April 15, 2021

SANDRA A. BROWN Vice Chancellor Research 0043

Subject: Foreign Influence (Systemwide)

Report 2020-01

The final report for Foreign Influence (Systemwide), Project 2020-01, is attached. We would like to thank all members of the department for their cooperation and assistance during the review.

Because we were able to reach agreement regarding management action plans in response to the audit recommendations, a formal response to the report is not requested. The findings included in this report will be added to our follow-up system. We will contact designated personnel at the appropriate time to evaluate the status of the management action plans, as listed in Addendum 2 of this document.

UC wide policy requires that all draft reports be destroyed after the final report is issued. We also request that draft reports not be photocopied or otherwise redistributed.

Christa Perkins Director

Audit & Management Advisory Services

Attachment

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AUDIT & MANAGEMENT ADVISORY SERVICES

Foreign Influence (Systemwide) Report No. 2020-01 April 2021

FINAL REPORT

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ADDENDUM 1: Systemwide Foreign Influence Audit, Project No. P20A004

ADDENDUM 2: Systemwide Foreign Influence Audit – Campus Management Corrective Actions

I. BACKGROUND

Audit & Management Advisory Services (AMAS) has completed a review of Foreign Influence as part of a Systemwide Audit of Foreign Influence, under the direction of the University of California Office of the President (UCOP). This report supplements the *Systemwide Audit of Foreign Influence, Project No. P20A004*, issued by the Office of Ethics, Compliance, and Audit Services (ECAS) (*Addendum 1*).

Since early 2018, federal agencies and policymakers have expressed heightened concern that foreign entities may be using the academic research enterprise in an attempt to compromise the United States' economic competitiveness and national security. Some of the key concerns include the diversion of intellectual property to foreign entities, sharing of confidential information by peer reviewers with foreign entities, and failure by researchers to disclose substantial resources from other organizations including foreign entities. As a result, federal funding agencies have increased their efforts to clarify long standing policies, and issue guidance on reporting requirements. It is critical that faculty and researchers maintain their diligence in disclosing all forms of research support, affiliations, and foreign components as required by federal regulations.

In January 2019, the Executive Vice Chancellor Academic Affairs (EVCAA) and the Vice Chancellor Research (VCR) issued a campus notice to all academics, key administrators and support staff at UC San Diego (UCSD) on the requirement to disclose all foreign engagements. Foreign engagements involve many areas of the UCSD research enterprise, and disclosure requirements are summarized for the following key areas:

- <u>Conflict of Interest (COI)</u>: COI policies require university employees who are conducting
 research or other related activities to disclose certain financial interests, whether domestic or
 foreign. The disclosure requirements vary between non-federal, Public Health Services (PHS)
 sponsored research, and other federal research. There are multiple UC policies and federal
 requirements for COI disclosures for National Science Foundation Awards, private sponsors of
 research, PHS awards, and sponsored projects.
- Conflict of Commitment (COC): UC policies require faculty to submit an annual COC report indicating whether or not they have engaged in outside activities during the fiscal year. Outside professional activities are separated into three categories (I, II and III). Categories I and II include activities that must be reported and in the case of Category I, must receive prior approval before the faculty member engages in the activity. Category I activities include serving in an executive or managerial role for an outside business, administering a grant outside the University, or serving as a salaried employee outside the University. Authority to approve Category I activities has been delegated to the EVCAA for campus and Scripps Institute of Oceanography (SIO), and the Associate Vice Chancellor (AVC) Academic Affairs for Health Sciences.
- <u>Federal award applications</u>: Applicants for federal grants must list all foreign affiliations in their biosketch and "other support" prior to award as required by the sponsoring agency, and are required to identify any changes in each annual progress report. In July 2019, National Institute of Health (NIH) issued a notice (NOT-OD_19-114), Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components. The notice reminded applicants to disclose all resources in "other support," including resources and/or financial support from all foreign and domestic entities. NIH also required recipients to

- disclose if there is a foreign component for the project, which is the existence of any "significant scientific element or segment of a project" outside of the United States.
- Exceptions for awards outside the University: UC Policy requires employees to submit proposals for extramural support through the University. Exceptions to this requirement may be granted by the on a case by case basis. At UCSD, exception requests must be submitted to the Research Compliance and Integrity Office, for approval by the VCR.
- Intellectual Property: The UC Patent Policy requires all employees to promptly and fully disclose the conception and/or reduction to practice of potentially patentable inventions. Disclosures are made to the Office of Innovation and Commercialization (OIC) through the Online Invention Disclosure System.

At UCSD, there are three sponsored project offices for pre-award management for general campus, Health Sciences, and Scripps Institute of Oceanography (SIO). Sponsored project offices review and authorize proposals for submission to extramural sponsors. They also assist researchers with the submission of technical reports when required by a sponsor, and submit prior approval requests to sponsors as Authorized Officials. Departments coordinate with researchers in the proposal and annual report preparation, and also administer COC form collection and sabbatical leaves for the faculty.

II. AUDIT OBJECTIVE, SCOPE, AND PROCEDURES

This objective of our review was to evaluate the system of internal controls in place to manage risks identified by the federal government related to foreign influence. The scope of the audit included evaluation of the design of internal controls and procedures in the following areas relevant to foreign influence risk:

- Foreign Influence & Disclosure Monitoring
- COI and COC (disclosure monitoring and reporting)
- Export controls
- Sponsored programs/grant processing (including Other Support and foreign collaborations),
- Development and alumni relations, including screening and reporting of gifts from foreign entities
- Visas for international scholars and student/graduate studies
- International activities & agreements / inventory of foreign collaborations
- Academic departments and faculty (sponsored project review, visiting scholars, security of laboratory space)
- Intellectual property security and control / disclosure of inventions and data exchange agreements
- Training for faculty on COI/COC disclosure requirements
- Policy review and identification of gaps between local and Systemwide policies and regulatory requirements.

In order to achieve our objective, we performed the following procedures in accordance with the Systemwide audit program:

• Interviewed appropriate personnel in the following areas to gain an understanding of current

practices in relation to foreign influence:

- Research Compliance and Integrity (RCI),
- o COI Office,
- Sponsored Project Offices: Office of Contract and Grants Administration (OCGA),
 Scripps Institute of Oceanography (SIO) OCGA, Health Sciences Sponsored Project Pre-Award Office (HSSPPO),
- o OIC,
- Office of International Affairs (OIA), and Global Education,
- o Export Control,
- Academic Affairs and Dean's Office (Health Sciences),
- International Student Program Office (ISPO), and International Faculty and Scholars Office (IFSO),
- Office of Postdoctoral and Research Scholar Affairs,
- o Advancement,
- Health Sciences Business Contracting,
- Health Sciences Office of Compliance and Privacy (OCP),
- Academic departments including Skaggs School of Pharmacy, Bioengineering, Medicine, Biological Sciences, and Chemistry and Biochemistry;
- Selected a sample of 15 NIH grants from emerging technologies as identified in the list of
 "Representative Technology Categories" in the Bureau of Industry and Security 11.19.2018
 Proposed Rule. Utilized the approach recently referenced by NIH to compare information in
 various grant documents (Biosketches, Other Support, COI Disclosures, Progress Reports) with
 COC disclosures, publications, and sabbatical documents to evaluate the accuracy of other
 support, affiliation reporting, and commitment (effort months on the grant) for the principal
 investigator (PI) and co-investigator on the grant; and
- Referred any potentially undisclosed affiliations and other discrepancies identified in the analysis of the sampled grants to the Locally Designated Official (LDO) or RCI for further evaluation.

III. CONCLUSION

Based on our review procedures, we identified opportunities to strengthen policies and procedures related to foreign influence risks. In general, the opportunities for improvement noted for our campus aligned with observations in the Systemwide Audit Report (*Addendum 1*), and were addressed through the Systemwide recommendations. Consequently, there are no additional local recommendations for our campus. The Systemwide Audit Report contains a total of 32 recommendations, including 17 to systemwide stakeholder groups and 15 to the campus locations. The management corrective actions (MCAs) for the 15 local recommendations are summarized in *Addendum 2*.

Although there were several opportunities of improvement identified, we noted that UCSD had taken steps to help mitigate foreign influence risks. Our observations and additional comments on selected UCSD practices evaluated in the scope of this review are discussed in Section IV of this report.

IV. SUPPORTING COMMENTS

A.

Foreign Influence Risk Areas

Disclosure Monitoring

We noted that the research project administration involved multiple offices across UCSD, including the departments for the researchers, RCI, COI Office, sponsored projects offices, and Export Control. COC disclosures were managed through academic departments. There was no administrative process to routinely compare data between COI, COC, sabbaticals, grant documentation and publication data (affiliations and acknowledgements) to determine if there were any potential foreign component or other support implications, or undisclosed items. Departments and sponsored projects offices expressed that they did not have the resources or access to fully validate the information, and relied on the PI for full disclosure. Campus departments generally indicated that they had had not been given specific directive to establish a process for examining foreign influence in research.

In 2020, RCI developed a plan to increase monitoring in this area, outlining two proposals to help identify potentially undisclosed faculty interests: (1) COI/COC Monitoring, and (2) Foreign Engagement Monitoring. The COI/COC Monitoring plan includes performing sample-based monitoring of COI and COC disclosures for selected researchers to ensure that necessary financial interests and outside professional activities have been properly and consistently disclosed. The Foreign Engagement Monitoring initiative expands on this review by performing sample-based monitoring of selected researchers on grants to ensure that necessary foreign components and collaborations have been properly and consistently disclosed. This would entail an initial review of the publications, COI and COC forms for the researcher to identify any foreign affiliations and disclosures, and compare results with grant documentation, and other documentation/information on travel, export control and intellectual property offices.

In addition, in January 2021, two new questions were added to the Research Questionnaire in Kuali Research, UCSD integrated contracts and grants management and conflict of interest system, to assist PIs in full disclosure of foreign components or other support. The researcher is asked whether there is any element of the project be performed outside of the United States, and whether the PI has received any resources (financial or non-financial) from any foreign entities. These questions will improve UCSD's process for identification and disclosure of foreign support.

Conflict of Interest

Consistent with the observation in the Systemwide Report, we also observed that the Office of Ethics and Compliance and Health Sciences Compliance Officer were not generally made aware of issues related to significant COI for faculty. The AVC Academic Affairs for Health Sciences and associated Chairs were copied on COI Independent Review Committee's (IRC) management strategy letters for Health Sciences faculty. In addition, the Human Subject Research Protections Program (HRPP) was copied on IRC letters for research involving human subjects. However, the Health Sciences Office for Compliance and Privacy was not informed of significant COI issues, which could be helpful as it evaluated compliance with additional COI policies unique to that environment.

Conflict of Commitment

We noted that Departments were responsible for administering the collection and evaluation of COC forms, but there were generally no consequences for late submission of the forms. However, there

have been recent developments in the monitoring practices for campus academic faculty COC reporting. The EVCAA now receives periodic reports on non-compliance with COC submissions, which are distributed to the Deans with the indication that non-compliance will be reflected in the annual performance review.

