UCSanDiego RESEARCH COMPLIANCE AND INTEGRITY

International Engagement Considerations, Existing and Evolving Federal, UC and Campus Requirements of Sponsored Research

Presenters:

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June 18, 2019

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

- Conflict of Interest (COI)
- Dual Use Research of Concern (DURC)
- Export Control and Facility Security
- Institutional Animal Care and Use Committee (IACUC)
- Research Ethics and Integrity (Research Misconduct)
- ClinicalTrials.Gov, NIH GCP and RCR Compliance

Website: RCI.UCSD.EDU

Helpline: (858) 822-4939

Email: rci@ucsd.edu

AGENDA



- Foreign Influence
- Agency Existing & Evolving Policies and Requirements
 - NIH Specific Guidance
- Post Doctoral and Visiting Scholars
- Export Control
- Conflict of Interest (COI) and Conflict of Commitment (COC)
- Questions

FOREIGN INFLUENCE

GOVERNMENT CONCERN OVER UNIVERSITIES & FOREIGN INFLUENCE

- Public cases of Export Violations involving Universities
- Increased scrutiny by Congress,White House, and Federal Agencies
- Increased visits by federal agencies to Universities, FBI, BIS, ICE
- Economic espionage concerns



WHY DOES IT MATTER?

- Heightened concern at federal level that certain foreign entities may seek to influence U.S. research at all levels including:
 - Peer review
 - Diversion of intellectual property
 - Sharing of confidential information and the use of resources originating outside the U.S. inconsistency in reporting drives federal concern

FEBRUARY 25, 2019

PROFESSOR FOUND GUILTY OF GRANT FRAUD

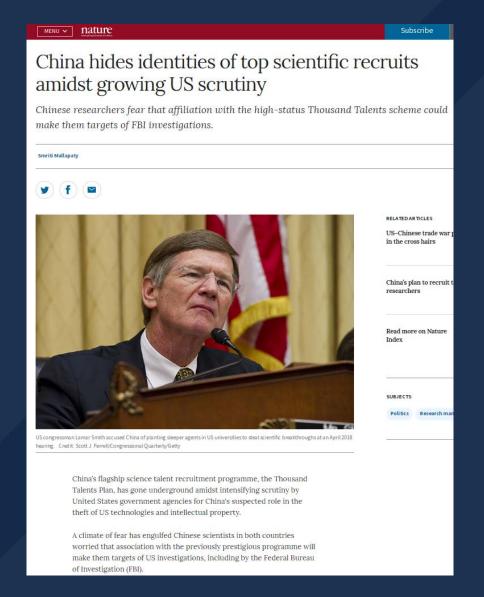


- Percival Zhang, founded & Chief Scientific Officer of Cell-Free Bioinnovations, Inc. ("CFB"), was awarded SBIR/STTR by NSF
 - Grad Student was listed at PI and CTO at CFB
 - Postdoc was listed as Chief Scientist at CFB
- Undisclosed external activity:
 - Worked as a paid researcher for the Tianjin
 Institute of Industrial Biotechnology, Chinese
 Academy of Sciences
 - Talents Program Funding
- NSF grant funds fraudulently obtained for research, Zhang knew had already been done in China
- Zhang intended to use the grant funds for other
 CFB projects rather than for the projects for which the funds were requested

https://www.roanoke.com/news/crime/ex-virginia-tech-biotech-professor-found-guilty-of-grant-fraud/article_9d08f719-6a76-528e-8ae5-f57ee7a66851.html http://apps.washingtonpost.com/g/documents/national/criminal-complaint-for-yiheng-percival-zhang/2558/

OCTOBER 24, 2018

CONCERNS OVER TALENTS PROGRAMS



Examples of Talent Programs:

- Global Experts
- Thousand Talents
- Project 111
- Yangtze River Scholars

https://www.nature.com/articles/d41586-018-07167-6

CHANGING FEDERAL LANDSCAPE

National Institutes of Health

The NIH issued a notice reminding the research community of their obligation to disclose Financial Conflict of Interest (FCOI). They specifically called out foreign financial interests as a concern (March 30, 2018)

