Office of the President

TO MEMBERS OF THE COMMITTEE ON COMPLIANCE AND AUDIT:

DISCUSSION ITEM

For Meeting of November 18, 2015

ANNUAL REPORT ON ETHICS AND COMPLIANCE ACTIVITIES 2014-15

This annual report highlights the outcomes of the annual Ethics and Compliance Program Plan in fiscal year 2014-15. The Plan, approved by the Regents in July 2014, was an overarching plan that identified and addressed significant risks facing the University. The Plan was a compilation of each UC location’s compliance work plan that was developed in partnership with departments across each campus including internal audit, risk services, and compliance.

During the year, the Office of Ethics, Compliance and Audit Services (ECAS) works with each campus as it develops its list of risk priorities and annual work plan. These plans are forwarded to ECAS and reviewed for common foci, risks, and compliance concerns. The Systemwide Ethics and Compliance Program Plan is then developed and submitted to the Committee on Compliance and Audit for discussion and approval.

During 2014-15, the following issues were identified to be of highest risk facing the University: research compliance, privacy, export control, governmental reporting regulatory activities, international activities, campus safety, sexual violence/sexual assault, and, in the health sciences, clinical research billing and coding.

The attached report outlines in more detail the work of ECAS and the University compliance program during the past fiscal year. The Annual Report summarizies compliance activities to address these highest risks. In addition, the Report provides highlights from each campus’ compliance program and includes the Annual Report from each campus.

(Attachment)
Annual Report on
Ethics and Compliance
FY 2014-15
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EXECUTIVE SUMMARY
The regulatory environment in higher education continues unabated and as a result has increased compliance focus on various areas of operations. The University of California—because of its mission, size, footprint, and innovation—is especially vulnerable with an unprecedented number of compliance risks and obligations from a myriad of state, federal, and international organizations. For instance, the University of California is the largest recipient of funds from the National Institute of Health (NIH) and National Science Foundation for any higher education institution. With this prominence comes increased scrutiny and need to mitigate and anticipate compliance concerns. The Affordable Care Act has resulted in increasing regulatory scrutiny and compliance activities in medical centers, the Foreign Corrupt Practices Act (FCPA) is heightening focus on international research activities, and the continued national spotlight on sexual misconduct on university campuses remains critical. Cyber attacks have increased the push on the University’s core functions of communication, information sharing, privacy, and Academic Freedom. And areas such as social media, online education, conflict of interest and the need to improve governance and accountability, remain a high priority for colleges and universities.

Quality and excellence are the foci of the University of California (UC). The UC ethics and compliance program is an investment supporting those efforts so that the system maximizes its resources, avoids unnecessary penalties, and delays, and sustains its high standards. The ethics and compliance program across the UC system is a vital, robust network staffed by dedicated, trained campus professionals monitoring compliance activities. Our goal is to anticipate and bring to early resolution or detect and mitigate compliance risks and establish protocols to meet and exceed compliance standards. The University of California’s ethics and compliance efforts strive to set the national standard for higher education. Together we work to maintain the highest quality programs and ethical culture of accountability, transparency, and doing the right thing for our students, faculty, staff, and the communities we serve.

Sheryl Vacca
Senior Vice President and Chief Compliance and Audit Officer
University of California
BACKGROUND: PRESSURES ON THE UNIVERSITY OF CALIFORNIA INCREASING

The federal government, when funding programs, often requires that an organization have an “effective compliance program” in place. Through guidance and regulations, national and international organizations are defining the key elements or benchmarks required to demonstrate that a compliance program is effective. Over recent years, the pressure for complying with established and new regulations continues to increase.

A recent national research project* looked at the regulatory climate for higher education. This study found that the number of regulatory/compliance agencies affecting higher education was over 270.

* Compliance at Hartwick College: A Special Report to the President of the College, December 2012 by Kelly Zack-Decker
Further, these regulatory and compliance activities touch virtually every aspect of our campuses:

![Pie chart showing offices responsible for regulations/compliance items]

*Compliance at Hartwick College: A Special Report to the President of the College, December 2012 by Kelly Zack-Decker*
Given its size, breadth of activities and prominence among world-class research institutions, the compliance pressures on the University of California are great.

**Compliance Matters Impacting the University of California (Subset Example) And Relevant Regulatory Bodies**

*Including but not limited to the agencies listed*

**HIGHER EDUCATION COMPLIANCE PROGRAMS**

Compliance programs are not unique or new in many settings such as financial, defense contractors, drug manufacturing, research and development, and even healthcare organizations. In fact, in these industries, compliance offices are standard operational costs.

However, this is not the case in higher education. Broad-reaching, independent compliance programs for institutions of higher education remain a relatively new endeavor. The University of California’s program—from its inception—is often cited as leading the nation in depth and breadth of oversight. Like the University of California, many institutions of the same caliber as UC have compliance offices with oversight responsibilities such as Princeton, Stanford, Johns Hopkins, USC, and Emory). Other institutions—such as Northwestern University—are just establishing their oversight centralized programs. Compliance programs in higher education continue to evolve and the UC program strives to maintain its national prominence through quality initiatives and broad oversight responsibilities.
UC COMPLIANCE PROGRAM

Legal and regulatory requirements affecting the University are constantly changing, and UC must have reliable and consistent processes in place for identifying and complying with applicable laws and regulations. The ongoing response of the University of California to the ever-changing compliance and regulatory climate has been to maintain leading-edge governance structures, policies and procedures, targeted training addressing ‘top risks’, real transparency, and optimal communication practices.

The University of California’s compliance program remains a long-established and oft-cited compliance program model for higher education. The University of California Board of Regents established the UC Ethics and Compliance program in 2008. The Office of Ethics, Compliance and Audit Services (ECAS) is led by Senior Vice President and Chief Compliance & Audit Officer (SVP/CCAO), Sheryl Vacca (the Audit Services Annual Report is reported separately). The program has evolved from an initial directive from the Regents to a systemwide oversight program with presence and collaboration at all UC locations.

Benchmarks for the University of California Compliance Program

As an industry leader for higher education compliance programs, ECAS strives to be the national leader by meeting and exceeding benchmarks and recommended guidance for effective compliance programs established by outside agencies. The University of California’s Ethics and Compliance program is predicated and built on the key elements and benchmarks identified in these sources.

In 2014-2015, ECAS reviewed six major compliance oversight organizations and reports to benchmark UC’s adherence to 17 established, and industry-recognized standards compliance standards. The UC Ethics and Compliance program met or exceeded the following standard:

- Written standards of conduct, policies, and procedures
- Designation of a Chief Compliance Officer
- Provision of education and training for employees
- Establishment of whistleblower hotline and whistleblower protections
- Response and enforcement for compliance issues
- Auditing and monitoring
- Investigation/Remediation of Systemic Problems & Screening of Sanctioned Individuals
- Defining Roles/Responsibilities & Assigning Oversight Responsibility
- Due Diligence to Prevent & Detect 3rd Party Criminal Conduct
- Periodic Evaluation of Compliance Program Effectiveness
- Promote Compliance Program throughout organization through incentives for ethical conduct and penalties for non-compliance
Annual Report on Ethics and Compliance FY2014-15

✓ Periodic Assessment of Risk of Criminal Conduct
✓ Policy Prohibiting Foreign Bribery
✓ Compliance is Duty of Employees at All Levels of Organization
✓ Risk-based Due Diligence in Hiring and Oversight of Business Partners
✓ Measures to Ensure Effective Control Over Areas such as Gifts, Travel, Hospitality, etc.

2015 Benchmark Survey for University of California

This past year, ECAS worked with the Compliance & Ethics Leadership Council of the Corporate Executive Board (CEB) to review the UC Compliance program. The CEB has 10,000 members across a whole range of industries and works to support and evaluate quality initiatives and programs. Its Ethics and Leadership Council includes 450 members. One of the CEB functions is to evaluate and support effective compliance programs.

CEB reviewed the UC Compliance Program across a host of factors within the following categories:

- Program structure and oversight
- Standards and Procedures
- Compliance risk management
- Training
- Communications
- Discipline and Incentives
- Measuring, monitoring, and surveillance
- Allegation reporting and investigations
- Corporate culture

The review looked at how UC’s compliance program ranked compared to the CEB benchmark data for both “importance” of the factor and “maturity” of developing of that factor across the University. Maturity is a critical component because it indicates the depth and breadth of the concept or element within the organization—how infused the particular element is within the culture of the University.

