal audit was performed related to effort reporting. The audit focused on two areas: (1) an evaluation of the development and implementation of the Effort Reporting System (ERS) and (2) an evaluation of each campus' compliance with OMB A-21 and UC Contract and Grant Manual requirements for effort reporting. To supplement the work done by Internal Audit, additional fact finding was performed by ECAS staff, in partnership with the Effort Reporting System (ERS) Management Workgroup, to incorporate process participant feedback on the tools, reference materials and overall process.

With the implementation of ERS at most of the campuses, UC has taken significant steps forward to meet federal effort reporting requirements. ECAS and the ERS Management Working Group have identified potential opportunities in the areas of data/system enhancements, training/reference materials, policy updates and exception reporting. While great progress has been made, the effort reporting process continues to be an area of focus for the compliance program and as such, continued efforts in identifying opportunities for enhancement as well as ongoing auditing and monitoring is necessary.

Conflicts of Interest

Compliance with financial conflict of interest regulations promulgated by federal sponsoring agencies (i.e., National Institutes of Health and NSF) continues to be a public focus for the federal government. For the University, this public focus garners attention as it relates to outside professional activities of clinical investigators in the academic setting.

While requirements for disclosure continue to evolve at the federal level, the University is currently in discussions to proactively implement a reporting process that will enable a level of transparency that provides the public the appropriate level of information. This approach is consistent with the actions currently being considered and/or taken by other national research universities.

The ECAS Research Compliance unit worked with the system-wide Office of Health Sciences and Services (HSS) to collect benchmark conflict of interest policies and institutional annual reporting forms from other institutions as possible models for UC. This process continues to be under development through the SVP Health Sciences & Services.

In FY 2009/2010, HSS will work toward implementing system-wide use of a more robust conflict of interest reporting form for the Academic Medical Centers. The Research Compliance unit will work with these medical center campuses to offer compliance assistance and use a monitoring tool for compliance with federal financial conflict of interest regulations in sponsored research.

Export Control

As a matter of longstanding policy, UC maintains the freedom to publish its research results and select the members of its research teams on the basis of scientific merit, rather than citizenship or visa status. This process allows UC to take advantage of certain protections for basic, fundamental research that are contained in the United States' export control laws. Recently, however, federal funding agencies have attempted to impose publication and citizenship restrictions in some research awards. Accepting such restrictions not only violates UC policy, but significantly increases the risk of violating the export control laws. This point was highlighted by the recent criminal prosecution of a university professor in another state for violating export control laws in a research project that contained citizenship restrictions. It was recently announced that the professor was sentenced to four years in prison.

In FY 2008/2009, the Research Compliance unit assisted campuses by supporting and facilitating in-person faculty export control training at each campus/location led by a nationally-known subject matter expert in export control. Also during this fiscal year, several campuses offered in-person export control training to their faculty. The remainder of the campuses will offer the export control faculty training in FY 2009/2010.

In FY 2008/2009, the Research Compliance unit hosted a webinar with internal experts from across the system to address export control language in non-disclosure agreements. Finally, the Research Compliance unit supported and directed the work of an outside consultant to advise campuses on specific export control issues and to develop export control guidance documents and model language for research agreements.

Health Sciences

In the Health Science arena, the Office of Inspector General at Health and Human Services, as well as active leaders in government, helps to provide the focus of health care compliance regulatory activities. This past year has seen increased focus on physician relationships, conflict of interest, billing and coding initiatives, and privacy and security initiatives. ECAS has been working closely with the Compliance and Privacy Officers and the office of Health Sciences to assist with identifying risk mitigation controls around these areas. Due to the complexities of the health care industry, our academic medical center environment and relationships with school of medicine and faculty practice groups, our efforts have focused on education in the key risk areas, self reviews and taking inventory of key business processes at each medical center related to some of the regulatory risk areas.

Several investigations occurred this past year in the health care arena and this office either directed or assisted with these investigations.

Privacy and Security

The following areas detail key potential compliance risks that have been identified nationally as area of focus for privacy and security:

Breaches

On the heels of the well publicized breaches within the UC system in FY 2007/2008, the HIPAA Privacy/Security functions within ECAS facilitated responsive system-wide strike teams that examined UC policy and industry best practices in the following areas:
- Education and training
- Surveillance and monitoring strategies
- Enforcement and sanctions

The system-wide strike team recommendations were presented to the Compliance and Audit Subcommittee of the Board of Regents at their January 2009 meeting. In FY 2008/2009, many of the recommendations were incorporated into one or more of the draft system-wide HIPAA policies.