- Over 55 academic and research institutions
- Publications listing foreign collaborations with support Contracts/Grants & COI
- Affiliations with or without support
- Comprehensive listing of other support (salary or non-salary)
- Research conducted outside U.S.
- Foreign talents programs

Department of Defense

 The National Defense Authorization Act requires the DOD to develop procedures limiting foreign access to technologies through grants, contracts, cooperative agreements or other transactions based on national security interest and to work with academic institutions to limit undue influence, including through foreign talent programs, by countries to exploit United States technology within the DOD research, science and technology, and innovation enterprise (August 13, 2018)

CHANGING FEDERAL LANDSCAPE

National Science Foundation

The National Science Board (NSB), which governs the NSF, issued a statement on national security and science. In it NSB Chair Diane Souvaine affirmed the board's commitment to the free exchange of ideas and information, while also acknowledging the need to create new policies to protect national interests. (October 23, 2018)

Department of Energy

- The DOE issued memos stating:
- Researchers in unspecified "emerging research areas and technologies" would no longer be allowed to collaborate with colleagues from unnamed "sensitive" countries (December 14, 2018)
- Restrictions on funded researchers from participating in any foreign talentrecruitment programs, whether that researcher is a U.S. citizen or not (January 31, 2019)

CHALLENGES WE HAVE IDENTIFIED



- Conflict of Commitment not filed annually
- Conflict of Interest not filed when needed
- "Other Support" reporting is incomplete
- Funding agencies are not updated on new foreign engagements
- Inconsistencies across campus
- Visitor support
- Lack of awareness

AGENCY EXISTING & EVOLVING POLICIES & REQUIREMENTS

LINDA COLLINS, AVC OFFICE OF CONTRACTS AND GRANTS ERIKA WILSON, DIRECTOR



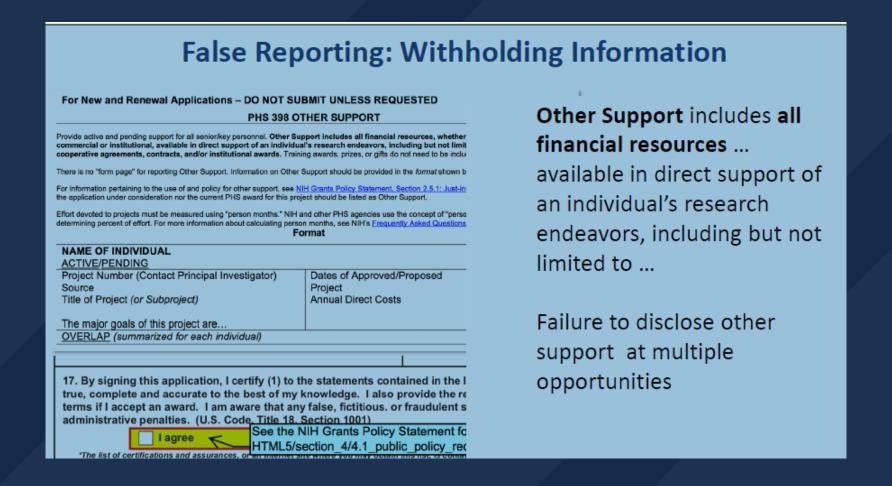
FEDERAL FUNDING SUBMISSIONS & REPORTING

- Disclose foreign affiliations and support on federal applications
 - List all foreign engagements and affiliations present in your proposal
 - Biosketch, Other Support / Current & Pending
 - Identify foreign engagements and affiliations in each annual progress report and closeout summaries
- Disclosure foreign engagements in what types of agreements
 - All types, including research contracts and grants, cooperative agreements and organizational awards, including any from foreign governments or entities
- For DOD proposals, disclose key personnel information as outlined in their memo dated March 20, 2019
- At the time of proposal, NSF requires disclosure of a foreign organization's involvement in a project via a check box and justification as to why that organization's participation is essential

REMINDERS

- Carefully read all proposal guidelines to ensure understanding of any changes to federal policies
- Export Control review must be flagged in the internal proposal record (ePD) to ensure review by UCSD's Export Control Office
- Any materials or information shared with a foreign entity must be covered under a formal agreement (sponsored research, material transfer, data use, confidentiality, collaboration, etc.)
- Disclose any foreign visitors to your departmental leadership prior to the visit, as additional on-boarding steps must be taken to ensure compliance

PROPOSAL CERTIFICATIONS: DON'T FALSE REPORT



WHAT DO REVIEWERS LOOK FOR IN OTHER SUPPORT?