For Health Sciences, there had been communication from the School of Medicine Dean to faculty on COC submissions, which improved compliance substantially for the last fiscal year. Although it was indicated that there is a potential that faculty will be taken out of good standing and compensation will be impacted, this has not been considered necessary. Campus did not have a documented framework for escalation or consequences for late disclosures.

Training / Awareness

UCSD has provided an array of training on COI, COC, and foreign influence offered to staff and faculty to increase understanding of foreign influence risks. In addition to the courses available through UC Learning, there are regular webinars, town halls, HSSPPO fund manager meetings, one on one sessions, and multiple campus websites that provided a wealth of information. RCI also has newsletters, small group presentations, and research compliance trainings offered regularly to educate researchers and support staff. Further implementation of Systemwide training will add to these efforts.

Export Control / Restricted Party Screening

We observed generally strong practices over restricted party screenings which were typically performed by departments or contracting offices, with positive screenings elevated to the Export Control Office for review. In addition, we observed strengths within the Export Control Office with documented internal procedures for reviews (foreign person, shipment, restricted entity), a record keeping matrix, restricted party screening responsibilities, and escalation protocols for reporting suspected violations to leadership.

Campus Academic Personnel compared entities on Category 1 requests to a list of institutions from Export Control to identify any red flags. However, for Health Sciences, the Compliance Advisory Group (CAG)¹ did not perform restricted party screening for Category I activities with foreign entities, as they were considered outside of their scope of review for compliance with the COC policy.

Postdoctoral Researchers and Visiting Scholars

The Office for Postdoctoral and Research Scholar Affairs (OPRSA) approved appointments and exceptions for postdoctoral researchers and visiting scholars. We noted that while practices for vetting postdocs appeared strong, similar processes for visiting scholars were inconsistent. Although OPRSA evaluated the appointment for red flags (for example, questioning the PI for scholars from a private company versus a research institution), we noted there was opportunity for improvement by having defined processes for the vetting of visiting scholars.

Research Data Protections

We also noted that data protections for pre-publication data generated by sponsored awards was not consistently managed. UCSD has an open academic environment and data protections and confidentiality provisions are documented within the contracts. Departments depended on the PI or faculty supervisor to manage data and research information for researchers under their supervision,

¹ The Compliance Advisory Group (CAG) is a UC San Diego Health Sciences committee comprised of senior leaders who review and advise all conflict of commitment matters.

and it was possible for trainees to take copies of data and research outcomes when they completed their research training. RCI and the Chief Information Security Officer have recently been coordinating on efforts to improve controls in this area.

Reporting of Foreign Contracts & Gifts

UCSD had also taken steps to provide oversight of foreign gift and contracts reporting under Section 117 of the Higher Education Act of 1965 which requires reporting on contracts with or gifts from foreign sources, with a value of \$250,000 or more for a calendar year. An HEA 117 committee was convened by the Chief Ethics and Compliance Officer, consisting of representatives from contracting offices across UCSD. OCGA has taken the lead to consolidate and review each Section 117 report for submission to the Department of Education.

B. Sample Testing Results

The audit also entailed sample-based review of 15 awards related to emerging technologies as identified in the list of "Representative Technology Categories" in the Bureau of Industry and Security 11.19.2018 Proposed Rule. The review entailed comparing information in the grant documents with publications and sabbatical documents to evaluate the accuracy of other support, affiliation reporting, and commitment (effort months on the grant) for the PI and co-PI on the grant.

Our analysis did not identify any foreign affiliations for the PI or co-PIs which had not been previously disclosed. We did identify indicators of foreign components or foreign other support that require further evaluation before a conclusion can be made as to whether additional disclosure would have been required. These issues were either referred to the Locally Designated Official (per criteria as defined by UCOP¹) or RCI for evaluation and appropriate action. The table below summarizes the issues by award:

Observations	# of Awards with Observations
Foreign Funding Support for PI or co-PI (per publications) - not on grant	
documentation	2
Foreign collaborations/financial support for PI (per sabbatical records) who	
are not co-authors	1
General Support from Foreign Sources on Publications	1
Co-Authors with foreign affiliations on Publications	6
Foreign Funding indicated for co-authors on publications	5
Scientific materials from foreign based companies (per publications)	5
Missing COC Forms	6
COI/COC Not Consistent or Possibly Incomplete (for US based sources)	7
Inconsistencies in COI and COC form (for foreign sources/disclosures)	3

¹ Criteria for referral to LDO for investigation: i) Talent program participation, ii) Grants from foreign governments or, iii) Significant time commitment at a foreign entity or university.

UNIVERSITY OF CALIFORNIA ETHICS, COMPLIANCE AND AUDIT SERVICES OFFICE OF THE PRESIDENT INTERNAL AUDIT SERVICES

SYSTEMWIDE FOREIGN INFLUENCE AUDIT Project No. P20A004 February 2021

University of California Ethics, Compliance and Audit Services Systemwide Foreign Influence Audit

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I. Executive Summary

Introduction

In accordance with the fiscal year 2019-20 University of California (UC) audit plan, the systemwide Office of Ethics, Compliance and Audit Services (ECAS) oversaw a systemwide audit of foreign influence. ECAS performed this audit in coordination with the internal audit departments at all UC campuses and the Lawrence Berkeley National Laboratory (LBNL) using a standard systemwide audit program.

ECAS developed this summary report based on information gathered by each location's internal audit department, and it provides a consolidation of the systemwide findings and a set of systemwide recommendations. Each campus's internal audit department will issue a separate report presenting both management corrective actions to address each of these systemwide recommendations and any local observations and their associated planned management corrective actions.

Objectives and Scope

The overall objective of the audit is to evaluate the system of internal controls in place to manage foreign influence risks identified by the federal government.

The scope of the audit included evaluation of the design of internal controls in the following areas relevant to foreign influence risk:

- Conflicts of interest
- Conflicts of commitment
- Export controls
- Sponsored programs/grant processing
- Development and alumni relations
- Visas for international scholars
- Foreign collaborations
- Academic departments and faculty
- Intellectual property security and control
- Training
- Policy

Additionally, audit procedures included sample testing of National Institutes of Health grants to assess the accuracy of reporting on affiliations and other support. The sample selection was limited to active grants in emerging technologies as identified in the list of "Representative Technology Categories" in the <u>Bureau of Industry and Security 11.19.2018 Proposed Rule</u>.

Internal audit departments at each of the 10 UC campuses and LBNL conducted audit procedures using a common audit program that ECAS developed for this review. These audit procedures generally consisted of interviews and process walkthroughs with location personnel in various departments. The local internal audit departments summarized the results of these procedures and provided them to ECAS for the development of this report. ECAS then reviewed this information and requested clarification and additional information when necessary.

UC Agriculture and Natural Resources (ANR) was not included in scope for audit fieldwork. However, due to UC ANR's academic and research mission, systemwide at UC, and statewide in California, the recommendations of this audit, where applicable, also apply to UC ANR.

The observations that we list in this report represent systemwide issues or any issues that did not arise from specific local conditions. As noted above, each campus will issue a separate audit report that addresses these systemwide issues as well as any specific local issues not already addressed in this report. See Appendix C for agreed-upon management corrective actions for each of the recommendations to systemwide units. For each recommendation to the locations, the locations will identify management corrective actions with assigned target dates. ECAS will review the campuses' management corrective actions to ensure that they appropriately address the systemwide recommendations. Ultimately, the campus internal audit departments, with oversight from ECAS, will track these management corrective actions to ensure completion.

Overall Conclusion

Our audit identified opportunities to strengthen policies and procedures related to foreign influence risks in the following areas:

- Protocols to identify potentially undisclosed faculty affiliations
- The compliance function's oversight of the financial conflict of interest process
- Policies and procedures to ensure that all individuals who develop research proposals for submission on behalf of the University submit complete conflict of commitment disclosures within required timeframes
- Training and awareness efforts regarding foreign influence risk and researcher disclosure requirements
- Consistency and effectiveness of restricted party screening processes
- Processes to identify and address export control red flags for agreements
- Vetting of international scholars
- Research data protection protocols
- Oversight of foreign gift and contract reporting

These opportunities for improvement and associated recommendations are described in detail in this report. See Appendix C for agreed-upon management corrective actions for each of the recommendations to systemwide units.

Additionally, our sample testing of NIH grants identified instances of potential discrepancies between internal or external sources of affiliation disclosure information. These issues were either referred to the local research compliance/integrity office or the Locally Designated Official for appropriate action.

II. Background

In early 2018, UC observed increased concern regarding foreign influence in academia within the federal government and amongst UC's peer institutions. Federal funding agencies have issued new requirements and guidance, federal law enforcement agencies have increased prosecutorial activity, and Congress has passed new legislation and sought information on how the academic research community is responding to this evolving issue. The University recognized that these issues were significant. Former UC President Janet Napolitano addressed the essence of these concerns in her letter to the Chancellors and the LBNL Director on February 7, 2019. In her letter, she tasked the Office of Ethics, Compliance and Audit Services (ECAS) with designing a compliance plan to address these issues in a manner that supports the University of California's core mission and commitment to openness in research and international research collaborations.

The University of California's commitment to global engagement is fundamental to its core values and is reflected in UC's vast global research enterprise. At the same time, the federal government and funding agencies have made institutes of higher education aware of some foreign governments initiating systematic programs to unduly influence and capitalize on U.S.-conducted research, including research funded by U.S. taxpayers via the National Institutes of Health (NIH). According to NIH, a small percentage of NIH-funded scientists have committed serious violations of its policies, including failures to disclose foreign financial conflicts of interest, other financial support, foreign components and conflicts of commitment. In some instances, scientists have failed to disclose affiliations and positions that often come with resources and equities.

In response, NIH and NSF have made efforts to enhance awareness of foreign influence risk and increased compliance enforcement. In 2018 and 2019, NIH¹ and the National Science Foundation (NSF)² issued Dear Colleague letters addressing the threat of foreign influence on research integrity. In partnership with the Federal Bureau of Investigation (FBI) and the Department of Justice (DOJ), both agencies commenced investigations of researchers across the U.S. In 2018, NIH convened an Advisory Working Group to the Director on Foreign Influences on Research Integrity (ACD-FI).³ The working group issued a report in December 2018 with extensive recommendations for recipient institutions (see Appendix A).

Additionally, NIH has issued what it considers clarifications of longstanding policies. In its policy topic page entitled "Protecting U.S. Biomedical Intellectual Innovation," NIH outlined responsibilities of applicant and recipient institutions. ⁴ These responsibilities broadly addressed the institution's responsibility to work with faculty and other staff to ensure full transparency in disclosures to NIH, protection of data, and prior approvals of foreign components, and included the following:

- Working with faculty and other staff to make sure all reports, communications, and submissions to NIH are accurate and complete account of all sources of research support, and relevant affiliations for individuals named as senior/key personnel
- Ensuring that all researchers working on a grant disclose their significant financial interests
- Protecting and preventing inadvertent disclosure of proprietary information, sensitive and confidential data, as well as personal information, as part of proper data stewardship of federally funded research
- Notifying NIH immediately of developments that have a significant impact on NIHsupported activities and seek prior approval for inclusions of any foreign components to NIH awards.

