UNIVERSITY OF CALIFORNIA

Ethics, Compliance and Audit Services

Annual Report 2019-20

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I. EXECUTIVE SUMMARY

The University of California (UC) is the world's leading public research university system and, as such, is routinely on the cutting edge of discovery in a multitude of fields and disciplines. This spirit of innovation and drive for discovery often occurs within a highly complex and evolving compliance landscape that touches every aspect of the University's operations.

The University is committed to the highest ethical standards in furtherance of its mission of teaching, research and public service. The University's Statement of Ethical Values and Standards of Ethical Conduct sets forth expectations for all of the University's operations.[1]

The Office of Ethics, Compliance and Audit Services (ECAS) is responsible for developing and administering UC's compliance and audit programs, ensuring that the University is in compliance with professional standards; internal policies and procedures; and all applicable local, national and international laws and regulations. ECAS accomplishes this mission through active collaboration with our risk, audit and compliance partners throughout the system as well as our state and federal partners.

Each year ECAS works with the ten campuses, Lawrence Berkeley National Laboratory (LBNL), the UC Office of the President (UCOP), the Division of Agriculture and Natural Resources (ANR), and the five UC academic medical centers (AMCs) in identifying their risk priorities and in developing and executing related annual work plans. This annual report sets forth the audit, compliance and investigations structures throughout the University of California and highlights the focus and outcomes of these functions' activities throughout the system for fiscal year (FY) 2019-20. It also reviews the impact of the COVID-19 pandemic on the regulatory compliance and audit functions and the challenges of keeping up with the new regulatory environment, data protection, and emerging trends.

II. BACKGROUND

AUDIT, COMPLIANCE AND INVESTIGATIONS STRUCTURE AT UC

ECAS is the independent audit and investigative arm of the University that reports directly to the Board of Regents.[2] ECAS is primarily responsible for coordinating audit, compliance and investigations efforts across the system. This can take a variety of forms but relies heavily on coordinated efforts with audit and compliance personnel imbedded within each of the campuses, medical centers and the national laboratory. This is necessary because each location is different in size, scope, structure of operations and demographics and these differences often translate into unique compliance and audit issues. Notwithstanding these differences, there are circumstances where collective efforts and standards are necessary. ECAS both assists campuses with their specific concerns and coordinates systemwide approaches to these common issues. Together, this shared effort allows the system to leverage the expertise throughout the system, identify opportunities to strengthen our compliance and risk management, and design improvements in a measured and proactive manner.

Each campus has an Internal Audit Director (IAD) and a Chief Ethics and Compliance Officer (CECO). The IADs provide independent assurance that a campus's risk management, governance, and internal control processes are operating effectively. The CECO is an independent official who is primarily responsible for overseeing and managing compliance issues at each location. These individuals report to both local leadership and to the Regents through ECAS' Senior Vice President – Chief Compliance and Audit Officer (SVP/CCAO).

There are five campuses that operate AMCs and one additional campus with a medical school, and each of those locations has a separate Health Care Compliance Officer (HCCO). The HCCOs have overall responsibility for maintaining and enhancing location-specific Health Sciences Compliance Program (HSCP) activities that include identifying, intervening and responding to potential compliance issues and assuring the effective operations of the HSCP. Similar to other compliance functions mentioned above, the HCCOs report to both the center's Chief Executive Officers and to the Regents through ECAS' SVP/CCAO.

The reporting relationship to the Regents ensures that these functions possess the necessary independence to provide impartial assessments of location operations and recommend actions to strengthen compliance and risk management efforts.

In addition to these reporting relationships, ECAS maintains other relationships with campus compliance personnel (e.g., privacy, research compliance and Export Control Officers (ECOs)). These partnerships are essential for ensuring that the system successfully addresses the myriad of compliance and regulatory responsibilities facing the University.

III. OFFICE OF ETHICS, COMPLIANCE AND AUDIT SERVICES

COMPLIANCE SERVICES

This year presented a series of unique compliance challenges for the University. In early 2020, the campuses, laboratory and AMCs performed detailed risk assessments that would have informed their regulatory and compliance efforts for the year. Shortly after these assessments were completed, locations were forced to address the unforeseen and evolving issues related to the COVID-19 pandemic, including the delivery of healthcare during the outbreak and increased federal scrutiny related to foreign influence issues involving research.

The University's compliance personnel pivoted significantly to refocus their limited resources to address these new challenges. Specifically, ECAS, working alongside CECOs and HCCOs from across the system, revised the shared risk priorities. CECOs and HCCOs created work plans to account for these new COVID-19 and foreign influence challenges while simultaneously addressing other known high risk priorities throughout the University.

COVID-19 Pandemic Response

Among the various impacts to the University, the pandemic resulted in an unprecedented surge in new governmental guidance and regulations. ECAS worked with compliance partners across the system, the Office of General Counsel (OGC), and Research Policy, Analysis and Coordination (RPAC) on creating compliance alerts and other training that specifically highlighted significant regulatory changes and raised awareness of these issues throughout the system. ECAS also built a COVID-19 compliance resource page,[3] which outlines federal and state regulations and provides resources to impacted compliance areas throughout the system.

Research Compliance

During the early phase of the pandemic, several federal agencies promulgated rules and regulations affecting the University and its operations.

- The White House Office of Management and Budget (OMB) issued multiple memoranda early in the pandemic authorizing federal funding agencies to provide administrative flexibilities to continue research and services supporting the emergency response to COVID-19.

- The National Institutes of Health (NIH) and the National Science Foundation (NSF) issued emergency guidance related to pandemic-related research that temporarily changed various research compliance rules.

- The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP), Centers for Disease Control (CDC), and the Federal Drug Administration (FDA) issued recommendations and enforcement discretion notices. These notices covered a variety of research compliance regulatory areas such as conducting clinical trials during the pandemic and flexibilities in consenting research subjects.

The rapid issuance of these rules created compliance challenges for the University as it coincided with the University's transition to a remote work environment. The pandemic-driven changes also introduced new funding streams with new compliance expectations. Working closely with compliance partners across the system, ECAS began promoting awareness and compliance with these new responsibilities by providing stakeholders throughout the system with timely guidance and training materials as well as establishing remote working groups. ECAS continues to work with our compliance partners across the system and within UCOP to address these matters.

Healthcare Compliance

The COVID-19 pandemic affected the regulatory environment in healthcare in significant and unprecedented ways. The Centers for Medicare and Medicaid Services (CMS) issued hundreds of new temporary rules and waivers of federal requirements to ensure that hospitals and health systems have the capacity to absorb and effectively manage potential surges of COVID-19 patients.

These changes impacted nearly all aspects of compliance overseen by HCCOs, and forced the reprioritization of local and systemwide initiatives to allow a focus on pandemic management. At the systemwide level, ECAS worked with HCCOs and OGC on analyzing and addressing the new guidance and promoting awareness of new requirements. At individual locations, HCCOs joined cross-functional COVID-19 teams to examine the federal waivers' specific impacts on their local AMC, issuing daily compliance communications, revising local procedures, and developing auditing and monitoring programs.

In addition to these new regulatory requirements, the pandemic created an unprecedented demand on remote patient care. The use of video platforms, such as Zoom and other technology (telehealth), to treat patients increased significantly since the onset of the pandemic. The University quickly adapted to meet this demand and now each UC AMC provides much needed services via telehealth. This increased demand for remote patient care also drove additional changes to federal policy and regulations.

In light of these complex changes, HCCOs helped implement a series of new processes. For example, waivers required system updates to allow for visits to occur and providers to receive payment. HCCOs had to analyze these issues and ensure that the AMCs were in compliance with overlapping federal and state requirements. Recognizing that these new requirements created an increased risk of fraud, the HCCOs are currently designing new monitoring mechanisms, educational materials and training to address compliance with changes to federal policy and regulations related to telehealth.

Cybersecurity

As research into COVID-19 therapeutics and vaccines increased, research data security in a remote environment rapidly became an emergent concern. Federal authorities warned universities about nation-state actors' heightened interest in COVID-19 research data. ECAS worked with various stakeholders to ensure research data safeguards were in place.

Export Controls

The pandemic resulted in international travel restrictions that directly impacted the University and required research, teaching and other collaborations to occur remotely. Many students and researchers were forced to return to or were prevented from leaving their native countries, increasing the need for remote collaborations. These restrictions not only presented new operational challenges to faculty, staff and students needing to teach, learn, research, or work outside of the United States but also created immediate and far-reaching compliance challenges.

The U.S. Treasury Department's Office of Foreign Assets Control (OFAC) administers and enforces U.S. economic and trade sanctions and can affect many of these remote collaborations. For example, a campus' desire to provide online educational courses to individuals in sanctioned countries may require the federal government's pre-approval. Researchers who wish to collaborate with their foreign counterparts may require pre-approval from the government

if their international colleagues reside in sanctioned countries and desire access to U.S.-based IT systems or information. Additionally, the shipment of equipment or material to students or faculty outside the U.S. may also require government approval.

These new realities created a surge in compliance risks throughout the University. ECAS coordinated with OGC, Academic Personnel, and ECOs across the system to provide immediate training and guidance related to these compliance risks as well as individual compliance reviews of foreign activity.