Privacy breaches continue to be a high risk priority for UC. In FY 2009/2010 the Privacy and HIPAA Security unit will focus on preventing non-compliance through policy revisions, education, and monitoring efforts.

Compliance with New State and Federal Privacy Laws

Two significant laws were enacted in California in FY 2008/2009. First, Assembly Bill (AB) 211 was established within the California Health and Human Services Agency's (CHHSA) Office of Health Information Integrity (OHII) to ensure the enforcement of state law mandating the confidentiality of medical information, imposing administrative fines on both individuals and organizations for the unauthorized use of medical information. Second, Senate Bill (SB) 541 required licensed health facilities to prevent unauthorized access to or disclosure of patients' medical information, or face penalties along with an onerous 5-day notification requirement to the state and the patient in the event of violations.

At the federal level, the American Recovery and Reinvestment Act (ARRA) of 2009 contained a subsection entitled the Health Information Technology for Economic and Clinical Health (HITECH) Act that modified the Privacy and Security provisions of the Health Information Portability and Accountability Act (HIPAA) of 1996. Major aspects of the revisions included substantially increased fines for violations; empowering state attorneys general to bring suit against organizations for HIPAA violations; subjecting "Business Associates" (business partners) to the information security and some privacy requirements of HIPAA, by imposing fines for non-compliance; and mandatory breach notification requirements to affected individuals and the federal government.

Campus Support for New or Revised Regulations

American Recovery and Reinvestment Act (ARRA) of 2009

ARRA was signed into law on February 17, 2009. This legislation provided economic stimulus monies to UC in a number of areas, including: education monies, research funding, medical center information technology initiatives, student financial aid, capital investments and other important projects.

With the potential infusion of monies into UC comes the responsibility of ensuring compliance to the stringent reporting requirements mandated by Congress. President Obama's theme of transparency as to how tax dollars are spent intersects well with UC's mission to maintain the public trust and fulfill its responsibilities to the citizens of California by conducting its business in an ethical and compliant environment. Public posting of recipient reports on the use of stimulus monies to the ARRA website will require UC to increase its internal scrutiny on the accuracy and timeliness of project data reporting.

ECAS will work collaboratively with each of the campuses, the national laboratory, and appropriate OP divisions to provide guidance and oversight in the establishment of monitoring activities to ensure internal controls are in place at each location to meet applicable reporting requirements. An over-arching, system-wide ARRA Funds Monitoring Plan is being developed by ECAS and will include:
- Collaboration with campus/laboratory liaison(s) to gather appropriate data and develop metrics for ARRA reporting monitoring that will include:
    § Identification and documentation of the receipt of funds from applicable federal agencies at a high level
    § Identification and inventorying of location and/or department processes for collecting appropriate data elements for the quarterly reporting of required information
    § Development of tools for campus use in documenting oversight of monitoring function
- Development, with Internal Audit, of a system-wide pre-submission reporting and a post-submission audit to determine general compliance with reporting requirements.
- Aggregation and trending of observations/findings and recommendation of campus-specific and/or system-wide "best practices"

Identity Theft Prevention/Red Flags Rule

The Federal Trade Commission's Red Flags Rule stipulated that institutions establish a written identity theft program to "detect", "prevent", and "mitigate" identity theft in connection with the opening of certain or existing accounts, which are termed "covered accounts".

Accordingly, the Regents approved the system-wide Identity Theft Prevention Plan at the January 7, 2009 Compliance and Audit Committee. ECAS worked with the campuses to develop campus specific plans and identify "covered accounts"; as well as provided a tool for assisting them in developing an implementation plan. As a result, a dashboard of accounts was compiled by campus leaders and a project plan template was developed to assist locations in defining further actions which will need to take place at the campus level.

ECAS has been working with all locations to ensure the respective plans are reviewed and approved by their campus ECRCs. The enforcement deadline from the FTC has been extended to November 1, 2009. Audit or monitoring activities will be developed by ECAS to determine campus compliance with the Red Flags Rule requirements.