UC Ranks Consistently High: Overall, the UC compliance program was well above the CEB’s average benchmark priority, indicating that for virtually all factors the University’s compliance program ranks significantly above the comparison group in terms of scope, implementation, maturity, and leadership. This is especially significant considering that the benchmark data compared UC to wide variety of industry leaders including some with more structured, mandated compliance requirements. The survey data and report is one indication that the structure and oversight of the UC Compliance program across the system continues to lead the way and is meeting and exceeding industry standards.

UC’s Compliance Program: An Investment in Quality and Excellence

As indicated above, the pressure of regulations and compliance for higher education continues to expand. Because of its size, the prominence of its programs, and its worldwide reach, the University of California’s need to address compliance and regulations is exponentially larger.

Cost of Compliance: Meeting the requirements of regulatory agencies does not come without significant cost. A recent study by the Boston Consulting Group (BCG) looked at 13 schools including UCB, UCSD, Vanderbilt, and UNC-Chapel Hill. The study aggregated the cost each campus spent on meeting compliance and regulatory requirements. It found the cost of compliance for these 13 schools totaled $27 billion with $11.1 billion of that earmarked specifically for higher education- specific compliance (like Title IX, Title IV, NCAA, etc.).
The study found that the cost of compliance per University ranged from two to 12 percent of each campus’s FY2014 operating budget. The average cost was six percent or the operating budget with research compliance driving the bulk of the costs. Not surprisingly, medical school research compliance is slightly more expensive as a percentage of costs than other non-medical school research (20% for medical school; 14% for non-medical school).

**Compliance burden for University of California:** UC-Berkeley and UC-San Diego participated in the BCG survey. It is critical to note that the costs for compliance identified in these surveys are typically required for the grant; if these costs were not incurred, the campus would not have received the funds.

Overall, the compliance burden for Berkeley was less than the national average. The FY14 regulatory cost burden for Berkeley was $116 million—about five percent of its operating expenses. The compliance cost per student was $3200 and the compliance cost was $70,000 per faculty. For San Diego, the overall compliance cost was $167 million—seven percent of the operating budget.

**Compliance budget not meeting benchmarks.** The investment in compliance noted above is significant. However, it is still critical to note that the investment was in line with other major universities in the survey. Moreover, it is important to note that in benchmark surveys noted above on essential elements for an effective the only standard from these benchmark surveys that the University was not meeting was “adequate budget.” One survey recommends $99,763 devoted to compliance for each 1000 employees. While compliance functions are often infused throughout each campus, dedicated compliance budget does not meet this standard at UC.

**Return on Investment (ROI):** The significant cost for compliance begs the question—what is the return on investment (ROI) for UC for these costs of compliance? ROI is often considered by two functions: reduction in losses and increase in the bottom line. While a compliance program for a university can certainly affect losses, measuring increases in the bottom line is problematic because campuses don’t look at the bottom line the
same way traditional businesses do. And even when we invest the costs as noted, there is still the real possibility of added costs if our compliance programs are ineffective.

The main challenge for determining ROI for a compliance program is that it’s difficult to measure “something that doesn’t happen.” Quality compliance programs exert considerable effort putting systems and processes in place to prevent formal complaints that have merit, breaches, fines, safety problems, and poor audit/reviews. The UC’s compliance program is fundamentally a “prevention program” and measuring how “prevention” activities save money for events that don’t happen is challenging—if not impossible. Consequently, the ROI of compliance is based on a counterfactual argument—it is impossible to quantify the value of an event. So measuring ROI in a traditional financial way—through increases in the bottom line—is overly simplistic for a university setting.

**Measuring ROI for UC’s Compliance Program:** This year ECAS queried several main organizations that monitor higher education activities. We reached out to the American Association of University Professors, the Association Public and Land-grant Universities, the Association of American Universities, the Council On Governmental Relations, and the National Association of College and University Business Officers among others for data on ROI for compliance programs. All unilaterally agreed such ROI data would be of immense value; but none had any data for ROI for higher education compliance programs. ECAS subsequently approached ROI by looking at the cost of non-compliance including loss of revenue, fines, and reputational damage. Loss of revenue is a serious potential consequence for non-compliance.

**Return on Investment on UC’s Compliance Programs**

![Diagram of Return on Investment on UC’s Compliance Programs]

**Loss of Revenue:** The University of California has approximately 7,700 grants and awards that bring in $4.7 billion in revenue. An integral part of these grants is required compliance with regulations specific to that grant. Often grants are not awarded until a program can guarantee or certify compliance. And as stated above, the breadth and reach of the regulations is immense. Non-compliance with these grant requirements and their underlying rules and regulations could lead to non-awards or awards being rescinded. Even a small loss of grant revenue through grant funding through non-compliance would obviously have disastrous impact on UC. Consequently, one measure of ROI is the prevention of loss of any grant awards or opportunities due to non-compliance or lack of a robust compliance program.
**Fines and Sanctions:** Issuing of fines or sanctions is another way that compliance is enforced. Most Federal agencies have the ability to levy fines on institutions for non-compliance. Moreover, several overarching Federal laws such as the Clery Act, Title IX, Title IV, and Title VI indicate that the Federal government can withhold “all Federal funds” including student scholarships, financial aid, and grants for non-compliance. More and more, Federal agencies are actually utilizing the ability to leverage fines. In areas like healthcare and Title IX, Congressional pressure is increasing on regulatory agencies to use this ability to levy fines.

A clear measure of ROI for compliance can be defined as avoidance of the fines. However, a challenge when looking at fines—at “how much are the fines that have been levied?” is that data for fines is not easily attainable. Many agencies keep the data confidential. However, one survey with published data on fines levied between 2012 and 2014 against institutions of higher education showed 181 fines total $21.5 million. While many of these fines ranged from a few thousand to tens of thousands of dollars, the overall average fine was around $1,000,000 and the median fine was around $335,000. Specifically, for the Department of Education during this period, the largest fine was almost $8.7 million and an additional four fines ranged from $1.7 million to $2.6 million.

Consequently, the University’s compliance program is oriented towards establishing and monitoring processes to avoid fines that would cost UC unbudgeted funds. To date, while the University of California has not been immune to fines, none have risen to the scope of these large published ones. The University has a strong record for positive reviews and responses from regulatory agencies. We obviously want to maintain that positive record. There are many factors and departments contributing to the University’s high rate of compliance with regulatory agencies’ rules and requirements. ECAS strives to put systems in place for a robust compliance program that contributes and continues this record.

**Reputational Damage:** Prevention of reputational damage is a final area to measure ROI for a robust compliance program. Every top-tier organization strives to ensure a stellar reputation. The current Volkswagen scandal around the misrepresentation of diesel-emissions in the news highlights how one major event has repercussions and reputational damage for a brand, a company, and even the German economy overall. The University of California is no exception and certainly prides itself on—and works toward maximizing—its reputation. Not a week goes by where UC is not featured in some top tier list and our reputation is what fuels our continued excellence, attraction of quality faculty and staff, and competitive students. Reputational loss also risks standing with Federal agencies (NIH, NSF, OCR), increases prospect of external audits, and is associated with individuals in leadership.

Every loss of grant, federal or state review, response to a complaint, or safety incident can affect reputation because it focuses negative or unwarranted attention on the University. Our compliance programs are established in large part to support, maintain, and protect UC’s reputation. Our compliance staff and programs across the system strive daily to meet and exceed regulations and requirements to support that effort. Having a robust compliance program helps UC respond to any incidents to support our reputation as a University of excellence.

**Compliance ROI—Staying Ahead of the Curve:** A key factor for UC’s investment in quality for our compliance program is “staying ahead of the curve.” The UC Compliance program is designed to support and lead the University to maintain the highest standards of ethics, regulatory guidance, and risk mitigation strategies. As is indicated in the highlights section below, this year saw ECAS having to shift programs, trainings, and efforts to respond to emerging compliance risks and areas of concern such as biosafety, sexual violence on campus, and, most recently, cybersecurity.
Unfortunately, even with the most robust compliance oversight and program, accidents and incidents will happen. But by investing in a rigorous compliance program, the University is better suited to respond quickly to these incidents to minimize future losses, complaints, and reputational damage. Without a strong compliance network, the loss could have been greater. UC must continue to remain vigilant and continually review protocols, regulations, and new governmental requirements to stay at the forefront of higher education compliance. The ROI for UC’s investment in its compliance program is to minimize loss of revenue, avoid unnecessary fines, and maintain our reputation. UC’s Compliance program puts in place programs and processes to meet all three and enhance the overall quality of UC’s mission.

