

University of California

Office of Ethics, Compliance & Audit Services



ETHICS AND COMPLIANCE PROGRAM PLAN FOR FY 2016 – 17

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I. Background and Overview

The Office of Ethics, Compliance and Audit Services (ECAS) is a Regental Office of the University of California (UC) responsible for leadership, strategic direction, campus guidance and resources to ensure the University fulfills its responsibilities in an ethical environment that is compliant with applicable laws, rules, regulations and University policies. ECAS develops an annual compliance work plan to mitigate non-compliance in high-risk areas and ensure that UC's core mission and objectives are supported by effective compliance controls which are evaluated on a periodic basis. The Senior Vice President and Chief Compliance & Audit Officer provides leadership for the University and as a Regental Office has the unique ability and expertise to direct a compliance program that is transparent, responsive and innovative as the University continues as a leader in education, research and public service.

The University of California Ethics and Compliance Program

Higher Education continues to operate within a strongly regulated environment ripe with regulatory, budget, and emerging cultural pressures. These overarching pressures articulate specific risks identified in this plan and necessitate a compliance program and Work Plan that is transparent and systematic while being fluid and responsive to change at system and local levels.



Figure 1: Overarching Pressures on UC's Compliance Program

The University of California is recognized nationally and internationally as having an industryleading compliance program for higher education. The University's compliance program is framed to support the key values and mission of the University by embracing the seven established elements of an effective compliance program from the United States Sentencing Commission's guidance. This compliance framework mitigates the various risks that constantly pressure the University environment.



Figure 2: The UC Compliance Program Framework

Development of the Plan

The UC Ethics and Compliance Program Plan (Plan) for FY 2016-17 (FY17) is developed in collaboration with the ten campuses, Lawrence Berkeley National Laboratory (LBNL), Office of the President, Division of Agriculture and Natural Resources (ANR), and the five academic medical centers. While the Plan presents the current prevention efforts organized for FY 17, a

key strength of the UC Compliance Program <u>is</u> its ability to change and prevent the impact of emerging issues, trends, and regulatory changes. Consequently, this Plan will change as new pressures, risks, and regulations affect the University. This year's Plan was developed by considering <u>four underlying priorities</u>, <u>identified emerging risks</u>, and the <u>President's Initiatives</u> <u>and Management Directives</u>.



Figure 3: Plan Development

Incorporate Four Underlying Priorities in Plan Development. The FY 17 Compliance Plan draws on the efforts of hundreds of staff across the UC system. As in past years, ECAS provided guidance for each campus's risk assessment and subsequent work plan development. There were four main priorities incorporated into this year's Plan development process.

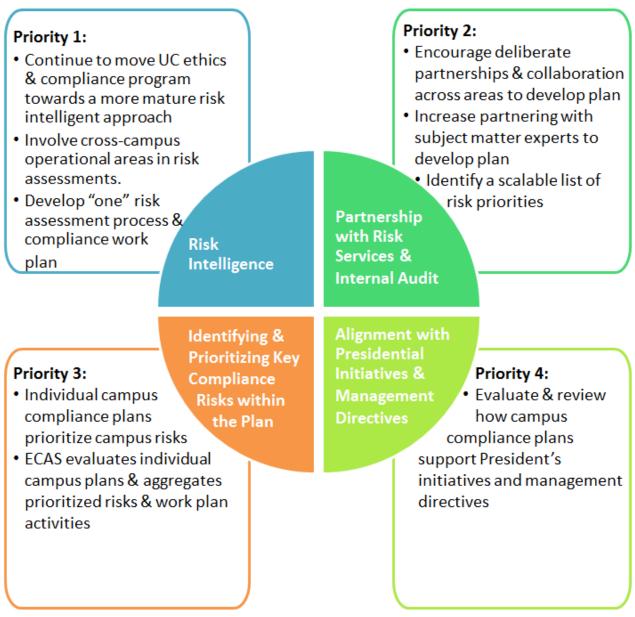


Figure 4: Underlying Priorities in Compliance Plan Development

Identifying Emerging Risks. Utilizing these four priorities within the Plan development process, individual campus plans were reviewed and key emerging areas of risk were identified:

- social media risks for reputation, data security, privacy, and safety
- electronic purchasing card transactions
- common electronic medical record systems
- data privacy and information security concerns
- expansion of the footprint of UC faculty and students in international activities
- foreign transactional compliance requiring improvements in governance and accountability in our relationships abroad

- continued focus on the safety of our students, staff, and faculty
- increased importance of ensuring our campuses are safe, accommodating, and welcoming.