Clery Act Compliance

The Department of Education (DoEd) administers the Jeanne Clery Disclosure of Campus Security Policy and Campus Crime Statistics Act (Clery Act). This federal statute requires colleges and universities participating in federal financial aid programs to maintain and disclose campus crime statistics and security information. It also requires these institutions to provide timely warnings of situations that represent a threat to the safety of students or employees. In April 2020, the DoEd issued guidance that expanded these timely warnings to include COVID-19 related notifications. As a result, ECAS partnered with OGC to promptly issue guidance to UC campuses to promote awareness and compliance. ECAS and OGC continue to work with Clery Act compliance partners across the system to promote implementation.

Campus Privacy

At the onset of the pandemic, the use of confidential personal data became fundamental in managing operations, such as remote work and learning, and ensuring health and safety in the workplace. The Campus Privacy Officers had to consider impacts of gathering student-, faculty- and staff- related data in COVID-19 surveillance efforts, balancing privacy requirements with operational needs. An additional area of focus this year involved the collection of confidential personal data in symptom screening, testing, contact tracing, rapid development of COVID-19 surveillance tools and other campus reopening efforts.

Foreign Influence

Throughout 2020, federal government and federal funding agencies continued their focus on foreign influences on research integrity at U.S. institutions of higher education.

- The White House Office of Science and Technology Policy (OSTP) released guidance on addressing foreign influence.

- NSF finalized changes to disclosure requirements, including implementing a new webportal to submit disclosures and mandatory use of new templates to submit biographical sketch and support information.

- The DoEd finalized substantial changes to the Higher Education Act's Section 117, Foreign Gifts and Contracts reporting requirements.

- The Department of Energy (DOE) issued a new order prohibiting certain foreign government-sponsored or affiliated activities for staff.

- NIH issued further clarifications to disclosure requirements relating to foreign influences on research integrity.

- Section 889(a)(1)(B) "NDAA 889 Part B" of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 went into effect prohibiting executive agencies from entering into, extending or renewing a contract with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, on or after August 13, 2020.

- U.S. Department of Defense (DoD) issued an Interim Rule to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a DoD Assessment Methodology and Cybersecurity Maturity Model Certification framework (CMMC).

In the last two years ECAS took the lead in addressing foreign influence concerns by engaging directly with multiple federal partners, creating a foreign influence compliance plan, systemwide protocols, training, and compliance alerts. This year, ECAS focused on these new, complex regulatory changes, collaborating with OGC, RPAC and campus stakeholders on developing guidance and training for the system. ECAS, in partnership with UCOP, continues to conduct extensive analysis of these evolving compliance risks, and addressing impacts to the University.

Training and Professional Development

ECAS has completed a number of training initiatives in FY 2019-20 related to foreign influence, conflicts of interest and commitment and disclosure requirements for federal granting agencies:

- ECAS created a Systemwide Ethics & Compliance Briefing for Researchers: this module will address general ethics and compliance matters, foreign influence matters and other issues related to researchers, such as disclosing affiliations with foreign entities to federal funding agencies. This module will launch in the first quarter of 2021.

- ECAS' Foreign Influence website covers the full spectrum of federal communications, disclosure requirements, regulations and policies. The website was launched in October 2019 and continues to be a top resource nationwide for aggregated and up-to-date foreign influence information.[4]

- In June 2020, ECAS delivered a presentation at the Society of Corporate Compliance & Ethics Institute of Higher Education titled "Foreign Influences on Research Integrity and the Shifting Landscape." ECAS discussed the federal government's recent concerns regarding foreign interests and potential threats to the research enterprise. The session included a review of federal funding agency disclosure requirements, federal enforcement activities, ECAS compliance overview, and emerging risks. ECAS is working on designing systemwide webinars focused on UC's response to foreign influence compliance, as well as export controls compliance in FY 2020-21.

- During the next year, ECAS will continue to publish infographics addressing foreign influence, including NDAA 889 Part B Compliance for Procurement and DOE Order 486.1A Foreign Government Sponsored or Affiliated Activities.

Additional Compliance Priorities

One of the largest systemwide efforts led by the Compliance team is to identify shared risk priorities across the system. As noted, this year the University's already vast and dynamic regulatory landscape was influenced dramatically by the pandemic. The compliance teams across the system had to contend with changes to already complex rules while managing current compliance risks identified through risk assessments. The risk assessments broadly addressed the areas of healthcare, research, export controls compliance, Clery Act, Americans with Disabilities Act (ADA), and privacy.

Healthcare Compliance and Privacy

As noted, COVID-19 prompted an unprecedented reprioritization of activities everywhere at the University, and healthcare regulatory compliance was most centrally affected. The HCCOs and their teams shouldered the new challenges while continuously administering important everyday compliance program functions, and redistributing department resources as priorities emerged.

Regulatory Environment

The systemwide healthcare compliance program covers a very broad spectrum of areas including facility licensing, staff qualifications, patient care (e.g., medical record documentation, supervision, Emergency Medical Treatment and Labor Act (EMTALA),[5] reimbursement process (e.g., coding, billing, payor audits), and Health Insurance Portability and Accountability Act (HIPAA)[6] Privacy and Security Rules. These activities are governed by numerous laws and regulations, with Medicare and Medicaid Program-related requirements comprising the majority of them. In addition, three central compliance laws protect the Medicare and Medicaid Programs against fraud: (1) the False Claims Act, (2) Physician Self-Referral Law (Stark Law) and (3) the Anti-Kickback Statute.[7] Together, the DHHS, the Office of the Inspector General (OIG) and the Department of Justice (DOJ) enforce these requirements.

Risk Assessments and Work Plans

In early 2020, ECAS and the HCCOs identified shared risks and began planning a joint approach to addressing these key priorities. With the disruptions related to the pandemic, a number of newly identified priorities emerged, as described earlier in this section. Other shared risk priorities are outlined below.

The FY 2019-20 risk assessment cycle built upon the first annual systemwide risk assessment cycle, and increased uniformity across the locations by standardizing reporting elements and requiring senior leadership to participate in the

risk assessment process and the approval and monitoring of the resulting work plans. The current process is evolving and work remains ahead. ECAS and the HCCOs will continue to build upon the current process, while providing more visibility to senior leadership and the Regents.

Conflict of Interest and Conflict of Commitment

University policy requires all UC Health system faculty to report income from sources external to UC to deter any perceived or actual conflict of interest and commitment. The HCCOs recognized that potential gaps in this process present a shared compliance and reputational risk. In early 2020, most locations audited publically available information against University records to address any potential discrepancies and recommended corrective actions to strengthen the reporting process. The AMCs also participated in training of all clinical faculty to raise awareness of the process.

UC Health, in collaboration with the OGC, ECAS and other location stakeholders, formed the multi-disciplinary systemwide Working Group on Conflicts of Commitment and Reporting Outside Professional Activities to review existing processes and develop recommendations to improve transparency and compliance of the University's conflict of interest and commitment processes.

Coding and Billing Oversight

Efficient, automated auditing and monitoring of the coding and billing process is fundamental to the University's healthcare compliance program. These systems assist in quickly identifying discrepancies within the process, thereby allowing for timely corrections. During FY 2019-20, ECAS and the HCCOs' revenue cycle compliance teams implemented a new UC-wide coding and billing audit system. In the next year, ECAS and the HCCOs will begin development of shared reporting metrics to track compliance performance across the system.

Patient Data Privacy and Governance

HCCOs identified the risk of inappropriate access, use and disclosure of patient health information as a shared risk priority due to the active enforcement of privacy regulations, increasing privacy expectations of research study participants, and the highly sensitive nature of UC's health research data. During the FY 2019-20, privacy compliance teams began designing monitoring mechanisms and training solutions to address this risk. For example, both University of California, Irvine (UCI) and University of California, Davis (UCD), launched robust assessments of clinical research privacy compliance. To address gaps noted and complement campus-

specific efforts, ECAS included several research privacy compliance training sessions at the 2019 Ethics, Compliance and Audit Symposium.

In 2020, ECAS, in collaboration with HCCOs, Information Security, and OGC, developed a new HIPAA Privacy and Security Training course. The new course incorporates necessary regulatory updates and technological upgrades, and is scheduled to launch in January 2021.

In addition, the HCCOs and ECAS participated in a systemwide effort to create a UC Health data governance infrastructure. Ongoing efforts include the development of standards, data sharing management tools, policies and procedures, and metrics to measure reduction in risk. The Research Data Privacy section in Research Compliance below further describes privacy risks and mitigation activities in research.

Drug Diversion Prevention
University policy and state and federal regulations address circumstances when prescription medicines in the medical centers are obtained illegally by healthcare staff (drug diversion) and threaten patient safety and quality of care. Drug diversion can also result in civil and regulatory liability. Oversight of controlled substances at the AMCs and compliance and regulatory risks associated with drug diversion are significant compliance priorities for the HCCOs.

HCCOs created or participated in the local controlled substances oversight committees. These committees meet regularly to oversee drug diversion control effectiveness. Most locations are making significant efforts to identify opportunities to strengthen the processes in this area. For example, UCD and University of California, San Diego (UCSD) have conducted targeted reviews and identified campus-specific opportunities for improvement. Recommendations from these reviews were addressed through the revision of local policies and procedures, mandatory training and education, and ongoing monitoring which is reported to the local oversight committees.