- Overlap of scientific goals
- Overlap of financial support
- Over-commitment of effort/person months for key personnel
- Foreign collaboration or support including talent programs

THREE TYPES OVERLAP

Scientific

- Substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration
- A specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source

Budgetary

Duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source

Commitment

Key or senior personnel time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application

HOW TO ADDRESS OVERLAP

- Explain
 - Potential scientific, budgetary and/or commitment overlap when submitting other support
- Resolution of Overlap
 - Address at the time of award in conjunction with applicant institution officials, the PD/PI, and awarding agency staff
- The PI should always address any scientific overlap
 - "Potential commitment overlap for Dr. ______ between (insert grant #) and the application under consideration is funded with Dr. _____ committed at (insert calendar months), Dr. _____ will (ex. request approval to reduce months, reduce effort accordingly, etc.)"

OTHER SUPPORT- JIT

For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED PHS 398 OTHER SUPPORT

Samples

ANDERSON, R.R.

ACTIVE

2 R01 HL 00000-13 (Anderson) 3/1/2013 – 2/28/2018

3.60 calendar

NIH/NHLBI \$186,529

Chloride and Sodium Transport in Airway Epithelial Cells

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) 4/1/2014 – 3/31/2019

1.20 calendar

NIH/NHLBI \$122,717

Ion Transport in Lungs

The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

PENDING

DCB 950000 (Anderson) 12/1/2017 – 11/30/2020 2.40 calendar

National Science Foundation \$82,163

Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.



There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff

Other federal agencies have similar other support requirements

NIH SPECIFIC GUIDANCE

FOREIGN COMPONENT: NIH DEFINITION

- The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended
- Activities that would meet this definition include, but are not limited to,
 - (1) the involvement of human subjects or animals,
 - (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or
 - (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country
- Examples of other grant-related activities that may be significant are:
 - collaborations with investigators at a foreign site anticipated to result in co-authorship;
 - use of facilities or instrumentation at a foreign site; or
 - receipt of financial support or resources from a foreign entity

Foreign travel for consultation is not considered a foreign component

From: https://grants.nih.gov/gants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm

FOREIGN COMPONENT IN NIH APPLICATION

6. Does this project involve activities outside of the United States or partnerships with international collaborators?

This field is required.

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check "Yes" or "No."

Applicants to NIH and other PHS agencies must check "Yes" if the applicant organization is a foreign institution or if the project includes a foreign component. See NIH Glossary for a definition of a foreign component.

If you have checked "Yes" to Question 6, you must include a "Foreign Justification" attachment in Field 12, Other Attachments. Describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting. In the body of the text, begin the section with a heading indicating "Foreign Justification" and name the file "Foreign Justification."

PAID DIRECT FOREIGN STUDENTS

- Prior to supplementing any Paid Direct from federal funds need to ensure the terms and condition allow and request prior approval
- Disclose on the NIH application and RPPR that the Paid Direct visiting foreign student or scholar is working on the grant
 - For G.9 Foreign component report:
 - X were visiting graduate students from X Foreign University. They were financially supported by a scholarship from the foreign government, which covered their living expenses in San Diego, with no fund brought here to support their research work in the lab at UCSD. All the research work and experimental data reported in our most recent paper were done in Dr.'s X UCSD lab.