Review President's initiatives and University-wide management directives. This year's campus and systemwide plans identified risks underlying the operationalization of University and President's initiatives in addition to the wide array of other campus risks:

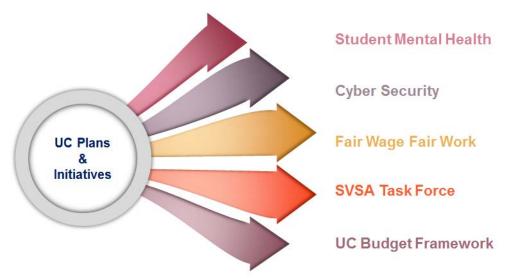


Figure 5: President's Initiatives & Management Directives Specifically Identified in Compliance Plan

Develop Final FY 17 Plan. Campus identified risks—along with risks associated with operationalization of the President's Initiatives and Management Directives, and external systemwide risk pressure—were combined into the eight key areas of risk pressure identified in the FY 17 Plan (See Figure 2): *Safety, Research, Government Reporting, Health Sciences, Data Privacy and Cybersecurity, General, International, and Culture*. Finally, within these eight key risk areas, 30 compliance focus areas were identified and confirmed. These compliance foci form the FY 17 Plan and are expanded and discussed in Section III.

III. Key Compliance Risk Focus Areas

Section III presents the 30 risk focus areas that form the compliance risk priorities for the FY 17 Plan. This Section outlines key goals and related activities that will be undertaken by ECAS to assist the locations in mitigating their specific risks within each of the systemwide prioritized risk areas.



1. Laboratory Safety

<u>Background:</u> Campuses continue to assess and mitigate risks associated with implementing laboratory safety procedures and processes. Environmental Health & Safety (EH & S) has implemented significant programs to improve laboratory safety. However, campuses continue to identify safety in our laboratories as a key risk area.

<u>Challenge</u>: This risk category is also driven by recent emphasis on biosafety and biosecurity, the work of The President's Task Force on Biosafety and Biosecurity, and the subsequent Presidential directives to campuses.

<u>Goal:</u> ECAS will partner with EH & S to assess compliance with the directives in the President's memorandum on biosafety and biosecurity as they are implemented across the system. Monitoring implementation of key laboratory safety requirements and regulations, and working with EH & S to review key training and education initiatives will also continue to be a major focus.

2. Sexual Violence/Sexual Assault Prevention and Response

<u>Background:</u> Continued elevated national awareness remains around sexual violence/sexual assault on college campuses. This is in part due to the Office of Civil Rights (OCR) regulations and investigations, the 2014 California State Audit report and recommendations, and other state and federal legislation. A key effort in FY15 was the implementation and support of the President's Task Force on Preventing and Responding to Sexual Violence and Sexual Assault (SVSA). Eight key initiatives form the substance of the Task Force's recommendations. ECAS will sustain monitoring for campus efforts to meet the goals in these recommendations in FY 17's Plan.

<u>Challenge</u>: The oversight and maintaining the momentum of the efforts surrounding the eight recommendations have been a continuous challenge. Changing work flows and the overall culture within the UC system around sexual violence and sexual assault is complex. The additional challenge is sustainability and it is crucial that, as a system, we continue to evaluate and monitor all of the recommendations and their effectiveness at all 10 locations.

<u>Goal:</u> ECAS will continue to focus monitoring implementation of the SVSA recommendations. In addition, continued focus on developing guidance tools for the CARE advocates and Title IX coordinators to assist them to fulfill their responsibilities and

reporting requirements for Title IX, and the SVSA recommendations. Additionally, offer and deliver targeted training to staff and faculty in related areas. Continued efforts with the campuses will include exploration of emerging issues around sexual violence prevention to ensure the University's model for sexual violence prevention is responsive, innovative and transparent.

3. <u>Clery Act Implementation</u>

<u>Background</u>: The Clery Act is a broad-based campus safety and crime statistic reporting act that requires annual security reports, designating campus security authorities (CSA) and key policy development. Specifically, the Clery Act requires institutions of higher education to collect, classify and publish annual crime statistics, provide statements of security policies to current and prospective students and employees, alert the campus community to emergency situations and provide training to the appropriate campus security authorities responsible for gathering the crime reports.

<u>Challenges:</u> Compliance with the multitude of reporting and notification requirements of the Clery Act continues to be critical as enforcement, review and potential fines by federal agencies are increasing. Campuses are faced with the difficult task of not only identifying the appropriate and typically vast number of CSAs but providing the necessary training to ensure compliance with the Act. As a multi-campus system, it is also incumbent that we are consistent with the interpretation and application of the required compliance requirements. The enforcement and scrutiny in compliance efforts related to sexual violence prevention and response is additionally heightened due to final regulations in the Re-authorization of the Violence Against Women Act (VAWA) as part of the Clery Act.

<u>Goals:</u> The following goals will be addressed by ECAS during FY 17:

- Guidance, coordination across campuses and training will be led by ECAS to support compliance with the Clery Act (including VAWA).
- Finalize the UC systemwide policy on Clery Act requirements.
- Continue providing systemwide leadership and training to the campus Clery Act Coordinators and the campus security authorities (CSAs).
- Conduct data analysis on nationwide Clery data submitted to the U.S. Department of Education to identify gaps, trends, and comparisons among UC campuses to develop appropriate tools and resources to support campus implementation of safety and crime prevention programs.



