

Office of the President

TO MEMBERS OF THE COMPLIANCE AND AUDIT COMMITTEE:

DISCUSSION ITEM

For Meeting of September 14, 2016

ANNUAL REPORT ON ETHICS AND COMPLIANCE ACTIVITIES 2015-16

This annual report highlights the outcomes of the annual Ethics and Compliance Program Plan in fiscal year 2015-16. The Ethics and Compliance Program Plan, approved by the Regents in July 2015, was an overarching plan that identified and addressed significant risks facing the University. The Program Plan was a compilation of each UC location's compliance work plan that was developed in partnership with many staff, departments, and programs across each campus. This year's work emphasized collaboration among 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 Board of Regents Compliance and Audit Committee for discussion and approval.

During fiscal year 2015-16, 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 Health Sciences: Clinical Research Billing and Coding.

The attached report outlines in detail the work of ECAS and the University compliance program during the past fiscal year. The Annual Report summarizes 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. This year's presentation to the Regents will also include a presentation from one campus on its efforts to implement its compliance plan. Finally, this year's presentation also includes an update on the Office of the President's efforts to create and launch a web portal for information and resources to support international activities.

(Attachment)



University of California
Office of Ethics, Compliance & Audit Services



Annual Report on Ethics and Compliance Activities 2015-16



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EXECUTIVE SUMMARY

The University of California — because of its mission, magnitude, and influence — is continually affected by the unprecedented number of compliance risks and obligations from a myriad of state, federal, and international organizations. As the largest recipient of funds from the National Institutes of Health (NIH) and National Science Foundation (NSF), the University continues to be scrutinized by our external sponsors, further increasing the need to mitigate and anticipate compliance concerns. Increased cyber-attacks on the University's information technology infrastructure, the Affordable Care Act, Clery Act requirements, the changing international landscape, Foreign Corrupt Practices Act (FCPA), California state audits, state and federal legislative changes and the continued national spotlight on sexual misconduct cases necessitate that the University continues to be compliant, to incorporate best practices and to further its mission of research and education. The University of California's ethics and compliance efforts strive to set the national standard for the higher education industry.

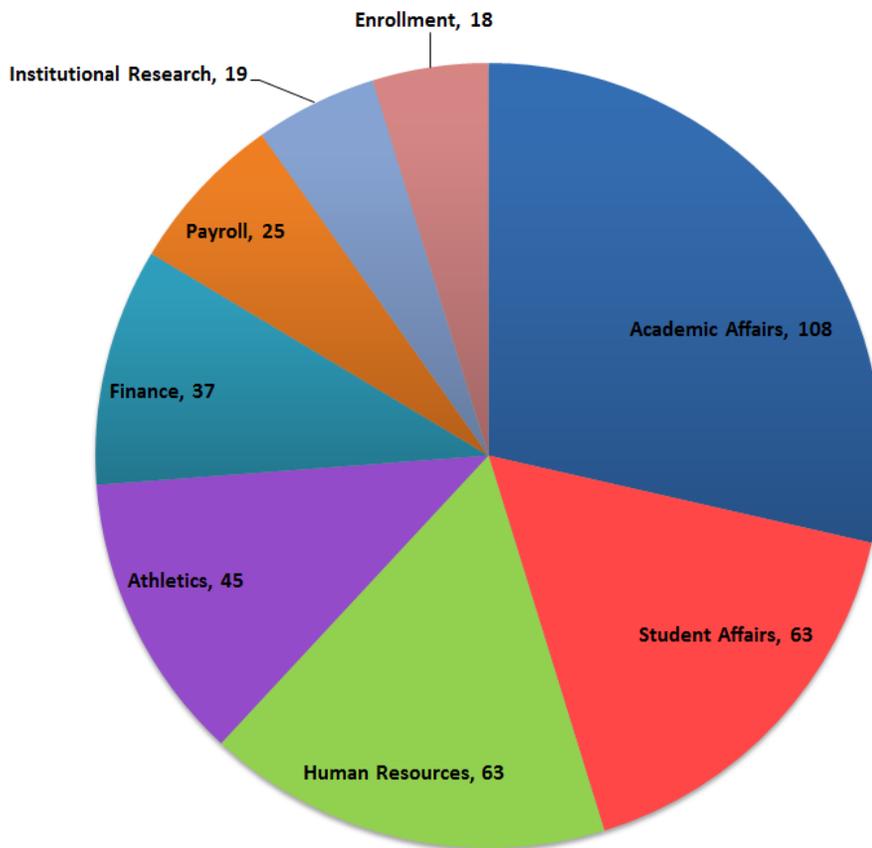
Because of the heightened regulatory environment in higher education, the University of California must remain vigilant. The University's response to continual pressures — through its ethics and compliance programs — is an investment in maximizing its resources, avoiding unnecessary penalties, and maintaining high standards. The ethics and compliance program across the UC system is a vital, robust network staffed by dedicated, trained campus professionals involved in compliance activities such as the development of tools and resources, along with monitoring, educating, auditing and advising business stakeholders. Our goal is to anticipate, detect and mitigate compliance risks, while establishing protocols to meet and exceed compliance standards. Together we work to maintain the highest quality programs and ethical standards of accountability and transparency for our students, faculty, staff, and communities we serve.

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

BACKGROUND: PRESSURES ON THE UNIVERSITY OF CALIFORNIA INCREASING

Higher education is continually subjected to a number of pressures and requirements from regulatory agencies. 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 in New York was over 270 with approximately 62% of the regulations coming from the Federal government and the remaining 38% from other agencies including the State. California's regulatory climate is equally as challenging. Further, these regulatory and compliance activities touch virtually every aspect of our campuses:

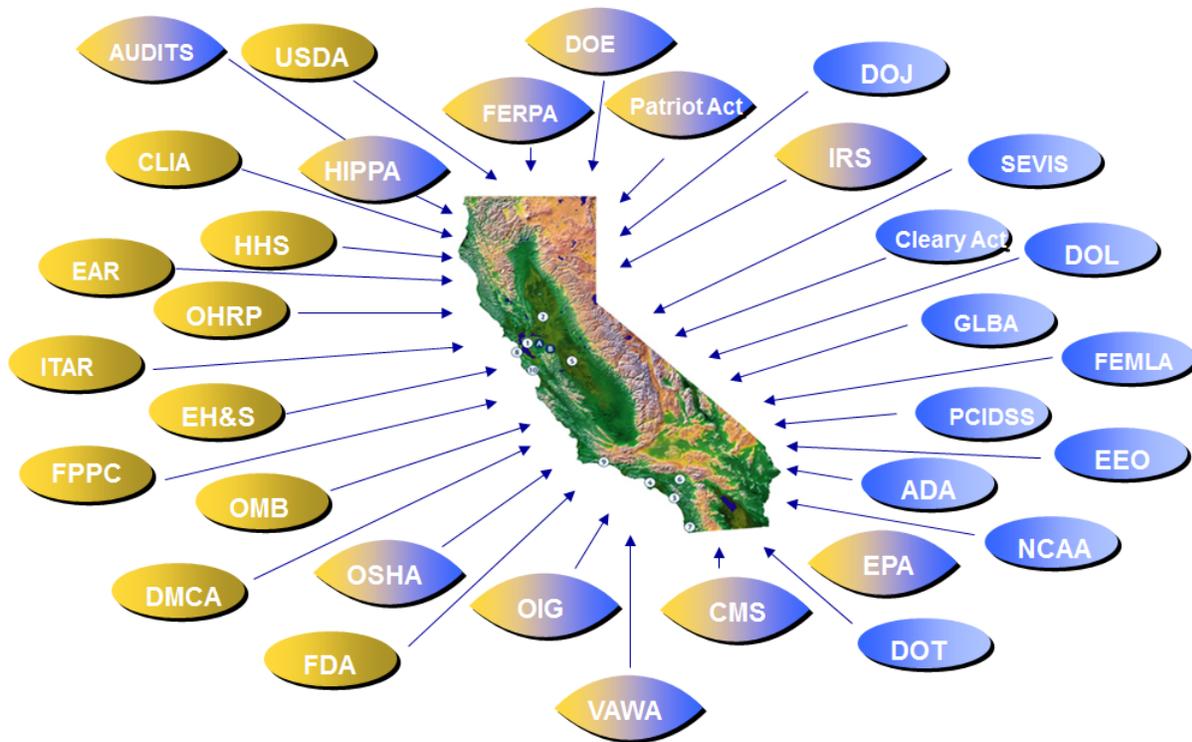
Offices Responsible for Regulations/Compliance Items



*Compliance at Hartwick College: A Special Report to the President of the College, December 2012 by Kelly Zack-Decker

Approaching the regulatory climate: The number of issues and impacts of the regulatory climate continue to increase each year. Consequently, the University of California's compliance program must necessarily be far-reaching, comprehensive, and collaborative as every aspect, location, and function of the University is affected by these regulations. Given its size, breadth of activities and prominence among world-class research institutions, the compliance pressures on the University of California are great. For example, the diagram below demonstrates a few of the regulatory bodies similar to those above that affect the University:

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



UC COMPLIANCE PROGRAM

Compliance programs remain relatively new for higher education. While robust compliance programs are not unique or new for financial institutions, defense contractors, drug manufacturers, research and development operations, and even healthcare organizations, many premier higher education institutions are in the early stages of establishing compliance programs. The University of California's program as one of the first and oldest compliance programs for higher education has—from its inception—been cited as leading the nation in depth and breadth of oversight.

The University of California Board of Regents established the UC Ethics and Compliance program in 2008. The Office of Ethics, Compliance & Audit Services (ECAS) is led by Senior Vice President and Chief Compliance & Audit Officer (SVP/CCAO) Sheryl Vacca. The Annual Report on Internal Audit Activities 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

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 ‘priority risks’, real transparency, and optimal communication practices. As an industry leader for higher education compliance programs, ECAS strives to be the national leader by meeting and exceeding benchmarks as well as recommended guidance for effective compliance programs established by outside agencies.