¹ NIH Protecting U.S. Biomedical Intellectual Innovation https://grants.nih.gov/policy/protecting-innovation.htm

² NSF Dear Colleague Research Protection letter https://www.ucop.edu/ethics-compliance-audit-services/ files/research protection.pdf

³ NIH Advisory Working Group https://acd.od.nih.gov/working-groups/foreign-influences.html

⁴ NIH Policy Topic Page "Protecting U.S. Biomedical Intellectual Innovation" https://grants.nih.gov/policy/protecting-innovation.htm

NIH Grants Policy Statement 2.1.2⁵ further explained the expectations of the institution through the Authorized Organization Representative (AOR) role. The policy states that "in signing a grant application, the AOR certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application." Further, it states that the AOR "is responsible to NIH for ensuring that the organization complies with applicable Federal laws and regulations, including required certifications and assurances, its application, and the terms and conditions of individual awards."

In May 2020, the Department of Health and Human Services Office of Inspector General (OIG) added the item "Grantee Institutions' Actions To Strengthen Policies in Response to Concerns Regarding Potential Foreign Influence on NIH-Funded Research" to its work plan. The work plan noted that NIH had "taken steps to improve the accurate reporting of all sources of research support, financial interests, and affiliations." The work plan added: "Given efforts to increase awareness among its grantee institutions' regarding financial interests and foreign influence," OIG's evaluation would "focus on grantee institutions' policies and procedures related to (1) ensuring that researchers report all foreign affiliations (including foreign positions and scientific appointments, financial interests in foreign entities, research support from foreign entities, and any other foreign affiliations) and (2) reviewing the foreign affiliations that researchers report." The work plan also indicated that its evaluation would "determine to what extent grantee institutions have updated or revised these policies and procedures to address recent concerns and NIH guidance."

The OIG initiated surveys related to this work plan item in October 2020. The questions in the survey focused on institutional oversight and verification of principal investigator grant submissions.

NSF also made clear its oversight expectations of recipient organizations in a recent NSF FAQ on Current and Pending Support.⁷ The document includes the following text: "In most cases, NSF accepts proposals from and awards grants to an organization, not to an individual. In submitting a proposal and/or accepting federal funds under a grant instrument, proposers/grantees assume legal and financial responsibility and accountability for the content of the submitted proposal ... and may need to confirm the accuracy and completeness of the information that its employees provide to the AOR in order to appropriately comply with NSF's policies on reporting current and pending support."

In addition to the NIH⁸ and NSF⁹ grant policies and guidance referenced above, the federal Financial Conflict of Interest (FCOI) regulation¹⁰ and University of California policies exist to manage conflicts of interest and conflicts of commitment in research.¹¹

Conflict of Commitment

A conflict of commitment occurs when a faculty member's outside activities interfere with their professional obligations to the University of California. Accordingly, the University of California has multiple policies that require academic appointees to submit an annual conflict of commitment (COC) disclosure indicating whether or not they have engaged in outside professional activities during the fiscal year. There are certain activities that require prior approval. It is the academic appointee's professional responsibility to completely and accurately disclose all external financial interests and support, affiliations, activities, and relationships with foreign entities.

⁵ NIH Grants Policy Statement 2.1.2 https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.1.2_recipient_staff.htm

 $^{^6}$ HHS OIG Work Plan March 2020 revision $\underline{\text{https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000448.asp}$

⁷ NSF Current & Pending FAQ https://www.nsf.gov/bfa/dias/policy/papp/pappg20 1/faqs cps20 1.pdf

⁸ NIH Grants Policy https://grants.nih.gov/policy/nihgps/index.htm

⁹ NSF Grants Policy https://www.nsf.gov/publications/pub_summ.jsp?ods_key=pappg

 $^{^{10}\} Federal\ COI\ Regulation\ \underline{https://www.govinfo.gov/content/pkg/FR-2011-08-25/pdf/2011-21633.pdf;}\\ \underline{https://grants.nih.gov/grants/policy/coi/coi_faqs.htm}$

¹¹ UC COI Policies Compendium https://policy.ucop.edu/doc/1200679/CompendiumCOIPoliciesGuidance

Federal funding agencies, specifically NIH and NSF, have emphasized the need for full disclosure to ensure all conflicts of commitment are identified. Funding agencies consider conflicts of commitment an important piece of the picture when evaluating a research proposal. For example, a funding agency needs to know if a researcher is affiliated with a foreign entity because oftentimes these positions include resources and equities that should be considered when allocating research budgets or considering national security concerns.

Conflict of Interest

Federal regulations, state law, and UC policies address conflicts of interest for researchers, recognizing that they may have financial interests in research sponsors and possibly in entities with business interests closely related to their research. A simple definition of conflict of interest found on the DHHS Office of Research Integrity website is "a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. An apparent conflict of interest is one in which a reasonable person would think that the professional's judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of interest. It is important to note that a conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential for bias, not a likelihood."¹²

For U.S Public Health Service (PHS)-funded research, a financial conflict of interest exists when the recipient's designated official(s) reasonably determine(s) that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the research. Investigators are defined in the regulation as the principal investigator, project director, and any other person, regardless of position, responsible for designing, conducting and reporting NIH-funded research. The definition also includes the investigator's spouse and dependent children. Per the regulation, investigators must comply with institutional policy and disclose to their recipient organization significant financial interests. While financial conflicts of interest are not prohibited, the federal regulation ensures that FCOIs are identified and managed through investigator disclosure, institutional review and management, and reporting to NIH. Recipient organizations are required to develop a policy, make it publicly available on a website, and enforce the policy. They must review investigator disclosures, manage those that are determined to be FCOIs, and report them to NIH.

Export Control

Export controls are federal laws that regulate the distribution of items, information, software, and services to foreign nationals and foreign countries for national security and foreign policy reasons. Violations of export controls can result in personal and institutional liability and substantial penalties. Federal agencies that are responsible for export control regulations outline guidelines for a compliance program and include the Department of Commerce, the Department of State, and the Office of Foreign Assets Control under the Department of the Treasury.

In May 2020, the Government Accountability Office (GAO) released a report evaluating the extent to which export compliance policies and practices developed by U.S. universities align with federal guidelines. The report identified four areas for improvement in university compliance programs:

- Risk assessment
- Training
- Internal audits
- Export compliance manual

The export compliance manual recommended by the GAO report encompasses roles, responsibilities, and procedures that guide the export control program and addresses significant risks, such as restricted party screening processes, procedures for identifying export license requirements and risks in agreements, and Department of Commerce "Know Your Customer Guidance"¹³. In its Export Compliance Guidelines, the U.S. Department of Commerce Bureau of

¹² DHHS ORI 1.1 Definition of a conflict of interest provided by Columbia University https://ori.hhs.gov/education/products/columbia wbt/rcr conflicts/foundation/index.html

¹³ 15 CFR Part 732, Supplement 3 https://www.bis.doc.gov/index.php/documents/regulation-docs/411-part-732-steps-for-using-the-ear/file

Industry and Security (BIS) notes that developing and adhering to procedures in an export compliance manual protects against unintended export violations that could disrupt day-to-day business, result in large administrative fines, require costly company time to resolve, and damage the organization's reputation.¹⁴

"Know Your Customer" guidance under the Department of Commerce's Export Administration Regulations (EAR) specifies requirements for due diligence for review of transactions such as agreements and collaborators that can result in unlicensed exports. Due diligence includes obtaining "knowledge of the end-use, end-user, ultimate destination, or other facts relating to a transaction or activity" and "the prohibition against proceeding with a transaction with knowledge that a violation of the EAR has occurred or is about to occur."

This "Know Your Customer" framework is echoed in the recommendations of a report by the independent science advisory group JASON¹⁵ commissioned by NSF. JASON concluded that in an open, fundamental research¹⁶ environment in which the goal is to share the results of research openly and broadly, "a powerful countermeasure against foreign influence would be the careful consideration of foreign engagements by stakeholders before they are initiated." JASON suggested that such consideration would include questions such as the following:

- Is there a risk to U.S. national security?
- What are the political, civil and human rights risks?
- Is there a risk to U.S. national competitiveness?
- Will export control compliance be assured?
- What are the intellectual property risks?
- Are there clear data and publication policies?
- What is misrepresentation risk?

UC has an export control policy, which is an element of an export compliance manual ¹⁷, that outlines many of the basic requirements for UC location export control programs, including the designation by leadership of an export control officer at each location. The policy does not outline specific procedures such as those in an export compliance manual.

Ethics and Values

As the University engages and collaborates with international partners on research activities, it is important that these activities are conducted in a manner consistent with its ethical values and those of its federal partners.

The University has outlined its commitment to core values in its Statement of Ethical Values and Standards of Ethical Conduct¹⁸, which includes the following statement related to the ethical conduct of research:

All members of the University community engaged in research are expected to conduct their research with integrity and intellectual honesty at all times and with appropriate regard for human and animal subjects. To protect the rights of human subjects, all research involving human subjects is to be reviewed by institutional review boards. Similarly, to protect the welfare of animal subjects, all research involving animal subjects is to be reviewed by institutional animal care and use committees. The University prohibits research misconduct. Members of the University community engaged in research are not to: fabricate data or results; change or knowingly omit data or results to misrepresent results in the research record; or intentionally misappropriate the ideas,

¹⁴ Department of Commerce, Bureau of Industry and Security, Export Compliance Guidelines 2017 https://www.bis.doc.gov/index.php/component/docman/?task=doc_download&gid=1641

¹⁵ JASON report, Fundamental Research Security https://www.nsf.gov/news/special_reports/jasonsecurity/JSR-19-2IFundamentalResearchSecurity_12062019FINAL.pdf

¹⁶ National Security Decision Directive-189 https://fas.org/irp/offdocs/nsdd/nsdd-189.htm

¹⁷ Department of Commerce, Bureau of Industry and Security, Export Compliance Guidelines 2017 https://www.bis.doc.gov/index.php/component/docman/?task=doc_download&gid=1641

¹⁸ University of California Statement of Ethical Values and Standards of Ethical Conduct https://www.ucop.edu/ethics-compliance-audit-services/files/stmt-stds-ethics.pdf

writings, research, or findings of others. All those engaged in research are expected to pursue the advancement of knowledge while meeting the highest standards of honesty, accuracy, and objectivity. They are also expected to demonstrate accountability for sponsors' funds and to comply with specific terms and conditions of contracts and grants.

At the federal level, the White House Office of Science and Technology Policy has outlined principles and values upon which the integrity of the research enterprise rests¹⁹:

- Openness and transparency enable productive collaboration and help ensure appropriate disclosure of potential conflicts of interest and commitment.
- Accountability and honesty help acknowledge errors and correct behaviors that can hamper progress.
- Impartiality and objectivity protect against improper influence and distortion of scientific knowledge.
- **Respect** helps create an environment where all can be heard and contribute.
- Freedom of inquiry allows individual curiosity to guide scientific discovery.
- **Reciprocity** ensures scientists and institutions exchange materials, knowledge, data, access to facilities and natural sites, and training in a way that benefits collaborating partners proportionally.
- **Merit-based competition** helps ensure a level playing field where the best ideas and innovations can advance.