ECAS: UNIVERSITY OF CALIFORNIA ETHICS AND COMPLIANCE DEPARTMENT

The mission of ECAS is to reinforce the University’s duty to perform its public responsibilities in an ethical and compliance-based environment where applicable legal, regulatory, Regental, and Presidential policies are followed and in which the public trust is maintained. Supporting and implementing an effective ethics and compliance program that aligns with industry benchmarks is of the utmost importance to the University of California. Goals for ECAS have been developed under leadership from the SVP/CCAO. ECAS staff works with campus partners to meet the following goals:

ECAS Goals

1) Enhance a culture within the University that promotes prevention, detection and resolution of instances of non-compliance with federal and state laws, public and private requirements, and the University’s legal and administrative policies.

2) Provide identification, assessment and evaluation of University internal controls and mechanisms to mitigate risk to the University, the President and the Regents.

3) Provide preventative, detective and deterrent resources to UC locations to help mitigate risk. Reduce damage to the reputation and goodwill of the University resulting from misconduct, lack of management controls or effective management systems. These resources help to reduce damage and assist management to mitigate financial, compliance, operational and reputational risk.

4) Provide an effective reporting system for allegations of non-compliance or improper governmental activities that is free of retribution and allows for anonymity.

5) Provide oversight and facilitation in development of best practices supported through research and evidenced based information for education, policies, processes and investigation related to sexual assault and sexual violence.

6) Promote awareness of management of compliance and audit risks with the Regents (Compliance and Audit Committee), the President, Chancellors, and senior campus leadership.

ECAS Program: Alignment of Programs With Goals

ECAS is organized across eight key functional areas that support and align with departmental goals, i.e. general compliance education and training, privacy program, research compliance, health science compliance program, whistleblower hotline and investigations, support of campus compliance, policy management and delegations of authority. ECAS continually works to assess and realign these functional areas as new initiatives, risks, external reviews, and regulations affect the University. Currently, each of these eight ECAS functional areas has specific initiatives, programs, and efforts that align within one or more of the six ECAS department goals. Specifically, each of these programs coordinates administrative and operational compliance by actively assessing and responding to compliance needs.
ECAS Program: Highlights and Accomplishments
During FY15, ECAS worked with a variety of constituencies across the system to support the University’s compliance and ethics efforts. The following information describes some of the highlights and accomplishments during the past year.

General Compliance Education & Training
In FY15, ECAS continued to offer a robust compliance education and training program, which includes in person training, webinars, and eCourses distributed through the UC Learning Center. In total, 18,666 staff hours were spent in ECAS in-person or webinar trainings. Content was focused on seven target compliance risk areas identified in the FY15 Ethics and Compliance Program Plan:

1. Safety (Clery, VAWA, SVSA)
2. Research Compliance
3. Government Reporting
4. Culture of Ethics and Compliance
5. Data Privacy and Information Security
6. Health Sciences
7. General Compliance

Over the course of the year, ECAS offered 145 in person and webinar-based trainings. A key highlight this year was the 2015 UC Compliance Symposium. Held every other year, this year’s Symposium was held on February 4-6 in Irvine. Nearly 300 total UC staff attended, including Regent Zettel, Chancellor Gilman, campus leaders, and approximately 58 speakers, taking advantage of low cost continuing education credit opportunities, and learning more about UC and regulatory compliance areas. In all, the Symposium offered 27 different sessions in tracks that included Campus Culture, General Compliance, Research, Privacy and Information Security and International Activities.

Other highlights of in-person training include a three-day workplace investigations training in Irvine, multiple Title IX Investigations trainings, several Clery Act trainings, and privacy training events for pertinent staff. Webinar trainings and educational sessions included the launching of a series focusing on international compliance and activities for faculty researchers.

In FY15, ECAS updated the mandatory supervisor training for sexual harassment (required by AB 1825) to comply with new state legislation. A new eCourse was rolled out on the Foreign Corrupt Practices Act (FCPA), and offered to all campus locations through the UC Learning Center. As the FCPA is a new risk and compliance concern for higher education, this eCourse is timely and necessary. ECAS is currently developing several new courses for rollout in FY16, including new versions of General Ethics & Compliance, Conflict of Interest for Researchers (COIR) and Sexual Harassment Prevention Training (SHPT), for both supervisors and non-supervisors.
Privacy
In FY 2013-14, the campuses began implementing the recommendations from the President’s Steering Committee on Privacy and Information Security. They named Campus Privacy Officials and began building Privacy and Information Security Boards. In FY 2015, the privacy program realized that despite a governance structure for privacy, there was still confusion about how best to define privacy in a way to drive practical outcomes. For this reason, in FY 2014-15, we focused on awareness, education, and partnership to strengthen the underpinnings of privacy governance throughout UC.

Awareness: Privacy as a practical aspect of UC management can sometimes be difficult to define. For this reason, the UC privacy staff delivered guidance and awareness about how to integrate privacy into every day
University management. Throughout FY 2014-15, several UC conferences featured tracks to raise awareness of both privacy and information security practices at UC, as well as how to spot these issues in everyday work. The Compliance Symposium (February 2015), Risk Summit (June 2015), and Information Security Symposium (June 2015) featured information about UC efforts to:

- Govern and manage privacy and information security
- Use contract solutions to protect valuable UC data assets,
- Protect privacy in the age of data monetization,
- Protect privacy, while assisting students in distress, and
- Ensure autonomy privacy and academic freedom in UC electronic communications.

In FY 2014-15, campus privacy officials also hosted the first UC Data Privacy Month (February 2015) using consistent awareness messaging across every campus. These messages could be found on campus shuttles, digital posters, and as handouts at various campus events. During this month, individual campuses hosted awareness events, including documentary screenings, brown bag lunch events, and mini-presentations at existing campus meetings to bring awareness to the impact of privacy on UC. Our systemwide privacy manager developed awareness postcards (two shown below) that were effective, low cost, and utilized by campuses.

### Education

Throughout the year, the ECAS privacy program also provided in-person and web training on various privacy topics. For privacy subject-matter experts, ECAS hosted in-person training about privacy at UC. They also provided in-person training on the distinctions between HIPAA and FERPA, as well as how privacy applies to CARE Advocates (sexual assault survivor advocates). There were also web trainings provided on topics from vendor privacy and security concerns to privacy program management to cloud computing concerns.
**Strategic Partnership:** Privacy is a discipline that layers over many functions of the university, meaning the many university functions must address privacy to meet their management obligations. In FY 2014-15, the privacy officials focused on building strategic partnerships with several functions, including information security, procurement, and student health and counseling. Through this work, the privacy program built a stronger foundation for data privacy and security in UC contracts, with special attention paid to the Appendix for Data Security and Privacy. Privacy management also integrated with the UC Cloud Services Work Group, which is focused on negotiating effective cloud services’ contracts and offering useful guidance on how best to deploy these services throughout UC.

**Government Reporting Regulatory Activities**
Monitoring external agency audit activities and facilitating systemwide responses to external agency audit activities and responses was of continued importance. The onsite review focus of government agencies, such as the National Sciences Foundation (NSF), the Center for Medicare/Medicaid Services (CMS) Office of Inspector General (OIG), and the Office of Federal Contract Compliance Programs (OFCCP), across a number of campuses and medical centers increased the resource burden on UC locations. In addition, FY15 saw an increase in scrutiny and review in National Science Foundation Inspector General audits, Clery Act reporting, by Office of Civil Rights (OCR) regarding Title IX complaints, and a focused review by the California State Audit (CSA) around Title IX compliance.

**Research Compliance**
Research excellence remains one of the cornerstones of the University, enabling the fulfillment of its mission and generating over $4.5 billion in expenditures in 2013-14. The University is committed to conducting its extramurally-funded research in accordance with all federal, state, and local laws, regulations, and policies. To that end, ECAS leads and supports campus efforts to build and sustain effective oversight of the research enterprise. ECAS convenes monthly calls of the Research Compliance Advisory Committee and the Health Science Compliance Officers to discuss emerging regulatory changes, compliance concerns, and campus needs. The Research Compliance Advisory Committee, made up of senior administrators from each campus and UCOP, also meets in-person on an annual basis for in-depth discussion and treatment of emerging issues. ECAS also convenes monthly calls and an in-person annual meeting of the Export Control Working Group, composed of campus export control liaisons, to address the challenges in this growing area. At UCOP, ECAS collaborates with the Office of Research and Graduate Studies’ Research Policy Analysis and Coordination office, as well as the Office of General Counsel, to draft new or revised research policy, respond to proposed regulatory changes, and offer individual and systemwide guidance on a full range of research compliance matters. Finally, ECAS is a core member of the High Containment Laboratory Committee, to oversee research activities involving Select Agents and Dual Use of Concern agents.