Investigations: Anonymous Hotline/New Vendor Implementation

Based on a market analysis, seven vendors were invited to respond to the Request for Information (RFI), which was the pre-qualification phase for the Request for Proposal (RFP). The evaluation process included scoring the responses to the RFI and RFP, scoring two finalist presentations, and scoring the 'sandbox' environment. The sandbox allowed representatives from various campuses and medical centers to experiment with a training version of the two finalist products and rate those products based on UC's workflow and reporting requirements. Our new vendor's product received the highest score in all evaluations.

Once contract negotiations were completed, an implementation plan was developed. Implementation activities included designing a web portal for reporters, in English and Spanish; defining call center procedures and configuring an auto-responder for foreign language support; establishing issue types and definitions, as well as mapping the issue types both to UC's existing 11 allegation categories and to a standard set of higher education allegation categories; identifying benchmark institutions from the new vendor's clients, based on the Carnegie Foundation's classification scheme, along with various national and international college rankings (US News & World Report, Quacquarelli Symonds, Washington Monthly); identifying location information for each campus, lab, medical center, and OP; setting up user accounts, access levels and case assignment criteria; mapping legacy data from prior hotline and databases for conversion; defining custom fields and customizing the dropdown values of the standard fields to reflect UC workflow and reporting needs; and developing communications materials, such as posters, brochures and flyers.

Communication and training activities were included in the implementation plan. The UC web portal and customized database was presented to the LDOs in March and, in April, four training webinars were conducted for users from across the system.

The system went live on April 30th and received its first hotline call that same day. Forty-two hotline reports were received between April 30th and June 30th, fourteen submitted through the web portal and 28 by phone. An additional sixty cases were added manually to the database during that period. The system allows ECAS and the campuses to track responsiveness to hotline reports, as well as to track outcomes and durations for all cases, regardless of their intake method.

Appendix A: Ethics and Compliance Program Activity Summary

Activities	Scoring Criteria			Comments
	1 Not Completed	2 Partially Complete	3 Completed	
Standards of Conduct and Policies and Procedures				
Continue developing Ethics Compliance & Audit Services (ECS) Department Policies		**Partially Complete**		Business processes being modified
Develop and implement Office of the President Policy Management Process		**Partially Complete**		Modifying approach due to budget impacts
Develop Health Insurance Portability & Accountability Act (HIPAA) System-wide Policies		**Partially Complete**		Privacy Officer on board 7/09
Oversight (Governing Body, Compliance Structure and Compliance Officer				
Assist/Facilitate Compliance & Audit Committee Meetings of the Board of Regents			**Completed**	
Facilitate and co-lead System-wide Ethics & Compliance Risk Council (SECRC)			**Completed**	
Participate in and co-chair President's Compliance Committee			**Completed**	
Establish System/Campus/Program Office performance metrics, aligned to President's Accountability measures		**Partially Complete**		1st year of implementation
Implementation of a compliance risk management and policy management and tracking system		**Partially Complete**		Initiated project implementation in 6/2009.
Name Campus Ethics and Compliance Officers (CECOs)			**Completed**	
Form Campus Ethics & Compliance Risk Committees (CECRCs) with the majority of campuses meeting as scheduled			**Completed**	
Appoint, Campus Provosts as Co-Chairpersons with Local Compliance Officer of the CECRCs			**Completed**	

Activities	1 Not Completed	2 Partially Complete	3 Completed	Comments
Campus discussions around risk identification		Partially Complete		Campuses continue working on risk assessment activities.
Assist/Facilitate system-wide compliance efforts around new regulations and rules, i.e. Red Flags Rule, Higher Education Opportunity Act, etc.			Completed	Ongoing
Education and Training				
Roll out Sexual Harassment Prevention/CA-AB1825 Training for all supervisors and faculty (January, 2009 - ongoing)			Completed	
Develop and schedule General Compliance Training for all UC employees		Partially Complete		Module developed for campus use
Develop Compliance and Conflict of Interest (CoI) for Researchers training as tool for campuses		Partially Complete		Training developed for campus use-modified approach due to budget implications
Develop General Privacy & Security Training module for all employees (System-wide training being developed for projected rollout 2Q09-10 & Medical Center staff exempted if HIPAA training has been completed during annual training period)		Partially Complete		HIPAA module nearly completed--awaiting Privacy Officer placement
Annual Compliance & Audit Symposium (2 days - February 2009; 200+ attendees system-wide) for system			Completed	
Host free audio conferences sponsored by external entities for relevant audiences system-wide on specific compliance risks			Completed	
Sponsor ECS in-person faculty export control training at each campus			Completed	
Develop CoI for Designated Officials (DOs) training and schedule for DOs across system			Completed	

