



COMPLIANCE ALERT

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Foreign Engagement

Department of Education Higher Education Act Section 117 Proposal

As of December 17, 2019, the Department of Education's proposal for the Higher Education Act (HEA) Section 117 is available online. Section 117 of the HEA states the circumstances in which higher education institutions should disclose foreign gifts and contracts. The DoE is requesting the OMB expedite the comment period under the Paperwork Reduction Act, making Friday, December 27, 2019 the final day of the comment period.

New Reporting Requirements for Chinese Delegations Visiting Universities

On October 15, 2019, the U.S. Department of State issued a new determination under the Foreign Missions Act, requiring members of the Chinese diplomatic corps to notify the State Department when making visits to educational and research institutions, among other entities. The Department's [determination](#) requires U.S.-based personnel of the People's Republic of China's (PRC) foreign missions (including personnel at the embassy and consulates of the PRC and those on temporary assignments conducting official business for the PRC government) to notify the State Department's Office of Foreign Missions in advance of:

- Official visits to educational institutions
- Official visits to research institutions, including National Labs
- Official meetings with state officials
- Official meetings with local and municipal officials

Chinese diplomats only need to inform the Department of these types of meetings. They do not need the State Department's permission to visit educational institutions. Depending on your location procedures, hosts should notify the appropriate office such as Global Engagement or Export Control, when hosting visiting delegations.

ECAS Foreign Influence Website

The new ECAS Foreign Influence website is live and contains resources covering:

- Disclosing requirements for all international activities and affiliations in grant applications;
- Overview of current federal funding policies and regulations and grant procedures;
- Best practices for data security while traveling abroad;
- An outline of ECAS initiatives to address foreign influence on research integrity;
- Federal grant policies and regulations, links to UC policies, information on export controls, UC systemwide contacts, campus-level

contacts, and Academic Personnel Manual policies related to conflict of commitment and conflict of interest.

New Reports from HHS Inspector General on COI and Foreign Influence

The U.S. Department of Health and Human Services Office of Inspector General recently issued three reports related to conflicts of interest and how the National Institutes of Health is addressing concerns about the threat of undue foreign influence in federally funded research.

- Vetting Peer Reviewers at NIH's Center for Scientific Review: Strengths and Limitations – Link to [OEI-01-19-00160 report](#).
- The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping to Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations – Link to [A-03-19-03003 report](#).
- The NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More – Link to [OEI-03-19-00150 report](#).

Congress Creates Two New Bodies to Tackle Foreign Influence on U.S. Research

The approval of the National Defense Authorization Act (NDAA) by congress would create two new groups to tackle risks to federally funded research. A White House based group will focus on coordinating the response of over a dozen federal agencies in protecting research from potential foreign threats. The second advisory group, chaired by the National Academies of Sciences, Engineering and Medicine (NASEM), will gather stakeholders from academia, government and the private sector to focus on maintaining international collaborations.

Healthcare Privacy and Security Pitfalls

OCR Imposes \$1.6M Penalty for HIPAA Violations

A Texas state agency, formerly known as the Department of Aging and Disability Services, reported to the Office for Civil Rights (OCR) in 2015 that electronic protected health information was visible on the internet when patient information on an internal application was moved from a private to public server due to a coding flaw. After further investigation, the OCR determined the agency also failed to conduct a risk analysis and imposed a \$1.6 million penalty.

Failure to Encrypt Mobile Devices Leads to \$3 Million HIPAA Settlement

After discovering an unencrypted flash drive was lost and an unencrypted laptop stolen, the University of Rochester Medical Center reported to the OCR that

protected health information (PHI) may have been compromised. The university medical center has agreed to corrective actions and to pay \$3 million.

\$2.175M HIPAA Settlement after Hospitals Failed to Properly Notify HHS of a Breach

The OCR received a complaint from a Sentara Hospital patient in receipt of a bill containing PHI of another patient. Sentara incorrectly reported the breach affected 8 patients, but the OCR determined the incorrect mailings included information for 577 patients and that Sentara Hospitals failed to obtain a business associate agreement with Sentara Healthcare.

Outside Professional Activities

Three Percent of NIH Grants Involved a Direct Financial Conflict of Interest

The Office of Inspector General (OIG) of the Department of Health and Human Services issued a report highlighting that approximately three percent of NIH funded researchers reported a direct conflict of interest (COI). Since a 2008 OIG report, the NIH improved tracking of COIs through an online system. The 2019 OIG report recommends the NIH create a periodic quality assurance process and take foreign affiliations and financial components into consideration.

Many Public Universities Refuse to Reveal Professors' Conflicts of Interest

An inquiry sent to public universities requesting academic conflict of interest disclosures resulted in varied responses. Responses from California institutions included over 2,600 forms.

Medical Professors are Supposed to Share Their Outside Income with UC

A comparison of University of California (UC) outside financial disclosures with federal data potentially reveals UC health faculty underreporting income received from outside professional activities.