**Conflict of Interest in Research**
With the implementation of the new Public Health Service (PHS) Integrity in Research regulations in late 2012, the regulatory environment around financial conflicts of interest in research grew in scope and complexity. ECAS has worked to provide expert-level regulatory guidance and training resources to the campuses. The recently revised mandatory online training course, “Conflict of Interest for Researchers,” is now designed to allow faculty and research personnel fulfill their ethics training while at the same time fulfilling their PHS and National Science Foundation educational requirements. The course also covers California requirements for financial disclosure under the Fair Political Practices Commission (FPPC). In 2015-2016, changes to the decades-old FPPC law will require a plan and implementation strategy for campuses for privately sponsored research. UC’s systemwide efforts in reviewing and managing conflicts of interest in research continue to be a national model for universities around the country. The UC system is represented on the prestigious Association of American Medical Colleges (AAMC) Steering Committee for Financial Conflicts of Interest in Academe through ECAS.
ECAS continues to monitor and update, as appropriate, University policies and procedures regarding conflict of interest and continually strives to be more responsive to concerns about conflict of interest issues.

**Biosafety**
This year, national attention focused on biohazardous materials and biosecurity/biosafety. The use of these materials is an indispensable part of the University’s mission and UC has more biosafety level 3 laboratories than the Centers for Disease Control and Prevention (CDC).
In response to this national focus and to ensure compliance with all safety regulations, ECAS partnered with Risk Services and OGC to staff a President’s Task Force on Biosafety and Biosecurity. This Task Force included esteemed experts across the system that work directly in our biosafety laboratories and are national leaders in the field. Supporting and leading the Task Force efforts, eight key recommendations were directed by President Napolitano to the campuses including naming of a High-Containment Laboratory Director, increased training, lab reviews and assessments of our facilities, and formation of both campus and systemwide “High-Containment Laboratory Oversight Group.”

ECAS will continue working with the Task Force to ensure the President’s directives are implemented and that compliance concerns are mitigated. Education and training in this area are paramount as is monitoring of the various safety protocols; consequently, this area will remain a high priority in FY16.

**Intellectual Property: Royalty Audit Program**
To address the concern that earned royalties from the licensing of university intellectual property are underreported by licensees and to recover potentially underpaid royalty income due The Regents, ECAS has been conducting and funding systemwide royalty audits using an outside consultant since July 2009. In FY 2013-15, royalty audits were conducted at UCSF, UCI, UCSB, UCLA, and UCSD; four new audits are currently in progress.

Since its inception, the Royalty Audit Program has identified more than $3 million in underreported royalties. Out of the five completed audits in FY13 and FY15, underreported royalties were identified in three (60%) of the audits. UC has recovered a total of $1,310,849 in underreported royalties identified since its inception. Additionally, two campuses received settlements from two licensees for a total of $16,101,508. The total professional fees incurred for the FY10-FY14 royalty audit program were $547,325, of which $202,406 was recovered from the licensees. These recovered fees reduced the total audit costs for the program to $344,919, for a return on investment (ROI) of 303% to date (actual recoveries/total audit fees).

**Conflict of Interest**
Conflict of Interest continues to be a high priority risk for UC due to our large health science and research enterprise, and continued public and regulatory focus in this area. In the health science arena, new provisions established by the Affordable Care Act (ACA) have provided increased focus on health care providers and disclosure of their relationships with drug manufacturers and medical device companies. The Open Payments provision of the ACA requires the Centers for Medicare and Medicaid (CMS) to collect and display information reported by drug manufacturers and medical device companies about the payments and other transfers of value these organizations have made to physicians and teaching hospitals. “Open Payments” is a federal program intended to promote transparency into financial relationships between the medical industry and healthcare providers by publishing all payments made to physicians and teaching hospitals by manufacturers of drugs, devices, biologicals and medical supplies on a publicly accessible website. Transparency about relationships between healthcare providers and industry is an essential component in maintaining public trust in our healthcare delivery and biomedical research. Relationships with industry are not inherently problematic, and can serve to improve health by facilitating biomedical research and advancing discovery.
ECAS assists campuses when specific relationships with industry pose potential conflicts of interest for physicians or researchers to ensure that we are appropriately engaged in the review, management, and oversight of those interactions. ECAS continues to monitor and update, as appropriate, University policies and procedures regarding conflict of interest and continually strives to be more responsive to concerns about conflict of interest issues.

**Health Sciences: Clinical Research Billing and Changes in Coding and Billing**

**Clinical Research Billing Compliance**

The clinical trials research billing process is one of the most complex in health care. The University conducts approximately $2 billion annually in clinical research activities between the five health science (HS) campuses. The Office of the Inspector General (OIG) Workplans regularly include clinical research billing in its top compliance initiatives. Non-compliance with clinical research billing rules undermines public trust in research and results in decreased industry support of collaborative research, increased paybacks of inaccurately billed services to insurers, potential monetary (civil) fines for billing errors, undercharging or overcharging study accounts. ECAS continues its systemwide focus on clinical research billing (CRB) activities to help the campuses simplify and clarify the CRB processes, ensure full cost recovery of clinical research studies, reduce the risks of inappropriately billing patients and/or third parties, enhance current CRB practices, and assure optimal compliance. ECAS is conducting site visits at all HS campuses including UCSF Benioff Children’s Hospital and UC Riverside School of Medicine to evaluate current clinical research billing practices and to catalog good practices and best practices that can be shared among the campuses.

**Professional Fees Billing and Coding Compliance**

ECAS continues to address compliance risks due to the overall lack of qualified coding resources and major changes in information technology systems (such as electronic health/medical records (EMR)), which have added to the complexity of completing daily transactions.

**ICD-10 Implementation:** After many years of delay, the ICD-10 system to code diagnoses for all healthcare encounters finally goes into effect on October 1, 2015. The transition from approximately 13,000 ICD-9 codes to approximately 68,000 ICD-10 codes is predicted to have a significant impact on UC healthcare operations. By contrast, the expanded ICD-10 code set provides more specific data than ICD-9 and better reflects current medical practice. The added detail embedded within ICD-10 codes informs health care providers and health plans of patient incidence and history, which improves the effectiveness of case-management and care-coordination functions. The new ICD-10 codes provide detailed information on patient condition, severity, comorbidities, and complications; in addition to streamlining payment operations by classifying detail within codes to accurately process payments and reimbursements.

ECAS support of UC Medical and Student Health/Counseling Centers ICD-10-CM training, including education, tools and documentation requirements provided is aimed at providing a smooth ICD-10 transition. ECAS works closely with our medical centers to ensure that recent CMS changes to ICD-10 implementation are communicated and will serve as a liaison to the CMS ICD-10 Ombudsman to triage physician and provider issues and identify and resolve issues caused by the new code sets.

ECAS continues to monitor the progress of the compliance audit system for professional fees services billing implemented in collaboration with the five HS compliance offices. Ongoing audit capability for monitoring assured accurate coding of professional fee claims in compliance with numerous audits that threaten revenue each with its own set of requirements. Establishing the professional fees compliance and auditing program has been crucial to managing organizational risk and examining provider billing patterns that are above the CMS national norm. As of July 1, 2015, all HS campuses are operational using MDaudit Hospital for hospital-based claims. This software has allowed HS compliance more flexibility to access billing and coding records to
improve responsiveness to the OIG Workplan, federal guidance, and Recovery Audit Contractors and to quickly gauge risk exposure. Where implemented, this tool has helped compliance and revenue management offices identify anomalies in key coding areas. ECAS will use benchmarking data for CMS provider utilization data to compare providers, usage of codes, etc. within UC, within California, and in evaluating compliance with federal and state billing regulations related to the provision of services.

**Whistleblower Hotline & Investigations**

Since 2003, the University has operated a systemwide whistleblower hotline to provide a 24-hour reporting system with a provision for anonymous reporting. In 2008, ECAS expanded the toll free telephone hotline system with the addition of web-based reporting.