Activities	1 Not Completed	2 Partially Complete	3 Completed	Comments
Sponsor audio/webinars with speakers from within UC (The Cleary Act, Time & Effort Reporting for Researchers, International Research, Export Control)			Completed	
Communication/Anonymous Reporting				
Complete RFP/procurement/implementation of Hotline/case management system			Completed	
Provide training on case management platform			Completed	
Develop and distribute campus communications including posters, flyers & brochures			Completed	
Implement Whistleblower Program training			Completed	
Provided Local Designated Officer (LDO)/campus training on investigations, etc.			Completed	
Enforcement and Screening				
Establish Senior level work group (SVP/Chief Compliance Officer, Provost/EVP, General Counsel/VP, Academic Senate Chair) to address consistency in enforcement and disciplinary/administrative actions between administrative staff and academic personnel policies		Partially Complete		Work group established and continuing to develop enforcement guidelines.
Establish system-wide HIPAA breach response strike team to develop consistent adjudication and discipline recommendations across system for HIPAA breaches		Partially Complete		Start date of Privacy Officer scheduled for July 20, 2009.
Response and Prevention to system-wide risk incidences and monitor for resolution		Partially Complete		Still working on communication systems to get timely information

Activities	1 Not Completed	2 Partially Complete	3 Completed	Comments
Audit and Monitoring Activities				
Effort Reporting Systems (ERS) - perform fact finding and in partnership with the ERS Management Working Group make recommendation to enhance effort reporting systems and processes			**Completed**	
System-wide Internal Audit - Indirect cost waivers				Final report being written
Royalty Audits--framework developed for implementation 09/10			**Completed**	
Response and Prevention				
System & Campus				
*Lead efforts in helping to create compliance **activities** around key potential risk areas: HIPAA Privacy, Delegation of Authority, etc.*			**Completed**	
Prevention Activities				
Oversee, from a compliance perspective, planning activities related to new and/or amended laws and regulations:				
· Red Flags Rule (Federal Trade Commission)			**Completed**	
· E-Verify (Dept of Homeland Security)			**Completed**	
· American Recovery & Reinvestment Act (ARRA)--development of monitoring activities and oversight		**Partially Complete**		Awaiting guidance on IG monitoring activities from various agencies
· National Science Foundation--America Competes Act			**Completed**	
· Higher Education Opportunity Act (HEOA)--development of monitoring tools		**Partially Complete**		Continue working on monitoring tools