The University of California’s Ethics and Compliance program regularly reviews industry-established benchmarks to ensure that its compliance program is meeting the highest standards. Reviews in 2013, 2014, and 2015 found that the UC Ethics and Compliance program met or exceeded the following standards:

- ✓ 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 and screening of sanctioned individuals
- ✓ Defining roles/responsibilities and assigning oversight responsibility
- ✓ Due diligence to prevent and detect third party criminal conduct
- ✓ Periodic evaluation of compliance program effectiveness
- ✓ Promote UC’s compliance program throughout organization through incentives for ethical conduct and penalties for non-compliance
- ✓ 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.

Moreover, the 2015 review by the Corporate Executive Board (CEB) found that UC met or exceeded all of 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 only benchmark not met by the University of California was budget. One recommendation was a budget of \$99,763 per 1000 employees and UC's compliance budgets are below that benchmark. While compliance functions are often infused throughout each campus, the dedicated campus compliance budget is not at that standard at UC as the intent of the program was for compliance to be embedded into the business at every site to leverage resources and spending.

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.” 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.

While these are overarching goals, ECAS continually works to assess and realign these functional areas as new initiatives, risks, external reviews, and regulations affect the University.

ECAS: Alignment of Programs with Goals

ECAS develops an Annual Work Plan that is approved by the Board of Regents each July. The approved Plan is typically organized across eight key functional areas that support and align with departmental goals and with the compliance risk pressures affecting the university. For this year, these risk pressures include: general compliance, research compliance, health sciences, government reporting, safety, culture of ethics and compliance, data privacy and cybersecurity, and international compliance.



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. Each of these programs coordinates administrative and operational compliance by actively assessing and responding to compliance needs.

General Compliance: Focus on Education & Training

In FY 2016, 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, 9,804 staff hours were spent in ECAS in-person or webinar trainings. Content was focused on seven target compliance risk areas identified in the FY 2016 Ethics and Compliance Program Plan:

- 1) Safety
- 2) Research Compliance Risk
- 3) Government Reporting
- 4) Data Privacy and Cybersecurity
- 5) Health Sciences Compliance
- 6) General Compliance
- 7) Culture of Ethics and Compliance

Over the course of the year, ECAS offered 169 in person and webinar-based trainings. Key highlights of *in-person* trainings included:

Annual Report on Ethics and Compliance Activities 2015-16

- Trauma-Informed Training for Investigators – sessions in Los Angeles and Oakland for a total of 120 UC staff
- UC All Auditors Forum – two days of training and networking for all UC auditors across the system
- Appendix DS Training – two sessions (Irvine and Oakland) training UC staff to support Procurement in negotiating University agreements using the Appendix - Data Security and Privacy (“Appendix DS”)
- Export Control Day – in-person training for select campuses
- Privacy: Incident Escalation Process
- SVSA Appeal Body Training – two sessions (Davis and Irvine) of two days of training on implementing new Appeal Body process for Sexual Violence/Sexual Assault cases on campus
- UC Workplace Investigations Training – two sessions (Irvine and Oakland) of three days of training each on conducting campus workplace investigations
- Advanced Title IX Investigations Training – one day session in Davis training UC staff on responding to and investigating sexual violence/sexual assault

Webinar highlights included:

- Digital Forensics and Security in the Workplace
- Effective Investigation Reports: Tips to Writing it Right!
- The Legal Mind: Solving Problems by Looking at Disputes and Conflicts Through the Eyes of the Legal System
- Outstanding International Operations Questions and Next Steps
- Information Technology General Controls (ITGC) 101
- Conducting International Research: Ethical and Policy Concerns
- Crafting Community: Our Role in Preventing and Responding to Sexual Violence/Sexual Harassment
- FCPA: Advanced Tools and Regulatory Update

Based on recommendations from the President’s Task Force on Preventing and Responding to Sexual Violence and Sexual Assault and as required in the new UC policy on Sexual Violence/Sexual Harassment, ECAS introduced Sexual Harassment Prevention Training for all non-supervisory staff and all incoming students for the first time in FY 2016. This is in addition to an updated Sexual Harassment Prevention Training for Supervisors course that was also rolled out in FY 2016. Additionally, the staff and faculty courses are being translated into three languages by fall 2016.

To reinforce the need for, and process of, securing computers and technology to ensure privacy and data security, ECAS, under the scope of the President’s Directive for the Cybersecurity Initiative, rolled out Cyber Security Awareness training in October 2015 for all UC employees. For fall 2016, we are revising the annual training based on feedback received.

ECAS is also currently finalizing two new Compliance Briefings: Conflict of Interest for Researchers (COIR) and UC Ethical Values and Conduct. Researchers are required to be transparent in their research and disclose any conflicts of interest they may have as they work for UC.

ECAS will continue to offer a dynamic and evolving compliance and education training program, while striving to be a leader in the field and a model for other university systems.

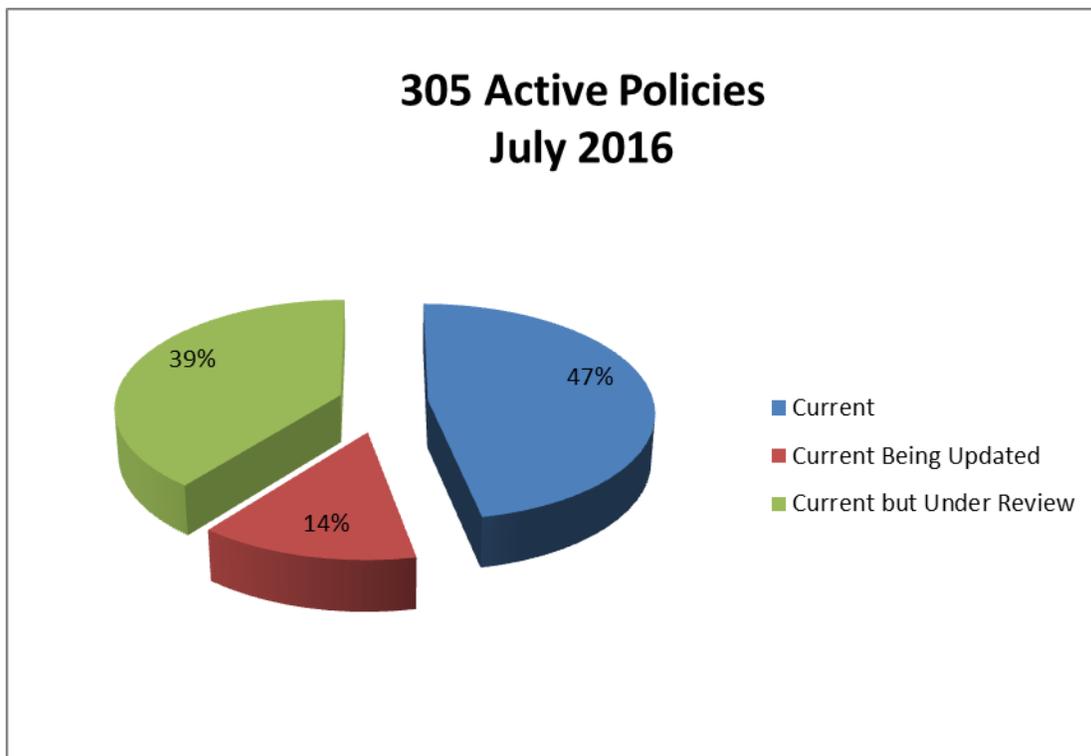
Priority Areas of Focus for FY 2016

I. Policy Management

The objectives in FY 2016 were to:

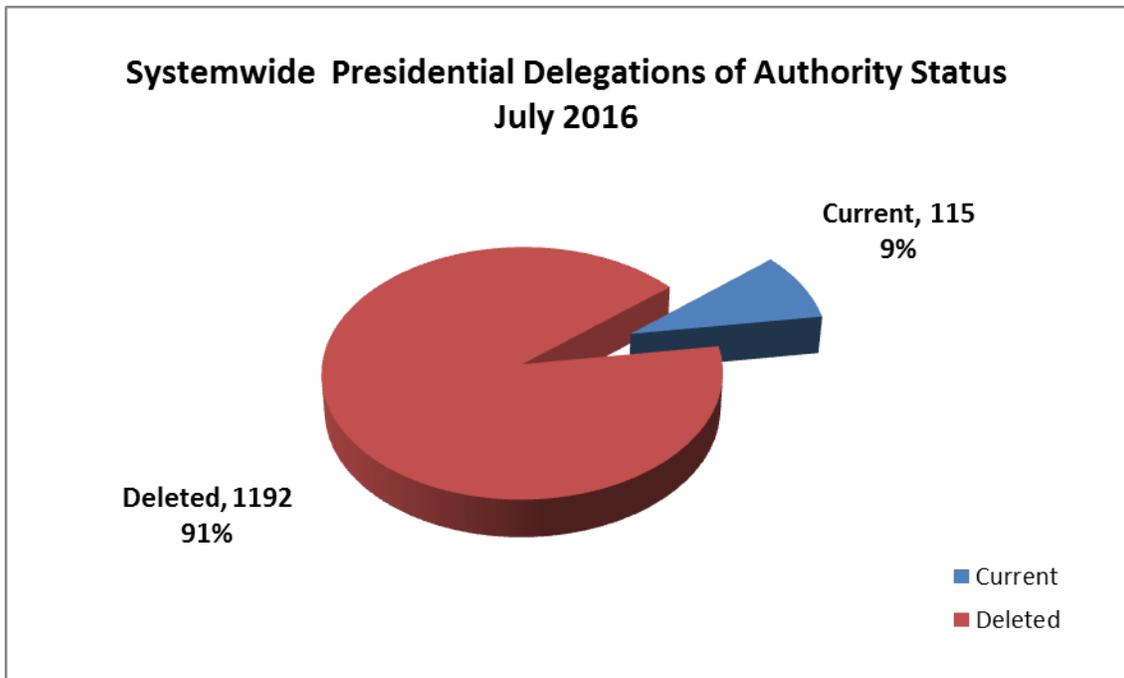
- Reorganize the University Policy Office (UPO) to ensure that Presidential policies are current, accurate, and regularly reviewed.
- Institute processes where the appropriate subject matter experts review proposed policies.
- Support campus Policy Managers to develop consistent “best practices” across the system, ensure accurate and timely conveyance of Presidential policies, and ascertain inconsistencies, gaps, or needs in both campus and Presidential policies.