Research Compliance

Research compliance aims to address shared research risk priorities through stakeholder facilitation and engagement with our academic community and administration, the development of systemwide communications, the development and implementation of training and education materials, and the use of systemwide risk assessments.

Regulatory Environment
The convergence of federal regulations, state law and UC policy creates a complex regulatory matrix for research compliance. Multiple federal agencies are responsible for regulations governing research — from the FDA's compliance oversight of clinical trials, to the Drug Enforcement Agency's oversight of controlled substances' use in research, and the DHHS oversight and enforcement of Human Subjects Research Protections. Further, federal and state privacy laws such as HIPAA and the Confidentiality of Medical Information Act (CMIA) govern research use of patient health information. Additionally, federal funding agencies such as the NSF and the NIH issue policies and guidelines that further shape the research compliance landscape.

Key Projects
Clinical Research Compliance Committee
ECAS and UCI co-chaired the Clinical Research Compliance Committee (CRC). CRC formalized its scope by establishing a committee charge which outlines its focus in healthcare related research compliance areas such as research data privacy and security, FDA clinical trial regulations, and clinical research billing, among others. The CRC charge includes development of a strategic plan for systemwide clinical research compliance coordination and systemwide risk assessment tools for campus use. CRC is also charged with preparation of guidance and educational materials, evaluation of the effect of new legislation on clinical research compliance practices, and monitoring and reporting on national clinical research compliance practices. In 2019 and 2020, CRC focused on establishment of data governance protocols for research use of health data. CRC also focused on the intersection of responsibility for research compliance, privacy compliance and human subjects protections professionals. These professionals will analyze compliance in genomics research and implications for HIPAA, FDA regulated research management, and impacts of Certificates of Confidentiality compliance in health records management.

Research Data Privacy

The University recognizes that use of technology, including artificial intelligence and machine learning, in the advancement of healthcare is a rapidly emerging area and depends fundamentally on the use, access, and sharing of large volumes of patient health data. Health data, including protected health information (PHI), is used in the research context to inform these tools, draw conclusions, and inform policy. This transformation amplifies the intersection of risk in the clinical research and privacy context, which is imperative to mitigate as the University charges forward. Further, the rapidly evolving nature of this technology has gotten ahead of the regulatory framework, which requires that the University establish and rely on ethical guidelines to move forward.

In early 2020, ECAS, in partnership with the systemwide Institutional Review Board Directors, RPAC, and OGC, planned the first two-day conference for clinical research compliance, privacy compliance and human subjects protection offices. This conference was postponed due the pandemic and other competing priorities. ECAS will return to this project in 2021. The goal of the conference will be to facilitate a discussion on high-risk issues and to develop communication channels between the groups. The conference will address topics such as:

- Certificates of Confidentiality in health records

- genomics research

- governance for research use of health data

- research deemed non-human subject research when HIPAA privacy rules apply

- de-identification standards in light of emerging technology

- collaborative research and associated intercampus transfers of PHI.

Training and Professional Development

ECAS has completed a number of training initiatives in FY 2019-20 related to conflicts of interest and commitment and disclosure requirements for federal granting agencies.

- In October 2019, ECAS' Ethics, Compliance and Audit Symposium included sessions covering clinical research compliance areas of interest such as research privacy, Export Controls in Medical Research, Regulatory and Ethical Challenges in Big Data Research, and an overview of resources provided by the U.S. National Library of Medicine related to clinical studies.[8]

- During the remainder of the year, ECAS and the CRC will focus on developing training in the areas of FDA oversight, digital health guidelines in clinical trials and artificial intelligence impact on de-identification standards in health data and genomics research.

ECAS will continue to convene the Research Compliance Advisory Committee (RCAC) and the CRC. All campus locations and AMCs now participate in one or both of the committees.

During the upcoming year, in partnership with CRC and RCAC, ECAS will conduct a systemwide research compliance risk assessment to assess the policies and procedures related to human subjects protection programs, animal research, FDA regulated research, controlled substances, sub-recipient monitoring, data ownership and security. Through this risk assessment process, ECAS aims to help strengthen the research compliance function across the system.

Additional Projects

For FY 2020-21, research compliance will focus on the implementation of anticipated recommendations from the systemwide foreign influence audit.

Additional projects will include:

- Monitoring compliance with Research Data Security and Cybersecurity Maturity Model Certification requirements

- Increasing awareness of the research compliance requirements to document activities in accordance with the U.S. OMB COVID-19 related Memos.[9]

- UC Presidential Artificial Intelligence Working Group – discussed in detail below.

- Creating a governance and compliance framework that addresses the area of research privacy and specifically addresses the risks presented by the use of technology and health data governed by HIPAA and human subjects regulations

- Assembling a UC workshop for clinical research, privacy compliance and human subjects protection professionals to coordinate systemwide efforts for research privacy compliance and mitigation strategies for risks associated with technology research.

UC Presidential Working Group on Artificial Intelligence (AI)

Over the past several years, we have witnessed AI and machine learning (ML) technologies become ubiquitous throughout many sectors. Every day, more use cases arise in higher education and medicine. To proactively address and mitigate the potentially negative downstream effects of AI/ML, ECAS, CITRIS and the Banatao Institute launched the UC Presidential Working Group on AI to develop overarching principles and guides for the appropriate development and use of AI applications within the UC system.

The interdisciplinary working group is composed of faculty, staff, and researchers from across the UC system. The working group co-chairs are SVP/CCAO Alexander Bustamante, Brandie Nonnecke, Center for Information Technology Research in the Interest of Society (CITRIS) Policy Lab Founding Director, and world-renowned expert in artificial intelligence, UC Berkeley faculty Stuart Russell.

Strategic Objectives

The working group will develop UC Ethical AI Principles to guide the development and application of AI in ways that are consistent with the University of California's values; establish methods and mechanisms to operationalize these principles in the development and application of AI within the UC system, especially in areas prone to impact individual rights, including admissions, human resources, health, and policing. Based upon these methods and mechanisms the workgroup will make further recommendations related to AI applications currently in use within the UC system in the above areas. The recommendations will also inform appropriate data stewardship standards for UC data that may be used in the development and use of AI-enabled tools and systems. To ensure continued guidance for UC's development and use of AI, the working group will create the foundation for a permanent council that will further the principles, standards, methods, and mechanisms developed by this working group to counter the potentially harmful effects of AI and strengthen positive outcomes.

Export Controls Compliance

For reasons of national security and foreign policy, export control laws regulate the distribution of items, information, software and services to foreign nationals and foreign countries. Violations of export control regulations may result in institutional liability and substantial penalties.

Export control risks are woven into the unique structure of the University, impacting almost every aspect including procurement, business contracts, international centers, cooperative extensions, research, shipping and international travel. Each UC location has a designated ECO with expertise in this complicated area to support faculty, staff, and students. ECAS supports the implementation, assessment and continuous improvement of the systemwide export control program.

Regulatory Environment

Federal agencies responsible for export control regulations include the Department of Commerce (DOC), the Department of State, OFAC, the DOE and the Nuclear Regulatory Commission.

These regulations change rapidly based on the dynamics of international affairs. For example, this year the DOC added export license requirements for military end-users and end-uses in certain countries, including exports to universities with military ties in these countries. Given these changes, ECAS remains diligent to quickly identify and address new risks at the University.

Key Projects

Over the last year, ECAS addressed increased export controls compliance risk related to remote access for faculty and staff, research collaborations and participation in online courses by overseas students and faculty. In most cases comprehensive OFAC sanctions require licensing for such activities in sanctioned countries. ECAS conducted significant outreach to stakeholders and provided guidance related to this compliance risk in coordination with OGC, Academic Personnel and Export Control Officers throughout the system.

In May 2020, the Government Accountability Office (GAO) released a report evaluating the extent to which export controls compliance policies and practices developed by U.S. universities align with federal guidelines. Some of these practices were evaluated by ECAS several years ago. Focusing on best practices outlined by the GAO, ECAS will collaborate with the systemwide Export Control Workgroup to update previous export control assessment results to capture progress made at each location and provide recommendations for further strengthening those operations.

ECAS is developing a comprehensive export control training plan to address the key shared risk priorities for the system. Based on the most recent federal requirements and internal audit recommendations, ECAS will develop guidance to cover four main areas: 1) export control review to identify transactions that require a license, 2) restricted party screening process, including roles and responsibilities, 3) red flags for agreements, and 4) international visitors vetting process. Identifying such transactions provides the location with the opportunity for escalation and timely visibility by the location Export Control Officer and campus leadership, if necessary.

ECAS will continue to support campus export control training initiatives through training materials and offering guidance and training for stakeholders.

Campus Privacy

Campus privacy programs ensure the appropriate protection, use, and release of student, faculty, staff, and research participant information. Privacy compliance at the University balances the dual aims of maintaining an open and robust academic and research environment and ensuring the University's vast amount of sensitive data is safeguarded. Systemwide awareness of privacy compliance is critically important because all academic, staff and student activities require access to protected sensitive data.

Regulatory Environment

Campuses in general must comply with the privacy requirements set forth in the Family Educational Rights and Privacy Act (FERPA), California Public Records Act (CPRA) and California Information Practices Act (CIPA). Those campuses performing research or treating patients must also comply with the privacy requirements of HIPAA, CMIA, FDA, and General Data Protection Regulation (GDPR). These privacy requirements subject the University, and in some cases its employees, to possible government fines, enforcement actions, and reputational harm. A violation of FERPA, for example, may result in loss of federal funding.