Complaints reported through the hotline system are automatically entered into a case management database for managing, investigating and tracking by campus and UCOP personnel. The hotline system provides investigators with the capability of engaging the anonymous reporter in a question and answer dialog by providing them with a secure log-on identifier that allows the reporter to come back and review their report. The hotline system did not replace other avenues for reporting complaints or concerns, as employees can also report in their supervisory chain or to appropriate University offices or officials. Complaints received through a variety of other intake points at the campuses and UCOP are managed through the same hotline case management database.

The ECAS Investigations Unit is responsible for coordinating, managing and investigating complaints of suspected improper governmental activity, workplace misconduct, and breaches of ethical conduct at the Office of the President and across the UC System. While many complaints are handled at the various locations, the University’s Whistleblower Policies require that complaints involving senior administrators be handled by the Office of the President. ECAS Investigators also conduct investigations systemwide to augment local resources and to enhance the independence of the investigation process. Conducting prompt, thorough and independent investigations is a serious and extremely important responsibility of the University of California.

The University Whistleblower Policy (WP) and Whistleblower Protection Policy (WPP) provide the framework for the University’s comprehensive program at all University locations and ensure compliance with federal and state whistleblower laws. During the past fiscal year, ECAS worked with the Office of the General Counsel to revise the Whistleblower Protection Policy. This was the first revision of this Policy since its implementation in 2002. The revision process had two primary objectives:

- Ensure that complaints filed under the WPP will be processed within 18 months in light of an amendment to the California Whistleblower Protection Act that allows a complainant to proceed to a lawsuit if the University has not “satisfactorily addressed” the administrative complaint within 18 months.
- Address difficulties in the administration of the WPP and better explain how the process operates, thereby making it easier to administer and improving the experience for complainants.

The new WPP became effective on May 1, 2015 and applies to all University employees and applicants for University employment. The new policy clearly articulates a grievance process for all employees.

The University recognizes that its employees are more likely to report suspected improper governmental activity and other workplace misconduct when they have confidence that their employer has a strong commitment to ethical conduct and will vigorously investigates allegations of retaliation. ECAS promotes confidence in the investigation process through annual messages to all employees, by identifying reporting channels on the Office of the President and campus web home pages, and by distributing an informational
poster systemwide that highlights how to use the telephone and internet-based Whistleblower Hotline. This independently operated hotline system not only allows for anonymous reporting but also the possibility of engaging in follow-up dialog with anonymous reporters. The hotline system operates 24 hours per day, 7 days per week with a capability of receiving complaints in many different languages.
Complaint/Concern Review Process
The University’s Whistleblower Program receives hundreds of complaints each year from staff, faculty and the public that require a review to conclude whether an investigation is warranted or the matter should be handled by another University process. The type and quantity of complaints cannot be predicted in advance, however, the University’s Whistleblower Policy investigation protocol has established an efficient and fair method for determining the appropriate handling of every reported matter. Complaints received through the hotline are automatically transmitted to the LDO at the location identified by the complainant for a review and determination of the proper disposition. The LDO is appointed by the Chancellor or the President with the primary responsibility to receive reports of improper governmental activity. Those complaints that identify conduct that, if verified, would not rise to the level of improper governmental activity by the University employee, may be referred to University management for review and consideration.

In accordance with the University’s Whistleblower Policies, reports of improper governmental activity involving senior leaders systemwide are managed by UCOP. The Systemwide LDO and the Systemwide Investigations Workgroup carefully review each complaint and make a determination as to next steps. If an investigation is required, the ECAS Investigations Unit conducts or manages that investigation under the direction of the Systemwide LDO. ECAS Investigators are also available upon request to assist campuses with their local investigations.

Export Controls
The Export Control Compliance Program focuses on maintaining compliance with federal export control regulations and protecting the University and individual researchers from civil and criminal penalties. The goal is to prevent non-compliance through visible management of areas including oversight, policies and procedures, training and education, auditing and monitoring, and response and prevention. Working closely with campus partners and across reporting structures, this program supports initiatives in training, restricted party screening, export licensing, policy support, and, more recently, international activities that are broader than just export controls such as the emerging concerns around anti-corruption and the Foreign Corrupt Practices Act (FCPA). Compliance is critical, as enforcement can include criminal as well as civil penalties.
As shown in the above chart, the Export Control Office (ECO) provided significant support to UC locations in FY15 and responded to 108 diverse export control related inquiries with the goal of preventing non-compliance. For example, classification and licensing support to obtain the appropriate approvals from the federal government to export controlled research-related items was provided. The ECO continued to serve as the systemwide empowered official and administered 13 International Traffic in Arms Regulations DDTC matters including licenses for the export of Defense Articles, Technical Assistance Agreements as well as related Technology Control Plans to facilitate fundamental research projects, enabling critical research programs at UC locations, and regulatory notifications to the Directorate of Defense Trade Controls. Handling of these matters by ECAS provided cost savings by managing internally as compared with the cost of retaining outside support and continued the year-over previous increase from FY14, which itself saw an increase.

ECAS participated in and supported local efforts to establish or expand campus-wide export control initiatives. Four locations added dedicated local export control support and one location formed a campus-wide provost-initiated export control task force.

As promised during FY14, In FY15, ECAS launched an online, interactive course entitled, Introduction to FCPA and Anti-Corruption, which educates UC personnel including faculty on the compliance risks and red flags associated with international collaborations with instrumentalities of foreign governments. The UC’s focus on FCPA compliance and anti-corruption resulted in ECAS working closely with an outside vendor to develop the FCPA online course for use on UC’s Learning Management System. Additional FCPA steps include:
a. Implementing World-Check Screening Online: ECAS administers this powerful online screening tool on behalf of locations and with it can identify Politically Exposed Persons and instrumentalities of foreign governments.

b. Awareness Campaign: ECAS launched a series of “Compliance Alerts” on international compliance, delivered by email to stakeholders across the system focused on export controls and international activities with an emphasis on FCPA and anti-corruption awareness. “International Travel Tips” from a compliance perspective are also being developed for use as a tool for faculty and staff.

c. Ongoing Education and Training: Webinars, tools, lectures and workshops will continue to emphasize these areas of importance and assist our stakeholders in making the right choices around these risk areas by increasing awareness, understanding and knowledge.

Other Regulatory Areas
As the regulatory context for research grows more complex, campus needs increase. ECAS has provided training in such areas as Biological and Chemical Exports, Clinical and Human Subjects Research, and Commodity Jurisdiction Determinations. Additionally, ECAS offers systemwide access to third-party training and webinars on a comprehensive range of research-related topics, including international human subjects research, the fundamental research exemption in the export control laws, and clinical trial management and billing, and privacy in research.

Policy Management
During FY15, the University Policy Office (UPO) continued working with systemwide policy owners to conduct a comprehensive review of policies to ensure their currency with regulations and to transfer them into the new approved policy template. To date, 131 active policies have been updated within the established process and 125 policies are under revision. An additional 42 policies were identified for review in the next six months. Additionally, the Policy Office worked with policy owners to identify 105 redundant or outdated policies that were officially rescinded.
The Policy Office continues to support an accessible website to make the policies transparent and easy to locate from the UC main webpage. This website received 82,893 “hits” in FY15. The updated website includes tools for users such as review schedules, FAQs, information on updated policies and contact information for the UPO. The chart below indicates the most active days for use of the policy website.

Delegations of Authority
ECAS continued its role in the review and streamlining of the Presidential Delegations of Authority (DA) process. This involved updating and identifying clearly defined roles and management titles for accountability. Below is the update for the Delegations of Authority chart for FY14-15. The chart below represents the activity that has occurred in FY15.
International Activities
ECAS continues to actively engage its partners (OGC, Risk Services, and Research Policy Analysis and Coordination (RPAC)) to ensure the UC compliance program is consistently applied and integrated into new and existing international efforts. The University of California continues its leadership as a global organization. One of President Napolitano’s major efforts is a “Global Impact” initiative that called for UC to enhance all stages of technology commercialization and a sustained, strategic, and equal partnership between UC and other nations. These continued initiatives and UC’s sustained and growing presence in the international arena require vigilance with international compliance efforts. An individual location’s laws, regulations and customs may conflict with those of the United States and University of California.