The UPO website continues to be active with a total of 109,937 sessions - 63,520 from new visitors, and 46,417 from returning visitors in FY 2016. The top policy lookups are Sexual Harassment and Sexual Violence (9.76%), legal medical records (6.23%), BFB-G-28 Travel (3.76%), PPSM-2-210 Absence from Work (3.32%). ECAS continually updates the policy development website to provide accurate information on the process for development, review, and categorization of policies. The University currently has 305 active policies with 120 under review.



II. Delegations of Authority

ECAS continued its role in the review and issuances of the Presidential Delegations of Authority (DA) process. ECAS continues to work with the President’s Office, appropriate designated UCOP offices, the campus Policy Managers and DA Business Owners to ensure that the all Presidential DAs are appropriate, up-to-date, and required for organizational purposes.



III. Data Privacy & Cybersecurity

Privacy is an important risk, and one that usually presents itself in combination with other areas of risk, including information security, data management, and payments made to UC. Since 2014 there have been appointed privacy leads across each campus; each campus and health location also has a HIPAA privacy and HIPAA security lead. Partnering with key subject-matter experts from across the system has been effective in driving change and awareness in our organization of the myriad privacy compliance requirements facing UC.

a. Challenge: Information security continues to be an increasing area of concern across UC’s risk landscape. Safeguarding information adequately in the digital age is a difficult task that cannot be done perfectly. There are increasingly sophisticated methods to breach technical systems across many organizations, but UC faces added risk because both health care and higher education are considered prime targets for cyber attacks.

Solution: As part of the President’s Cyber Risk Governance Committee, ECAS has been advising on audit and privacy concerns that intersect with the information security landscape. ECAS additionally provided training on how to report suspected data breaches, as well as about managing risk in this area. ECAS partnered with IT Services to develop a consistent systemwide reporting protocol for security incidents potentially involving protected data, which will help develop metrics to measure UC’s efforts in this area.

b. Challenge: UC retains large amounts of data from its business operations, academic research, and health records. Each area is obligated to follow strict regulatory



requirements while simultaneously supporting the sharing of this data on a large scale, and with the legally-defined expectation that UC will adequately safeguard this data. These two forces have created an enormous challenge: UC must, as part of its educational and research mission, facilitate broad access to much of our data, yet we must simultaneously protect our data from unauthorized access. This is a significant challenge for two reasons. First, the regulatory requirements for data security are becoming more numerous and more onerous, with significant penalties for failures to adequately protect data. New California laws, for instance, increase privacy and data security obligations impacting UC's business operations. The Office of Civil Rights (OCR), the agency responsible for enforcing HIPAA protections, has recently issued increased fines against health care organizations that have suffered data breaches. Yet, at the same time that regulators are cracking down on organizations that suffer a breach, the imperative to *broaden* access to data is growing stronger. The NIH and NSF have made clear that research grants will be awarded to those who are willing to collaborate across disciplines, institutions, and countries. OCR has spoken frequently in the last year about the need for patients to have access to their personal health information. In this environment, where data is a vital institutional asset and a major vector of risk, a cohesive information classification and management strategy is essential.

Solution: In FY 2016, ECAS undertook a series of actions to address this challenge. Our business and research agreements are key levers to facilitate data sharing while managing the risks associated with such



arrangements. ECAS partnered with Procurement, Information Security, and Legal to improve standard contract language around Data Security and Privacy. This language heightens contractual protections for the University and requires stronger security practices on the part of our partners who receive data. Further, ECAS led training for campus subject-matter experts from Procurement, Risk, Privacy, and Information Security across all UC locations to establish a consistent understanding of UC standard contract language and appropriate ways to negotiate those protections. In recognition of the unique risks in the health sciences space, ECAS also offered additional training and awareness on working with HIPAA business associates, safeguarding data in the cloud and with third parties, and UC values and principles for keeping our data private and secure.

c. Challenge: An emerging risk identified across the system is the capturing and storing of information to the Payment Card Industry Data Security Standard (PCI-DSS), a proprietary information security standard for organizations that handle branded credit cards. PCI-DSS is mandated by credit card brands and administered by the PCI Security Council. This Standard's purpose is to detect and prevent fraud through improper credit card use.

Solution:

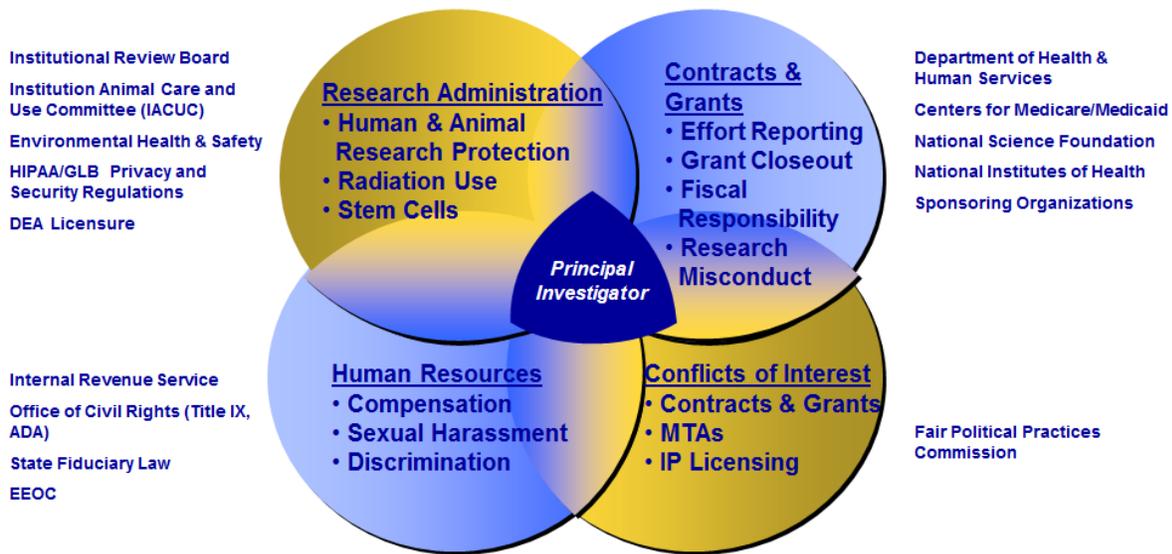
ECAS will continue to collaborate with Finance, Audit Services and Risk Services to assist campus efforts to implement PCI-DSS compliance processes that meet the PCI standards. Information will be gathered and incorporated into the systemwide compliance guidance and direction.

d. Challenge: Universities are incubators of innovation, which increases some of the privacy and security challenges new technology creates. UC faculty, staff, and students avail themselves of technology to fulfill UC's mission, including cloud storage and services, secure text messaging, wearable devices, drones, etc. Clear and frequent communication across disciplines is one of UC's strongest, and more challenging, tools to prevent and respond to breaches and other privacy violations.

and OCR regarding Title IX complaints. During FY 2016, ECAS maintained the response and monitoring of the focused review by the California State Audit (CSA) around Title IX and Clery requirements.

The figure below indicates relevant compliance matters that have an impact on principal investigators, along with relevant regulatory bodies:

Compliance Matters Impacting Principal Investigators And Relevant Regulatory Bodies*



*Including but not limited to the matters listed

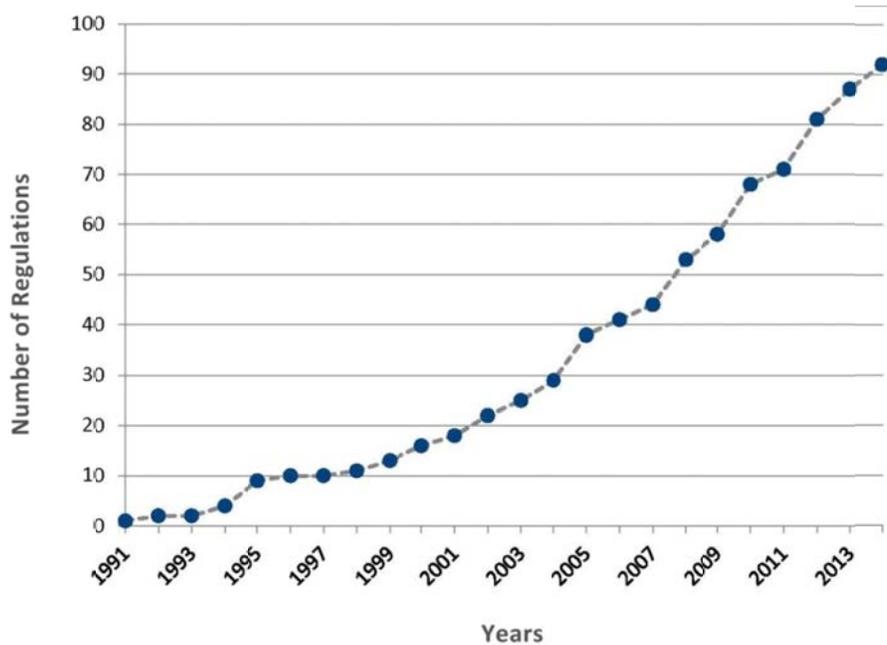
V. Research Compliance

As a key component of its core mission, research activities at UC occur in more than 800 research centers, institutes, laboratories, and programs, spanning ten campuses, five medical centers, a national energy laboratory, and numerous specialized research facilities. The research enterprise at UC accounts for approximately one-fifth of the University's annual operating budget, or about \$5 billion. More than \$4 billion of this is provided to UC through contracts and grants from governmental and private sponsors. These extramural sources provide nearly a billion dollars annually in awards to support training, public service, and related activities.¹

With these contracts and grants comes the responsibility to comply with the terms, conditions, and regulations that govern the conduct of basic, applied, and clinical research. Promoting compliance with federal, state, and local regulations and policies pertaining to research remains a primary focus for ECAS.