The regulatory environment in the area of privacy has become increasingly more complex in 2020. The California Consumer Privacy Act (CCPA) in 2019 and its subsequent amendment in 2020 strengthened privacy protections.[10] There are also several other proposed legislative initiatives that would affect privacy requirements in the fields of health, genetic, and human subjects' research data.

Key Projects

ECAS participates and provides expertise to multiple cross-functional privacy and security committees. ECAS also convenes the systemwide UC Campus Privacy Officers group.

The resources and support dedicated to the privacy program across the system are uneven. To address this, the systemwide privacy group works to harness the unique expertise and resources available at some locations to jointly address common areas of concern. Recognizing the size and complexity of University activities, and in an effort to dedicate limited resources to the most significant priorities, the Campus Privacy Officers are working on a risk-based project plan.

At the onset of the pandemic, the use of confidential personal data became fundamental in the creation of symptom screening, testing and surveillance tools, addressing changing county and municipal requirements and campus reopening efforts. ECAS and the Campus Privacy Officers collaborated with OGC and UC Health to create guidance and awareness materials.

ECAS led the effort with the Campus Privacy Officers to create a Privacy Principles Model document that could be used throughout the system. This document addressed privacy risks and sound data stewardship practices and provides consistency in handling these matters at each location. The Privacy Principles were included in the UC Health's Consensus Standards Task Force guidance on symptom screening, testing and tracing programs and used by campus committees developing reopening programs.

ECAS is leading efforts with the Campus Privacy Officers on other key initiatives briefly described below.

Campus Privacy Program Plan — ECAS and the Campus Privacy Officers will conduct a baseline assessment of current program infrastructure, resources and potential gaps to create a model program plan and leverage systemwide resources across all locations.

Collaborative projects with the Chief Information Security Officers (CISOs) — ECAS and the Privacy Officers identified several shared risk priorities between privacy and security, and will collaborate with CISOs to develop a more strategic and collaborative approach to resolving ongoing issues, such as breach analysis, and privacy and security assessments of prospective vendors.

Privacy analysis of the University's Electronic Communications Policy — the University policy on electronic communications was developed over 20 years ago and covers a wide range of activities. Many of its provisions have been rendered nearly obsolete by advances in technology and increasingly complex regulatory data security practices required to safeguard the University's data. ECAS will work with the Privacy Officers to initiate analysis and start developing recommendations related to the privacy provision of this large and complex policy.

Clery Act Compliance

The Clery Act is a federal statute requiring colleges and universities participating in federal financial aid programs to maintain and disclose campus crime statistics and security information. The U.S. DoEd conducts reviews to evaluate an institution's compliance with the Clery Act requirements.

Over the past year, ECAS convened the systemwide Clery Act Officers and Coordinators meetings, provided in-person training by nationally recognized Clery Act experts, engaged with the DoEd Director to deliver training at the 2019 Ethics, Compliance and Audit Symposium, and issued guidance on compliance with the DoEd emergency notifications of COVID-19 cases.

Annual Training — In November 2020, ECAS delivered annual Clery Act training tailored to the University and AMCs' unique environment. The course focused on risk related to appropriately identifying Clery Act geography for campuses located in large cities, and addressed recent DoEd enforcement actions, the new Title IX regulations and COVID-19 compliance.

CSA Working Groups — In the next year, two working groups will address other risk priorities such as identification of Campus Security Authority (CSA) as required by law, and training for CSAs.

The CSA Identification working group will evaluate the methodology used to identify CSAs at each location, as required by the UC Clery Act policy and the Federal Clery Act. The working group will include analysis of systemwide data examining job codes, job descriptions, reporting structure and level of involvement with students. The working group will develop a report with a baseline CSA list which can be expanded by each location.

ECAS launched a working group to revise the online mandatory training for CSAs in September 2020 and will roll out the new training to the University community in March 2021. The training module will include required revisions, including the new Title IX requirements.

2019 Ethics, Compliance and Audit Symposium

In October 2019, over 300 people across the system attended the ECAS 2019 Ethics, Compliance and Audit Symposium. The goal of the symposium was to ensure UC personnel are informed and trained on all significant compliance and audit-related risks and requirements, and to share best practices and subject matter expertise with colleagues across the UC system. The program included topics related to AI, data analytics, cybersecurity, healthcare, research and privacy compliance, internal audit, workplace investigations, policy topics, export controls, and foreign influence, among others.

AUDIT SERVICES

It is the policy of the University of California to maintain an independent and objective internal audit function to provide the Regents, UC President, campus Chancellors and Laboratory Director with information and assurance on the governance, risk management and internal control processes of the University. Internal Audit provides independent and objective assurance and consulting services designed to add value and improve operations. We do this through communication, monitoring and collaboration with management to assist the campus community in the discharge of its oversight, management, and operating responsibilities. Internal Audit brings a systematic, risk-based and disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

The internal audit function enables the University to consistently assess the efficiency and effectiveness of its operations as well as monitor for fraud, waste and abuse. The Board of Regents set forth the purpose, authority and responsibility of the internal audit function, including guaranteeing it has "full, free and unrestricted access" to all University information, as indicated in the University's Internal Audit Charter.[11] The Charter also articulates Internal Audit's organizational independence by establishing a direct reporting line from the SVP/CCAO, the head of the internal audit function, to the Board of Regents. The internal audit function is required to follow industry-recognized professional standards in the course of its work.[12]

The internal audit function provides three lines of service:

- **Audits** provide an independent assessment on governance, risk management, and control processes for the organization. Examples include financial, performance, compliance, systems security and due diligence engagements.

- **Consulting services** are advisory in nature, are generally performed at the specific request of the client, and are intended to add value and improve an organization's governance, risk management and control processes without the internal auditor assuming management responsibility. Examples include reviews, recommendations (advice), facilitation and training.

- **Investigations** are independent evaluations of allegations generally focused on improper governmental activities, including misuse of University resources, fraud, financial irregularities, significant control weaknesses and unethical behavior or actions.

The following chart depicts the number of hours of effort allocated to each of our service lines over the past seven years:

Effort Distribution by Service Line
(7 Year Trend)

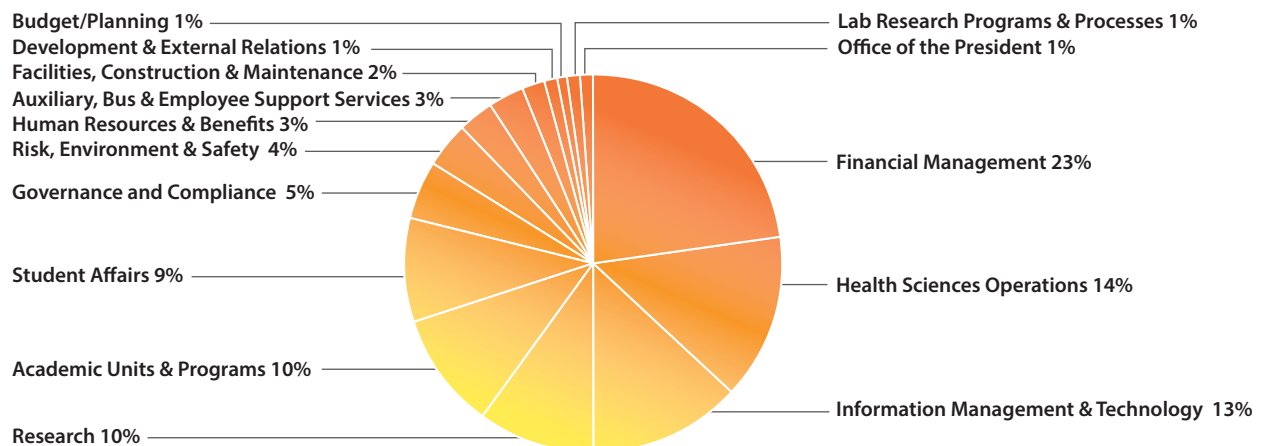Planned Audit Program   Advisory Services   Investigations
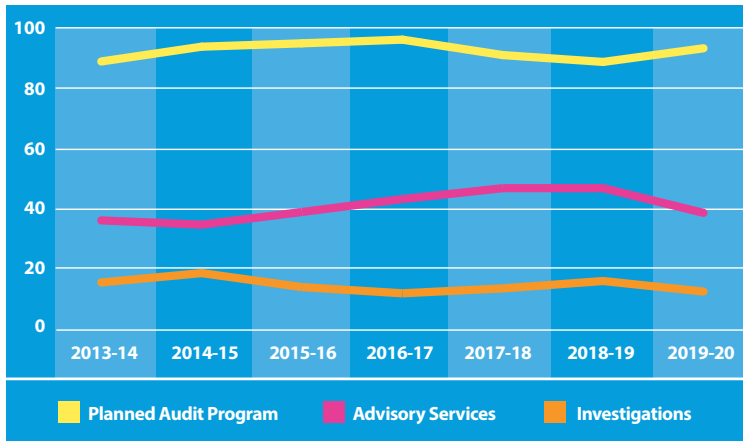
Each of the ten UC campuses, UCOP and the Lawrence Berkeley National Laboratory has an internal audit department headed by an IAD. These local audit departments are tasked with understanding their unique environments and tailoring much of their audit efforts to their location needs in order to be effective. Each local internal audit department is responsible for performing direct oversight and quality assurance over its local internal audit activities. ECAS provides broad oversight of systemwide audit activities and ongoing support to the campus audit departments to ensure local risks are appropriately addressed.