This year, ECAS formed an International Compliance Work Group, that includes representation from the Research Policy Analysis and Coordination (RPAC), the Provost’ Office, and Office of the General Counsel (OGC), Risk Services, Financial Management, and Innovation Technology Transfer. This work group is focusing on education and tools to support campus researchers engaged in international work. This year saw the presentation of a series of webinars on international compliance efforts. In addition, ECAS is partnering with RPAC to develop a web portal that will provide a “one stop” site for information, tools, links, and resources for campus faculty to learn about compliance issues and to get answers to questions about international activities and research.

ECAS continues to participate in the Provost’s work group developing the International Activities Policy that will include the Administrative Guidelines for the Establishment and Operation of Foreign Affiliates and Foreign Operations. UC campuses have many of their own policies governing international activities and one of the goals of the Working Group is to develop a uniform policy with the campuses. This effort dovetails with ECAS’s partnership with Research Policy Analysis and Coordination (RPAC), the Provost, and Office of the General Counsel (OGC) as we continue to assess the impact of global regulatory practices and risks on UC including international research collaborations, global health, and international travel. This initiative will identify underutilized resources, lessons learned, hidden risks for international travelers, needs for training, and opportunities to benefit from cost savings and synergies on international compliance risks.

Campus Safety: Clery Act
The University of California is committed to providing a safe and secure environment for UC students, faculty, employees and the community by creating a culture of safety through crime reporting, compliance, awareness and prevention. The federal Clery Act law requires the University to collect and disclose information about crime on or near campus. Not only do we want to ensure compliance with legal and policy requirements, but we also want to ensure that the entire UC community has access to accurate and timely information about campus crimes and emergency situations, and awareness of campus security policies.

Background
The Jeanne Clery Disclosure of Campus Security Policy and Campus Crime Statistics Act (Clery Act) requires institutions of higher education to report crime statistics and provide statements of security policies to current and prospective students and employees. This Act was enacted in memory of Jeanne Clery who was murdered in her University dorm room in Pennsylvania. Information disclosed under the Clery Act can assist students, parents and employees in making decisions which affect their personal safety. It also provides prospective and current students and employees valuable information about our campus and our surrounding communities.

Each UC campus has appointed a Clery Act coordinator who is responsible for compliance with the Act requirements, and has identified Campus Security Authorities (CSAs) that are responsible for collecting and reporting the crimes to the campus Clery Act coordinator. It is critical that the University be consistent, not only in the reporting of campus crime statistics, but in the identification and training of CSAs. With this in
mind, it is incumbent that the University provides the necessary guidance and resources to the campuses to aid in their compliance efforts with the Clery Act. ECAS has expended significant effort assisting the campuses in the development and implementation of Clery Act resources, tools and training.

Accomplishments

- ECAS has sponsored a number of in-person training sessions for campus Clery Act coordinators and CSAs during the past year. The objectives of these training sessions were to help build a compliant Clery Act program that included compliance with Clery Act policies, procedures and requirements, including identifying and clarifying consistent reporting issues. These facilitated sessions were offered at Northern and Southern locations by a national Clery Act authority.

- A major emphasis has been to ensure that there is sufficient coordination with other key campus areas, such as Title IX, police, and general counsel. Communication of the intersection of these areas has been a significant objective and awareness training has been provided both through webinars and in person sessions.

- ECAS, at the request of the campuses, is coordinating the development of a UC system-wide policy that addresses the Clery Act. The policy, entitled “Crime Awareness and Campus Safety”, is currently in draft form and is undergoing the established procedures for policy development and review. The draft policy outlines the campus responsibilities to comply with the Clery Act, including reporting responsibilities, annual report requirements and the identification and training of CSAs. The target date for the issuance of the Clery Act policy is January 2016.

- As previously noted, CSA training is a vital component of Clery Act compliance. A sub-group of Clery Act coordinators has revised the current introductory training session for CSAs. As part of this revision, the training content was expanded to be more extensive and robust in order to provide CSAs with detailed and sufficient information on their reporting responsibilities. The revised content is currently being evaluated internally by the sub group before being converted to training module for use within the campus Learning Management Systems. ECAS has contracted with a vendor to assist with the final training module that will include voice over and audio clips.

- A campus Clery Act coordinator group developed a comprehensive reference document. This reference tool includes requirements of not only the Clery Act, but requirements under other significant policies and laws, such as the Gatto Bill, DeLeon Bill, VAWA amendments and Title IX. Included in this tool are detailed worksheets that provide clarifications and best practices related to the many requirements. This tool resides on the ECAS Clery Act compliance SharePoint site which is accessible by all UC Clery Act coordinators.
• ECAS has established a role for a Systemwide Director of VAWA, Clery, Title IX and Sexual Violence and Sexual Assault (SVSA). The Director will work with campus Clery Act staff to help ensure compliance with the requirements, including aiding with systemwide and campus consistency issues.

• As part of our in-going communication of compliance requirements information to Clery Act coordinators, ECAS, in consultation with the Office of General Counsel, has created a ‘frequently asked questions’ (FAQ) section on our UC Clery Act Compliance SharePoint site. The FAQ listing contains questions and answers to current issues that require additional information or clarification.

**Sexual Violence/Sexual Assault/Violence Against Women Act**
During FY15, ECAS dedicated staff time and resources to the University’s efforts around preventing and responding to sexual violence and sexual assault on our campuses. The changing national landscape and awareness of this issue placed increased pressure on UC campuses and the system to respond.

**Responding to Federal and State Efforts & Initiatives on Sexual Misconduct**
During FY14, ECAS facilitated response to and implementation of the following Federal and State regulations, reports, and inquiries:

• Updates required under the federal Violence Against Women Reauthorization Act of 2013 (VAWA), which includes provisions to improve and expand how institutions address domestic and sexual violence.

• ECAS played a critical role in the monitoring of state and federal legislation on campus sexual harassment and sexual violence. Legislation included Senator McCaskill’s bipartisan *Campus Accountability and Safety Act* (CASA), Senator Boxer’s *Survivor Outreach and Support Campus Act* (SOS Campus Act), and multiple bills introduced in the California Legislature. ECAS continued to work with UC State and Federal Governmental Relations Offices to respond to drafts of these bills, testify as requested at Legislative hearings, meeting with State and Federal legislators, and addressing specific questions raised by legislative offices.

• More than 100 institutions across the nation are currently under federal investigation by the U.S. Department of Education’s Office for Civil Rights (OCR) for possible violations in the handling of sexual violence and harassment complaints under Title IX. Four UC campuses are among the institutions currently under OCR investigation – UC Berkeley (announced March 25, 2014) and UCLA (announced August 13, 2014). While the initial OCR reviews are requested, requests for subsequent information is ongoing and no final reports have been issued. ECAS worked closely with these two campuses to respond to these federal inquiries and continues to work with all the campuses on OCR requests.
The California State Auditor (CSA) released its report and recommendations on June 24, 2014 on the handling of sexual harassment and sexual violence incidents on California campuses (including UCB and UCLA). Those campuses audited were required to report their progress implementing the audit recommendations at 60 days, six months, and one year. ECAS worked very closely to meet the audit response requirements for the two campuses and the Office of the President. ECAS continues to coordinate the responses from UC on the audit and to meet with CSA staff as needed to meet the goals of the recommendation.

University of California Sexual Harassment Policy Update
In addition to VAWA, guidance from the Office for Civil Rights of the Department of Education ("OCR Guidance Letter") and other regulatory obligations required revision of the University's institutional policy and procedures. ECAS worked with OGC, Title IX, human resources, student affairs, and the Office of Academic Personnel and Programs to update the UC Policy on Sexual Violence and Sexual Harassment. An interim UC Policy on Sexual Harassment and Sexual Violence was signed and issued by President Napolitano in June 2015. ECAS continues to work on the final Policy that will incorporate the newest elements of the President’s Task Force on Preventing and Responding to Sexual Violence and Sexual Assault. A final UC policy is anticipated by January 2016 with ongoing revisions as necessary.