Behavior that violates these principles jeopardizes the integrity of the research enterprise and the University's ability to fulfill its mission.

Relevant Policies and Regulations

Refer to Appendix B for relevant policies and regulations for each of the areas described above.

¹⁹ National Science and Technology Council Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise https://trumpwhitehouse.archives.gov/wp-content/uploads/2021/01/NSTC-Research-Security-Best-Practices-Jan2021.pdf

III. Opportunities for Improvement and Recommendations

1. Protocols to Detect Undisclosed Faculty Affiliations

The University would benefit from additional processes or protocols to identify potentially undisclosed faculty affiliations.

As discussed earlier, the University's most significant federal research partners have issued guidance establishing expectations that institutions take measures to ensure the accuracy and completeness of researchers' affiliation disclosures. Further, some agencies' enforcement units have announced their intent to evaluate grantee institutions' policies and procedures to ensure the completeness of researchers' foreign affiliation reporting.

In our walkthroughs, we found that the federal award proposal review process and existing systems of monitoring may not be sufficient to identify nondisclosure of foreign affiliations and support. Locations reported that there is generally significant reliance on principal investigators to make required disclosures.

We noted that some locations have established limited procedures to evaluate the completeness and accuracy of conflict of interest disclosures. For example, one location reported that conflict of interest disclosures are reviewed against other sources of available information to enable an assessment of the relevance of disclosures to the grant. Another location reported that conflict of interest disclosures are reviewed against previous disclosures, publications, or conflict of commitment disclosures as deemed necessary. However, we found that locations generally do not perform a holistic review of faculty activity (e.g., COC activities, travel, and sabbaticals) to assess completeness of foreign affiliation disclosures related to sponsored research. Additionally, at most locations, there is no process in place to routinely compare internal and external sources of information, including conflict of interest and conflict of commitment disclosures, grant proposals, visiting scholars, research publications, and websites, to identify potentially undisclosed affiliations.

We observed that some locations are planning new protocols to evaluate the completeness of financial conflict of interest disclosures. For example, one location has put forward a proposal for the research compliance office to perform sample-based reviews of conflict of interest and conflict of commitment disclosures for selected researchers to ensure that necessary financial interests and outside professional activities have been properly and consistently disclosed. An additional proposed activity at this location involved sample-based reviews of selected researchers on federal grants to ensure that necessary foreign components and collaborations have been properly and consistently disclosed. Establishment of protocols like these would serve to demonstrate stronger institutional oversight and provide better assurance of the completeness and accuracy of disclosures.

Recommendations:

The Council of Vice Chancellors of Research, Academic Senate, Academic Personnel, and Research Policy Analysis and Coordination (RPAC), in consultation with UC Legal, Research Compliance and Advisory Committee/Research Compliance Officers, and Sponsored Projects Offices, should:

1.1 By June 30, 2021, collaborate to develop recommended baseline institutional protocols to minimize the risk of inaccurate or incomplete information related to foreign research support, foreign talent programs, and affiliations of key personnel in contract and grant proposals, targeting high-risk cases.

Locations should:

1.2 Evaluate the recommended baseline institutional protocols and modify them as necessary vis-à-vis their own infrastructure, resources, and communication and IT systems to implement them locally. For example, templates developed by the working group could be tailored to meet local needs.

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2. Conflict of Interest

The University's compliance function does not have adequate insight into the financial conflict of interest process.

Generally, a financial conflict of interest is a situation in which an individual could personally benefit from his or her official actions. Regardless of whether one actually realizes any personal benefit, a conflict of interest exists when an independent observer could reasonably perceive it to exist. Thus, providing reasonable assurance to stakeholders that researchers' work is free of bias begins with disclosure of researchers' financial interests, which is a principle that is echoed by Regental policy:

"Outside professional activities, personal financial interests, or acceptance of benefits from third parties can create actual or perceived conflicts between the University's mission and an individual's private interests. University community members who have certain professional or financial interests are expected to disclose them in compliance with applicable conflict of interest/conflict of commitment policies. In all matters, community members are expected to take appropriate steps, including consultation if issues are unclear, to avoid both conflicts of interest and the appearance of such conflicts."²⁰.

It is important for the local compliance function to be engaged on financial conflict of interest issues because its independence from research operations helps ensure that significant issues are escalated to leadership when appropriate. We identified one location where a compliance function oversees the financial conflict of interest process. That location's COI program, which is within its Office of Ethics and Compliance, is responsible for research-related disclosures and reports to the local Chief Ethics and Compliance Officer. In contrast, most locations have placed this responsibility with their Office of Research, Vice Chancellor of Research, or another comparable office that is not independent of operations. At these locations, we did not identify any formal mechanism to ensure that the local compliance office regularly receives information on significant conflict of interest issues.

Further, at most health sciences locations, the Healthcare Compliance Officer either has no role or is engaged in a limited manner in COI oversight in the health enterprise. More specifically, at two locations, Healthcare Compliance Officers are inconsistently engaged in clinical research COI matters only, and at another location the Healthcare Compliance Officer is only involved when COI issues pertain to physicians and healthcare vendors. In our discussions with Healthcare Compliance Officers, some expressed concern that faculty who are omitting disclosures in the health system are likely to be doing the same in the research realm, and that it would benefit both offices to be aware of disclosure-related compliance issues.

Recommendations:

Locations should:

2.1 Implement protocols at the campuses, health systems, and LBNL to ensure that the compliance function (CECO and HCCO) regularly receives information (such as copies of determination letters sent to PIs after identification of significant financial interests in foreign entities) and is engaged, as appropriate for each location, on significant conflict of interest issues and management plans. An example of engagement by the compliance officer could be ex-officio membership on a financial conflict of interest committee.

3. Conflict of Commitment

Conflict of commitment ("outside activity disclosures") policies and procedures should be enhanced to ensure that all individuals who develop research proposals for submission on behalf of the University submit complete disclosures within required timeframes.

A conflict of commitment occurs when a faculty member's outside activities interfere with the faculty member's professional obligations to the University of California. Conflict of commitment issues are governed by the University's Academic Personnel Manual (APM - 025), Conflict of Commitment and Outside Activities of Faculty Members (APM - 671), and Conflict

²⁰ Regents Policy 1111: Policy on Statement of Ethical Values and Standards of Ethical Conduct

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of Commitment and Outside Activities of Health Sciences Compensation Plan Participants policies. APM - 671 is specific to faculty members who are participants in the Health Sciences Compensation Plan. According to APM - 025 and APM - 671, eligible faculty must report to the university annually all Category I and II activities²¹ engaged in during the previous 12 months, and this report must be completed even if no Category I or II activities were undertaken.

Scope of Conflict of Commitment Policies

Conflict of commitment reporting is frequently referenced by the University and by Federal agencies as an important component of an institution's system of controls to ensure researchers' outside interests are disclosed. Additionally, conflict of commitment disclosures can be used as a basis for comparison to evaluate completeness and accuracy of financial conflict of interest disclosures. However, we noted that the University's conflict of commitment policies do not cover all academic appointees who could potentially submit research proposals on behalf of the university.

APM - 025 specifies that all faculty holding at least 50 percent appointments in the Professor, Professor in Residence, Adjunct Professor, and Lecturer with Security of Employment series, are subject to the policy. The categories of eligible faculty in the policy are not comprehensive as it does not specifically identify emeritus faculty and principal investigators who are not ladder-rank faculty as being subject to the reporting requirement.

APM - 671 addresses conflict of commitment for members of the Health Sciences Compensation Plan (HSCP). All faculty who participate in the HSCP are subject to this policy; however, faculty holding appointments of less than 50 percent time are not subject to the annual reporting and prior approval requirements.

Reporting Compliance

Department Chairs are responsible for monitoring compliance with the required reporting by collecting and reviewing annual reports and consulting with the Dean about any concerns. APM - 025 identifies out of compliance situations, such as compliance with time limits for Categories I and II activities, and further states that "failure to comply with this policy may subject a faculty member to discipline, corrective action, or administrative remedies pursuant to APM - 016, University Policy on Faculty Conduct and the Administration of Discipline, and APM - 150, Non-Senate Academic Appointees/Corrective Action and Dismissal." APM - 671 states that the "University reserves the right to impose administrative remedies and/or to take corrective action and disciplinary measures toward any faculty member who fails to comply with Implementing Procedures on outside professional activities".

We noted that most locations indicated that there were no consequences for submitting late annual disclosures. Although APM - 025 and APM - 671 identify possible actions for non-compliance with conflict of commitment reporting requirements, locations have not put in place local policies that clearly define the consequences for failure to submit conflict of commitment disclosures forms within established timeframes. Some locations indicated that late or missing disclosures could impact promotions or compensation, but we did not observe any evidence of these consequences being imposed on a routine and consistent basis.

Conflict of Commitment Reporting System

UC has implemented an IT system called OATS (Outside Activity Reporting System) to facilitate tracking, compliance, and education related to conflict of commitment policies for academic appointees. This system has now been implemented at all ten UC campuses.

While the implementation of an IT system for conflict of commitment reporting helps ensure consistency and compliance with reporting requirements, some stakeholders noted that institutional offices or personnel, such as research compliance or conflict of interest coordinators, do not have the necessary access in the OATS system to perform ongoing compliance

²¹ From APM - 025 Conflict of Commitment and Outside Activities of Faculty Members: "Category I activities are outside professional activities that are most likely to create a conflict of commitment because: 1) they are activities related to the training and expertise that is the individual's qualification for University appointment, but performed for a third party, and/or 2) they require significant professional commitment...Category II activities are typically shorter-term outside professional activities that are outside the course and scope of University employment. Category II activities have a lesser potential for a conflict of commitment than do Category I activities." https://www.ucop.edu/academic-personnel-programs/files/apm/apm-025.pdf

monitoring. Further, we observed that functionality of the OATS system could be enhanced by allowing users to identify activities as foreign activities.

Recommendations:

Systemwide Academic Personnel should:

- 3.1 Update APM 025 and 671 to specify that they apply to all academic appointees listed as key personnel on proposals submitted by the University, regardless of faculty series or appointment percentage. If any of these individuals are union represented, implementation of these requirements should be handled as appropriate for represented employees.
- 3.2 Consider modifying APM 025 and 671 such that all foreign activities are Category I activities which require prior approval, including the benefits and drawbacks of such modifications.

The Council of Vice Chancellors of Research, Academic Senate, Academic Personnel, and Research Policy Analysis and Coordination (RPAC), in consultation with UC Legal, Research Compliance and Advisory Committee/Research Compliance Officers, and Sponsored Projects Offices, should:

3.3 By June 30, 2021, collaborate to develop protocols and/or measures to help ensure complete and timely submission and review of outside activity disclosures, including recommended consequences for late or missed outside activity disclosures.