There are issues that each location must also handle in concert with the other locations across the system. These systemwide issues occur when a risk presents itself at each of the locations and a common approach is necessary to minimize the risk to the University as a whole. In these cases, ECAS will coordinate efforts with all of the IADs throughout the system.

The systemwide Office of Audit Services oversees and facilitates internal audit activity across the system by coordinating systemwide internal audit projects; consolidating and reporting on internal audit activities to stakeholders; maintaining UC internal audit risk assessment and audit planning methodology, guidance and standards; providing training and professional development to UC's internal auditors; and escalating matters to the Board of Regents when required. Additionally, a specialized team within the Office of Audit Services provides cybersecurity auditing services for the entire system.

Each year, Internal Audit develops an annual Internal Audit Plan consisting of internal audit and advisory projects to be completed in the upcoming year. The annual Internal Audit Plan is driven by consideration of strategic, financial, operational, regulatory and reputational risks at both the systemwide and local level. This assessment is performed in coordination with other risk partners such as Compliance, Risk Services and OGC. The risk assessment process involves the collection of risk information through interviews with management, surveys, review of regulatory and industry information, and data analysis. This information is then

Distribution of Hours

The chart below depicts the breadth of projects covered by Internal Audit hours over 15 functional areas. As in prior years, our effort remained concentrated in the areas of financial management, health sciences operations, information management and technology, and academic units and programs.

Distribution of FY 2019-20 Effort by Functional Area

Budget/Planning 1%
Development & External Relations 1%
Facilities, Construction & Maintenance 2%
Auxiliary, Bus & Employee Support Services 3%
Human Resources & Benefits 3%
Risk, Environment & Safety 4%
Governance and Compliance 5%
Student Affairs 9%
Academic Units & Programs 10%
Research 10%

Lab Research Programs & Processes 1%
Office of the President 1%
Financial Management 23%
Health Sciences Operations 14%
Information Management & Technology 13%

consolidated and synthesized to identify the top institutional risks to be addressed through internal audit projects comprising the annual Internal Audit Plan. The Internal Audit Plan is approved by the Board of Regents at the beginning of each fiscal year.

Local Internal Audit Activity

The majority of Internal Audit's efforts are driven by each location's execution of locally identified audit and advisory projects (systemwide audit projects are discussed in the next section). This section highlights the outcomes of local internal audit activities in FY 2019-20, as well as key statistical information and performance metrics related to the efficiency and effectiveness of Internal Audit's efforts.

Key Statistics and Performance Metrics

Internal Audit routinely captures data relating to the effort its staff expends on project and non-project time, the number of projects it completes, and management corrective actions in response to internal audit activity.

Fiscal Year 2019-20 Statistical Highlights

During FY 2019-20, the UC Internal Audit Program:

- Completed 90 percent of the Regents-approved Internal Audit Plan
- Completed audit, advisory services and investigation projects resulting in 308 reports
- Produced 1,171 recommendations for improvements to governance, risk management, and control processes, with corresponding agreed-upon Management Corrective Actions (MCAs)
- Validated that 961 MCAs were completed by management
- Operated at an 85 percent efficiency level[13]

Management Corrective Actions

Every observation identified by Internal Audit has a reciprocal management corrective action to address that observation, including a target date for completion. Local internal audit departments and the systemwide Office of Audit Services track and monitor MCAs until completion. The table below provides a summary of MCA activity for FY 2019-20.

Summary of MCA Activity

|	
Beginning MCAs *(open at start of FY 2019-20)*	255
MCAs added	1,171
MCAs closed	961
Ending MCAs *(open at end of FY 2019-20)*	465
ENDING MCAs PAST DUE *(past due at the end of FY 2019-20)*	
High-risk past due MCAs	27
Medium/low risk past due MCAs	93

Internal Audit reviews all management responses to ensure the corrective action is appropriate and timely. An escalation process to senior leadership and the Regents is in place if there are difficulties related to completion of the corrective actions. MCAs that have not been resolved in 300 days (from the audit report date) are discussed with leadership of the Regents' Compliance and Audit Committee. These unresolved MCAs often address complex risk areas which may be costly or require excess time to implement and therefore may reasonably require extended timelines. In these cases, management usually has implemented mitigating controls in the interim to assure that the risk area is controlled. Longer-term solutions typically focus on developing a "best practice" solution that is more efficient, reliable, and a more permanent approach to risk mitigation.

In October 2018, Internal Audit, with support from Regents Compliance and Audit Committee leadership, implemented a new protocol to notify the Chancellor or Laboratory Director of all MCAs from their local internal audit projects that have exceeded the 300-day threshold. Since this new protocol has been in place, the number of MCAs over 300 days old has decreased significantly, from 114 to 8, representing a reduction of approximately 93 percent.

The October 2018 protocols for MCAs over 300 days old continue to have a cascading effect on driving expedited resolution of all outstanding MCAs. As stated previously, the current balance of MCAs as of June 30, 2020 was 465. While this amount is up slightly from the prior year, it continues to represent a much lower balance as compared to the previous years before the new protocol was initiated when the ending MCA balance averaged over 600.

Number of Open MCAs Over 300 Days Old

There has been significant progress in closing management corrective actions over 300 days old. The chart below displays a downward trend over the past several years:
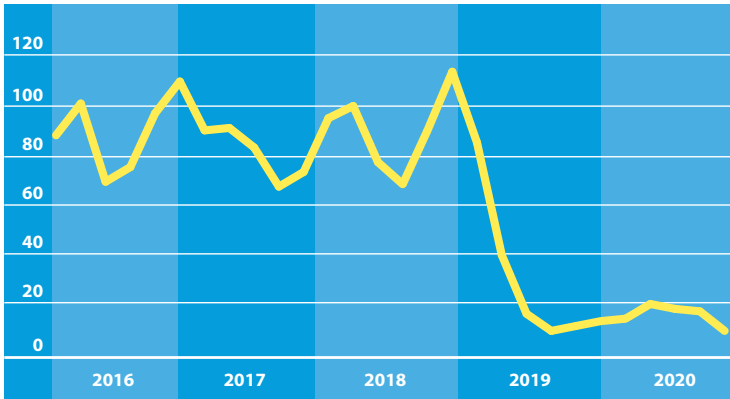
Ending Inventory of Open MCAs

The year-over-year trend in the number of open MCAs shows that, overall, good progress has been made in reducing the inventory of open MCAs. The uptick in MCAs for the current year was mainly attributable to the significant number of corrective actions identified as a result of our systemwide admissions audits. The chart below depicts the activity over the last seven years:
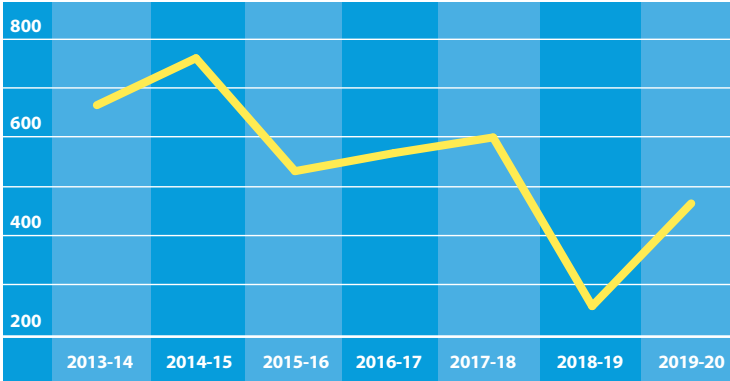
Themes in Internal Audit Results

From the body of internal audit work performed during FY 2019-20, the following are the most significant and recurrent internal control issues. Many of these are the subject of specific management corrective actions in the environment where the issues were identified in an effort to improve internal controls. Others are the subject of broader systemwide initiatives, while still others are endemic and require continual management attention.

IT Security and Information Privacy

UC internal audit departments continue to place significant emphasis on evaluating IT security programs and controls. Internal Audit has identified control weaknesses related to IT security and protection of sensitive and restricted information. We have noted decentralized environments for managing sensitive data and the lack of monitoring systems to ensure that access is appropriate as common challenges contributing to IT security issues. Campuses have also faced challenges associated with changing business requirements and new business strategies to leverage information systems.

Business Continuity and Disaster Recovery

As a result of the COVID-19 outbreak, our campuses and national laboratory have faced disruptions to normal instruction, research, and business operations. COVID-19 tested our overall preparedness for an emergency, and many business processes and internal control structures were modified given the circumstances. The current pandemic, along with consequences of severe weather and natural disasters, has reinforced the need for proper planning to ensure the safety of faculty, staff and students as well as to provide continued operations to the campus community.

Research and Regulatory Compliance

Research compliance has been an emerging risk area due to the breadth of compliance issues in areas such as international research, conflict of interest, conflict of commitment, laboratory safety, controlled substances, and export controls. As research compliance requirements become increasingly complex and burdensome, management is challenged to maintain compliance with limited resources. New systems and changes to key employee and organizational structures have contributed to compliance with federal agency requirements. Furthermore, compliance activities are often decentralized across a variety of campus and health system departments making it difficult to manage compliance efforts.