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

1. <u>The Common Rule</u>

<u>Background:</u> In 2011, the Office of Human Research Protections (OHRP) 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.

<u>Challenge</u>: 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.

<u>Goals:</u> This year ECAS will:

- Identify gaps and risks associated with revised human research protection regulations.
- Assist campuses in the development of common interpretations of the new regulations and guide implementation plans to ensure compliance.

2. Dual Use Research of Concern (DURC)

<u>Background:</u> In response to the H1N1 influenza controversy of 2012, the National Institutes of Health promulgated new regulations and requirements for certain biological Select Agents (biological agents and toxins that the Departments of Health and Human Services (HHS) and Agriculture (USDA) 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.

<u>Challenge</u>: 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.

<u>Goal:</u> Assess DURC policy implementation at all campuses. Evaluate process gaps and redundancies to ensure that DURC regulations are enforced

3. <u>Research Compliance Strategic Plan</u>

<u>Background:</u> In light of the NAS report, strategic coordination of research compliance risk areas is critical. The Research Compliance Advisory Committee (RCAC) is the primary system-wide work group devoted to Research Compliance. RCAC met late 1025 to discuss past accomplishments and future goals and strategic needs for the system.

<u>Challenge:</u> Research Compliance at the campus level is dispersed among many area-specific units (i.e., human research protections, animal welfare, biosafety, lab safety, conflict of interest, export control, research integrity). Campuses look to ECAS for assistance in understanding/addressing specific questions that arise from their work; in identifying trends and commonalities across the system; in developing guidance and training materials that may be adapted to the local level. RCAC recommended areas of focus: Research Integrity/Research Misconduct; Export Control Program; Dual Use Research of Concern; Drones in Research; Conflict of Interest in new entrepreneurial activities.

<u>Goals</u>: Assess the status of Research Compliance programs across the system and develop a 5-year strategic research compliance plan that emphasized coordination of efforts and reduces redundancies.

- Develop regular meetings of the Research Integrity Officers to develop best practices, shared tools, and resources.
- Conduct regular system-wide discussions with Vice Chancellors Research, Assistant Vice Chancellors Research to identify gaps, needs, and opportunities for strategic alliances and partnerships.

4. Export Control Program Strategic Review

<u>Background</u>: Export control regulations create a complex environment for research involving advanced technologies, materials, travel, and collaborations. An effective export control program requires on-the-ground expertise and comprehensive support systems so that researchers' needs may be addressed quickly and efficiently.

<u>Challenge</u>: Export Control authority and responsibility currently resides within ECAS even though research activities and direct line reporting occurs entirely at the campus level. This structure may be outdated now that campuses have developed more robust local programs.

<u>Goals</u>: Export Control Program Strategic Review: Continue the development of a new strategic plan for export controls. Ensuring that our program is structured appropriately to maximize compliance efforts is critical.

- Form an initial work group (with campus, OGC, and RPAC participation) to model alternative approaches and to make recommendations about the strategic plan of the program. Convene campus representatives to assess alternative models and make a recommendation to the Senior Vice President Ethics and Compliance for program strategic directions.
- Implement system-wide Export Control policy.
- Implement changed language in the standard Terms and Conditions used by Procurement to avoid export controlled items coming on campus without proper controls. Audit use of these terms by Procurement across 10 campuses.

5. Conflict of Interest/Conflict of Commitment in Research

<u>Background</u>: As the University engages in new and innovative research partnerships and collaborations, conflict of interest and conflict of commitment issues arise.

<u>Challenge</u>: New relationships and partnerships may fall outside the current policies and procedures for disclosure, institutional review, and management of conflicts of interest, creating the possibility of bias in the resulting research and exposing the University to public concerns of undue influence.

<u>Goals</u>: ECAS will continue to work closely with the campus Conflict of Interest officers to monitor emerging partnerships, develop guidance for managing new relationships, and providing oversight of management plans, when necessary.



1. <u>Uniform Guidance</u>

Background: The Uniform Guidance represents the federal government's effort to revise the long-standing 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.

<u>Challenge</u>: 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.

<u>Goals</u>: Partner with Internal Audit to begin targeted reviews of internal controls. Work with campuses to develop consistent system-wide approach to agencies failing to adopt the UG as a single standard.

2. Clery Annual Security Report (ASR) reporting

<u>Background</u>: The Clery Act requires that institutions of higher education collect and classify certain crime statistics and publish these crime statistics in an annual security report (ASR). The ASRs are public and listed on the campus websites.

<u>Challenge</u>: As a multi-campus system, each campus collects, collates, and reports their own data. However, as one legal entity, maintaining consistency with the interpretation and application of the required compliance requirements, including the collecting of consistent data across the system, is a challenge. The myriad of definitions, Clery guidance, and legal interpretations make it challenging to be be consistent and clear across the U.S. let alone within the University.