OATS Governance Board should:

- 3.4 Update OATS to include functionality to identify activities as foreign activities.
- 3.5 Evaluate whether system functionality enhancements are required (e.g. reporting, user access roles) in order for institutional offices to receive the necessary information from OATS to perform ongoing compliance monitoring. Identify best practice solutions for institutional offices to perform compliance monitoring in OATS and communicate this solution to UC locations.

Locations should:

- 3.6 Evaluate the protocols and measures developed to help ensure complete and timely submission and review of outside activity disclosures vis-à-vis their own infrastructure resources, and communication and IT systems to implement these or other measures to achieve the same goal.
- 3.7 Evaluate the best practice solutions for institutional office compliance monitoring recommended by the OATS Governance Board and modify them as necessary to implement them locally.

4. Training and Awareness

Training should be enhanced to clarify and reinforce awareness of foreign influence risk and researchers' financial disclosure requirements.

Conflict of interest and conflict of commitment are complex and dynamic issues that require continued training and awareness. It is therefore crucial that faculty and staff have resources available to ensure that Federal research disclosure and University requirements are communicated and followed.

Disclosure Requirements

During our review, several locations indicated that there was confusion in the research community regarding disclosure requirements due to the fact that the conflict of interest disclosure requirements vary between different federal agencies. Further, the State of California has separate financial conflict of interest disclosure requirements. Currently, UC systemwide policies do not address and clarify these different requirements. This lack of consistent and

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current disclosure information contributes to reporting inaccuracies and jeopardizes effective compliance efforts.

Inconsistent Training and Awareness

Consistent and comprehensive training is critical to ensure researchers comply with all foreign influence-related regulations and procedures. Our review found that not all locations provide training on conflict of interest, conflict of commitment, and foreign activities disclosure requirements, and locations generally lack regular and formal training devoted to these issues. While most locations indicated that they provide training to address conflict of interest, several do not. For those that do provide training, it is typically informal and ad hoc, and the content varies across locations.

For example, one campus noted that it does not provide formal training on COI/COC or foreign activities disclosure to staff members, and instead relies on the COI material included in the systemwide mandatory General Compliance Briefing required by staff every two years. Another location indicated that the UC OATS system contains guidance on COC disclosures, but its local training and guidance are not focused on foreign activities and it does not provide COC training as a stand-alone course. Additionally, several locations indicated that they rely on required online training specific to various organizations that provide grant funding (e.g., NIH, NSF).

Most locations reported that departments do not receive awareness training that would advise faculty and staff on foreign affiliation information that is required to be included in grant applications and progress reports. For example, one location indicated that although their research analysts may assist with proposal information and application review, they do not specifically review proposals to ensure that they include identification of foreign activities based on COC activities, travel, or sabbaticals. Locations have reported that much of their awareness has been through informal methods such as internal memos and forums, outside agencies, and external websites (e.g., Researchers Administrators, Inc.).

Systemwide Training

ECAS is currently updating the "Ethics and Compliance Briefing for Researchers" systemwide training module, as a revision to a prior training module that only addressed general ethics and compliance, NSF, PHS, and California 700-U²² conflict of interest disclosure requirements. The updated training module is scheduled to be released in March 2021 and will address general ethics and compliance matters and matters related specifically to researchers, such as disclosing affiliations with foreign entities to federal funding agencies. All researchers receiving research funding will be required to take this training every two years.

Recommendations:

RPAC, and ECAS, in consultation with UC Legal and campus representatives (to include members from the conflict of interest and research compliance offices) should:

- 4.1 Conduct a review of existing extramural research funding conflict of interest policies and update them as necessary to ensure they align with current agency requirements. Establish an ongoing process to regularly update conflict of interest policies in response to changes in agency requirements.
- 4.2 Develop a communication plan for foreign influence risk to be used by the locations. The plan should address target audiences, topics, and intervals.
- 4.3 Develop required systemwide training on foreign influence, inclusive of foreign talent programs and reporting requirements.

ECAS and RPAC should:

4.4 Finalize and release the mandatory "Ethics and Compliance Briefing for Researchers" systemwide training module.

²² California Form 700-U is a statement of economic interests that must be filed by all persons employed by UC or CSU who have principal responsibility for a research project if the project is to be funded or supported, in whole or in part, by a contract or grant (or other funds earmarked by the donor for a specific research project or for a specific researcher) from a nongovernmental entity.

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ECAS should:

4.5 Monitor systemwide compliance with the mandatory systemwide training and report completion metrics to the relevant systemwide and campus stakeholders (VCRs, CECOs, etc.).

Locations should:

- 4.6 Implement the system-developed "Ethics and Compliance Briefing for Researchers" training module and require, at a minimum, all researchers receiving research funding to complete the training biennially. Consider expanding the training audience to graduate students, visiting scholars, and grant key personnel.
- 4.7 Address consequences for non-compliance with the completion requirement for the mandatory systemwide training.
- 4.8 Implement a local foreign influence risk communication plan, taking into consideration the systemwide guidance.

5. Restricted Party Screening

Restricted party screening processes are inconsistent and require improvement.

The UC Policy on Export Control (UC export control policy) requires each location to establish an effective compliance program that identifies exports as defined under Federal regulations²³ and ensures compliance with the regulations' controls, including those applicable to restricted parties. A restricted party is an individual or entity appearing on a U.S. government restricted party list that is prohibited from receiving U.S. exports or engaging in U.S. financial transactions. Because many UC activities meet the Federal definition of an export, various business functions²⁴ are responsible for complying with regulations by screening potential exports to ensure that they are not provided to restricted parties, which is a process known as restricted party screening. Under the UC export control policy, all offices and departments impacted by export control issues are expected to support and cooperate with their Export Control Officers (ECOs) to create and implement procedures to perform restricted party screening.

However, the UC export control policy does not provide specific guidance on restricted party screening roles and responsibilities. As a result, the extent of restricted party screening varies between locations in different ways. More specifically, some locations do not perform restricted party screening on non-U.S. sponsors of research. Some other locations do not perform restricted party screening for gifts from non-U.S. persons or entities, while one location only does so when it identifies specific concerns. In addition, some locations do not perform restricted party screening on foreign entities associated with Category I activities. For these locations, we found that one campus performs this screening inconsistently and another excludes health sciences from its screenings. Finally, some locations do not have a procedure in place to escalate positive screenings to the ECO.

Recommendations:

ECAS and RPAC, in consultation with systemwide and campus export control officers, should:

- 5.1 Create guidance on restricted party screening roles and responsibilities.
- 5.2 Develop a required training module (or add to existing required training) to educate faculty and staff on the importance and requirements of restricted party screening, and which types of entities or persons should routinely be screened as part of normal business

²³ Exports and deemed exports include shipments or transmissions out of the United States, even to a United States citizen; release or transfer to a foreign person in the United States; transfers of registration, control, or ownership to a foreign person; and performing of services on behalf of a foreign person.

²⁴ See Section IX Appendix in UC Policy on Export Control https://policy.ucop.edu/doc/2000676/ExportControl

practices (inclusive of university employees and students performing work and academic study in a foreign location).

Locations should:

- 5.3 Create and implement export control procedures as outlined in the UC export control policy. At a minimum, these procedures should include:
 - Defined roles and responsibilities for restricted party screening as outlined in the export control policy
 - Escalation procedures for positive screenings
 - Periodic ECO monitoring to ensure that the responsible parties are performing these procedures.
- 5.4 Implement the system-developed training module to educate faculty and staff on the importance and requirements of restricted party screening.

6. Export Control Red Flags

Several locations do not have formal processes to identify and address export control red flags for agreements.

BIS's "Know Your Customer Guidance (Supplement No. 3 to part 732 of the Export Administration Regulations) guides institutions to "take into account any abnormal circumstances in a transaction that indicate that the export may be destined for an inappropriate end-use, end-user, or destination," and refers to such circumstances as "red flags." The UC export control policy requires establishment of a local compliance program that is consistent with U.S. export control regulations. As described in the policy, the program is to include processes for material transfer, license, sales and service, and other agreements. Since export control regulations span several federal agencies and are notably complex, a red flag process that consolidates the various requirements to identify and flag issues appropriate for escalation and license review by the export control officers can facilitate compliance.

In our walkthroughs with departments, we found that several locations have not established location-wide formal processes to flag, escalate, and resolve export control red flags for agreements such as memoranda of understanding (MOUs) and research and service agreements. For example, one location reported that processes for identifying and addressing export control red flags are managed within each contracting office, while another location noted that these processes are not "reliably institutionalized."

Documented procedures for export control red flags for agreements are important to establish and reinforce specific expectations for campus personnel to ensure red flags are appropriately identified and addressed.

Recommendations:

ECAS and RPAC, in consultation with systemwide and campus export control officers, should:

6.1 Create systemwide guidance and training on identifying and addressing red flags in research and other agreements/arrangements, heightened legal, financial, and reputational risk related to such red flags, review for defense services, restricted proprietary technology inputs and outputs, restricted end uses, know your customer red flags, sanctioned countries, and tangible exports.

Locations should:

- 6.2 Implement written procedures to address red flags in accordance with systemwide guidance, including escalation procedures that are specific to the location.
- 6.3 Develop localized training on the red flags procedures leveraging the systemwide training content and implement the training for appropriate personnel.

7. Vetting of International Scholars

Most locations do not consistently perform adequate vetting of international scholars in accordance with Federal guidance.

Federal funding agencies expect award recipients to be aware of any related foreign influence risks posed by international scholars that require mitigation, and this awareness is facilitated through disclosure. As the NSF-commissioned JASON report notes, "disclosure of activities presents our main defense against foreign influence." Accordingly, in Section 7.3 it advises that "a powerful countermeasure against foreign influence would be the careful consideration of foreign engagements by stakeholders before they are initiated," which may be assessed through a series of questions appropriate to a given stakeholder.

As part of assessing foreign influence risks posed by international scholars, locations must also consider how they will maintain compliance with export license requirements. These requirements concern access to technology subject to Export Administration Regulations (EAR), International Traffic in Arms Regulations (ITAR), and National Nuclear Security Administration (NNSA) oversight, such as by restricted parties and members of defense services.

Despite these funding agency expectations and federal regulations, we found via our walkthroughs with departments that some locations do not have defined procedures for vetting international scholars, while other locations have defined procedures that are either inconsistent or incomplete.

Recommendations:

ECAS and RPAC, in consultation with systemwide and campus export control officers and international offices, should:

7.1 Create guidance for assessing risk and identifying and vetting international scholars (e.g., via restricted party screening), including postdoctoral researchers, visiting scholars and graduate students, and their associated entities, in accordance with Export Administration Regulations, International Traffic in Arms Regulations, or National Nuclear Security Administration regulations. The guidance should include sample distributed roles and responsibilities and should address vetting for incubators and accelerators.

Locations should:

7.2 Implement the systemwide guidance, vis-à-vis the location's infrastructure, resource, communication and IT systems, etc., in the form of local procedures, which should include escalation procedures that are specific to the location.

8. Research Data Protections

Locations vary on protocols to address research data protections.