¹ Source: UCOP Institutional Research and Academic Planning, <http://www.ucop.edu/institutional-research-academic-planning/areas-of-expertise/research/index.html>. Accessed May 12, 2016.

The administrative burden of these federal regulations on UC – and academic institutions across the country – grows at a steady annual rate. According to the National Academies of Science, the rate of new or substantially revised federal regulations impacting the seeking or conduct of research has increased from about 1.5 per year in the 1990’s to 5.8 per year in the past decade. In 2012 alone, there were 10 major new or revised regulations implemented. Each revision requires significant change to internal policies and procedures. The graph below shows the cumulative number of regulatory changes applicable to research institutions since 1991.² The increasing number of changes continues unabated with no signs of decreases.



Cumulative Number of Regulatory Changes Applicable to Research Institutions (Since 1991a). SOURCE: Courtesy of the Federation of American Societies for Experimental Biology, 2015. Based upon data collected by the Council on Governmental Relations.

The administrative burden of these regulations on faculty, campuses, and the UC system is substantial. UC participated, by invitation, in the 2015 discussions leading to the recommendations in the National Academies report. This report proposes a new approach to the promulgation of research regulations and recognizes the need to coordinate and assess the true administrative burden on research institutions. To date, there has been no adoption of these proposals, although presently there is legislation before the US House of Representatives and the US Senate based, in part, on the National Academies report.

ECAS has worked consistently over the past year to assist campuses in managing the implementation of new research regulations and in monitoring compliance with existing ones. In FY 2015-16, in addition to its general support services, ECAS focused particular attention on the following areas of concern:

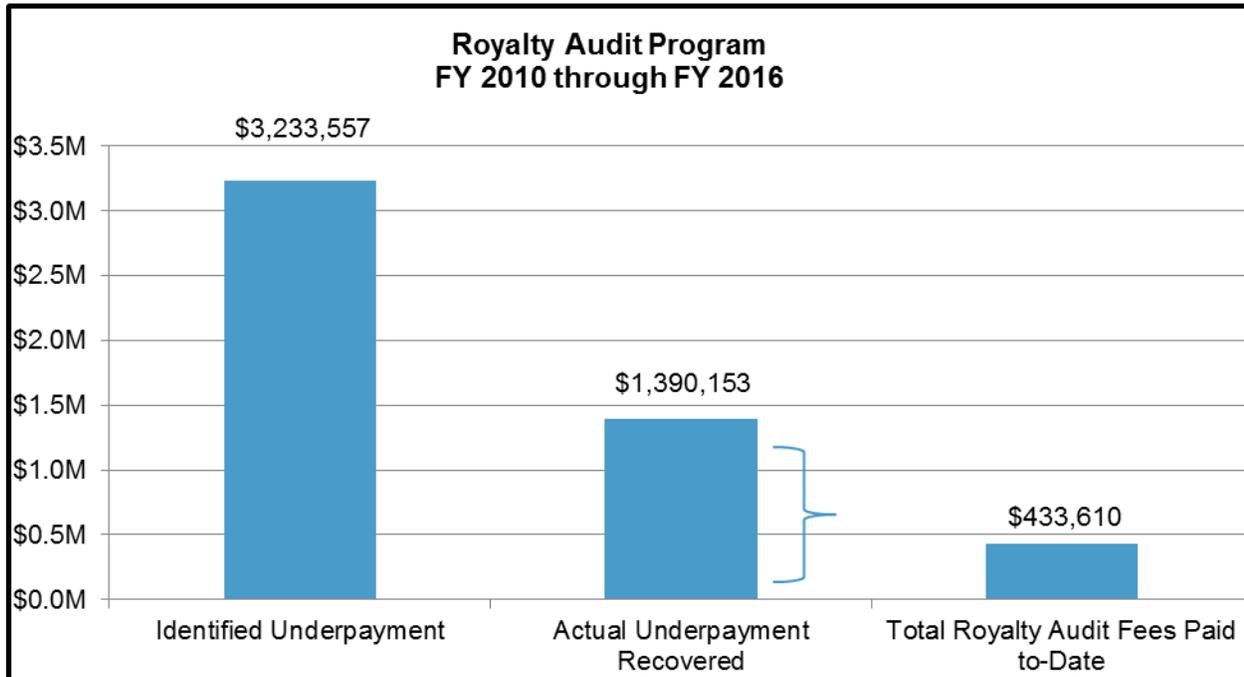
a. Research-Royalty audits

Background: UC faculty produce research results that may include patentable and licensable intellectual property and/or technologies. Once licensed to a company, royalties are due The Regents according to the payment terms and schedule in the licensing agreement.

Challenge: Some companies do not follow the agreed upon terms of the licensing agreement, resulting in a loss of royalty revenue to the University.

² Source: National Academies of Sciences, Engineering, and Medicine. *Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century, Part 1*. The National Academies Press, page 43. 2015.

Solution: 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 funding and conducting systemwide royalty audits using an outside consultant since July 2009. The Royalty Audit Program has identified more than \$3 million in underreported royalties since the inception of the program. Since 2010, audits have identified \$3,233,557 in underpayments. As of May 2016, \$1,390,153 in underpayments of royalties has been recovered, representing a 22% return on investment for the program.

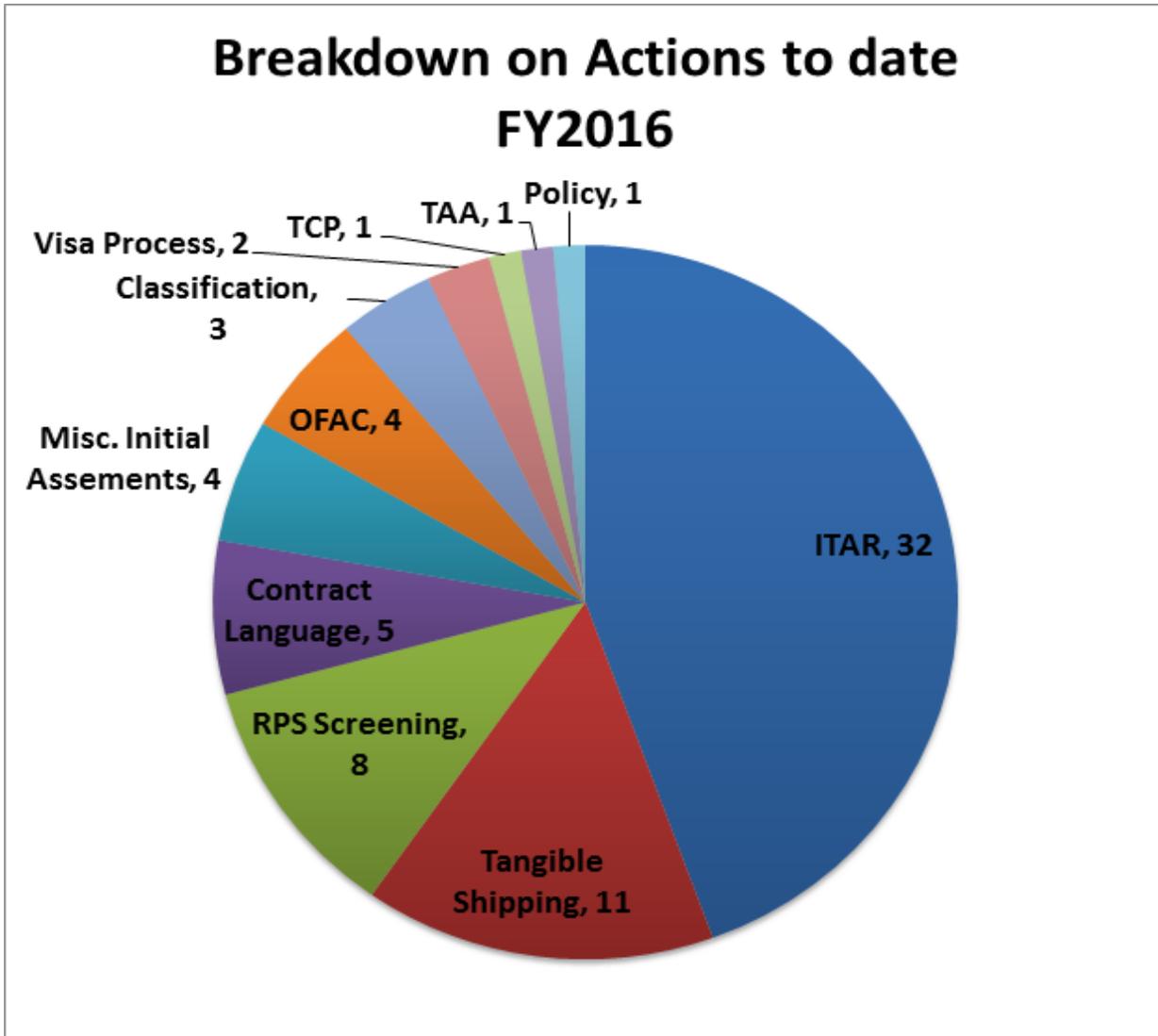


b. Research-Other Regulatory Areas

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.

c. Export Control

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.



