

Compliance Plan for 2022-23

July 20, 2022



Compliance Plan

COMPLIANCE RISK ASSESSMENT RESULTS

ECAS identified the following compliance risk priorities for 2022-23 through the systemwide risk assessment process.

	EXPORT CONTROL	RESEARCH	HEALTHCARE	PRIVACY	GENERAL COMPLIANCE
TOP RISKS	<ul style="list-style-type: none"> Research Security Restricted Party Screening 	<ul style="list-style-type: none"> Foreign Influence / Research Security Conflicts of Interest/ Commitment 	<ul style="list-style-type: none"> Revenue Cycle Compliance Clinical Data Security 	<ul style="list-style-type: none"> Data Management – Classification, Mapping, Minimization 	<ul style="list-style-type: none"> Clery Act
	<ul style="list-style-type: none"> International Shipping International Collaborations and Economic Trade Sanctions (OFAC) International Travel Hosting foreign visitors International Traffic in Arms Regulations (ITAR) Export Administration Regulations (EAR) 	<ul style="list-style-type: none"> Resource/Funding Research Data Security/Privacy Clinical Research Contracts & Grants reporting IP/Patent Control Cybersecurity Maturity Model Classification (CMMC) requirements 	<ul style="list-style-type: none"> Health/Research Data Governance & Privacy Conflicts of Interest/ Commitment – Clinical Setting Drug Diversion Telehealth Student Health/Counseling 	<ul style="list-style-type: none"> Artificial Intelligence and Machine Learning Information Security Policy Compliance Data Subject Privacy Integrated Security & Privacy Assessment of Vendors 	<ul style="list-style-type: none"> ADA/Disability Lab Safety Emergency Management Child Abuse and Neglect Reporting Act (CANRA) National Collegiate Athletic Association (NCAA) Compliance

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EXPORT CONTROL PROGRAM

UC is at the forefront of research and innovation, and many aspects of our operations include an international component that requires export control considerations. Export control laws prohibit the unlicensed transfer of certain materials or information for reasons of national security or protection of trade. ECAS provides general export control support and advice to UC locations. The Empowered Official in ECAS ensures compliance with the International Traffic in Arms Regulations (ITAR) administered by the Department of State.

Identified Risk

- Global conflict has created new sanctions and technology restrictions for UC.

Major Initiative

Evaluation of Systemwide Shipping Software Tool

- The shipment of items, information or software outside the U.S. may create export control risks. ECAS' Export Control Office will evaluate the various shipping practices throughout the system and recommend options to reduce compliance risks and create cost-savings for the system.

Training

Advanced Training for Export Control and Agreements Officers

- ECAS will create a series of export control courses to strengthen systemwide Export Control Officers' skills in areas such as technology and software controls, end-user controls and license exceptions.
- ECAS will create a maturing risk assessment framework to support Procurement and Agreement Officers in identifying transactions requiring export control and license review, focusing on technology controls, restricted parties and destination concerns.

Collaboration with Federal Agencies

- ECAS will continue to actively partner with the Bureau of Industry and Security (BIS) and State Department, including providing joint presentations and trainings.

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RESEARCH SECURITY PROGRAM

ECAS is closely monitoring impacts of the White House Office of Science & Technology Policy (OSTP) issued National Security Presidential Memo 33 (NSPM-33). This memo provides best practices to sponsoring agencies on addressing undue foreign influence at institutions of higher education that receive federal research funding. ECAS has been closely monitoring developments in this area since January 2022 to better prepare UC.

Identified Risk

- NSPM-33 will require UC to develop and certify research security programs in order to qualify for federal research funds.

Major Initiative

Research Security Forum

- ECAS will lead a systemwide partnership to coordinate research security program requirements initiated by federal sponsors and resulting implications to the UC research enterprise.

Training

Building Outreach and Awareness Related to Program Awareness

- ECAS will develop a research security program awareness training covering disclosure requirements, export control key issues, international travel and security risk awareness.

Collaboration with Federal Agencies

- ECAS will collaborate with the White House Office of Science Technology Policy Working Group regarding NSPM-33 to share UC best practices.