President’s Task Force on Preventing and Responding to Sexual Violence and Sexual Assault
During the past year, ECAS devoted significant time and resources to lead and support the President’s Task Force on Preventing and Responding to Sexual Violence and Sexual Assault. This effort included over 300 hours of workgroup and Task Force meetings, coordinating responses and input for over 200 active participants, gathering input and data from all UC locations, and meeting with key constituents across the system. During FY15, ECAS led the implementation of key recommendations from the President’s Task Force including:

- A 100% full-time, independent, confidential, and privileged advocate on each campus
- Common structures for managing responses to sexual violence including a Case Management Team (CMT) and Community Review Response Team (CCRT) on each campus
- Common elements for campus and system communications through web design, including a common URL address.
- Development of consistent educational content matrix for training of faculty, staff, and students across the system
- Design of common, transparent, and consistent adjudication process, investigation standards, and sanctioning levels on all campuses for student cases.
SUMMARY
This year’s highlights and reviews indicate the breadth and oversight of the University of California’s compliance program and the ECAS’s leadership role. The successes indicated in this report are the result of partnership with dedicated compliance professionals at each location, strong leadership from senior leaders, and key leadership from President Napolitano and the Board of Regents. Compliance is certainly now a cost of “doing business” in higher education; more importantly, however, a strong compliance and ethics program is the right thing to do. The University’s compliance program remains an investment in the overall quality of UC and the return on investment for the compliance program is the continued contribution its oversight and monitoring have on the mission of the University.

APPENDIX
Support of Campus Compliance
ECAS collaborates with campus compliance programs throughout the year to support individual campus compliance and ethics programs. Coordinating with campus compliance officers, ECAS supports UC locations to ensure compliance with laws, regulations, and policies. Moreover, ECAS monitors campus activities to ensure potential systemwide risks are addressed and mitigated. Each campus conducts its own risk assessment and these are utilized in developing the individual campus compliance work plans. These work plans are reviewed and form the basis for the University of California Annual Compliance Plan that is approved by the Regents. The Annual Reports from each campus are attached but below are selected highlights provided by the campuses.

Campus Highlights

ANR


❑ Information Technology Security Risk: Successfully recruited position of Chief Information Officer (CIO), with duties for IT security and privacy. Formed and began implementation of ANR Privacy and IT Security Board, with the CIO as co-Chair. Board is engaged in organization-wide broad-based risk assessment for privacy and security risk, to be followed by the development of best practices, policy, and training for IT security and privacy.

❑ Safety and Environmental Compliance Exposures: ANR Risk & Safety Services conducts onsite reviews of off-campus facilities to identify potential safety hazards and assess compliance with regulations and policies. Conduct onsite reviews at 100% of Research & Extension Center (REC) sites and 20% of UC Cooperative Extension (UCCE) locations each year. Completed full cycle of UCCE site reviews in FY2014/15.

❑ Grant Tracking System (GTS): ANR has developed and implemented an online Grant Tracking System (GTS) to review and monitor external grants. This system collects general information about research proposals as well as specific information related to research compliance. The GTS Compliance Checklist collects information from Principal Investigators (PIs) about potential risk or compliance activities that may be associated with the proposed project. Based on responses to the Compliance Checklist, a
project may be referred to Risk & Safety Specialists for further review and engagement with the PI to assess potential compliance issues and assure that appropriate controls (such as training, facilities, protective equipment, permits, etc.) are in place before the start of the project. During the past year, more than 50 grant applications were proactively reviewed and assessed by Risk & Safety Services based on compliance checklist responses.

BERKELEY

- OPHD responded to 196 reported cases of sexual harassment & sexual violence representing a significant increase from the prior year.
- Disability Compliance oversaw the creation of The Information Technology Accessibility Policy.
- Investigations closed 94 cases of suspected improper governmental activity.
- Enterprise Risk Services oversaw an increased rise in costs in the area of claims and lawsuit payouts.
- Public Records reviewed in excess of 20,000 pages of documents, responding to almost 1,000 public records act requests and inquiries.
- Privacy Office established & convened the Information Risk Governance Committee and launched the privacy.berkeley.edu website.

DAVIS

- The Provost charged a task force to oversee the development of a comprehensive export control compliance program. The task force identified an improved structure for export control compliance oversight, began work on an export control policy, recommended the development of a one-stop website for export control compliance information, identified improvements in resources for international shipping, and developed tools to enhance export control information available to international travelers. This work will continue under a new Export Control Oversight Committee.
- The Electronic Accessibility Committee continued its efforts to build awareness about electronic accessibility and to improve resources to assist faculty, staff and students with accessing the University’s electronic environment. Specifically, the committee hosted a Global Accessibility Awareness Day and Accessibility Technology Fair, overhauled a campus website devoted to the accessibility needs of the campus community, created a guide for creating accessible course content, piloted a campus-wide video captioning tool, created an inventory of accessibility-related training and tools, and developed guidelines for working with vendors on electronic communications projects.
- Enhanced our Title IX compliance program by hiring additional staff to conduct sexual violence investigations and manage sexual violence cases and began meeting weekly to manage cases through our Case Management Team. We also increased support in our CARE program, which now has three full-time victim advocates. UC Davis required mandatory sexual violence prevention education for all incoming undergraduate and transfer students and placed registration holds on the accounts of students who failed to participate. We also offered in-person sexual violence prevention education to all new graduate and professional students.
- Conducted a comprehensive assessment of our PCI-DSS compliance program and implemented significant improvements.
LOS ANGELES

❑ **Main Campus HIPAA Policies**: Developed and promulgated HIPAA administrative, privacy, and security policies applicable to the main campus HIPAA components as distinguished from the Health System components. Work on main campus HIPAA policies has been initiated; implementation expected next Spring.

❑ **Revised Affiliation Agreements Policy**: Major revision of campus affiliation agreement policy that will provide agreement templates to avoid ad hoc forms of agreement that is not reviewed by counsel. The policy has gone through revisions and is expected to be reviewed by a group of internal stakeholders.

❑ **Campus Reporting of Child Abuse and Neglect Policy**: Promulgate campus reporting child abuse and neglect (RCAN) policy that establishes responsibilities for the identification and training of designated mandated reporters. Policy 136 went into effect 8/14/14 and published on the APP website. The taskforce will meet the end of this year to coordinate a communication plan expected to be launched soon.

❑ **Federal Awards Uniform Administrative Requirements**: Office of Research Administration is developing local procedures to implement federal grants management streamlining changes effective December 24, 2014, designed to reduce waste, fraud, and abuse in federal award programs per new Uniform Administrative Requirements, Cost Principles, and Audit Requirements.

❑ **HIPAA Privacy Official Designations**: Designate HIPAA Privacy and Security Rule officials in each main campus HIPAA component organization. Designations will be when policies are promulgated.

❑ **RCAN Oversight**: Establish oversight responsibilities for campus identification and training of RCAN mandated reporters. Oversight responsibilities are outlined in the Policy. IRM oversees the coordination and communication of the on-line training.

❑ **International Visitors Visa Issues**: Audit & Advisory Services to effect clarification of roles and responsibilities and establish appropriate oversight of visa issues relating to international and domestic visitors (scholars and others).

❑ **HIPAA Training**: Establish training requirements and system for documenting HIPAA training for main campus components. Policies to be promulgated will contain training requirements.

❑ **RCAN Training**: Extend RCAN training and implement training tracking process for identified mandated reporters, and yearly additions to list of such reporters. Online Mandated Reporter training has been on-going. The training is online through Praesidium.com. As of 9/1/14, over 2,400 employees & volunteers have completed the Mandated Reporter training and over 7,000 have completed other modules including how to identify child abuse.

❑ **Sponsored Research Auditing**: Audit & Advisory Services monitored and oversaw the National Science Foundation (NSF) Office of the Inspector General audit of all UCLA NSF programs for the period July 1, 2009 thru June 30, 2012, and 19 other external audits. The oversight resulted in a saving of approximately $2,200,000.
Visa Issues related to International Visitors: Audit & Advisory Services assessed the need for implementing procedures to comply with homeland security requirements, confirming oversight and required documentation, and improving instructions and training for administrators concerning visa issues of post-doc scholars and other international visitors.

Laboratory Safety: Environmental Health & Safety completed a centralized chemical inventory system to satisfy the requirements of AB 2286 which mandates the development of the California Environmental Reporting System (Cers) AND REQUIRES ALL regulated businesses to electronically submit chemical inventories. Currently, 37% of UCLA research labs have entered their inventories. To date, between 50%-60% of labs are compliant and have chemical inventories online. Currently, Environmental Health & Safety is working with the 40% to assist them with their inventory and will be using a “softer” approach to compliance issues and may take a little longer to obtain full conformity.