ECAS’s Export Control Office (ECO) provided significant support to UC locations in FY 2016, responding to 72 diverse export control-related inquiries with the goal of preventing non-compliance (see above figure). 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 as the focus on International Traffic in Arms Regulations (ITAR) increased significantly with an emphasis on documented compliance including Technology Control Plans and Training to facilitate fundamental research projects, enabling critical research programs at UC locations, and regulatory notifications to the Directorate of Defense Trade Controls. The handling of these matters through internal management by ECAS provided cost savings (as opposed to of retaining outside support), which continued to increase again over FY 2016, which itself saw a substantial increase in ITAR compliance-related activity.

ECAS participated in and supported local efforts to establish or expand campus-wide export control initiatives. All locations expanded their local export control support and one location formed a campus-wide provost-initiated export control compliance oversight committee which resulted from last year’s task force.

ECAS previously launched an online, interactive course entitled, “Introduction to FCPA and Anti-Corruption,” for use in UC’s Learning Management System. This course educates UC personnel including faculty on the compliance risks and red flags associated with international collaborations with instrumentalities of foreign

governments and is recommended for international pre-travel briefings. UC's focus on FCPA compliance and anti-corruption expanded further with three new webinars made available systemwide that were created and presented by ECAS on the subject of FCPA compliance tools and best practices.

ECAS launched the first phase of on-site export control and ITAR awareness training geared specifically toward Procurement and Materials Managers and other groups beyond the traditional areas of research. This first phase of training provided for in-person mandatory training at all campuses and locations. The second phase will expand this further by partnering with UCOP's commodity management team on a series of full-day events of which export controls and ITAR training will be a significant focus.

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.

Policy: After 18 months of effort working closely with our campus stakeholders, the UC Export Control Policy is being readied for final vetting and may be in place as soon as 1Q FY 2017.

Looking ahead to 2016-17

Several new and pending federal regulations, in particular, will impact our researchers in the coming year:

Uniform Guidance

Situation: The Uniform Guidance represents the federal government's effort to revise the long-standing Office of Management and Budget (OMB) Circulars that set out the standards governing the administration and expenditure of federal funds related to contracts and grants awarded to academic institutions. The Uniform Guidance was intended to bring a single set of common, uniform standards to all federal agencies.

Challenge: To date, many federal agencies have not adopted the single standard and have, instead, implemented variations on those standards, creating a more complex regulatory environment and requiring additional effort at the campus level.

Dual Use Research of Concern (DURC)

Situation: In response to the H1N1 influenza controversy of 2012, the NIH promulgated new regulations and requirements for certain biological Select Agents (biological agents and toxins that the Departments of Health and Human Services and Department of Agriculture have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products) used in academic research. Termed "dual use research of concern," this research involves a defined subset of biological agents and experiment types that could potentially be used for harmful purposes (i.e., biological weapons). The new DURC regulations require institutions to develop policies and procedures to collect, review, manage, and report on all possible DURC.

Challenge: These regulations are in addition to already existing biosafety, Select Agent, and export control regulations. Campuses have had to create a separate process for reviewing and managing this subset of projects. These new regulations are an unfunded mandate.

The Common Rule

Situation: In 2011, the Office of Human Research Protections announced significant proposed changes to The Common Rule, the regulation that governs the conduct of research involving human participants. Public comments on the 2015 Notice of Proposed Rulemaking were received last year, and we await the issuance of the Final Rule.

Challenge: Should all of the terms of the Proposed Rule be adopted, UC’s human research protections programs will see significant changes to how they oversee research involving bio-specimens, patient medical records, and minimal risk studies. With few exceptions, the Proposed Rule would increase the administrative burden on both faculty researchers and our administrative support offices.

These pending changes, as well as other identified research risks, will be addressed in the ECAS Research Compliance FY 2016-17 Work Plan.

VI. International Activities

A significant area of risk for UC is across the plethora of international activities engaged in by students, faculty and staff and the related stresses associated with those activities:



During FY 2016, the objectives for international activities included:

- Improve international activities compliance guidance through the work of the UCOP International Compliance Work Group
- Provide education and training on a variety of topics around international laws, regulations and compliance needs
- Review and participate in the International Activities Policy as developed by the Provost.
- Develop a UC-Wide “web portal” that will be accessible for faculty and staff.

Situation: UC is a global organization and the international activities in which the University is involved include faculty/student exchange programs, intercollegiate consortia, sponsored research, research collaborations, work with nonprofit corporations, clinical operations, joint ventures, international foundations, trusts, and

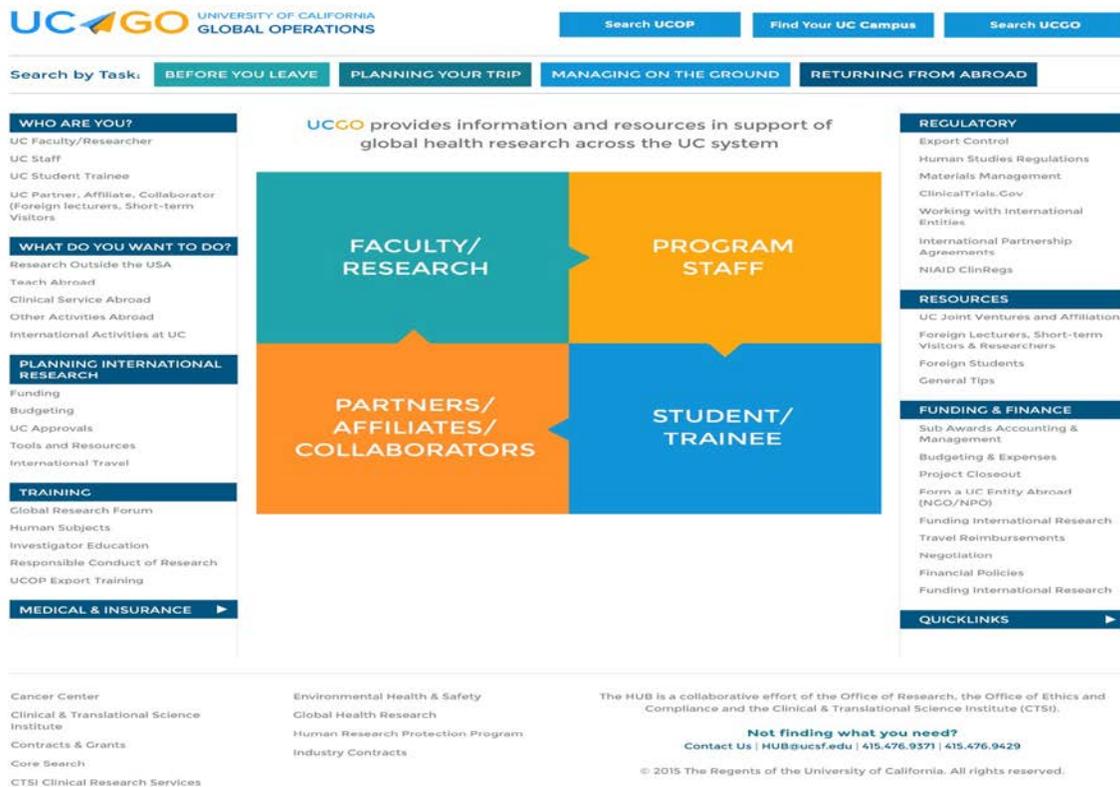
more. Through these rich collaborations and relationships abroad, the University extends its global influence and shares its contributions to the world.

Challenge: UC’s international activities continue to expand in both number and complexity, increasing the risk for violations of a range of U.S. and multinational laws and regulations, as well as University policies. Many faculty, staff and students are unaware of the range of regulations and policies that they must consider when engaging in international activities.

Solution: Develop comprehensive, easy-to-find and easy-to-use tools that will guide UC personnel to the right resources on campus and at UCOP to assist them in their international activities.

Progress/Update: ECAS has sponsored and facilitated numerous training opportunities, both web-based and in person, around issues related to international travel and international shipping. Working with private vendors, ECAS has also made available to campuses enhanced screening tools, such as World Check One, a Thompson-Reuters tool for comprehensive screening of foreign entities and individuals. This tool supports compliance with the Foreign Corrupt Practices Act, as well as other regulations and laws.

In partnership with the Office of Research Policy Analysis and Coordination, ECAS has developed the ‘UCGO’ website, a tool to provide UC faculty, staff, and students with information about all aspects of international travel, research, teaching, and clinical care. The tool is in final development and expected to be released in fall 2016. A screenshot of the home page appears below.



VII. Safety

Lab Safety

Situation: In July 2012, The Regents signed the Prosecution Enforcement Agreement and agreed to hold the campuses to enhanced chemical safety standards and monitoring schedules.

Challenge: Subsequent to the agreement, Risk Services, through the Environmental Health and Safety Office, implemented significant programs and distributed protective personal equipment (PPE) across the system. However, campuses continue to identify safety in our labs as a key risk area as Cal-OSHA site visits identify specific areas to be addressed.

Solution: Assist the campuses in identifying risks of non-compliance and assist in the expansion of training and education opportunities.

As we reach the final year of the settlement agreement, campuses continue to identify and address specific lab safety concerns. The focus in FY 2015-16 was centered on solutions for particular problems – finding appropriate fire-resistant gloves and other PPE; further enhancing targeted training for researchers and lab staff; addressing specific findings during Cal-OSHA site visits. Campuses are devoting significant resources and personnel to addressing Lab Safety. ECAS works closely with Environmental Health and Safety/Risk Management to support campus efforts.