All information systems, whether electronic or hard copy, that contain Federal data must be protected from unauthorized access. Congress and the Office of Management and Budget (OMB) have instituted laws, policies, and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The Federal Information Security Management Act (FISMA) defines a comprehensive framework to protect government information and provides a method to reduce security risks to federal data. Accordingly, UC is required to comply and is responsible for the security of this data when it is collected, stored, processed, transmitted, or used.

A draft policy addressing UC research data and tangible research materials has been circulated to UC locations for comment. The draft policy states that the Regents of the University of California owns all research data and tangible research materials, and addresses procedures related to the access to and retention of research data and tangible research materials to ensure they are accurately collected, recorded, securely retained, and appropriately accessible.

It is critical that the University appropriately safeguard pre-publication research data and ensure its integrity and security. Our audit noted that locations vary on protocols that address the protection of pre-publication data generated by sponsored awards and grants, data sharing with other UC campuses, third parties, and sponsors, and data sharing documentation. For example,

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several locations indicated that research data storage and protection procedures vary by school or department. One location stated that it had too many gatekeepers for storing research data and that some data is centrally stored, while some departments use outside storage providers. Another location indicated that there were no data protections for pre-publication data.

We further noted that not all locations have processes in place to prevent researchers from removing copies of data and research outcomes from their labs when their time as a researcher is over. For example, one location indicated that departments rely on principal investigators to manage the process but it was common practice for data to be removed. Another location stated that postdoctoral researchers are not allowed to remove any data and copies of research but it is difficult to monitor.

Recommendations:

The Office of Research and Innovation should:

8.1 Finalize and distribute the UC Research Data and Tangible Research Materials policy.

Locations should:

8.2 Implement guidelines for compliance with UC Research Data and Tangible Research Materials policy. At a minimum, these guidelines should establish responsibility for tracking compliance with sponsor research data protection requirements.

9. Oversight of Foreign Gifts and Contracts Reporting

Oversight of foreign gifts and contracts requires improvement.

Section 117 of the Higher Education Act of 1965 requires most two-year and four-year postsecondary schools to report ownership or control by foreign sources and contracts with or gifts from the same foreign source that, alone or combined, have a value of \$250,000 or more for a calendar year.

Oversight of Foreign Gifts and Contracts Reporting

To ensure that foreign gifts and contracts reporting is accurate, complete, and fulfills all requirements, oversight of foreign gifts and contracts reporting should be assigned to an entity with broad purview that can review a report before it is submitted. A recent report issued by the Department of Education criticized some higher education institutions for failing to establish clear responsibility for oversight of Section 117 reporting, saying that these deficiencies "suggest that universities may not be adequately prioritizing and adapting to meet their reporting obligations and, consequently, lack the institutional tools — even as minor as identifying a project coordinator for the reporting process — to achieve compliance."²⁵

We observed that at most UC locations, the financial aid office is charged with primary responsibility for reporting foreign gifts and contracts to the Department of Education. This is likely due to the fact that the Department of Education initially provided access credentials to the foreign gifts and contracts reporting portal to university financial aid offices. However, financial aid offices only oversee one component of required reporting under Section 117. Campuses should have the ability to assign reporting responsibility to an entity with broad purview that can review the data and file the report. The financial aid office is able to create a separate administrative account for this purpose. To ensure the completeness and accuracy of foreign gifts and contracts reporting and compliance with Section 117 requirements, university locations should thoughtfully evaluate oversight of foreign gifts and contracts reporting to ensure that the compiling and review processes facilitate complete and accurate reporting from all required sources.

Categorization of Foreign Donations with Stipulations

In our evaluation of locations' handling of foreign gifts, we observed that they do not use consistent criteria for determining whether a foreign donation with stipulations should be

²⁵ Institutional Compliance with Section 117 of the Higher Education Act of 1965 https://www2.ed.gov/policy/highered/leg/institutional-compliance-section-117.pdf

categorized as restricted, nor are they consistent on who is responsible for making this determination. For example, some membership agreements include terms that allow access to prepublication data, while others include benefits to donors such as participation in technical retreats. University locations could reduce compliance risk by having a clear and consistent approach to categorization of foreign donations with stipulations.

Recommendations:

RPAC, ECAS, Institutional Advancement, and UC Legal should:

9.1 Evaluate whether further systemwide guidance is necessary, and/or how the existing guidance can be better socialized such that all campus departments managing foreign donations can determine whether a gift or contract would be considered "restricted or conditional" in accordance with U.S. Department of Education definitions.

Locations should:

- 9.2 Convene a working group or committee to oversee Section 117 reporting that consists of representatives from all reporting departments. The working group should identify a central office with the appropriate knowledge of the U.S. Department of Education requirements to review each Section 117 report prior to submission.
- 9.3 Establish protocols to ensure individuals responsible for making determinations on selling membership agreements are not also receiving the benefit from associated fees.

Appendix A: Excerpt from NIH Advisory Committee to the Director (ACD) Working Group for Foreign Influences on Research Integrity December 2018 Report

Recommendations for Recipient Organizations

Communication and Awareness

Recipient organizations should consider acting on the following recommendations to the extent they are able:

- Recipient organizations should implement a broad education campaign to raise awareness about the need to disclose other foreign support and international collaborations as part of disclosure processes for NIH, and international affiliations, international collaborations, and financial interests to home recipient organization
 - o Incorporate these messages into regular Responsible Conduct of Research training
 - o Increase training and awareness for new faculty who are foreign nationals
 - Ask investigators to document in writing their conversations and decisions about what each student and post-doctoral fellow will take with them when they leave a laboratory
- As part of raising awareness and assessing risks, recipient organizations should consider educating leadership, officials, and investigators regarding the scientific topics that are more prone to interest by untoward actors.
 - o Identify all key stakeholders (PDs/PIs, peer reviewers, visiting scientists and scholars, hosting and sponsoring faculty, laboratory administrators, and faculty administrative support) and tailor the communications plans accordingly
- Discuss how to safely host laboratory and VIP medical visits, which can be potential entry points for unwanted information gathering, especially if associated with suspicious activities like adding unrelated additional visitors with little advance
- Consider developing guidelines or considerations for securely hosting visiting scholars or students
 - Recipient organizations should also encourage additional vetting or discussions regarding project ownership and appropriate data exchange
- For all international travel to selected countries, recipient organizations should consider initiating broadly pre-travel 'safety briefings' to educate investigators and encourage precautions

Risk Mitigation

- Recipient organizations should consider assessing the physical, technical, and administrative controls frameworks they employ that host foreign scientists for the risk of data misappropriation and exfiltration. This would include:
 - o Examine the robustness of internal processes to identify potential breaches
 - Initiate or amplify cybersecurity approaches that may identify possible data breaches or inappropriate use of authorization credentials to access systems, or inappropriate sharing of information
 - Evaluate and implement mechanisms for identifying and verifying financial support, for example, using ORCID number to disambiguate individuals, or asking companies for lists of researchers working in foreign universities with company support
 - Have other support/foreign support and cybersecurity monitoring reported and tracked centrally (e.g., Office of Sponsored Research) using a single, accessible database
- Consider suggesting that faculty or staff traveling to certain regions to use loaner computers and electronic equipment
- Prior to hiring potential foreign employees, recipient organizations should consider vetting through unclassified searches, reviewing any agreements they have with businesses, organizations, and institutions; checking their FCOI and conflicts of commitment
- Consider adding to existing scientific misconduct or other similar policies:
 - That employees must disclose other funding support (i.e., financial conflicts)

- That employees must disclose positions and affiliations at other universities or institutions (i.e., conflicts of commitment)
- Language explicitly addressing the need to uphold peer review integrity and consequences of violations of NIH peer review
- Ensure that newly amended policies are actionable and commit to enforcing them
 - O Develop review and adjudication processes that are appropriate for examining potential misconduct related to foreign influences
 - o Include conflicts of commitment in FCOI policy and processes
 - o Implement systematic audits to ensure FCOIs and conflicting commitments are accurately reported
 - The reporting system through which recipient organizations implement these audits may vary (for example, may be conflict of interest annual reporting system for all employees, or FCOI system put in place for NIH grantee reporting specifically)
 - May be random checks or initiated by 'flags' (see below), or a combination of both approaches
- Always proactively notify NIH about peer review violations and inaccurate or undisclosed foreign support or affiliations with outside organization

Ongoing Monitoring

- Recipient organizations should consider working with their professional organizations (APLU, AAU, etc.) to obtain guidance for developing processes for ongoing monitoring that are consistent with the risks associated with the research on the campus
- Consider developing a list of 'flags' that may trigger a recipient organization to conduct an audit, particularly if inconsistent with funding
 - Parameters may include: frequent foreign travel; lab resources inconsistent with funding; unexpected or inappropriate assets; personnel count disproportionate to funding; publishing frequently with collaborators outside the U.S., especially if no other authors are from the home recipient organization
 - o If 'flag' is raised, consider unclassified searches, including viewing public posts
- Consider initiating post-travel follow-up questionnaires for research-related trips to select countries
 - Track at the department level international travel that triggers questionnaire completion
- Work with OSSI and other security agencies to gather lessons learned and best practices
 for identifying potential threats. Through this collaboration, recipient organizations may
 also receive guidance regarding access to unclassified databases used by the FBI and the
 federal Office of Personnel Management

Appendix B: Relevant Policies and Regulations

Conflict of Commitment Policies

• APM - 025

"Conflict of Commitment and Outside Activities of Faculty Members"
This policy defines which outside professional activities must be disclosed to the
University, approved prior to engagement, and/or reported annually. This policy limits
the amount of time a faculty member may devote to outside professional activities and
describes the requirements when involving a student in outside professional activities. It
defines activities as Category I, II, or III, and includes a Prior Approval form as well as
an Annual Reporting form. All faculty who are not members of a Health Sciences
Compensation Plan (HSCP) are subject to this policy; however, faculty holding
appointments of less than 50 percent time are not subject to the annual reporting and prior
approval requirements.

• APM - 240

This policy is specific to academic deans, defined as a head of a division, college, school, or other similar academic unit, with administrative responsibility for that unit. APM - 240-20c outlines additional restrictions on outside professional activities for deans beyond the requirements of APM - 025/671.

• <u>APM - 246</u>

"Faculty Administrators (100% Time)"

Faculty Administrators who are appointed at 100% time are primarily responsible for administrative duties, but maintain their underlying faculty appointment. A Faculty Administrator holds a concurrent University faculty appointment. APM - 246-20c outlines additional restrictions on outside professional activities for Faculty Administrators beyond the requirements of APM - 025/671.

• <u>APM - 671</u>

"Conflict of Commitment and Outside Activities of Health Sciences Compensation Plan Participants"

Faculty who are members of a Health Sciences Compensation Plan (HSCP) have additional requirements related to outside professional activities that are specific to income earned while engaged in outside professional activities. This policy also defines monitoring, compliance, and consequences for noncompliance. Faculty members appointed in Health Sciences schools that are not participants in the Health Sciences Compensation Plan are subject to APM - 025.