Appendix B: List of Education and Training

Offerings for FY 2008-2009

Date	Title	Organization
8/29/2008	Still in the Dark? Reporting Meaningful Metrics to the Board	HCCA
9/3/2008	Visual Compliance Quarterly Training	eCustoms
9/3/2008	RACS/MIPS/Third-Party Denials: Managing the Convergence of Compliance & Revenue Cycle Management Process Improvement	HCCA
9/4/2008	Compliance Effectiveness in the Era of Increased Regulatory Enforcement	CHS
9/9/2008	Health Care Vendor Relations Policy Implementation Webinar	Internal
9/9/2008	Practical Stark Law Issues Including Operational Pitfalls and Fair Market Value Documentation: Part 1	HCCA
9/11/2008	Documentation and Coding for Physician Practices	HCCA
9/23/2008	Practical Stark Law Issues Including Operational Pitfalls and Fair Market value Documentation Part II	HCCA
9/25/2008	Whistleblower Claims in Healthcare: The Enforcement Perspective Part I	HCCA
10/1/2008	A Stark Contrast: Recent Revisions to the Federal Physician Self-Referral Regulations	UHC
10/1/2008	The Clery Act	N/A - Internal
10/1/2008	Red Flag Alert - Red Flags Rules May Apply to You	AHLA
10/7/2008	Compliance 101	SCCE
10/8/2008	Whistleblower Claims in Healthcare: The Enforcement Perspective Part II	HCCA
10/8/2008	Medicare Secondary Payor Rules & Clinical Research Billing	Aegis
10/14/2008	MACs and RACs: What it Means for the Lab	HCCA
10/15/2008	Red Flags Rules	SCCE
10/22/2008	Creating a Compliance Program for Identity Theft Rules	Educause
10/23/2008	Risk & Compliance Seminar for IT Security Professionals	RiskWatch
10/30/2008	Help with HEOA: Understanding the New Higher Education Act Reporting and Disclosure	NACUA
10/30/2009	An Insider's Guide to Workplace Investigations	SCCE
11/6/2009	Data Privacy Security Enforcing Rules	SCCE
11/11/2008	Foreign Corrupt Practices Act: Part 2	SCCE
11/11/2009	Practical Solutions for Management and Oversight of Conflicts of Interest in Health Care	HCCS
11/12/2008	Conducting Investigations in a University Environment	N/A - Internal
11/20/2008	The Operational Impact of the Changes to your Compliance Program in Long-Term Care Part 2	HCCA
12/9/2008	Visual Compliance Quarterly Training	eCustoms
12/17/2008	CMS's Latest Guidance on Research Billing: The Good, the Bad and the Really Ugly	HCCA
1/8/2009	Disability and Sickness: Understanding the New Amendments to the ADA and FMLA and the New FMLA Regulations	HCCA
1/13/2009	Siemens: Cooperation and Remediation	SCCE
1/28/2009	Export Control Training w/Barbara Yoder, presentation from 2005	Internal

Date	Title	Organization
1/29/2009	Family Educational Rights and Privacy Act Presentation	Internal
1/29/2009	Understanding California's New Privacy Laws: A Briefing on the Law & Answers to Frequently Asked Questions	CHA
1/29/2009	Compliance 101	HCCA
2/3/2009	First Annual Compliance and Audit Symposium	Internal
2/4/2009	First Annual Compliance and Audit Symposium	Internal
2/5/2009	First Annual Compliance and Audit Symposium	Internal
2/11/2009	A New Look at the Internal Auditing Standards...Applying Them Every Day and What's Changing	EthicsPoint
2/18/2009	Shaping the Middle: Leveraging Line Leadership to Promote Ethics and Compliance	Internal
2/19/2009	HEOA Reauthorization (1)	Department of Education
2/20/2009	Export Control Presentation at MTA Forum	Internal
2/24/2009	A Guide to Wage and Hour Compliance/Litigation: Strategies to Meet New and Stricter Enforcement in 2009	SCCE
2/25/2009	HEOA Reauthorization (2)	Department of Education
3/12/2009	Visual Compliance Quarterly Training	eCustoms
3/12/2009	Updates - Conflicts of Interest in Research and Health Care	HCCA
3/13/2009	The Government's Three Prong Approach to Quality of Care and Practical Strategies for Operational Improvement and Risk Reduction	HCCA
3/13/2009	COGR Webinar on Stimulus Package	COGR
3/18/2009	ARRA Compliance for Federal Research Funding	llaw.com
3/23/2009	PTC Demonstration	Axentis
3/24/2009	Health Care IT Security: A Corporate Compliance Matter	HCCA
3/30/2009	HIPAA Amendments in Federal Stimulus Bill	HCCA
3/31/2009	The Recovery Act of 2009	Ethics Resource Center
4/8/2009	Overview of New UC System-wide Hotline Software	EthicsPoint
4/8/2009	Overview of RAC Program	CMS
4/9/2009	HIPAA Amendments in Federal Stimulus Bill, Part 2: Immediate Action Items You Need to implement	HCCA
4/15/2009	Overview of New UC System-wide Hotline Software	EthicsPoint
4/27/2009	Sexual Harassment Training	Internal
4/29/2009	Sexual Harassment Training	Internal
5/4/2009	Sexual Harassment Training	Internal
5/5/2009	Overview of NEMEA's Compliance and remediation Software-as-a-Service Tools	NEMEA
5/7/2009	Why Annual HIPAA Training is More Important Than Ever	HCCA
5/11/2009	Don Fischer Export Control Talk @ UCD	Internal
5/12/2009	Gifts & Entertainment: Do Your Policies Measure Up?	SCCE
5/13/2009	Ethics: Lessons Learned from the Trenches	EthicsPoint/ACUA
5/13/2009	Evaluating and Measuring Quality and Safety: A Real Life Case Study	HCCS
5/14/2009	Voluntary Disclosures in 2009: Practical Considerations in Light of Federal and State Regulatory Developments (including OIG's 2009 Open Letter to Providers)	HCCA
5/14/2009	Learn Answers to the Latest Top 10 Most Frequently Asked Questions	EthicsPoint