Clery Act

Overview: 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. The Act requires that the University gather, classify and publish crime data from multiple sources to ensure that students and others know about campus crime statistics and specific types of reported criminal offenses.

Throughout the year, ECAS worked with Campus Clery coordinators and the Office of the General Counsel (OGC) to help campuses comply with the Clery Act. Specific support activities included the following:

- Sponsored in-person training sessions for Campus Clery Coordinators
- Developed a Presidential policy for Clery Act compliance (will be finalized in FY 2017)
- Developed a draft systemwide training module for all UC Campus Security Authorities (CSA). (All CSAs are required to be trained about their reporting obligations under the Clery Act)
- Worked with Campus Clery Coordinators and OGC in an effort to document consistent naming of CSAs, and clarify the non-campus locations that are subject to Clery Act reporting
- Supported a comprehensive reference document library for Campus Clery Coordinators and staff
- Partnered with OGC to ensure accurate, timely, and consistent legal interpretation of the University's obligations under the Clery Act; and this information was communicated to Campus Clery Coordinators and related staff.

Sexual Violence/Sexual Assault/Violence Against Women Act (VAWA)

ECAS continued its leadership role in the University’s comprehensive review of its policies, practices, prevention programs, and reporting of incidents and allegations of sexual violence, sexual assault, and sexual harassment among students, staff, and faculty. FY 2016 saw increased activity as the student-to-student model recommendations of the President’s Task Force on Preventing and Responding to Sexual Violence and Sexual Assault were implemented. This year, ECAS oversaw compliance with the following initiatives:

- Full implementation of the confidential, privileged CARE advocate on each campus
- Mandated training for all incoming students (three points of contact within first six weeks on campus)
- Implementation of the revised student investigation and adjudication model
- New mandated student sanctions for sexual violence incidents
- Training of a variety of key campus personnel including student conduct officers, Title IX, investigators, CARE advocates, prevention and education specialists
- Completion and issuance of revised systemwide policy on Sexual Violence/Sexual harassment
- Development and implementation of mandated annual training for all UC employees including new e-courses for supervisors/faculty and non-supervisors
- Training and provision of consistent messages for new requirements of “responsible employees” that makes ALL UC employees (except those that are exempt as confidential and privileged resources, i.e.: CARE Advocate, Licensed Professionals under penal code, etc.) responsible for reporting allegations by students of sexual violence/sexual assault.
- Development of metrics collection process for campus data

Improving the UC Culture to Prevent & Respond to Sexual Violence, Sexual Assault & Sexual Harassment



VIII. Culture of Ethics & Compliance

Whistleblower Hotline & Investigations

The ECAS Investigations Unit demonstrates that the University of California takes seriously any allegations of improper governmental activity, workplace misconduct, harassment, discrimination, retaliation, and other alleged ethical breaches by conducting prompt and thorough workplace investigations. Fact-finding investigations conducted by ECAS also help the University identify areas of risk and inform local and systemwide training and prevention efforts. Our robust internal grievance and investigative process, coupled with prompt remedial actions, can also deter costly litigation and help ensure compliance with state and federal law and UC policy.

Investigators and Expanded Subject-Matter Expertise: The ECAS Investigations Unit conducts, manages, and coordinates the investigation of complaints of suspected improper governmental activity, workplace misconduct, and other ethical breaches for UCOP and, when appropriate, for campuses. ECAS handles investigations both internally at the UC Office of the President and throughout the system when local investigators are recused from conducting an investigation, at the campus request, or when a local investigation may pose a real or perceived conflict of interest. Additionally, ECAS investigators are available to support individual investigative units as needed.

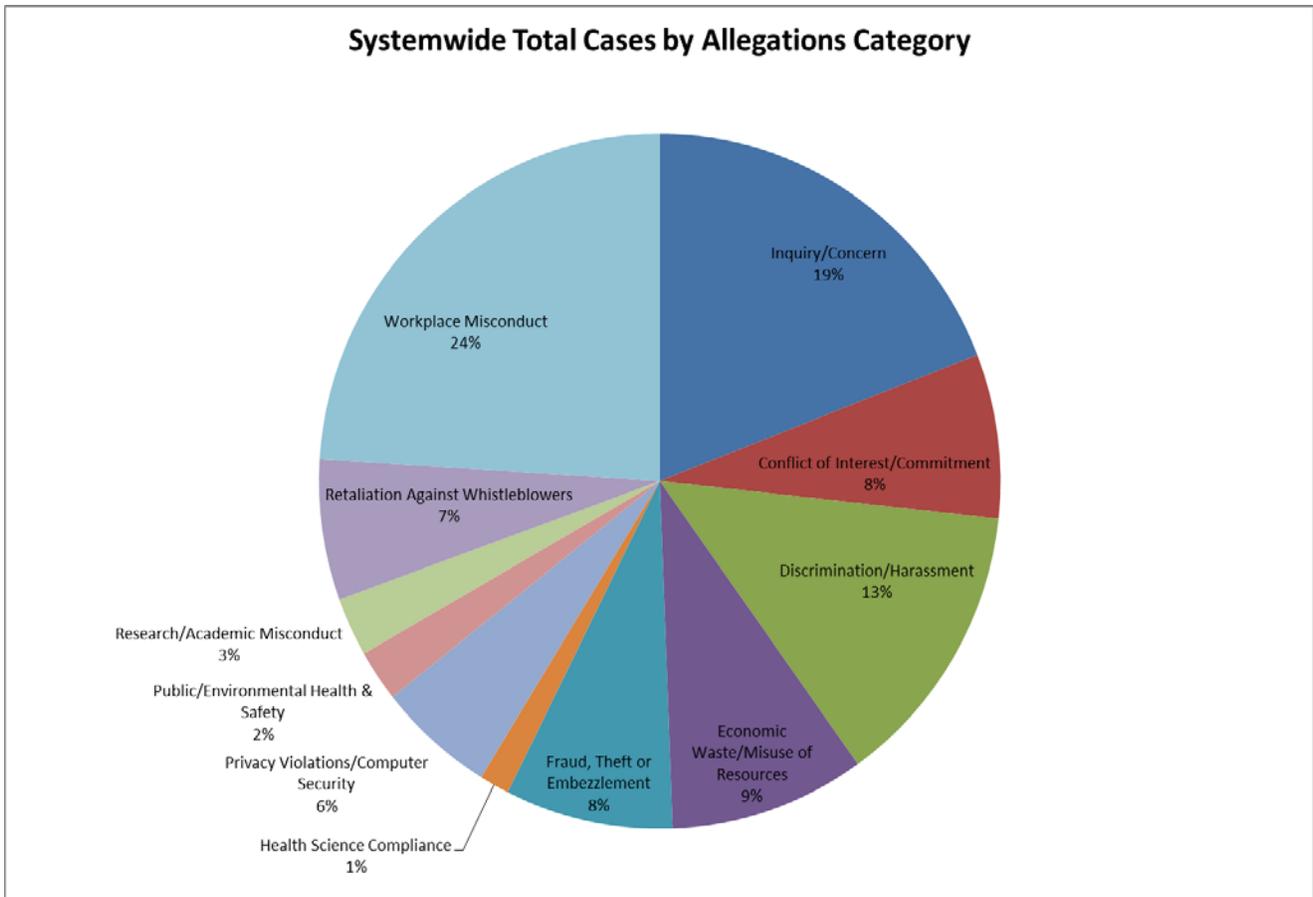
In FY 2015-16, ECAS created and filled a Health Sciences Principal Investigator position. This investigative position harnesses the incumbent's subject-matter expertise in health care settings to efficiently investigate matters typically arising at our Medical Centers and UC Health locations. In the past, the University has relied on costly external investigators to conduct these types of investigations in which healthcare-related knowledge is a prerequisite. ECAS now has this investigative skill-set as an internal resource.

Average Hourly Cost Comparisons:

Internal Investigators	External Investigators
\$ 75 – 100	\$ 200 - 400

The University of California is committed to creating and maintaining a working and learning environment free of all forms of sexual violence and sexual harassment. ECAS Principal Investigators are now cross-trained and experienced at conducting Title IX Investigations, including allegations of sexual violence and sexual harassment involving students, faculty, and staff. Locations have primary responsibility for responding to these types of complaints. However, governmental agency reviews, heightened media and public scrutiny, new state and federal regulations, new UC policies and adjudication procedures, and higher incidences of reporting have increased individual Title IX office's workloads. ECAS is now in a position to offer individual locations investigatory support for Title IX cases, as needed. Additionally, the Investigations Unit plans to add two additional Principal Investigators with Title IX expertise specifically to assist locations systemwide.

Whistleblower Hotline: Employees and others are encouraged to report all allegations of suspected improper governmental activities and other suspected wrongdoing within the University. The ECAS Investigations Unit manages an independently operated systemwide Whistleblower Hotline that employees and members of the public may utilize to report concerns, including anonymously. In FY 2015-16, 917 reports were made via the Hotline, a 4% increase from FY 2014-15. The most common reported concerns were in the following categories: Workplace Misconduct (including UC policy violations), Discrimination/Harassment, Economic Waste/Misuse of Resources and General Inquiry/Concerns.



Training and Centralized Resources: Individual locations have primary responsibility for the investigation of suspected improper governmental activity, and other workplace misconduct. ECAS provides systemwide trainings and investigative resources to bolster consistency and proficiency in workplace investigations throughout the system. In FY 2016, ECAS hosted two sessions of a comprehensive three-day Workplace Investigations Training instructed by recognized experts in the field. More than 120 UC employees who conduct investigations for the system attended the sessions held in northern and southern California.