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RESEARCH COMPLIANCE PROGRAM

The federal government heavily regulates the basic and applied research conducted at UC. Regulations come from various entities including: the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), Health Information Portability and Accountability Act (HIPAA), National Science Foundation (NSF) and National Institutes of Health (NIH). ECAS routinely collaborates with research offices across the UC system towards programmatic research compliance oversight with risk assessments, monitoring, training and awareness.

Identified Risks

- Oversight of mandatory public disclosures for clinical trials, use of artificial intelligence in software as medical devices, oversight of controlled substances in research, human subjects research protections and research subject data privacy.

Major Initiative

Creation of a Conflict of Interest and Conflict of Commitment Disclosure Portal

- ECAS and the Office of Research, Policy, Analysis and Coordination (RPAC) will review current research disclosure practices in an effort to design a systemwide conflict of interest and conflict of commitment disclosure portal to reduce administrative burden on faculty while improving research disclosures.

Training

Federal Grant Disclosure Requirements Training

- ECAS will create training material, infographics, disclosure matrixes and webinars to assist research administration professionals and faculty members navigate the evolving disclosure requirements for federal grants.
- Topics: Grant disclosure requirements, conflict of interest and conflict of commitment, foreign component, publications and affiliations.

Collaboration with Federal Agencies

- In consultation with National Institutes of Health (NIH) creating an infographic on NIH foreign influence case studies to raise risk awareness for the research community.

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CLERY ACT COMPLIANCE PROGRAM

The Jeanne Clery Disclosure of Campus Security Policy and Campus Crime Statistics Act of 1998 (Clery Act) compliance program is coordinated by ECAS and Clery Act Officers and Coordinators at each location. In accordance with Clery Act requirements, each campus publishes an Annual Security and Fire Safety Report, including crime statistics, information on various campus and community resources related to crime prevention and community assistance. ECAS will continue to regularly convene meetings with Clery Act Officers and Coordinators throughout the system to ensure awareness and coordination on these issues.

Identified Risk

- The Department of Education (ED) is currently monitoring and reviewing multiple campuses' Clery compliance and has increased scrutiny of UC's Clery Act policies and procedures.

Major Initiative

- ECAS will initiate a comprehensive systemwide review and update to the UC Clery Act Policy to comply with ED expectations under the Clery Act.

Training

Clery Act Annual Training

- ECAS will provide training and a practical skills workshop for locations' Clery compliance professionals, focusing on high-risk areas and lessons learned.
- Topics: timely warnings and emergency notifications, record keeping for audits, lessons learned, counting crimes, memoranda of understanding, and academic medical centers.

Systemwide Support

- ECAS recently contracted with a national Clery Act expert to provide subject matter expertise to ECAS and the system.
- ECAS is initiating the recruitment process for a dedicated systemwide Clery Act Compliance Officer.

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HEALTHCARE PROGRAM

UC's academic health centers are some of the most complex and heavily regulated entities within the system. Healthcare compliance obligations largely center around laws designed to protect government health programs (e.g., Medicare and Medicaid) from fraud and abuse.

Identified Risks

- Cybersecurity, management of conflicts of interest and commitment, health and research data governance and privacy, revenue cycle compliance, drug diversion, and telehealth.

Major Initiatives

UC Health Annual Risk Assessment and Workplan Process Improvement

- ECAS and Healthcare Compliance Officers will focus on strengthening existing risk assessment processes at the academic health centers to ensure locations are taking a risk-based approach in identifying their locations' highest compliance risks and allocating the necessary resources to manage or mitigate them.

Compliance Auditing System Implementation

- ECAS and Healthcare Compliance Officers are collaborating on the implementation of an automated auditing system that identifies potential errors in billing that may result in errant charges, allowing academic health centers to quickly address them and design timely training or controls.

Conflict of Interest and Conflict of Commitment

- ECAS is collaborating with UC Legal to revise current policy to address conflicts of interest and commitment risks at academic health centers.

Training

Standards for the Access and Sharing of Health Data

- ECAS will develop training for UC personnel with access to health data to ensure their understanding of the law and policies governing the compliant use and sharing of UC patient, employee, and student health information.