<u>Goal</u>: Support consistent data collection of Clery crimes with the development of a UC template for the campus annual security reports.



1. <u>International Activities</u>

<u>Background:</u> UC's international presence around the globe continues to expand. With expansion has come increased compliance monitoring activity and enforcement by the federal government. This increase reflects the climate of national security issues existing today. Development of the International web portal, UCGO, is on target for a June 30 targeted go-live.

The Provost's International Activities Policy Work Group is circulating a draft International Activities policy for review and revision. Upon policy acceptance and implementation, UCGO will need to provide consistent and, at times, new support for this policy.

<u>Challenges:</u> Changes in applicability of the Foreign Corruption Practices Act (FCPA) to higher education provide both opportunities and challenges for UC. Intercollegiate consortia, sponsored research, research collaborations, international alumni relations, foundations, trusts, etc., increase the pressure on UC to ensure compliance with both U.S. and multinational laws and regulations.

Goals: This year ECAS will work to:

- Identify new areas for UCGO to allow and support full implementation of a new system-wide International Activities policy.
- Further enhance training opportunities related to international compliance and evaluate and promote policy development around areas that are currently underdeveloped, including, for instance, FCPA, data privacy and security in international contexts, and the convergence of compliance regulations in complex situations such as foreign affiliates and overseas partnerships.



"The law [Affordable Care Act] is also a serious platform for improving the quality of healthcare and changing the delivery system so we stop doing things that don't work for patients and start doing things that will work. It's about better care: care that is safe, timely effective, efficient, equitable and patient centered."

> Secretary Kathleen Sebelius U.S. Department of Health and Human Services IHI Annual Meeting December 7, 2010

1. ACA Reimbursement Reform: Focus on Quality

Background: The ACA has resulted in a shift away from volume-driven care and towards value-driven care. On April 27, 2016, the Department of Health and Human Services (HHS) issued a proposed rule to begin implementing provisions of the Medicare Access and CHIP Reauthorization Act (MACRA). MACRA, signed into law in 2015, will transform health care delivery and reimbursement linking physician and hospital payments to quality care. MACRA will provide payment incentives for meeting quality and outcome measures; demonstrating how electronic technology is used to coordinate care; implementing clinical practice improvements, such as activities focused on care coordination, beneficiary engagement, and patient safety; and using Medicare resources more efficiently.

The transition from relying exclusively on single encounter documentation to determine medical necessity and appropriate reimbursement will be disruptive. New performance categories and quality measures will determine reimbursement and providers as well as hospitals must submit correct data on quality, resource use, clinical practice improvement activities and meaningful use of certified electronic health record technology as a condition of payment. Under MACRA, CMS proposes to begin measuring performance for doctors and hospitals in 2017, with payments based on those measures to begin in 2019. In this new reimbursement environment, compliance offices will be challenged to implement new

compliance activities and work closely with business operations to effectively monitor the program integrity provisions of MACRA.

<u>Challenge:</u> Under MACRA, CMS proposes to begin measuring performance for doctors and hospitals in 2017, with payments based on those measures to begin in 2019. In this new reimbursement environment, compliance offices will be challenged to implement new compliance activities and work closely with business operations to effectively monitor the program integrity provisions of MACRA.

<u>Goals</u>: Work with key stakeholders to prepare proactively for MACRA implementation. Assess the quality measure reporting process and develop monitoring activities to ensure compliance.

2. Health Sciences Compliance Strategic Plan

<u>Background:</u> In FY 17, compliance programs at Davis, Irvine, Los Angeles, and San Diego will have new leadership. Due to the competitive local health care markets and state and federal regulatory changes and enforcement activities, ECAS will evaluate current compliance governance structures and practices in support of program objectives. New leadership provides an opportunity to identify best practices and pinpoint gaps in compliance program activities. ECAS will recommend process improvements, identify opportunities to align processes, procedures and tools, and develop local and systemwide compliance initiatives to support UC Health Strategic Priorities.

<u>Challenge:</u> A strategic plan helps to provide direction and focus to meet operational objectives. The Health Sciences Compliance Strategic Plan provides senior leadership, the new UC Health Services Committee and The Regents with insight into key Health Sciences compliance risks and the activities being undertaken to mitigate those risks. The challenge is to develop a consensus view of the top risks, resulting from structured and comprehensive conversations with managers across health system functions so that the strategic plan points to specific compliance results that are to be achieved and establishes a course of action for achieving them. The strategic plan must assist the various units in the health system align themselves with common goals.

<u>Goals</u>: Assess the status of Health Sciences Compliance programs across the system and develop a 5-year strategic health sciences compliance plan. Facilitate regular meetings with the Office of General Counsel – Health Law Group and UC Health. Establish work groups to develop systemwide compliance initiatives in four UC Health operational priority areas: Clinical Research Billing Clinical Research Billing, Conflict of Interest/Conflict of

Commitment, Telehealth/Telemedicine, and Clinically Integrated Networks. Identify gaps, needs, and opportunities for strategic alliances and partnerships.