Date	Title	Organization
5/14/2009	California Health IT and HIE Update	California Health and Human Services Agency
5/14/2009	Confidentiality Statement for Medical Center	Internal
5/14/2009	Identity Theft Red Flag Rules	Jefferson Wells
5/19/2009	FTC/DHHS ePHI Breach Guidance group	Internal
5/19/2009	International Research Presentation	Internal
5/19/2009	Don Fischer Export Control Talks @ UCSD - 2 sessions	Internal
5/19/2009	Tax: Are Non-Profits Under Attack? Strategies for Tax Compliance	HCCA
5/20/2009	The Long Arm of Compliance: Reaching Beyond Your Four Walls	HCCA
5/20/2009	Facebook, Twitter & Blogs: What's Legal in Healthcare, What's Not	Progressive Health Conferences
5/21/2009	Lilly Ledbetter Fair Pay Act	EthicsPoint
5/21/2009	Analyst Café: Physician Profiling Reports	UHC
5/21/2009	State Regulations, HITECH & More	SCCE
5/21/2009	Planning for the New Landscape in Privacy & Security Compliance	HCCA
5/22/2009	Fraud Enforcement and Recovery Act of 2009 (FERA) The Impact for Health Care Providers	HCCA
5/23/2009	Open RAC Forum	HCCA
5/26/2009	Use and Disclosure/Patient Rights Policy Group	Internal
5/26/2009	Don Fischer Export Control Talks @ UCLA - 2 sessions	Internal
5/28/2009	Don Fischer Export Control Talks @ UCR - 2 sessions	Internal
5/28/2009	Breach Response and Enforcement Task Group	Internal
5/29/2009	Don Fischer Export Control Talk @ UCI - 2 sessions (videotaped for web)	Internal
6/?/2009	Visual Compliance Quarterly Training	eCustoms
6/2/2009	Emerging Governance and Enterprise Risk Management Practices	Jefferson Wells
6/2/2009	Developing a Compliance Program in a Complex Environment	SCCE
6/3/2009	System-wide Institutional Animal Care and Use Committee Workgroup	Internal
6/3/2009	Assessing ARRA Compliance: Is Your Institution Ready?	EthicsPoint
6/3/2009	FCA - Widening the Net	Sidley Austin
6/8/2009	Risk Problem Areas and Risk Solutions in Credentialing Practices	Internal
6/10/2009	Ensuring Compliance with Current Stark Laws: An Operational Guide	Compliance 360
6/11/2009	ARRA Workgroup Conference Call	Internal
6/12/2009	Visual Compliance Research Administration Training Workgroup	Internal
6/15/2009	Non-Disclosure Obligations and Receipt of Export Controlled Proprietary Data: Impact and Solutions	Internal
6/16/2009	Navigating the Briar Patch of Federal State & Local Regulations that Govern Corporate Interaction with Government Officials	SCCE
6/17/2009	Don Fischer Export Control Talk @ LBNL	Internal
6/17/2009	Export Control Talk w/Barbara Yoder @ UCSF Town Hall	Internal
6/22/2009	Fraud Enforcement and Recovery Act of 2009 (FERA) The Impact for Health Care Providers	Jones Day
6/23/2009	Effort Reporting Presentation	Internal
6/23/2009	Open RAC Forum	HCCA
6/24/2009	Corporate Responsibility Lecture	HCCA
6/25/2009	Using the Form 990 as a Risk Management Too	HCCS
6/25/2009	Foreign Corrupt Practices Act & Health Care	HCCA

Date	Title	Organization
6/26/2009	American Recovery & Reinvestment Act (ARRA) Recipient Reporting Requirements for Grants & Contracts Webinar	Huron Consulting Group
6/26/2009	Impact of New Fraud Enforcement & Recovery Act of 2009 (FERA)	HCCA
6/30/2009	HITECH Act Webinar	CHA