Clery Act

A Record Fine for Underreporting

The U.S. Department of Education (DoE) has fined Michigan State University (MSU) \$4.5 million for underreporting sexual abuse allegations against former athletics doctor Larry Nassar. Under investigation, the university was found to have violated several provisions of the Jeanne Clery Disclosure of Campus Security Policy and Campus Crime Statistics Act (Clery Act). Under two agreements, the university will need to: reevaluate its Title IX office, hire a Clery compliance officer, investigate and possibly discipline involved employees, and undergo visits by the DoE.

UC Policies and Guidance

BFB-IS-3: Electronic Information Security

Technical updates as of October 25, 2019 include:

- Consistent use of the terms “portable media,” “portable computing device,” and “electronic

media.”

- Removal of duplicate word in III.2.
- Fixed numbering error in III.10.1.
- Clarified encryption requirement in III.10 by removing extra words.
- Changed “campus” to “location” in 16.1.2.

Interim Policy: Responding to Immigration Enforcement Issues Involving Patients in UC Health Facilities

The California Values Act (Cal. Gov. Code § 7284 et seq.), which went into effect on January 1, 2018, requires that the California Attorney General “publish model policies limiting assistance with immigration enforcement to the fullest extent possible consistent with federal and state law” at several kinds of public institutions and facilities, including “health facilities operated by the state or a political subdivision of the state.”

The Act further requires that all such health facilities implement these policies or equivalent policies, and encourages “all other organizations and entities that provide services related to physical or mental health and wellness,” including the University of California, to adopt the model policies.

Given the California Values Act’s requirements that the model policies limit immigration enforcement assistance “to the fullest extent possible consistent with federal and state law” and all State- and local government-operated health facilities implement them, as well as UC Health’s commitment to creating the safest environment possible for all patients to obtain medical care regardless of their immigration status, UC Health has chosen to adopt the Attorney General’s model policies as set forth in this Policy while maintaining flexibility for UC Health Facilities to implement them consistent with local conditions.

BFB-RMP-7: Protection of Administrative Records Containing Personally Identifiable Information

The University is committed to protecting personal privacy in its operations, activities, and management of information. The University must balance this commitment with other important commitments, including public accountability and the right of people to access information about the conduct of the public’s business. This policy outlines the requirements and processes for ensuring the University protects Personally Identifiable Information found in Administrative Records by meeting its legal obligations, as well as balancing information privacy and autonomy privacy with competing institutional obligations, values, and interests.

This policy replaces policies: BFB-RMP-7, BFB-RMP-8, BFB-RMP-11, BFB-RMP-12. September 16, 2019 revisions to this policy include:

- Limited scope to personally identifiable

information in administrative records.

- Identified areas of the old policies that are still relevant.
- Identified areas that needed updated content.
- Built on foundation of UC Statement of Privacy Principles & Values
- Defined GDPR and identified that it is not addressed in this policy
- Clarified roles of subject-matter experts
 - Privacy Officials
 - Records Management Coordinators
 - Information Practices Coordinators

AM-P-196-13 Payroll: Attendance, Time Reporting and Leave Accrual Records

As of September 1, 2019, this reformatted policy:

- Includes UCPATH with PPS as the payroll system.
- Removes magnetic tape and magnetic file.
- Updates references from OMB Circular A-21 to 2 CFT Part 200.
- Adds information on Leave Accruals, rates, and procedures.
- Excludes UC Hasting from scope except where expressly noted.

What's Happening at UC

ECAS Annual Report

Each year, the Office of Ethics, Compliance and Audit Services (ECAS) works with the ten campuses, Lawrence Berkeley National Laboratory (LBNL), the Office of the President (UCOP), the Division of Agriculture and Natural Resources (ANR), and the five academic UC medical centers in identifying their risk priorities and in developing and executing related annual work plans. The 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 2018-19.

2019 Ethics, Compliance and Audit Symposium

Between October 28-30, 2019, over 300 attendees gathered for the 2019 Ethics, Compliance and Audit Symposium, hosted by the Office of Ethics, Compliance and Audit Services. The program opened with a welcome by Senior Vice President and Chief Compliance and Audit Officer Alexander Bustamante and included general sessions on: Ethics, Regulatory Updates, a Federal Foreign Influence Update, and a keynote by the Chair of the Board of Regents, Regent John A. Pérez. Further compliance and audit-related

sessions consisted of:

- Accountability and Compliance in the Age of AI
- Clery Act Compliance
- Disaster Recovery / Business Continuity
- UC Health Affiliations: Assessing and Reducing Compliance Risk
- Laboratory Safety at UC
- Fraud Red Flags
- Clinical Research: Operations and Compliance; Staying in Compliance with FDA and Clinicaltrials.gov Requirements
- Export Controls
- TeamMate Analytics
- Controlled Substances Programs
- Research Privacy
- A Science Based Approach to Implicit Bias and Decision-Making; Emotional Intelligence
- Plus many more. A few presentations are available on the ECAS website: [ECAS Symposium Presentations](#).

On behalf of SVP Bustamante and the ECAS team, we extend a thank you to all attendees and speakers for their participation and for contributing to UC in reaching new heights. Below we share a few captured Symposium moments.