3. Clinical Research Billing

<u>Background:</u> Clinical research billing (CRB) continues to present challenges to health care providers. The interpretation of reimbursable clinical items and services is being challenged by requirements for enhanced documentation for claim payment and appeal processes. The key to compliant clinical research billing is the seamless exchange of information across distinct units of the research enterprise. Clear processes for managing study-related charges and the proper oversight of offices/individuals assigned to a function in the process are critical to mitigate risks of inaccurately billed services and non-compliance with clinical research billing rules.

<u>Challenge</u>: The challenge is to improve organizational communication on implementation questions related to the CRB policy, procedures (coverage analyses, clinical trial modifiers), the clinical trial management system, study data management, and billing review tools.

<u>Goals:</u> ECAS will establish a Clinical Research Billing work group to review the clinical research billing processes and procedures and assess the extent that campus processes include timely Coverage Analyses, coordination with Institutional Review Boards (IRBs) and appropriate charges to third party payers. The CRB work group will identify new areas for systemwide collaboration and evaluate risks and develop systemwide approaches to mitigate these risks in an effective and consistent manner. Training opportunities related to clinical research billing and coverage analysis will be enhanced.

4. Telehealth/Telemedicine

<u>Background:</u> UC Health is exploring the use of telemedicine to deliver real-time clinical services to patients at locations beyond hospitals and physician offices. Nationally, telemedicine is experiencing rapid growth and deployment across a variety of applications. The quick market adoption of telemedicine is fueled by powerful economic, social, and political forces — most notably, the growing consumer demand for more affordable and accessible care. UC researchers have found that providing remote monitoring and access to specialty care not only enhance patient safety but are also cost-effective measures in most cases and can even be cost-saving in certain circumstances. While telemedicine enables providers to better treat patients and expand access to care, it presents compliance challenges in licensing, credentialing, prescribing, treatment, and reimbursement.

<u>Challenge</u>: While telemedicine enables providers to better treat patients and expand access to care, it presents compliance challenges in licensing, credentialing, prescribing, treatment, and reimbursement.

Goals: ECAS will:

- Establish a Telehealth/Telemedince work group to monitor regulatory changes, identify compliant operational structures and assist in compliance efforts.
- Partner with UC Health (and the UC Telehealth Initiative at the Center for Health Quality and Innovation) to assess the impact and develop new policies and guidelines as necessary.

5. <u>Clinically Integrated Networks</u>

<u>Background:</u> A stated goal of health reform is to foster greater integration and collaboration among health care providers to improve patient care and reduce health care costs. UC is forming clinically integrated networks (CINs) to manage health care services and improve health care delivery for populations of patients. There are challenges in structuring CINs in compliance with federal regulations and applicable health care laws.

<u>Challenge:</u> Clinical integration holds the promise of greater quality and improved efficiency in delivering patient-centered care. However, UC Health faces a number of legal and regulatory barriers while embarking on clinical integration. There are challenges in structuring CINs that involve collaboration among different health care providers and sites so that they are in compliance with federal regulations and applicable health care laws.

Goals: In FY 17, ECAS will:

• Establish a Clinically Integrated Networks work group to identify compliance issues and develop systemwide compliance activities during program development and implementation to meet federal requirements for CINs.



In FY 17, UC Privacy will focus its efforts on identifying gaps, developing consistent approaches to response, and educating subject-matter experts on chosen solutions.

1. Identifying Gaps

<u>Background:</u> Privacy obligations can be found across many areas of UC's work; sometimes there are competing privacy obligations in a given area. When this occurs, UC Privacy professional work

with the UC community to identify and then close gaps in UC process.

<u>Challenges:</u> The federal patient privacy protections under HIPAA carve out a specific exception for student care, stating that the associated Federal Education Rights Privacy Act (FERPA) will control. For a large university serving a complex population, this creates confusion and difficulty in providing health care services in a compliant manner. Additionally, the guidance provided to explain certain nuances between HIPAA and other legal protections for human subjects research, require focus and cross-functional subject matter experts to determine that UC is following its legal requirements.

Goal: For FY 17, ECAS will:

- Develop training and guidance concerning areas of intersecting privacy obligations.
- Focus compliance efforts, resources, and guidance on student health and its intersecting obligations under Federal Education Rights Privacy Act (FERPA) and HIPAA, as well as privacy of research subjects under Common Rule and HIPAA.

2. Developing Consistent Approaches to Address Privacy Concerns

<u>Background:</u> UC locations have been combining efforts to better lower risks involving certain privacy obligations, particularly when using technology in new ways. Specifically, UC Health locations, drone use on campuses, and increased use of cameras on campus are pushing the boundaries on privacy concerns. Researchers, UC colleagues, and privacy advocates continue to engage in robust conversations about balancing privacy responsibilities with research and campus safety concerns.