The Investigations Unit also provides resources for local investigation groups such as report-writing templates, standard notification letters and other investigatory tools. The Unit also convenes systemwide forums for Locally Designated Officials and location investigators to share best practices and to foster systemwide consistency in the response to allegations of improper governmental activity and other misconduct.

Policies: The University of California has a responsibility for the stewardship of University resources and the public and private support that enables it to pursue its mission. The University is committed to compliance with the laws and regulations to which it is subject and to promulgating University policies and procedures to interpret and apply these laws and regulations in the University setting. Laws, regulations, policies and procedures strengthen and promote ethical practices and ethical treatment of the members of the University community and those who conduct business with the University.

The University’s internal controls and operating procedures are intended to detect, prevent or deter improper activities. However, even the best systems of control cannot provide absolute safeguards against irregularities. Intentional and unintentional violations of laws, regulations, policies and procedures may occur and may constitute improper governmental activities as defined by statute. The University has a responsibility to

investigate and report to appropriate parties allegations of suspected improper governmental activities and the actions taken by the University.

The University of California Policy on Reporting and Investigating Allegations of Suspected Improper Governmental Activities (“Whistleblower Policy”) governs reporting and investigation of potential employee misconduct at all University locations, and together with the *Whistleblower Protection Policy*, represent the University’s implementing policies for the California Whistleblower Protection Act.

The *Whistleblower Protection Policy*, effective May 1, 2015, was revised through a multi-disciplinary effort to enhance efforts to encourage reporting. As the policy states, “The University of California is committed to providing a work environment where employees are free to report suspected Improper Governmental Activity or conditions that significantly threaten the health or safety of employees or the public without fear of retribution and where employees can be candid and honest without reservation in conducting the University’s business.”

IX. Health Sciences Compliance

Overview

Promoting compliance with the complexities associated with the Affordable Care Act (ACA), clinical research and related billing, general billing and coding, and other regulatory compliance areas remains a primary focus for the Health Sciences Compliance Program in the Office of Ethics, Compliance and Audit Services. Over the past fiscal year, UC Health has developed strategic priorities focused on cost management, positioning for population health management and growth, enhancing market-leading clinical and research programs, transforming the governance structure and enterprise-wide strategic planning. The five Health Science Compliance Programs located at UC Davis, Irvine, Los Angeles, San Diego and San Francisco along with the compliance program at the UC Riverside School of Medicine continue to evolve to meet the challenges of clinical organizational change, state and federal regulatory changes and enforcement actions; and compliance continues to be recognized as an important aspect of clinical enterprise business operations.

Update of FY 2015-16 Health Sciences Compliance (detailed campus reports will be shared with the new committee on Health Sciences Governance):

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. Accurate and timely submission of billing and coding data to government reimbursement agencies continues to be a key compliance program risk that requires continual and focused vigilance. For UC’s academic medical centers (AMCs), the risks associated with clinical research billing (CRB) represent an ongoing challenge. Due to changes in the California Medicare Administrative Contractor, the interpretation of reimbursable clinical items and services is being challenged by requirements for enhanced documentation for claim payment and appeal processes. Non-compliance with CRB 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 continued its systemwide focus on 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 conducted site visits at all AMCs including UCSF Benioff Children’s Hospital and UC Riverside School of Medicine to evaluate current CRB practices and to catalog best practices that can be shared among the campuses.

Conflict of Interest/Conflict of Commitment: Open Payments

Conflict of Interest (COI) and Conflict of Commitment (COC) 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 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 served on the Media Communications workgroup for the American Association of Medical Colleges Forum on Conflict of Interest in Academe to develop a resource document to inform physicians and help the general public analyze data reported in the Open Payments system. ECAS continues to monitor and update, as appropriate, University policies and procedures regarding conflict of interest and encourages transparency and responsiveness to concerns about conflict of interest/conflict of commitment issues.

Billing and Coding - ICD-10 Implementation: After many years of delay, the ICD-10 system to code diagnoses for all healthcare encounters went into effect on October 1, 2015. The transition from ICD-9 to ICD-10 is predicted to have a significant impact on UC healthcare operations. By contrast, ICD-10 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, co-morbidities, and complications, in addition to streamlining payment operations by classifying detail within codes to accurately process payments and reimbursements.

ECAS has provided training, guidance, and leadership to our academic medical centers to monitor and audit coding. Additionally, ECAS provided on-site ICD-10 implementation for providers and staff at our Student Health/ Counseling Centers ensuring a smooth ICD-10 transition. 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, which have added to the complexity of completing daily transactions. ECAS will continue to work 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.

Professional Fees Billing and Coding Compliance:

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 auditing and monitoring capability supported 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.

Progress/Update: As of July 1, 2015, all UC health sciences compliance programs 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, Recovery Audit Contractors, and to quickly gauge risk exposure. 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.

Contract Management: Contracts are generated and managed within different functions throughout our organization. Due to this fragmentation, areas of potential risk may be missed, i.e. proper privacy protections, appropriate rules addressed and correct application of regulations.

ECAS coordinated with the OGC Health Law Group to convene the inaugural joint meeting of UC Health attorneys and health system chief compliance officers to develop a common understanding of existing and emerging legal and compliance risks in the UC Health enterprise, including contract management, and identify initiatives to eliminate or reduce those risks. ECAS worked with UC Health Procurement to identify a more common approach to contract management with the goal of identifying a systemwide contract management system that covers all stages of the contract lifecycle enabling the UC Health enterprise to actively manage all types of contracts including enterprise, procurement and sales contracts.

ECAS was instrumental in coordinating these and other administrative and operational HS Compliance programs. The HS Compliance programs remain focused and are directed at efficiently and effectively detecting, deterring, and preventing instances of fraud, waste and abuse.

CAMPUS HIGHLIGHTS

Division of Agriculture & Natural Resources (ANR)

- **Volunteer Management:** During FY 2015-16, centralized screening and monitoring of volunteer criminal record information was fully implemented, with consistent standards applied to respond to criminal arrests or convictions of volunteers.
- **Regulatory Compliance in Applied Research:** ANR has targeted training specific to its Principal Investigators (PIs) and processes to ensure that PIs are aware of compliance requirements. Additional online training for Responsible Conduct of Research was also made available.
- **IT Security Risk:** ANR's Privacy and Information Security Board (PISB) was established, with routine meetings and objectives. The PISB has developed a website to gather policies, guidelines, and other resources related to privacy and information security.

UC Berkeley

- **Information Security and Privacy:** The Privacy Office has established a new campus health and privacy information working group to coordinate campus compliance efforts. Several high priority projects have been identified and will be executed during FY 2017.
- **Response to Allegations of Sexual Harassment and Violence:** New investigation and adjudication model rolled out in January 2016. UCB is implementing a new case management system (GME Advocate), aligned with the recommendation about data tracking. Annual training for undergraduates and graduates rolled out in the fall 2015 semester. Mandatory online training for faculty and staff rolled out in February 2016.

- **Federal Fund Accounting:** Developed uniform guidance pre-award and post-award guidance, which has been integrated into the campus's processes for complying with federal grants and contracts, and no longer require a special call-out on the campus's compliance plan.

UC Davis

- **Privacy and Security:** Engaged an external consultant to conduct an information security assessment in fall 2015. The assessment has been completed and UC Davis is in the process of implementing key recommendations resulting from the review. There is a project underway to determine which locations on the main campus have systems that contain sensitive health information and to assess the adequacy of current measures to protect that information from improper access/disclosure. The review should be completed in the coming year and determinations made about next steps.
- **Export Control:** The Provost accepted the recommendations of an Export Control Workgroup and charged an ongoing committee to oversee the development of a comprehensive export control compliance program. The committee meets monthly and is responsible for identifying activities subject to export control regulations, developing a campus-wide export control policy, evaluating and approving written operating procedures related to export control activities, monitoring the status of export control compliance, evaluating complicated or special export control matters, including license determinations, developing an export control website, and enhancing export control compliance through outreach and education.
- **Title IX/Clery:** Like all UC campuses, implemented all changes required by the President's Task Force on Preventing and Responding to Sexual Violence & Sexual Assault and engaged in several best practices in the performance of sexual violence prevention work. This work included the following: developing new adjudication processes, adopting new investigation and adjudication practices, revising our local sexual harassment policy and annual security report, providing sexual violence prevention training to all incoming undergraduate, graduate and professional students, providing sexual violence prevention training to faculty and staff and monitoring completion of this training, ensuring all key personnel received skill-based training, rolling out a new awareness campaign, enhancing our sexual violence website and reporting metrics to our campus community.

UC Irvine

- **Lab Safety:** Increased Environmental Health & Safety (EH&S) presence in lab areas along with the frequency and types of inspections and hazards that are monitored. Reporting practices were enhanced to generate metrics that can be shared with department chairs and deans. Metrics were established to identify hazards and assess risks based on likelihood and severity, which increased deficiency correction rates to 86%.
- **Cybersecurity:** Implemented mandatory cybersecurity training for all staff, students, and faculty and provided Security Staff Training. Implemented two-factor authentication as a security measure for employees to login onto their workstation computer. Implemented new systems to improve cybersecurity, Intrusion Detection and Threat Analysis and enterprise vulnerability scanning.
- **Major Systems Implementation:** Major student information system replacement project, SIS (Student Information System), underway since early 2015, has scheduled go-live dates staggered throughout fall 2017 to summer 2018. Oversight provided by SIS Project leadership to ensure new systems are operational, on schedule, and within budget.

UCLA

- **Sponsored Research Auditing:** Audit & Advisory Services monitored and oversaw the NSF Office of the Inspector General audits and investigations of UCLA's NSF programs and 19 other external audits.