Conflict of Interest Policies

- UC NSF Policy
- UC NIH (PHS) Policy
- Institutional Conflicts of Interest RPAC Memo 11-05
- 45 CFR Part 50
- NIH Guide Notice: NOT-OD-18-160 Financial Conflict of Interest: Investigator Disclosures of Foreign Interest
- NIH Guide Notice: NOT-OD-19-114: Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components: NOT-OD-19-114

Export Control Policies and Regulations

Policies

• UC Policy on Export Control

Regulations

- Department of State Directorate of Defense Trade Controls
 - o International Traffic in Arms Regulations (ITAR)
- Department of Commerce
 - o Bureau of Industry and Security
 - Export Administration Regulations (EAR)
 - o Census Bureau
 - Foreign Trade Regulations (FTR)
- Department of Treasury Office of Foreign Asset Controls
 - o Sanctions Regulations
- Department of Energy
 - o Assistance to Foreign Atomic Energy Activities
 - o <u>Nuclear Regulatory Commission</u>
 - o Export and Import of Nuclear Equipment and Material

Appendix C: Management Corrective Actions for Recommendations to Systemwide Units

Recommendation	Management Corrective Action	Target Date
1. Protocols to Detect Undisclosed F		
The Council of Vice Chancellors of Research, Academic Senate, Academic Personnel, and Research Policy Analysis and Coordination (RPAC), in consultation with the UC Legal, Research Compliance and Advisory Committee/Research Compliance Officers, and Sponsored Projects Offices, should: 1.1 By June 30, 2021, collaborate to develop recommended baseline institutional protocols to minimize the risk of inaccurate or incomplete information related to foreign research support, foreign talent programs, and affiliations of key personnel in contract and grant proposals, targeting high-risk	The Council of Vice Chancellors of Research, Academic Senate, Academic Personnel, and Research Policy Analysis and Coordination (RPAC), in consultation with UC Legal, Research Compliance and Advisory Committee/Research Compliance Officers, and Sponsored Projects Offices, will develop recommended baseline institutional protocols to minimize the risk of inaccurate or incomplete information related to foreign research support, foreign talent programs, and affiliations of key personnel in contract and grant proposals, targeting high-risk cases. MCA Assigned to: Deborah Motton, RPAC Executive Director Lourdes Demattos, RPAC Associate Director	June 30, 2021
3. Conflict of Commitment		
Systemyvida Asadamia Damanus I shaul 1	Systemyvida A andomia Daman - 1 1	April 20, 2022
Systemwide Academic Personnel should: 3.1 Update APM - 025 and 671 to specify that they apply to all academic appointees listed as key personnel on proposals submitted by the University, regardless of faculty series or appointment percentage. If any of these individuals are union represented, implementation of these requirements should be handled as appropriate for represented employees.	Systemwide Academic Personnel and Programs will conduct a systemwide review of APM - 025 and 671, circulating language that would expand the academic appointees covered by the policies. This expansion would include all academic appointees listed as key personnel on proposals submitted by the University, including those in faculty and nonfaculty titles series, and regardless of appointment percentage. Systemwide Academic Personnel and Programs will work with Labor Relations to ensure that, if any of these appointees are union represented, implementation of these requirements will be handled as appropriate for represented employees. MCA Assigned to: System Carlson Vice Provost Academic	April 30, 2022
	Susan Carlson, Vice Provost, Academic	
Systemwide Academic Personnel should: 3.2 Consider modifying APM - 025 and 671 such that all foreign activities are Category I activities which require prior approval, including the benefits and drawbacks of such modifications.	Personnel and Programs Systemwide Academic Personnel and Programs will consider modifying APM - 025 and 671 such that all foreign activities are Category I activities which require prior approval, and will develop the benefits and drawbacks of such modifications. If such a change has preliminary support, revised policy language for APM – 025 and 671 will be circulated as a part of a systemwide policy review. MCA Assigned to:	April 30, 2022
	MCA Assigned to: Susan Carlson, Vice Provost, Academic Personnel and Programs	

Recommendation	Management Corrective Action	Target Date
The Council of Vice Chancellors of Research, Academic Senate, Academic Personnel, and Research Policy Analysis and Coordination (RPAC), in consultation with UC Legal, Research Compliance and Advisory Committee/Research Compliance Officers, and Sponsored Projects Offices, should: 3.3 By June 30, 2021, collaborate to develop protocols and/or measures to help ensure complete and timely submission and review of outside activity disclosures, including recommended consequences for late or missed outside activity disclosures.	The Council of Vice Chancellors of Research, Academic Senate, Academic Personnel, and Research Policy Analysis and Coordination (RPAC), in consultation with UC Legal, Research Compliance and Advisory Committee/Research Compliance Officers, and Sponsored Projects Offices, will develop protocols and/or measures to help ensure complete and timely submission and review of outside activity disclosures, including recommended consequences for late or missed outside activity disclosures. MCA Assigned to: Deborah Motton, RPAC Executive Director	June 30, 2021
OATS Governance Board should: 3.4 Update OATS to include functionality to identify activities as foreign activities.	The OATS Governance Board discussed a proposal to add the following statement to the disclosure requirement for outside activities: "To the best of your knowledge, is this organization a foreign company or subsidiary of a foreign entity?" The Board does not recommend adding this statement to the disclosure requirement in OATS at this time. In making this recommendation, the OATS Governance Board considered a number of issues relevant to the proposal and its	N/A
	implications: UC does not have a policy to support adding this question to OATS.	
	OATS is a disclosure system specifically developed to address potential conflicts of commitment related to University roles and responsibilities. It was not designed as a system to monitor or disclose conflicts of interest. While there are ongoing discussions about how to integrate disclosure of potential conflicts of commitment and conflicts of interest, UC does not currently have a single disclosure system.	
	The information provided will not be reliable. Most faculty members will not have the necessary information to accurately respond to this question.	
	A number of faculty members raised concerns about how this information will be used by the University and the potential impact on their academic and outside professional opportunities, particularly because the information disclosed by faculty may be inaccurate or incomplete.	
	The Governance Board recommends that any changes in disclosure requirements await review and revisions to APM 025 and APM 671. This process will allow for input from multiple stakeholders which may also lead to a more effective strategy for tracking foreign influence.	

Recommendation	Management Corrective Action	Target Date
OATS Governance Board should: 3.5 Evaluate whether system functionality enhancements are required (e.g. reporting, user access roles) in order for institutional offices to receive the necessary information from OATS to perform ongoing compliance monitoring. Identify best practice solutions for institutional offices to perform compliance monitoring in OATS and communicate this solution to UC locations.	The OATS Governance Board will request that the OATS Working Group determine if there are access barriers to OATS that are not being met at any of the UC campuses. If the Working Group identifies technical or other limitations on access to faculty disclosures for compliance and research staff, it will make recommendations to the OATS Governance Board for how best to address them.	June 30, 2021
4. Training and Awareness		
RPAC and ECAS, in consultation with UC Legal and campus representatives (to include members from the conflict of interest and research compliance offices) should: 4.1 Conduct a review of existing extramural research funding conflict of interest policies and update them as necessary to ensure they align with current agency requirements. Establish an ongoing process to regularly update conflict of interest policies in response to changes in agency requirements.	RPAC and ECAS, in consultation with UC Legal and campus representatives, will conduct a review of existing extramural research funding conflict of interest policies and update them as necessary to ensure they align with current agency requirements, and will establish an ongoing process to regularly update conflict of interest policies in response to changes in agency requirements. MCA Assigned to: Deborah Motton, RPAC Executive Director Lourdes Demattos, RPAC Associate Director	September 30, 2021
RPAC and ECAS, in consultation with UC Legal and campus representatives (to include members from the conflict of interest and research compliance offices) should: 4.2 Develop a communication plan for foreign influence risk to be used by the locations. The plan should address target audiences, topics, and intervals.	RPAC and ECAS, in consultation with UC Legal and campus representatives, will develop a communication plan for foreign influence risk to be used by the locations. The plan should address target audiences, topics, and intervals. MCA Assigned to: Deborah Motton, RPAC Executive Director, Lourdes Demattos, RPAC Associate Director	September 30, 2021
RPAC and ECAS, in consultation with UC Legal and campus representatives (to include members from the conflict of interest and research compliance offices) should: 4.3 Develop required systemwide training on foreign influence, inclusive of foreign talent programs and reporting	RPAC and ECAS, in consultation with UC Legal and campus representatives, will develop required systemwide training on foreign influence, inclusive of foreign talent programs and reporting requirements. MCA Assigned to: Shanda Hunt, Systemwide Research Compliance Officer	December 31, 2021
requirements. ECAS and RPAC should: 4.4 Finalize and release the mandatory "Ethics and Compliance Briefing for Researchers" systemwide training module.	Marci Copeland, Associate Director, Systemwide Export Controls ECAS and RPAC will finalize and release the mandatory "Ethics and Compliance Briefing for Researchers" systemwide training module. MCA Assigned to: Shanda Hunt, Systemwide Research Compliance Officer	April 30, 2021

Recommendation	Management Corrective Action	Target Date
ECAS should:	ECAS will monitor systemwide compliance	August 31,
	with the mandatory systemwide training and	2021
4.5 Monitor systemwide compliance with	report completion metrics to the relevant	
the mandatory systemwide training and	systemwide and campus stakeholders (VCRs,	
report completion metrics to the	CECOs, etc.).	
relevant systemwide and campus	, ,	
stakeholders (VCRs, CECOs, etc.).	MCA Assigned to:	
, , , , , , , , , , , , , , , , , , , ,	Shanda Hunt, Systemwide Research	
	Compliance Officer	
5. Restricted Party Screening		
ECAS and RPAC, in consultation with	ECAS and RPAC, in consultation with	December 31,
systemwide and campus export control	systemwide and campus export control	2021
officers, should:	officers, will create guidance on restricted	
	party screening roles and responsibilities.	
5.1 Create guidance on restricted party		
screening roles and responsibilities.	MCA Assigned to:	
	Marci Copeland, Associate Director,	
	Systemwide Export Controls	
ECAS and RPAC, in consultation with	ECAS and RPAC, in consultation with	December 31,
systemwide and campus export control	systemwide and campus export control	2021
officers, should:	officers, will develop a required training	
527	module (or add to existing required training) to	
5.2 Develop a required training module (or	educate faculty and staff on the importance and	
add to existing required training) to	requirements of restricted party screening, and	
educate faculty and staff on the	which types of entities or persons should	
importance and requirements of	routinely be screened as part of normal	
restricted party screening, and which	business practices (inclusive of university	
types of entities or persons should	employees and students performing work and	
routinely be screened as part of normal	academic study in a foreign location).	
business practices (inclusive of		
university employees and students performing work and academic study	MCA Assigned to:	
	Shanda Hunt, Systemwide Research	
in a foreign location).	Compliance Officer	
	Marci Copeland, Associate Director,	
	Systemwide Export Controls	
6. Export Control Red Flags		
ECAS and RPAC, in consultation with	ECAS and RPAC, in consultation with	December 31,
systemwide and campus export control	systemwide and campus export control	2021
officers, should:	officers, will create systemwide guidance and	
	training on identifying and addressing red flags	
6.1 Create systemwide guidance and	in research and other	
training on identifying and addressing	agreements/arrangements, heightened legal,	
red flags in research and other	financial, and reputational risk related to such	
agreements/arrangements, heightened	red flags, review for defense services,	
legal, financial, and reputational risk	restricted proprietary technology inputs and	
related to such red flags, review for	outputs, restricted end uses, know your	
defense services, restricted proprietary	customer red flags, sanctioned countries, and	
technology inputs and outputs,	tangible exports.	
restricted end uses, know your	_	
customer red flags, sanctioned	MCA Assigned to:	
countries, and tangible exports.	Marci Copeland, Associate Director,	
	Systemwide Export Controls	