<u>Challenges:</u> Data sharing and collaboration is growing in almost every sector of our institution. Grant awarding institutions, particularly the National Science Foundation and the National Institute of Health have made it clear that they expect researchers to collaborate across areas of expertise, sites, and institutions. Regulators and patients expect us to find newer and more convenient ways to share information with patients securely. Our staff are always looking for ways to use technology to strengthen our campus safety initiatives. Each pressure is for a strong reason, but also requires balancing newly-created challenges around the privacy and security data protections because there are additional state and even international protections that may come into play.

Goal: ECAS, in FY 17 will:

- Review and finalize key policies and templates necessary to ensure consistent mitigation of privacy risks.
- Revise as necessary the UC HIPAA policies and condensed Records Management and Privacy Policy.

• Assist in safeguarding privacy concerns within UC policies on drones and video security cameras.

3. Educating UC Community on Privacy

<u>Background:</u> UC privacy experts continue to provide training and education about key privacy risks. In addition, advising the UC community about evolving privacy risks continues to be of critical importance.

<u>Challenges:</u> In a large, decentralized university community, UC must work to make faculty, students, and staff understand their role in safeguarding data entrusted to UC. While UC understands its compliance obligations, we must work it is challenging to operationalize those obligations in a way that includes all parties.

Goal: In FY 17, ECAS will:

- Provide training to UC Privacy professionals on emerging risks and changes to UC procedures, including:
 - Key issues in working with patient data and research
 - Understanding and negotiating obligations for HIPAA business associates
 - Providing baseline HIPAA training for campus professionals advising researchers.

4. Cybersecurity Awareness and Training

<u>Background</u>: Cybersecurity including attacks on our information technology systems continues to be of highest priority for the University. This increased threat on our infrastructure requires continued vigilance and concerted efforts to mitigate and prevent these cyber-attacks. Important work was done in FY16 to educate all UC staff about the basics of preventing cyberattacks. However, the effort, training, and education must continue to lessen the vulnerability of our systems.

<u>Challenge</u>: The reality of today's technologically-savvy environment is that attempts to breach the UC cyber system are made thousands of time each day. Ensuring that our faculty, staff, and students that access our network, rely on it for their research and education, and need to trust its security is a continual challenge.

<u>Goals</u>: This year ECAS will:

• Partner with Informational Technology to conduct a systemwide cybersecurity risk assessment to baseline risks and controls at each location and help inform cyberrisk governance, inform risk reduction decisions, and prioritize

- Perform vulnerability assessments and penetration testing at all UC locations.
- Evaluate options to offer an advanced cybersecurity awareness training course that could be serve as another option to satisfy completion of this training requirement for faculty and staff.
- Evaluate methods for cybersecurity awareness training for students at each location as supported by the Vice Chancellors of Student Affairs.

5. PCI Standards

<u>Background</u>: The Payment Card Industry (PCI) data security standard (DSS) is required for all entities involved in processing payment cards including all entities that store, process, or transmit cardholder data and/or sensitive authentication data related to payment cards. Failure to comply with PCI can result in steep fines and penalties levied by the card brands, revocation of credit card payment services, or even suspension of accounts. In addition, data breeches related to noncompliance with PCI DSS can result in lawsuits, and other associated cybersecurity incident response costs.

<u>Challenge</u>: The distributed nature of IT services and the varying methods to accept payment cards in various lines of business across the University create a challenge to ensure units are taking the proper steps to be in compliance with PCI. In addition, the evolving nature of the PCI standard from year to year and the annual assessment processes and oversight of PCI at each campus location can be a challenge.

Goals: During FY 17, ECAS will:

- Partner with finance and cybersecurity to ensure appropriate steps are being taken to enhance ability to support campuses in securing payment card data and being compliance with PCI.
- Identify gaps and needs to assist in compliance efforts across the system.



1. <u>UAV/Drones</u>

<u>Background</u>: Over the past 5 years, the use of unmanned aerial vehicles ("drones") has grown significantly. UC researchers use drones to conduct research in a variety of contexts, including coastline erosion surveys, marine mammal migrations, and natural habitat evolution. Drones are also used for UC public affairs projects, athletics, and student engineering clubs. Current Federal

Aviation Administration (FAA) regulations covering drone uses are complex, changing, and unfamiliar to many in the academic setting.

<u>Challenge</u>: Expected revisions to the Federal Aviation Administration regulations governing the use of UAV's are forthcoming. These changes will likely impact not only research drones, but also the widespread use of drones for campus publicity, athletics, and student clubs.

Goals: During FY 17, ECAS will:

- Monitor regulatory changes.
- Partner with Risk Management (and the newly established UAV Center of Excellence) to assess the impact and develop new policies and guidelines as necessary.
- Identify gaps and needs to assist in compliance efforts.