Foreign Influence

Foreign influence continues to be a high-risk issue for UC and for higher education in general. Increased scrutiny from federal agencies, coupled with limited resources to monitor and provide institutional control over research disclosures, export controls, restricted party screening, research data protection, and foreign gifts and contracts reporting, contribute to foreign influence being a priority risk area. A systemwide audit was initiated in FY 2019-20 to evaluate management of these risks.

Financial Management

Financial oversight and fiscal responsibility continue to emerge as common themes in our work. Internal audits have identified issues related to inadequate management of financial deficits, insufficient authorization and documentation of expenditures, a lack of monitoring over accounts and programs, and reliance on inaccurate data. Additionally, we have observed instances of regular reconciliations not being performed, a lack of separation of duties and departments that do not have the adequate tools and knowledge to perform efficient financial processes.

Large Scale IT System Implementations

Over the past several years, most of our campuses have initiated significant enterprise IT system implementation initiatives, and Internal Audit has been assisting management in addressing key issues associated with these system implementation efforts. Commonly observed issues include resource challenges, complexity of data integration, and the ability of current key campus systems to integrate with the new systems and processes.

Systemwide Efforts

The systemwide Office of Audit Services oversees and coordinates internal audit activities at the campuses and the Lawrence Berkeley National Laboratory. The office also maintains UC's internal audit methodology and guidance and provides support to the location internal audit departments by coordinating training and professional development programs, providing subject matter resources when required, facilitating implementation of internal audit technology solutions and monitoring compliance with professional standards. This section provides an overview of internal audit activities led by the Office of Audit Services in FY 2019-20.

Systemwide Audits

Systemwide audits are conducted for the purpose of reviewing an existing or potential issue across the University system to identify and address common risk areas. Typically, these audits are performed at the request of the systemwide Office of Audit Services, the Regents and/or the UC President, have a common scope and approach, and the fieldwork of these audits is usually conducted by the local internal audit departments at each University location.

The Office of Audit Services coordinates the execution of these audits and summarizes the results in a systemwide audit report. Corrective action and associated follow-up is performed at locations and at the systemwide level.

The following is an overview of systemwide audits performed in FY 2019-20.

Undergraduate Admissions

In response to recent nationwide issues involving third parties exploiting vulnerabilities in college admissions processes specifically related to athletics, former UC President Napolitano requested that ECAS conduct a systemwide audit of undergraduate admissions. The audit was conducted in two phases, and collectively identified 48 recommendations to strengthen internal controls over admissions processes. The first phase was completed in the prior fiscal year and the second phase was completed in FY 2019-20.

The objectives of the second phase of the Systemwide Audit of Undergraduate Admissions were to assess campuses' adherence to their controls over undergraduate admissions, assess the effectiveness of campus policy and controls over undergraduate admissions, and identify any effects of deficiencies in those controls. ECAS also attempted to determine the demographic characteristics of admitted applicants who received recommendations based on special talent.

The audit identified significant issues regarding recordkeeping for admissions, particularly related to admitted applicants who received recommendations based on special talent. In addition to the special talent area, we found that additional opportunities exist to strengthen controls and to further reduce the risk of admissions fraud in the areas of admissions documentation, application verification process, admission by exception, monitoring student athletes' participation in athletic programs, admission IT system access and admission appeals processes.

Fair Wage/Fair Work

The Office of Audit Services conducted its fourth annual systemwide audit to assess UC's suppliers' compliance with the University's Fair Wage/Fair Work (FW/FW) Plan requirements. The purpose of this audit was to review contracts and leases executed in the last year to ensure that they contain the required FW/FW provision, determine whether procurement and real estate units are reviewing and monitoring compliance with the annual audit verification requirement, and validate that suppliers complied with the annual audit requirements. The FW/FW Plan applied to real estate agreements effective May 1, 2016; however, this was the first year that real estate was specifically included in the scope of the systemwide audit to ensure compliance with the established guidelines.

In general, the campuses and medical centers have implemented adequate processes to ensure the FW/FW provision is included in procurement contracts, FW/FW contracts are identified and tracked, and supplier annual verifications are monitored. We found that the campuses and AMCs have made progress on rates of compliance since the prior year's FW/FW internal audit in implementing effective processes for monitoring supplier compliance with FW/FW requirements. We further noted that increased oversight of the campus real estate offices is necessary to ensure that the FW/FW Plan is followed as many of the campuses either lacked sufficient FW/FW lease tracking information or an adequate process to monitor and collect annual verifications.

Management corrective actions have been identified at both the local and systemwide levels to strengthen controls and improve compliance rates.

Outside Professional Activities

The Office of Audit Services conducted a systemwide review to assess the adequacy of internal controls over Outside Professional Activities (OPA) requests, approvals and reports, and to assess compliance with Regents Policy 7707.

While we observed general adherence to the OPA policy, we noted several areas for improvement related to approval and certification timeliness, completeness, and reporting.

Executive Compensation

Since 2007, the Office of Audit Services has coordinated annual reviews of executive compensation reporting at UC locations. This year, relatively minor exceptions were noted and were corrected at the local level. No issues were identified that required action from a systemwide perspective.

Foreign Influence

The Office of Audit Services coordinated an audit to evaluate the system of internal controls in place to manage risks identified by the federal government related to foreign influence. As part of the audit, we identified controls and mechanisms in place to identify and respond to noncompliance with required disclosures related to conflicts of interest, conflicts of commitment, monitoring of disclosure information and third party screening. We also reviewed record keeping practices and any escalation procedures when discrepancies or other concerns are identified. Audit fieldwork was completed in FY 2019-20 and the audit report is expected to be issued in FY 2020-21.

Cybersecurity Audit Team (CAT)

The CAT is a specialized internal audit team based out of the systemwide Office of Audit Services that conducts reviews focused on cyber-risk across the University of California system. The CAT is unique in that it is a systemwide resource, supporting campus' local internal audit offices with cybersecurity expertise, as well as performing specialized internal audit projects across multiple UC locations. The team was established in the fall of 2016 in response to the increasing cyber threats facing the University and recognition of the need to have subject matter expertise that can review these high-risk areas. The team consists of three cybersecurity audit specialists led by a director. In FY 2019-20 the CAT was able to fill two open positions after extended recruitments in a highly competitive job market.

In addition, the CAT leverages outside professional services to support its projects, and access specialized capabilities as necessary. The following is a summary of the CAT's key projects and accomplishments in FY 2019-20.

UC Systemwide Threat Detection and Identification (TDI) Cybersecurity Audit

In 2015, the UC President and the Board of Regents made a collective decision to enhance UC's cybersecurity program and invested heavily from a financial and human resources perspective to address cyber-risk through a variety of efforts, all designed to strengthen the University's ability to address these challenges as a system. A significant part of this effort centered on the implementation of a systemwide TDI capability that would provide active monitoring and threat intelligence for the entire system and its networks.

This audit is the first effort to evaluate the implementation and efficacy of the TDI program since its inception in December of 2015. The overall objective of this review was to determine the University's ability to identify, monitor, alert and investigate attacks on high-risk networks and research areas leveraging the systemwide investment in the FireEye threat detection and intelligence platform. The audit fieldwork was completed by the end of the fiscal year and report issued in early FY 2020-21.

Vulnerability Assessment and Penetration Testing

The CAT completed vulnerability assessment and penetration testing audits across all 10 UC campuses focusing on financial aid, student health and counseling services. These audits started in FY 2018-19 and were completed FY 2019-20. The audits looked for weaknesses in the computer systems by using similar tools and techniques as an attacker would use trying to gain access. In cases where weaknesses were

identified, the CAT worked with leadership to not only fix the vulnerability that allowed access, but also make improvements to the location's overall process for managing vulnerabilities on an ongoing basis.

Federal and Industry Partnerships

The CAT continues to foster the partnerships it has with federal and industry leaders in cybersecurity. The CAT has leveraged these relationships to stay abreast of the most advanced and emerging threats facing the University and to remain at the forefront of addressing these risks.

Training and Professional Development

In order to ensure that internal audit staff have the necessary professional competency and subject matter expertise to address the University's highest risks, and to ensure adherence to professional standards related to professional development, the Office of Audit Services coordinates various training and professional development programs for internal audit staff across the system. This section provides highlights of these efforts for FY 2019-20.

Webinar Program

The Office of Audit Services administers a monthly webinar program in which campuses present information on a variety of audit and related topics and best practices. Each month, a different UC location audit department presents a session that either addresses emerging risk areas or relates to topics on our UC audit plan. In FY 2019-20, monthly webinar topics included fraud prevention and awareness, cybersecurity, data analytics, incubators and accelerators on campus, critical thinking skills, campus environmental controls and auditing ADA compliance. This program has been well received by internal audit staff and is a valuable component of our internal training program.

New Auditor Training

In March 2020, the Office of Audit Services sponsored a one-day in-person training session for new UC auditors. The purpose of this training session was to provide our new Internal Audit staff with information about the UC system and the UC internal audit program. It also gave these new staff members the opportunity to meet and listen to a number of senior leaders from UCOP. The agenda included presentations on areas such as data analytics, the UC budget process, report writing, the UC Compliance Program, risk assessment coordination and information technology.