- **Export Controls:** Coordinating with UCOP and the local Research Administration on expanding knowledge of export control compliance issues. Working with Campus Research Compliance on export control compliance and providing audit and financial support when needed.
- **Website:** Combining the websites from Administrative Polices and Compliance and the Campus Ethics and Compliance Groups into one under the Chancellor's Office. Website to provide general guidance and direction related to the campus compliance program in addition to linking to the UCOP and other campus compliance sites.

UC Merced

- **Child Abuse and Neglect Reporting Act (CANRA):** Implemented campus CANRA assurance process and received the first annual certification letters from Responsible Officials and Offices. Responsible Offices performed a review of employees and provided lists of Mandated Reporters in their units. As of October 31, 2015, Responsible Offices reported identifying and obtaining signed acknowledgments from 1,212 employees.
- **Hiring Practices:** Internal Audit completed a hiring practices audit that identified improvement opportunities in recruiting and hiring practices. Management drafted a plan to implement a more rigorous recruitment and hiring process with more stringent controls throughout the end to end process. The new process and requirements will be rolled-out and monitored during FY 2017.
- **Lab Safety:** Continued to monitor lab safety compliance and track results of lab inspections. Completed 34 lab inspections and reported 11 major and 288 minor violations. Resolved 91% of major and 42% of minor violations. Offered 74 in-person training classes and 10 online courses, with a total of 709 staff trained this year. Working to develop a dashboard to highlight issues and metrics around languishing findings to drive better accountability. Additionally, drafted a new lab safety policy and will roll out a new escalation process during FY 2017 to improve cycle time of finding and issuing resolutions.

UC Riverside

- **Emergency Management/Business Continuity Planning:** With the Campus Emergency Manager taking the lead, a variety of educational and informational resources were developed to prepare the campus Emergency Management Policy Group (EMPG) and senior leaders to better understand and effectively execute their roles and responsibilities in response to campus-wide, community, regional, state, national, and international emergencies. These resources include the drafting and implementing of a long-range training plan for EMPG members and senior leaders and the creation of two resource websites for emergency management and emergency services.
- **Health Sciences Compliance:** Under the oversight of the Director for Clinical Compliance and Privacy, the School of Medicine (SOM) has put in place an active compliance program that continues to identify and addresses federal, state, and institutional requirements. Highlights of these on-going efforts include: 1) commissioning of a SOM Compliance Committee; 2) implementing of an SOM Compliance website; and 3) introducing of a number of self-study modules that deal with a host of compliance concerns relating to HS. Additionally, the SOM brought on board a Compliance Analyst and a Contracts Manager, both supporting the Director for Clinical Compliance and Privacy.
- **Lab Safety and Integrity:** Using the UC Regents Agreement Compliance Internal Timeline as a guide, the EH&S Director closely monitored, verified and reported that the UCR successfully complied with the terms and conditions of UC Regents settlement agreement and continues to comply with associated regulatory requirements. Through a variety of initiatives, including: 1) quarterly lab safety status reports—providing key metrics to senior leadership; 2) an EH&S SharePoint site containing an electronic library of safety-related concerns; 3) a Hazard Assessment website with a variety of analytical and assessment tools; and 4) the augmentation of additional human resources to assess labs

and advise researchers, the campus continues to enhance the effectiveness of its Laboratory Safety Status Compliance program.

UC San Diego

- **Title IX & Clery Act:** Under the leadership of the Clery Compliance Officer, partnerships were enhanced with Student Conduct, CARE, Residence Life, the Office for the Prevention of Harassment & Discrimination, UCSD PD, EH&S, Fire Marshall, Real Estate, Capital Planning and many others. In-depth compliance reviews occurred related to crime statistic and student disciplinary reporting. Timely Warning templates for all Clery crimes were created and implemented and new training programs were developed and conducted for required reporters (CSAs). A substantial compliance review of all UCSD Clery geography is in progress. All requirements of the *UC President's Task Force on Preventing and Responding to Sexual Violence & Sexual Assault* have been implemented.
- **Governance:** A Risk Steering Committee has been established to continue development of organization-wide risk intelligence. The Committee will conduct on-going risk assessments, work with each Vice Chancellor area and other identified groups to increase UCSD's capacity to identify, prioritize and manage significant risks.
- **Investigations, Prevention and Education related to Workplace Misconduct:** A new investigations team has been created within the Office of Ethics and Compliance. Tasked with Hotline management, developing a cost-efficient case management system for use by several units, conducting investigations and identifying workplace misconduct trends across all of UCSD, this unit will work with the Risk Steering Committee to identify misconduct trends that present significant risks and will recommend actions to be taken to decrease those risks.

UC San Francisco

- **Human Research Protection Program (HRPP):** A new HRPP Director was hired with the goal of streamlining and modernizing the Institutional Review Board (IRB) processes. Several new and improved versions of the IRB application have been deployed. The Director has completed extensive outreach and provided support for a wide range of investigators. Three new key hires have been hired to replace departing staff and each new staff member brings a wealth of experience and insight.
- **Institutional Animal Care and Use Program:** The Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation inspection for the animal care and use program occurred in fall 2015. Full re-accreditation was secured with no findings and many commendations for an excellent program. A new iPad-based method for conducting required animal inspections was developed and rolled out with success. Process improvement study was developed for testing at a new Institutional Animal Care and Use Committee (IACUC) meeting location at UCSF Mission Bay.
- **New Investigations Unit:** The former Human Resources Investigational Unit was renamed the Investigations Unit and relocated to the Office of Ethics and Compliance. A new Investigations Lead has invigorated the unit and facilitated improved communication and collaboration between the Investigations Unit and Office of Diversity and Outreach.

UC Santa Barbara

- **Clery Act:** The FY 2015-16 Compliance Work Plan reported on campus efforts to create and fill a position in the UCSB Police Department that is fully dedicated to Clery Act compliance, reporting, and outreach and training. Funding for a Clery Coordinator position was approved, and the recruitment was in progress at the end of the fiscal year. Among other duties, this position will be tasked with identifying and training additional CSAs.
- **Lab Safety:** The FY 2015-16 Compliance Work Plan included an Audit and Advisory Services audit of compliance with the terms of the UC Regents Laboratory Safety Settlement for the Department of Chemistry-Biochemistry. The purpose of this audit was to assess whether EH&S and the Department

of Chemistry & Biochemistry have implemented appropriate processes to ensure compliance with Cal/OSHA and settlement regulations and requirements. The audit found no instances of non-compliance with the settlement agreement.

- **Credit Cards/Payment Card Industry Compliance:** There was significant progress in bringing the campus into compliance with Payment Card Industry Data Security Standard (PCI-DSS) requirements. The FY 2015-16 Compliance Work Plan detailed plans for a full-time credit card analyst position, the development of a plan to bring the campus into compliance with the current version of PCI DSS, and an audit of campus PCI compliance. All of these objectives were met. The audit verified that the campus has made significant progress in bringing the campus into compliance, and that the compliance plan it has developed includes the necessary elements for further progress.

UC Santa Cruz

- **Governance Oversight Group:** UCSC successfully launched a new governance structure to advance a risk intelligent culture. A new Risk Intelligence Oversight Committee (RIOC) and Risk Intelligence Working Group (RIWG) began meeting every quarter. The new model also utilizes the Administrative Leadership Team (ALT), which meets weekly and can review any risk mitigations or prevention activities requiring principle officer involvement.
- **Warning and Escalation Indicators:** A predictive indicator work group was formed to generate a draft set of indicators that can be utilized as part of the campus risk sensing activities. Some indicators are leading and some are trailing. Indicators align with the risk intelligence priorities identified for FY 2015-16. The work group will now identify additional indicators to cover risk areas added for FY 2016-17.
- **Communication Model:** This year UCSC launched a new monthly strategic communications meeting with the campus Emergency Management Policy Group (EMPG). This monthly session uses a leadership dashboard, which is updated regularly and contains the highest risk topics for that month. These meetings ensure that the campus is being proactive developing communication strategies, both internally and externally, to address high-profile risk areas.

Lawrence Berkeley National Laboratory

- **Fire Protection:** Fire Protection Program improvements are in progress and proceeding on schedule. Line management conducts periodic program reviews to monitor improvements. Effectiveness reviews have been integrated into the Project Management Plan (PMP), and the Chief Operating Officer chairs the governance board tasked with oversight of the PMP. The Effectiveness Review is scheduled to begin in September 2016.
- **Electrical Safety:** Overseen by A&I, Berkeley Lab EH&S, Facilities, and Engineering divisions developed an Electrical Safety Improvement Plan to identify and mitigate significant risks in this area. Implementation is in progress and proceeding on schedule. Qualified Electrical Worker training and practical certification are in process for Facilities and Engineering. Effectiveness reviews have been integrated into the PMP, and the Chief Operating Officer chairs the governance board tasked with oversight of the PMP. Effectiveness Reviews, scheduled as plan components are finished, are underway, with a final Effectiveness Review scheduled for completion in the third quarter of FY 2017.
- **Work Planning Control:** LBNL completed the transition to Work Planning and Control (WPC) work authorization system on March 15, 2016. The WPC system has replaced three work authorization databases: (1) Job Hazard Analysis, (2) Activity Hazard Document, and (3) Bioauthorization System. Since the launch of WPC on November 3, 2013, over 1,300 work activities have been created and authorized, and approximately 5,200 workers have been added to one or more activities in Activity Manager. Future enhancements include more robust management capabilities for Project Leads, Activity Leads and Supervisors, a nanoregistry component, and an improved renewal process management. An effectiveness review of WPC is scheduled for completion on or before September

30, 2017 and will include participation from multiple divisions through the division self-assessment process.

SUMMARY

This year's highlights and reviews indicate the breadth and oversight of the University of California's compliance program and ECAS's leadership role. The successes indicated in this report are the result of partnerships 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, a strong ethics and compliance 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 are the continued benefits of oversight and monitoring for the University.