MERCED

CANRA: Published campus CANRA procedure and a comprehensive Working with Minors website. Provided face-to-face training to more than 100 individuals (175 hours) on child abuse and neglect red flags and statistics, CANRA Mandated Reporter requirements, and requirements of our campus procedure. Identified and worked with campus points of contact (POCs) in responsible offices (HR, AP, SA) to ensure formal processes are being put in place to capture and maintain current, accurate and complete lists of Mandated Reporters, comply with the law and UC policy, and perform our campus annual review and certification procedures. First annual certifications are due by September 30, 2015.

Sexual Assault/Sexual Violence Taskforce: Implemented the President’s Taskforce recommendations. UC Merced has a robust action plan that centralizes all administrative investigation handling of sexual violence reports with the Title IX Officer. The Title IX office works very closely with University police, the campus advocate, and the adjudication personnel to affect prompt and effective responses. We have a robust advocacy and prevention education program, overseen by the CARE office (previously known as VPP). This year we trained 97% of incoming/transfer students, more than half of our ongoing students, and we train at all new employee orientations, graduate student orientations, departmental welcomes, etc. The campus has revised its complaint management and community response teams in accordance with system-wide charters, as well as amended the advocacy office to effect requisite charter requirements.

Risk Assessment: Conducted a collaborative risk assessment between Internal Audit, Compliance, and Risk Services to ensure we identified the most critical risks for our Leadership to discuss and include in our audit and compliance plans. We conducted risk workshops to get maximum coverage and diverse points of view; analyzed claims data from risk reports and applications; and discussed findings in audits, investigations and risk and compliance workplans to enable our campus to concentrate on the biggest risk areas. Presented our collaborative risk assessment approach at the Risk Summit in June 2015.

Changed Governance Structure: Changed governance structure to create more synergy in the Office of Campus Culture and Compliance. We moved our victim advocacy group from University Police Department to the Chancellor’s Office, and formally brought policy and campus delegation functions into the Ethics and Compliance area.

SANTA BARBARA

SVSA; Title IX, VAWA, Clery: Among other objectives, our 2014-15 plan included addressing the recommendations of the Report to the President: President’s Task Force on Preventing and Responding
to Sexual Violence and Sexual Assault, when released, including updating processes and reporting. With the Campus Ethics and Compliance Officer acting as the lead on the campus SVSA Task Force, the campus has made substantial progress in timely implementing Task Force recommendations. For example, although efforts are ongoing, the core components have been addressed for Recommendation 1, which outlines the requirements for a consistent “response team” model; and Recommendation 5, which outlines the requirements for an independent, confidential advocacy office for sexual violence and sexual assault on each campus.

- **Privacy**: The 2014-15 plan addressed this area by providing for creation and distribution of certain notices to campus; create a training plan and incorporating it into existing or new programs; and complying with a UCOP Office of Compliance request to designate a privacy “point person” and initiate privacy programs to train and educate the campus. During 2014-15, the campus:
  - Appointed a campus point person for privacy issues and questions.
  - Hosted a campus cleanup day during February for data privacy month. The campus shredded 8.25 tons of paper materials, and securely destroyed 9 boxes of media tape and 12 boxes of CDs.
  - Distributed a reminder notice to campus IT professionals about responding to information requests – including litigation hold requests.
  - Developed guidelines on click-through agreements, with assistance from the campus CISO, Procurement Services, and Audit and advisory Services, and distributed finalized guidelines to the campus.
  - Completed updates to the campus privacy notification statement.
  - Updated campus record keeping practices for the Retention of Employment Related documents to eliminate the collection of social security numbers in personnel files.
  - Performed/hosted 3 live trainings focusing on Information Stewardship, which combined records management and privacy topics.

- **Credit Card Security Risk**: Consistent with our 2014-15 plan, the campus has:
  - Successfully recruited for a newly funded career campus Credit Card Coordinator position.
  - Approved a master strategy for PCI compliance activity that included identification of key senior leadership PCI DSS stakeholders; development of a campus PCI DSS Advisory Committee charged with campus-wide policy and issue remediation, and other measures.
  - Moved forward with implementation of the strategy.

- **Conflict of Interest in Research**: Our plan highlighted campus efforts to better control this area by moving to an electronic disclosure system in 2014 that would enhance existing controls, which include holding extramural funds until potential conflicts are mitigated or minimized. The new e-disclosure system has been in use since September 2014, and has been successfully adopted by the campus.

**SAN DIEGO**

- **The Compliance, Audit, Risk and Ethics (“CARE”) Committee – Developing Risk Intelligence**: The CARE Committee advises the UC San Diego Chancellor and provides oversight on matters pertaining to compliance with laws, regulations, and UC policies and procedures; the external and internal audit
program; the compliance program; and the identification and assessment of institutional enterprise risk. Membership includes the Executive Vice Chancellor and the UC San Diego Chief Ethics & Compliance Officer (co-chairs), all Vice Chancellors and other key leaders. The CARE Committee meets bimonthly, conducts UC San Diego-wide assessments of known and emerging risks, and develops and monitors mitigation plans. The Committee calibrates these risks across the institution and prioritizes the allocation of resources to address identified issues.

Campus Safety – Clery Act Compliance: The UC San Diego Office of Ethics & Compliance has partnered with the UC San Diego Police Department to further enhance and develop the Clery Compliance Program. UC San Diego is on the forefront among institutions in higher education for recognizing the need for increased leadership with respect to Clery Act compliance. The newly hired Clery Compliance Officer provides leadership for all Clery related responsibilities on the campus and will lead collaborative partnerships to ensure effective and efficient compliance with the Clery Act and related laws.

Laboratory Safety: In creating a culture of safety consciousness, accountability and education, the Environment, Health & Safety Department (“EH&S”) has worked effectively with faculty to:
- Create a “Lab Hazard Assessment Safety Tool,” which identifies hazards and the personal protective equipment (“PPE”) to be used for certain activities. Unannounced inspections occurred to prepare labs for state inspections.
- Develop approximately 3,000 individualized chemical hazard control plans, which incorporate risk assessments, planning and step-by-step safety protocols for working with specific types of chemicals.
- Review all labs considered at-risk for personal safety and has ensured the proper training in and distribution of PPE.
- Create a PPE Fitting Room, where lab members are fitted with appropriate PPE and can ask lab safety questions of EH&S employees.

Sexual Violence & Sexual Assault: As of January 1, 2015, UC San Diego expanded its long-standing student sexual and gender-based violence advocacy and education program to provide services to faculty and staff. Additional highlights include:
- UC San Diego completed a comprehensive review of all applicable UC San Diego policies and procedures to comply with VAWA and the UCOP SVSA Task Force recommendations. Newly developed trainings were rolled out to campus.
- CARE organized the first meeting of the San Diego County Campus Victim Advocates Coalition, which included representatives from five local universities. This new partnership provides the opportunity to share resources, discuss current federal and state legislation, and plan for future collaborations.
- CARE continued to manage the Coordinated Community Response Team (“CCRT”) and Sex Offense Case Management Team (“CMT”). The CCRT serves in an advisory capacity to campus leadership and community members about best practices in policies, education, prevention and response.

SANTA CRUZ

UCSC completed its first academic year under a revised organizational structure, wherein the Office of Diversity, Equity and Inclusion was expanded to include: Harassment and Discrimination Investigations, EEO and AA Compliance, Disability, and Diversity and Inclusion. In addition, the responsibility for policy coordination was shifted from the Information Practices unit to the Records, Policy and Delegations unit. The Privacy and Information Practices Unit has moved from the Executive Vice Chancellor/Provost
office to the Office of Campus Counsel. While there were the typical adjustment challenges inherent in such a restructure, the new model has proven to enhance communication and coordination on critical issues.

- UCSC completed the development of a single risk register and revised it compliance plan to become a Risk Intelligence Priority Plan approved by the campus senior leadership team. During the summer of 2015, a revised governance structure will be implemented to support this new model.

- UCSC completed its first academic year with a revised Risk and Safety Services unit. This new operational model moved Fire Services to the City of Santa Cruz and integrated Emergency Management, Fire Marshal and Business Continuity into the Risk and Safety Service Unit where Risk Services, Environmental Health and Safety and University Police are organizationally housed.

SAN FRANCISCO

- New CECO hired March 1, 2015 with agenda to review all research (animal and human) processes and eliminate unnecessary burdens to researchers.

- Campus investigations unit moved to the Office of Ethics and Compliance under CECO direction and will handle whistleblower and retaliation cases along with age and race complaints.

- Human subjects and animal research compliance undergoing streamlining: compliance-researcher committees formed for process improvement and fostering collegial relationships.