Professional Certifications

The Office of Audit Services continues to provide opportunities for staff development and enrichment through the support of professional certifications. At present, approximately 75 percent of our internal audit staff hold one or more professional certifications. The Certified Internal Auditor (CIA) is the only globally accepted designation for internal auditors and the standard by which individuals demonstrate their professionalism in internal auditing. We have encouraged our audit staff to obtain one of many audit-related professional certifications. Accordingly, we initiated a drive to increase CIA certifications systemwide.

Cybersecurity Training

The CAT, with support from Risk Services, hosted two specialized cybersecurity training courses this year. One five-day in-person course focused on cloud security and the other a six-day course on web application security held virtually after the start of shelter-in-place protocols. The cloud security training, delivered by the SANS Institute, was attended by over 110 cybersecurity practitioners from across the University. The course, "Cloud Security Architecture and Operations," focused security controls, services, and architecture models for public cloud environments. The second course, "Defending Web Applications and Security Essentials," taught attendees how to secure and protect web applications.

Mentorship Program

The Office of Audit Services continues to offer a mentorship program to our audit staff. This program provides mentors and mentees with a valuable learning and professional growth experience by pairing members of our professional staff with a mentor at another campus who has significant experience and leadership responsibility within our UC internal audit community. Through a series of monthly meetings or calls, the mentor and mentee identify areas that contribute to professional and personal enrichment and satisfaction for both parties.

Leadership and Experience

Over the past several years Internal Audit staffing levels have remained fairly constant. At present, our staffing level is at 110 total employees, including 102 internal audit professionals and eight administrative support staff. We take pride in hiring well-trained and experienced staff and encourage continuous professional growth. All of our professional audit staff have a college degree and 38 percent hold advanced degrees. As the chart below indicates, our audit leadership has a wealth of experience and is committed to mentoring their staff as they provide the University with assurance and consulting services.

EXPERIENCE OF INTERNAL AUDIT STAFF	YEARS
Average Years **Total Audit** Experience – All staff	15
Average Years **UC Audit** Experience – All staff	10
Average Years **Total Audit** Experience – Leadership	23
Average Years **UC Audit** Experience – Leadership	15

External Audit Support and Coordination

The Office of Audit Services generally serves as the audit coordinator for external audits involving multiple UC locations. In this role, the office serves as the central point of contact for external auditors, ensures that auditors have the appropriate access to perform their work, facilitates information requests, informs management of potential audit issues as they arise, and coordinates management responses to audit reports. External audit coordination drives audit efficiency and ensures appropriate information is provided to external agencies in a responsive and timely manner.

In FY 2019-20, the Office of Audit Services served as external audit coordinator for the California State Auditor's audits of admissions policies and practices, the Native American Graves and Repatriation Act (NAGPRA), and the Tobacco Tax Act. It also advised management on their efforts to implement outstanding recommendations from past California state audits on sexual harassment cases, contracted employees and contracting practices, UCOP administrative expenditures and budget, enrollment and executive compensation.

INVESTIGATIONS SERVICES

The Investigations unit and the whistleblower policies it operates under are critical to UC's Ethics and Compliance Program. One of the biggest risks an organization faces is the perpetuation of an environment where employees do not come forward to make management aware of suspected wrongdoing. Employees are often aware when violations occur, yet they will be hesitant to report if they do not feel both encouraged and protected for doing so. The University maintains a series of policies, trainings and resources to encourage employees to raise concerns and feel confident that they can do so without fear of retaliation. The University's efforts are centered on two key policies: the Whistleblower Policy and the Whistleblower Protection Policy.[14]

The Whistleblower Policy encourages employees to come forward if they have concerns about improper activities within the organization. The University has created a series of mechanisms to support employees "speaking up" regarding ethical, policy or legal violations. Employees can report misconduct in a variety of ways, including a systemwide whistleblower hotline and web-based reporting to provide a 24-hour reporting system with a provision for anonymous reporting. These mechanisms enable the University to identify warning signs for problem areas within the system, to conduct internal investigations on those matters and then to take appropriate remedial actions including the implementation of additional controls to prevent future misconduct.

The Whistleblower Protection Policy creates a series of protections for individuals reporting misconduct to ensure that people can come forward without fear of being punished for their disclosures.

The University ensures awareness of these mechanisms by regularly training employees and supervisors on how to make and respond to reports. ECAS ensures that University employees are informed of their responsibilities to report suspected misconduct, and the mechanisms to do so:

- All employees are required to complete the General Compliance Briefing: University of California Ethical Values and Conduct every two years. This is the primary ethics and compliance training provided to UC employees, which must be completed by all new employees within two months of their start dates. This compliance briefing provides guidance to employees on how to recognize potential misconduct by providing various scenarios, and includes information regarding the process of reporting misconduct.

- The ECAS Investigations unit distributes various materials regarding whistleblower reporting to each UC campus. Each Locally Designated Official (LDO) also sends a notification to all employees at their campus regarding the California Whistleblower Protection Act and University whistleblower policies on an annual basis. The notification reminds employees of their responsibility to report misconduct, protection from retaliation and the various reporting mechanisms available, including the option for anonymous reporting.

- Each campus maintains whistleblower websites, providing links to the policies and additional location-specific procedures for reporting suspected misconduct.

The University has dedicated investigative resources to review these reports and to investigate allegations of misconduct and retaliation.

Systemwide Coordination

ECAS provides guidance, training and investigative support to the UC locations regarding the University's whistleblower policies. The LDOs report to their campus senior leadership and elevate significant matters to the SVP/CCAO and the Systemwide LDO.

The distribution of complaints received by each campus varies greatly, with locations including medical centers receiving a higher number of complaints due to the longstanding compliance requirements related to the health care industry.

The ECAS Investigations unit conducts investigations into matters that are highly sensitive and critical across the system, including allegations against high-level officials throughout the system. ECAS also investigates all whistleblower matters occurring at UCOP. In addition, ECAS will accept cases from campuses where there may be resource limitations, a conflict of interest or highly complex investigations.

The Investigations unit provides training to investigators throughout the system to align procedures with best practices, strengthen investigative skills, and provide lessons learned in an effort to enhance investigative practices. Training programs range from onboarding training for investigators that educates individuals on the whistleblower policies and practical skills to lifecycle training that refines existing skills or develops new ones. This training is necessary to ensure that investigations are conducted at the highest levels throughout the system.

Whistleblower Hotline

As previously noted, UC provides multiple mechanisms for individuals to report concerns, including the whistleblower hotline. The hotline is available both online *https://secure.ethicspoint.com/domain/media/en/gui/23531/index.html* and by phone (800-403-4744) 24 hours a day, seven days a week. The website and phone operator translators are available in over 150 languages. The hotline is a confidential means of reporting suspected misconduct and complaints can be made anonymously.

The whistleblower hotline is managed through a secure, third-party vendor, providing employees a way of submitting concerns even if they are not comfortable reporting through their supervisor or campus. The hotline is also available to members of the general public who may have information about possible misconduct at the University. Providing 24/7 access allows reporters to make contact at a time and place they feel comfortable and increases availability to individuals located internationally. An important element of the whistleblower hotline is the reporter's ability to remain anonymous. In FY 2019-20, nearly 60% of reports were made anonymously.