Recommendation	Management Corrective Action	Target Date
7. Vetting of International Scholars		
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ECAS and RPAC, in consultation with systemwide and campus export control officers and international offices, should: 7.1 Create guidance for assessing risk and identifying and vetting international scholars (e.g., via restricted party screening), including postdoctoral researchers, visiting scholars and graduate students, and their associated entities, in accordance with Export Administration Regulations, International Traffic in Arms Regulations, or National Nuclear Security Administration regulations. The guidance should include sample distributed roles and responsibilities and should address vetting for incubators and accelerators.	ECAS and RPAC, in consultation with systemwide and campus export control officers and international offices, will create guidance for assessing risk and identifying and vetting international scholars (e.g., via restricted party screening), including postdoctoral researchers, visiting scholars and graduate students, and their associated entities, in accordance with Export Administration Regulations, International Traffic in Arms Regulations, or National Nuclear Security Administration regulations. The guidance should include sample distributed roles and responsibilities and should address vetting for incubators and accelerators. MCA Assigned to: Marci Copeland, Associate Director, Systemwide Export Controls	December 31, 2021
8. Research Data Protections		
The Office of Research and Innovation should: 8.1 Finalize and distribute the UC Research Data and Tangible Research Materials policy.	The Office of Research and Innovation will finalize and distribute the UC Research Data and Tangible Research Materials policy. MCA Assigned to: Deborah Motton, RPAC Executive Director	December 31, 2021
9. Oversight of Foreign Gifts and C	ontracts Reporting	
RPAC, ECAS, Institutional Advancement, and UC Legal should: 9.1 Evaluate whether further systemwide guidance is necessary, and/or how the existing guidance can be better socialized such that all campus departments managing foreign donations can determine whether a gift or contract would be considered "restricted or conditional" in accordance with U.S. Department of Education definitions.	RPAC, ECAS, Institutional Advancement, and UC Legal will evaluate whether further systemwide guidance is necessary, and/or how the existing guidance can be better socialized such that all campus departments managing foreign donations can determine whether a gift or contract would be considered "restricted or conditional" in accordance with U.S. Department of Education definitions. MCA Assigned to: Deborah Motton, RPAC Executive Director	June 30, 2021

CAMPUS: UCSD		
Recommendation	Management Corrective Action	Target Date
1. Protocols to Detect Undisclosed Fac	ulty Affiliations	
1.2 Evaluate the recommended baseline institutional protocols and modify them as necessary vis-à-vis their own infrastructure, resources, and communication and IT systems to implement them locally. For example, templates developed by the working group could be tailored to meet local needs.	Research Compliance and Integrity (RCI), in collaboration with other campus offices as appropriate, will evaluate the recommended baseline institutional protocols and modify them as necessary vis-à-vis UCSD's infrastructure, resources, and communication and IT systems to implement them locally.	April 1, 2022 Note: Date is 9 months after UCOP completion of protocols per 1.1 (estimated 6/30/2021).
2. Conflict of Interest		
2.1 Implement protocols at the campuses, health systems, and LBNL to ensure that the compliance function (CECO and HCCO) regularly receives information (such as copies of determination letters sent to PIs after identification of significant financial interests in foreign entities) and is engaged, as appropriate for each location, on significant conflict of interest issues and management plans. An example of engagement by the compliance officer could be ex-officio membership on a financial conflict of interest committee.	The Conflict of Interest (COI) office (which is part of the RCI Office) will coordinate with the CECO and HCCO to implement protocols to ensure that the compliance function (CECO and HCCO) regularly receives information and is engaged, as appropriate for UCSD.	January 1, 2022 Note: Date is approximately 9 months from finalization of report, which is expected in March 2021.
3. Conflict of Commitment		
3.6 Evaluate the protocols and measures developed to help ensure complete and timely submission and review of outside activity disclosures vis-à-vis their own infrastructure resources, and communication and IT systems to implement these or other measures to achieve the same goal.	The Academic Personal Office and Health Sciences Academic Affairs will evaluate the protocols and measures developed to help ensure complete and timely submission and review of outside activity disclosures vis-à-vis UCSD's infrastructure resources, and communication and IT systems to implement these or other measures to achieve the same goal.	April 1, 2022 Note: Date is 9 months after UCOP completion of protocols per 3.3 (estimated 6/30/2021).

CAMPUS: UCSD		
Recommendation	Management Corrective Action	Target Date
3.7 Evaluate the best practice solutions for institutional office compliance monitoring recommended by the OATS Governance Board and modify them as necessary to implement them locally.	The Academic Personal Office and Health Sciences Academic Affairs will evaluate the best practice solutions for institutional office compliance monitoring recommended by the OATS Governance Board and modify them as necessary to implement them locally.	April 1, 2022 Note: Date is 9 months after UCOP completion of best practices per 3.5 (estimated 6/30/2021).
4. Training and Awareness		
4.6 Implement the system-developed "Ethics and Compliance Briefing for Researchers" training module and require, at a minimum, all researchers receiving research funding to complete the training biennially. Consider expanding the training audience to graduate students, visiting scholars, and grant key personnel.	Office of the Vice Chancellor (VC) Research, in coordination with other campus offices as appropriate, will implement the system-developed "Ethics and Compliance Briefing for Researchers" training module and require, at a minimum, all researchers receiving research funding to complete the training biennially. Office of VC Research will also consider expanding the training audience to include graduate students, visiting scholars, and grant key personnel participating in the research but are not receiving extramural research funding.	February 1, 2022 Note: Date is 9 months after UCOP completion of training per 4.4 (estimated 4/30/2021).
4.7 Address consequences for non-compliance with the completion requirement for the mandatory systemwide training.	Office of the VC Research, in coordination with other campus offices as appropriate, will address consequences for non-compliance with the completion requirement for the mandatory systemwide training.	June 1, 2022 Note: Date is 9 months after UCOP completion of training metrics per 4.5 (estimated 8/31/2021).
4.8 Implement a local foreign influence risk communication plan, taking into consideration the systemwide guidance	Office of the VC Research, in coordination with other campus offices as appropriate, will implement a local foreign influence risk communication plan, taking into consideration the systemwide guidance.	July 1, 2022 Note: Date is 9 months after UCOP completion of communication plan per 4.2 (estimated 9/30/2021).

CAMPUS: UCSD		
Recommendation	Management Corrective Action	Target Date
5. Restricted Party Screening		
 5.3 Create and implement export control procedures as outlined in the UC export control policy. At a minimum, these procedures should include: Defined roles and responsibilities for restricted party screening as outlined in the export control policy Escalation procedures for positive screenings Periodic ECO monitoring to ensure that the responsible parties are performing these procedures. 	The Export Control Office (which is part of the RCI Office) will create and implement export control procedures as outlined in the UC export control policy. At a minimum, these procedures will include: • Defined roles and responsibilities for restricted party screening as outlined in the export control policy • Escalation procedures for positive screenings • Periodic ECO monitoring to ensure that the responsible parties are performing these procedures.	January 1, 2022 Note: Date is approximately 9 months from finalization of report, which is expected in March 2021.
5.4 Implement the system-developed training module to educate faculty and staff on the importance and requirements of restricted party screening	The Export Control Office (which is part of the RCI Office) will implement the system-developed training module to educate faculty and staff on the importance and requirements of restricted party screening.	Note: Date is 9 months after UCOP completion of training module per 5.2 (estimated 12/31/2021).
6. Export Control Red Flags		
6.2 Implement written procedures to address red flags in accordance with systemwide guidance, including escalation procedures that are specific to the location.	The Export Control Office (which is part of the RCI Office) will implement written procedures to address red flags in accordance with systemwide guidance, including escalation procedures that are specific to the location.	Note: Date is 9 months after UCOP completion of guidance per 6.1 (estimated 12/31/2021).
6.3 Develop localized training on the red flags procedures leveraging the systemwide training content and implement the training for appropriate personnel.	The Export Control Office (which is part of the RCI Office) will develop localized training on the red flags procedures leveraging the systemwide training content and implement the training for appropriate personnel.	Note: Date is 9 months after UCOP completion of training per 6.1 (estimated 12/31/2021).

CAMPUS: UCSD		
Recommendation	Management Corrective Action	Target Date
7. Vetting of International Scholars		
7.2 Implement the systemwide guidance, vis- à-vis the location's infrastructure, resource, communication and IT systems, etc., in the form of local procedures, which should include escalation procedures that are specific to the location.	The Office for Postdoctoral and Research Scholar Affairs (OPRSA), in coordination with other campus offices as appropriate, will implement the systemwide guidance, vis-à-vis UCSD's infrastructure, resource, communication and IT systems, etc., in the form of local procedures, which will include escalation procedures that are specific to UCSD.	Note: Date is 9 months after UCOP completion of guidance per 7.1 (estimated 12/31/2021).
8. Research Data Protections		
8.2 Implement guidelines for compliance with UC Research Data and Tangible Research Materials policy. At a minimum, these guidelines should establish responsibility for tracking compliance with sponsor research data protection requirements.	RCI and the Chief Information Security Offices (CISO) will implement guidelines for compliance with UC Research Data and Tangible Research Materials policy. At a minimum, these guidelines will establish responsibility for tracking compliance with sponsor research data protection requirements.	Note: Date is 9 months after UCOP completion of policy per 8.1 (estimated 12/31/2021).
9. Oversight of Foreign Gifts and Cont	tracts Reporting	
9.2 Convene a working group or committee to oversee Section 117 reporting that consists of representatives from all reporting departments. The working group should identify a central office with the appropriate knowledge of the U.S. Department of Education requirements to review each Section 117 report prior to submission.	The Chief Ethics and Compliance Officer charged a HEA 117 workgroup with representatives from reporting departments. Office of Contracts and Grants Administration (OCGA) has been identified as the central office to review each Section 117 report prior to submission. OCGA, in coordination with the workgroup as appropriate, will finalize HEA 117 procedures on the review of each Section 117 report prior to submission, including the roles of the offices involved in submission of the report.	January 1, 2022 Note: Date is approximately 9 months from finalization of report, which is expected in March 2021.
9.3 Establish protocols to ensure individuals responsible for making determinations on selling membership agreements are not also receiving the benefit from associated fees.	OCGA, in coordination with Advancement and other campus offices as appropriate, will document protocols on membership agreements to include definitions, responsibilities, and separation of roles for offices involved in the classification and processing of these agreements.	January 1, 2022 Note: Date is approximately 9 months from finalization of report, which is expected in March 2021.