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PRIVACY PROGRAM

ECAS supports UC locations in handling a diverse array of privacy compliance challenges. The Family Educational Rights and Privacy Act (FERPA), California Information Practices Act (CIPA), and General Data Protection Regulation (GDPR) are some of the key privacy regulations. Health information is also regulated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Confidentiality of Medical Information Act (CMIA).

Identified Risk

- Protecting sensitive personal data is critically important. Privacy compliance permeates all UC activities including research, healthcare, student life and operational processes.

Major Initiatives

Compliance Toolkit for Sharing Health Data Outside the University

- ECAS will create training, checklists and other tools for systemwide personnel to ensure health data sharing outside the University is consistent with laws and UC policies.

Data Classification/Breach Analysis Tool

- ECAS will create an “At-a-Glance” digest of privacy laws and breach reporting triggers for Health Privacy and Campus Privacy Officers, Information Technology personnel, and other risk partners to enable more accurate data classification and breach reporting analysis.

HIPAA Policy Suite Revisions

- ECAS will initiate a multi-phase project to assess and reconcile UC’s multiple systemwide HIPAA policies to ensure consistency with current health privacy law requirements and UC practices.

Training

Protecting Data Privacy – Training for Data Set Owners

- ECAS will create briefing and implementation resources for owners of large employee and student data sets to build awareness of UC’s duties and data subject rights provided by various privacy laws.

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ADA PROGRAM

ECAS coordinates compliance efforts with UC locations related to the broad requirements of the Americans with Disabilities Act (ADA) and other regulations. These laws prohibit discrimination on the basis of disability by ensuring that entities receiving federal funds are equally accessible to individuals with disabilities. California State Disability laws and UC policy also prohibit discrimination based on disability.

Risk Priorities

- There is significant risk to UC operations in breadth of issues and persons affected by the entire landscape of disability law, policy, and regulations; the potential harm to individuals; reputational harm; and fiscal harm of non-compliance.

Major Initiatives

Academic Accommodations Tool Kit

- ECAS will develop, in collaboration with UC Legal and systemwide ADA Compliance Officers, infographics and compliance alerts on academic accommodations for campus use as tools to educate UC personnel on ADA requirements/processes for classroom accommodation requests.

Training

ADA Compliance and Administrative Structure

- ECAS is creating a guide for faculty and staff addressing student requests for accommodations, implementing academic adjustments and engaging in the interactive process at UC.

Emergency Management and ADA Best Practices

- ECAS is developing a guide for UC administrators on incorporating ADA considerations and compliance into campus emergency planning.

ADA Considerations in Investigations

- ECAS is creating training materials for systemwide investigators on best practices when investigating ADA discrimination/harassment claims.

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ECAS routinely engages with a host of systemwide stakeholder groups to raise awareness of regulatory issues, share best practices, discuss challenges and prioritize compliance initiatives.

COMPLIANCE AREA	STAKEHOLDERS
ADA	Campus ADA Compliance Officers, UC Legal, Chief Accessibility & Inclusion Officers
Clery	Campus Clery Officers, UC Legal
Clinical Research	Clinical research compliance professionals, UC Legal, Research Policy Analysis & Coordination (RPAC)
Export Control	Export Control Officers, Senior International Officers, UC Legal, OP Research Policy Analysis & Coordination, and Research Compliance Officers
General Compliance	Campus Chief Ethics and Compliance Officers
Healthcare	Healthcare Compliance Officers, UC Legal, UC Health, RPAC, UC procurement offices, International Review Board (IRB) Directors
Health Privacy	Health Privacy Officers, UC Legal, UC Health, Systemwide Information Security, UCOP security and IT teams, RPAC, UC procurement offices, IRB Directors
Campus Privacy	Campus Privacy Officers, UC Legal, Systemwide Information Security, UCOP security and IT teams, Risk Services, UC procurement offices
Research	Associate Vice Chancellors of Research, Research Compliance Officers, Conflict of Interest Officers, Export Control Officers, UC Legal, and RPAC