Whistleblower Hotline Anonymous Reports
FY 2019-20

Identified 41.02 / Anonymous 58.98
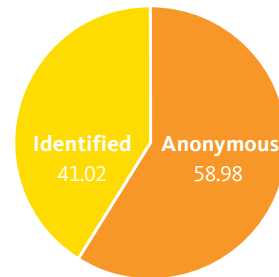
The hotline creates a record of all actions taken on the report, from first review through the closing of the complaint. Reporters are provided with a case number, whether reported through the website or call center. The case number allows reporters to review their reports through the web portal so they can provide additional information, upload documentation and review responses from the University while remaining anonymous.
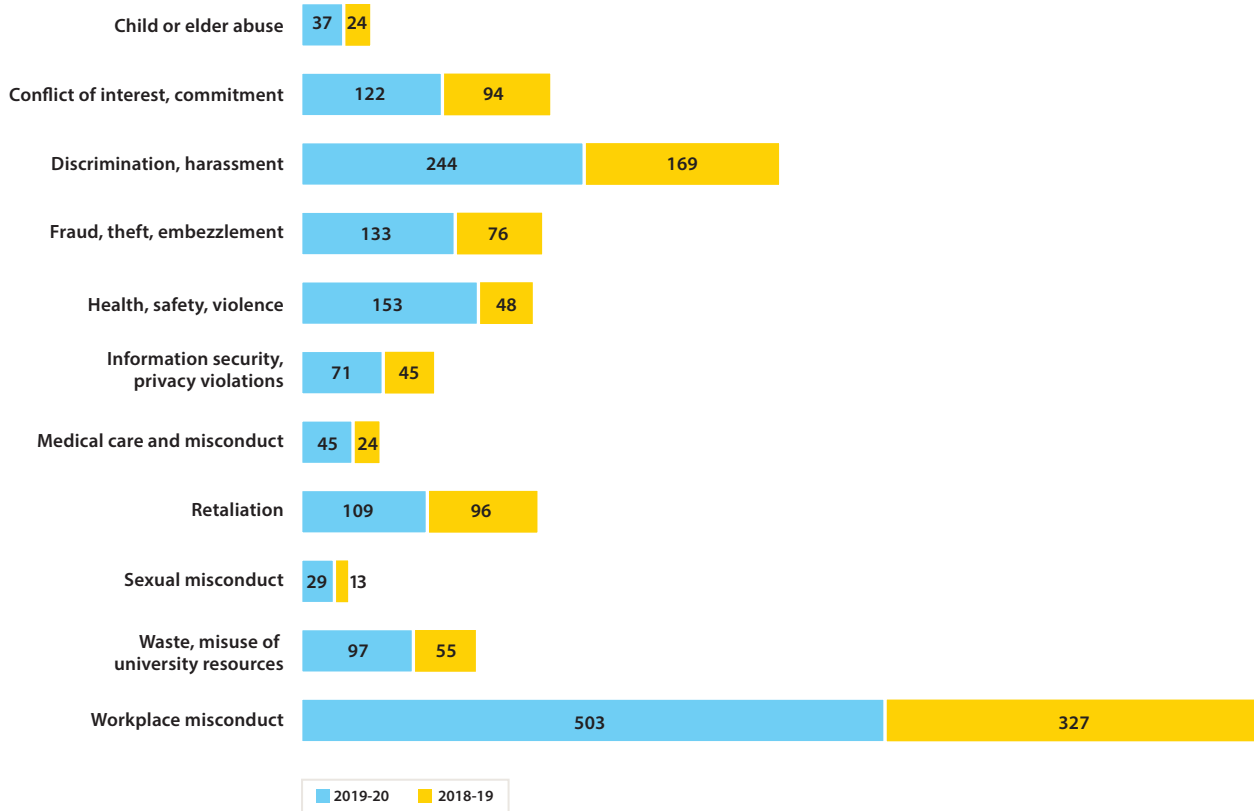
The hotline provides a mechanism for reporting various types of misconduct, as well as submitting other inquiries. In addition to accepting reports of misconduct subject to the Whistleblower Policy, reporters who don't know where else to report an issue can use the hotline to report other concerns requiring attention, such as concerns regarding health, safety or violence. Reports are reviewed and routed to appropriate parties to be addressed.
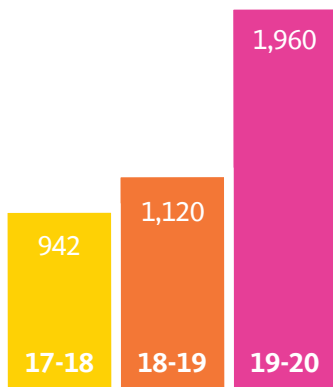
Additional Data and Trends

The number of cases reported in 2020 has more than doubled from 2018. The increase demonstrates a continuing increase in awareness and willingness to report suspected misconduct, but may also be related to the unique experiences of 2020.

By monitoring reports over time, ECAS is able to identify trends and focus compliance efforts effectively. Notably, FY 2019-20 has seen significant increases in Workplace Misconduct (35%), and Discrimination/Harassment (31%) complaints. There was also a 69% increase in Health/Safety/Violence complaints, primarily due to the reporting of COVID-19 related concerns.

Total Whistleblower Hotline Cases by Issue *FYs 2018-19 and 2019-20*

Issue	2019-20	2018-19
Child or elder abuse	37	24
Conflict of interest, commitment	122	94
Discrimination, harassment	244	169
Fraud, theft, embezzlement	133	76
Health, safety, violence	153	48
Information security, privacy violations	71	45
Medical care and misconduct	45	24
Retaliation	109	96
Sexual misconduct	29	13
Waste, misuse of university resources	97	55
Workplace misconduct	503	327

■ 2019-20   ■ 2018-19

Whistleblower Hotline Total Cases *FYs 2017-18 through 2019-20*

FY	Total Cases
17-18	942
18-19	1,120
19-20	1,960

Key Projects

ECAS is focused on increasing outreach to and creating strong collaboration with the UC locations to ensure best practices are consistently applied throughout the system.

COVID-19 restrictions in place during most of the 2020 calendar year heavily impacted some planned activities, such as the Investigator Academy that was planned to take place in April 2020. As investigators throughout the system moved to remote investigations, ECAS adapted its educational approach to deliver a variety of resources and critical training online:

- **Investigator Listserv** — The investigations unit initiated a listserv following the Investigator Roundtable as a method to continue communications and distribute resources. The listserv has rapidly grown to 160 subscribers and is regularly used to solicit input and advertise webinars.

- **Monthly Webinar Series** — Leveraging both internal and external resources, the unit implemented a monthly webinar series for investigators across the system. Over 130 investigators, human resources professionals, auditors, compliance staff, and Title IX investigators regularly attended the webinars. The webinar series provided training on a variety of topics, including the following:

  – Zoom Security Practices for Investigators Conducting Remote Investigations

  – Building Rapport in a Virtual Environment

  – Lessons Learned from Investigations Across the UC System

  In 2020, ECAS started a webinar series focused on best practices for report writing. These webinars will continue in the next fiscal year. ECAS will leverage expertize of several internal speakers and engage external experts to present on fundamental writing skills, writing executive summaries, and analysis, such as credibility assessments.

- **Quarterly Newsletter** — In April 2020, ECAS introduced a quarterly Investigations Newsletter. The goal of the newsletter is to provide an opportunity for investigators across the system to connect, collaborate, and share lessons learned. The newsletter featured articles on a variety of relevant topics, including best practices for virtual interviews and keeping investigations on schedule while working remotely, announcements from around the system, and information on upcoming training opportunities.

IV. CONCLUSION

Whether engaging with federal legislators and administrative agencies on complicated national and international matters, recommending improvements to campus safety practices, or establishing best practices on emergent research compliance issues, the University's compliance efforts are as unique and diverse as the University's operations. Through leveraging expertise throughout the system and maintaining strong collaborations, the University's compliance, audit and investigative efforts are able to both address the current slate of challenges and identify emergent local, state and federal issues.

ECAS will continue fostering relationships with our cross-functional risk partners across the system to further strengthen our compliance and audit efforts and ensure that the President, senior leadership and the Regents have the information necessary to discharge their oversight responsibilities.

V. ENDNOTES

1 Regents Policy 1111: Policy on Statement of Ethical Values and Standards of Ethical Conduct: "Members of the University of California community are committed to the highest ethical standards in furtherance of our mission of teaching, research and public service." *https://regents.universityofcalifornia.edu/ governance/policies/1111.html*.

2 The Regents reaffirmed the University's Ethics and Compliance Program in March, 2017 *https://regents.universityofcalifornia.edu/ regmeet/mar17/c1.pdf*

3 COVID-19 Compliance Resource page: *https://www.ucop.edu/ ethics-compliance-audit-services/compliance/coronaviruscovid-19-compliance-resources.html*

4 *https://www.ucop.edu/ethics-compliance-audit-services/compliance/ research-compliance/foreign-influence.html*

5 The Emergency Medical Treatment and Labor Act (EMTALA) is a federal law that requires anyone coming to an emergency department to be stabilized and treated, regardless of their insurance status or ability to pay.

6 Health Insurance Portability and Accountability Act of 1996 (HIPAA) is the U.S. legislation that provides data privacy and security provisions for safeguarding medical information.

7 False Claims Act (FCA) 31 U.S.C. §§ 3729 to 3733 *https://www. govinfo.gov/app/details/USCODE-2011-title31/USCODE-2011-title31-subtitleIII-chap37-subchapIII-sec3729* Under the False Claims Act, a healthcare provider is subject to civil and criminal penalties for submitting claims for payment to Medicare or Medicaid that the provider knows or should know are false or fraudulent. Claims for services that are not medically necessary, of substandard quality, or are not actually rendered may be considered false claims.

Physician Self-Referral Law (Stark Law) 42 U.S.C. 1395 *https:// www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral* The Stark Law prohibits healthcare providers from paying for referrals or referring patients to receive certain healthcare services payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/ investment and compensation arrangements.

Anti-Kickback Statute (AKS) *https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp* The Anti-Kickback Statute prohibits the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by the federal health care program. Remuneration includes anything of value (cash, free rent, meals, excessive physician compensation).

8 *https://clinicaltrials.gov* is a database of privately and publicly funded clinical studies conducted around the world.

9 Office of Management and Budget Memos *https://www.whitehouse. gov/omb/information-for-agencies/memoranda/*

10 *https://vig.cdn.sos.ca.gov/2020/general/pdf/topl-prop24.pd*f

11 Internal Audit Charter: *https://www.ucop.edu/ethics-compliance-audit-services/audit/internal-audit-charter.html*

12 Internal Audit is required to adhere to the Institute of Internal Auditors' Code of Ethics and International Standards for the Professional Practice of Internal Auditing (IIA Standards), and undergoes an independent assessment every five years to assess its conformance to these standards. Among other requirements, the IIA Standards require that internal auditors be independent and objective in performing their work, and that Internal Audit be free from interference in determining the scope of internal auditing, performing work and communicating results. Any such interference must be disclosed to the Board of Regents.

13 Efficiency level is the percentage of direct hours that are devoted to audit, advisory services, investigations and audit support activities.

14 The Whistleblower Policy is available at *https://policy.ucop.edu/ doc/1100171/Whistleblower* The Whistleblower Protection Policy is available at *https://policy.ucop.edu/doc/1100563/WPP* Translations into the primary languages used by large groups of UC employees are also available.