2. Conflict of Interest/Conflict of Commitment

<u>Background:</u> Conflict of Interest (COI) and Conflict of Commitment (COC) authority and responsibility currently resides in separate units and direct reporting occurs entirely at the departmental level. This structure may not be optimal for ensuring compliance.

<u>Challenge</u>: Conflicts of interest and conflicts of commitment must be recognized and identified, then managed, reduced, or eliminated. The institutional challenge is that multiple functional areas across UC require reporting of COI-COC and current systems are not designed to recognize multiple disclosures of financial interests or share the information so that COI/COC can be effectively mitigated.

Goals: ECAS will:

- Establish a Conflict of Interest/Conflict of Commitment work group to review reporting processes, map units involved in COI/COC reporting, review, decision making and management, and recommend process improvements to ensure compliance.
- Continue ongoing work in conjunction with the American Association of Medical Colleges (AAMC) to partner and develop Convey, a comprehensive, tool for tracking and managing conflict of interest and reporting outside professional activities and compensation.

3. Third-Party Relationships Risks

<u>Background</u>: UC's ability to partner with key entities, businesses, institutions and community agencies is key to its leadership in the world. A strategic focus for UC is innovation partnership to increase the University's footprint, reputation, legacy and

financial foundation. However, campuses identified that this increased network of partners increases possible risks that come with memoranda of understanding, affiliation agreements, partnership arrangements and joint ventures.

<u>Challenges:</u> Regulators have become more focused on how organizations are managing third-party risk associated with affiliation agreements, partnership arrangements and joint ventures. Although the University faces greater scrutiny in this area, third-party risk has not been institutionally examined nor has a framework and defined process for assessing third-party risk been developed. The challenge is to define the risks inherent in third-party relationships and determine appropriate steps to mitigate and properly manage these risks.

Goal: In FY 17, ECAS will:

- Coordinate efforts across the system to inventory key legal, compliance, risk and regulatory issues that can arise from third-party arrangements.
- Share this inventory with senior leadership along with suggested guidance.

4. UCPath

<u>Background:</u> UCPath is the University's priority program to implement a single payroll, benefits, human resources, and academic personnel solution for all UC employees. In November 2015, the University successfully deployed UCPath at UCOP and operationalized the UCPath Center in Riverside. The PMO has targeted August 2017 for the campus pilot deployment, which is planned to include UCLA, ASUCLA, UC Riverside and UC Merced.

<u>Challenge:</u> While the UCOP deployment was successful, the upcoming campus pilot deployment brings a significant amount of additional complexity to the implementation with the introduction of the academic and health system environments. With this additional complexity, it will be important to both implement the lessons learned from the UCOP deployment, and have sound project management and risk management practices in place to ensure objectives are met.

Goal: This year ECAS will:

- Monitor, in collaboration with Audit Services and Risk Services, ongoing implementation of UCPath to identify and mitigate risks associated with people (governance, risk management, organizational change management) process (future state process and control design), and technology (system implementation best practices, security).
- Work with the UCPath PMO and campus leadership to communicate and address compliance concerns resulting from UCPath implementation.

5. Compliance and Risk Mitigation Education and Training

<u>Background</u>: The provision of systemwide training and education around a myriad of compliance issues is embedded throughout the Plan for FY 17.

<u>Challenge</u>: Training and education—both for ongoing issues and emergent "just in time" issues—is critical for a transparent and effective compliance program.

Goal: In FY 17, ECAS will:

- Continue to develop and support leading-edge training and education programs on specific compliance topics. These trainings will include:
 - Delivery of revised general ethics and compliance courses for all faculty and staff
 - Launch new online required training on conflict of interest for researchers training
 - New courses implementing sexual violence prevention information for students, faculty and staff
 - o Continued trainings in cybersecurity prevention and support
 - Training for campus security authorities (CSAs)
 - Specific, focused trainings for topics of need as identified by this Plan and new compliance risks.



Working to maintain a culture of ethics and compliance requires constant education, training, and assessment of current efforts. This year's plan includes ongoing efforts in addition to new foci.

1. <u>ADA/EEOC/Accessibility (including electronic</u> accessibility)/Fair Wage-Fair Work

<u>Background:</u> The Americans with Disabilities Act (ADA), Equal Employment Opportunity Commission (EEOC) regulations, and the

California Fair Employment and Housing Act (FEHA) continue to be crucial legislation for campuses and pose significant compliance risks. Specifically, these regulations mandate electronic accessibility to information technology for students, faculty and staff. In addition, new amendments to FEHA require that key policies be translated into languages other than English when 10% of the workforce uses that language as their primary language. Finally, the University's new "Fair Wage, Fair Work" policy and President initiative requires awareness and education around a variety of operational issues.

<u>Challenge</u>: The increased reliance on computer technology for all facets of University business highlight the risk of non-compliance with mandatory access issues. For instance, campuses must provide equivalent access for students, faculty and staff who require information technology for their work. Language translations of key policies, training materials, and websites is also needed. As campuses comply with the University's Fair Wage, Fair Work initiatives, campuses need to review policies, procedures, budgets, and hiring practices to comply.

Goals: ECAS will:

- Facilitate the review of questions and issues around IT accessibility by partnering IT Services and Risk Services to develop necessary policies, trainings and recommendations for senior leadership.
- Work with systemwide and campus resources to translate key policies and trainings into appropriate languages.
- Monitor and develop tools and resources as necessary with campuses, internal audit, and key offices as they comply with the Fair Work, Fair Wage initiatives and mandate.

2. Student Health

Background: The University of California has long recognized student health and wellness to be an ongoing and urgent issue for our campuses. The University has developed a comprehensive framework for meeting the fundamental mental health needs of our students and providing for safe and healthy campus environments across the system. Broadening the resources available to improve student mental health services, intensifying contagious disease preparedness and strengthening efforts to combat drug and alcohol abuse are systemwide initiatives underway to expand the wide range of services available to assist our students in maintaining their mental and physical health and maximizing their intellectual growth.

<u>Challenge</u>: Most campuses have multi-disciplinary teams to provide critical mental health services, respond to emerging public health threats and address the issue of campus and community alcohol and drug-related problems. The challenge is to expand education, prevention, surveillance, and various controls to manage these services to create healthier learning environments.

Goals: In FY 17, ECAS will:

• Encourage collaborative partnerships on the campuses and in the community that build upon our extensive Student Health and Counseling Center programs aimed at

improving services to address the most relevant student mental health and wellness issues.

 Actively engage our diverse students to promote mental health awareness, expand contagious disease preparedness activities, and strengthen drug and alcohol abuse prevention programs.

3. Standards of Conduct and Policies & Procedures

<u>Background:</u> The University's Standards of Ethical Values and Conduct, delegations of authority, and library of policies and procedures form the underpinnings of carrying out the University's mission. ECAS manages the University Policy Office (UPO) where the Presidential policies are processed and monitored. Working in partnership with key policy owners and business partners across the system, the UPO is the repository for all these key documents and is responsible for ensuring they are accessible, timely, accurate, and available.

<u>Challenges:</u> The oversight and maintaining of the momentum, review, accuracy, and accessibility for over 400 Presidential policies and over 100 delegations of authority requires constant vigilance and working with hundreds of staff and senior leaders.

Goal: In FY 17, ECAS will:

• Refine the UPO process and work with key business owners and campus policy managers to streamline the development process, review all Presidential policies, and increase the accessibility of University policies for all audiences.

4. Compliance Program Review

<u>Background</u>: A key component of an effective compliance program is ongoing assessment of the program. While UC's compliance program has undergone previous outside reviews, the changing landscape across the university culture mandates continual reviews.

<u>Challenge</u>: There are many key staff vacancies in the compliance program due to retirements and personnel changes. In addition, many campuses have undergone restructuring to improve the visibility and strength of the compliance program. This changing culture provides a good opportunity to review the "state of compliance" across the University.

Goal: In FY 17, ECAS will

- Conduct a comprehensive review of both healthcare and campus compliance efforts on each campus. This review initiative will guide ECAS's strategic leadership efforts of the UC compliance program ensuring sustainability, transparency, and ongoing focus on the highest levels of compliance. The objectives for this review are to:
 - Update compliance infrastructure information for each location

- Identify best practices implemented in campus compliance programs
- Understand how compliance programs are integrated within the research, academic, and operational structures
- Work with campus leadership to identify areas for improvement and change to better effectiveness of the compliance program.

IV. Summary

The Compliance Plan for FY 17 includes 30 overarching goals within eight key high level risk areas. The Plan was developed in collaboration with the campuses and discussion with the Campus Ethics and Compliance Officers. During the year, ECAS will further review and refine the goals and objectives related to this Plan in partnership with key senior leaders, business owners, and campus leadership.

Future Steps: As our risk intelligent model for compliance expands, ECAS will continue to foster critical relationships with cross-functional risk owners to share different perspectives and reduce duplication of effort and conserve resources. For FY 17, ECAS will continue working with the campus ethics, compliance and risk committees and mid-management compliance risk committees to help implement a "best practices" to continue implementing UC's model of risk intelligence.

It is also important to realize that due to the dynamic nature of risks, the goals in the FY 17 Compliance Plan may be revised during the fiscal year to meet additional priorities or other business risks identified by the University, initiated by the Regents, or directed by the President. Changes necessary to respond to emerging or new risks will be incorporated into the Plan and required revisions will be aggregated on a periodic basis and reported to the Regents' Compliance and Audit Committee.

Our ongoing goal is to maintain the University of California's premier status as having a highquality, effective compliance program with the "best practices" in place. ECAS staff is involved with a variety of external collaborations that provide a forum to discuss and review compliance program best practices and process improvements. Maintaining our status challenges the UC compliance program to have the most robust, transparent, and responsive compliance program among higher education campuses. This challenge drives our passion for effective compliance and commitment to the University of California.