FOREIGN COMPONENT REPORTING FOR NIH APPLICATION

For New, Renewal, Resubmission, and Supplement Applications in ASSIST:

- R&R Other Project Information Form: Item 6: Does this project involve activities outside of the United States or partnerships with international collaborators? Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check "Yes" or "No." If Yes, list the country(ies) as well as you are required to upload a Foreign Justification under Item 12: Other Attachments.
- Justification under Item 12: Other Attachments
 - The **Foreign Justification** should "[d]escribe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting. In the body of the text, begin the section with a heading indicating "Foreign Justification" and name the [PDF] file "Foreign Justification."
- R&R Other Project Information Form: Item 10: Facilities & Other Resources. Describe any use of facilities or instrumentation at a foreign site
- Project/Performance Site Location(s) Form: Project/Performance Site Location 1 or Additional Location(s): enter all applicable non-U.S. performance sites that fit UC San Diego's interpretation of foreign involvement
- R&R Senior/Key Person Profile (Expanded) Form: Bio sketch: B. Positions and Honors: list all foreign affiliations in this section of the Bio sketch as well as list all foreign awards in D. Research Support
- **R&R Budget Form:** Travel, Foreign: "Identify the total funds requested for foreign travel. Foreign travel includes any destination outside of the U.S., Canada, Mexico, or U.S. possessions. In Section L. Budget Justification, include the purpose, destination, dates of travel (if known), and the number of individuals for each trip. If the dates of travel are not known, specify the estimated length of trip (e.g., 3 days)."

FOREIGN COMPONENT REPORTING FOR NIH

For Just-in-Time

 Other Support: indicate all foreign support, awards, and applications under current support and pending support as well as any possible overlap issues with said foreign awards and/or applications

For SNAP & Non-SNAP RPPR Progress Reports

- Section D Participants: if the individual's primary affiliation is with a foreign organization, provide the name of the organization and country
- **Section E Impact: E.4:** indicate what dollar amount of the award's budget is being spent in foreign country(ies), and if more than one foreign country identify the distribution between the foreign countries
- Section G. Special Reporting Requirements: G.9 Foreign Component: provide the organization name, country, and description of each foreign component
- Human Subjects System (HSS): Planned Inclusion Enrollment Report: indicate whether the IDR involves participants from a non-US site (i.e., foreign) or a US site (i.e., domestic)

For more information, please see the RPPR Instruction Guide

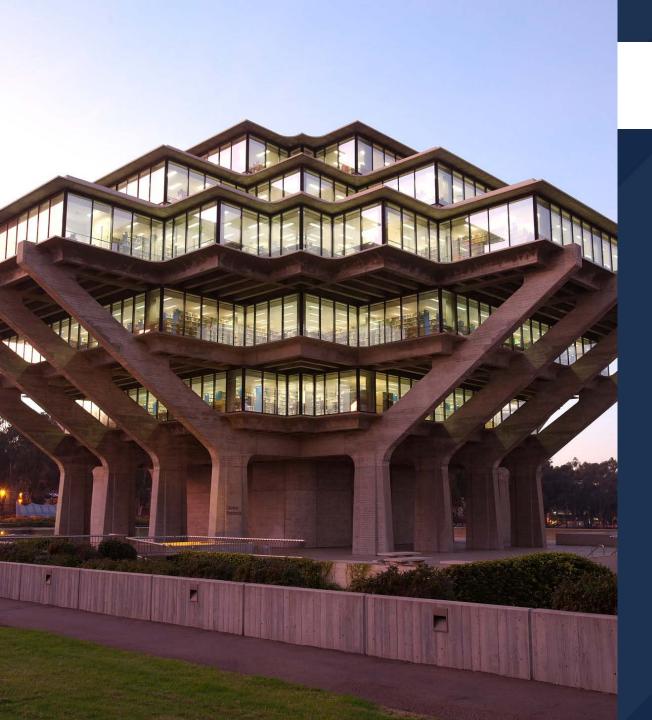
POST DOCTORAL AND VISITING SCHOLARS JENNIFER BOURQUE, DIRECTOR



Appointment Process

- All Postdoctoral and Visiting Scholars must have an official appointment
- One benefit of the official appointment process is Export Control office checks all foreign Postdoctoral and Visiting Scholars through the Restricted Party Screening system (Visual Compliance)





Do's and Don'ts

- Do communicate/educate your research team on foreign entity issues, export control policies and regulations, and data ownership policy to protect intellectual property and to mitigate risk
- Do safeguard research data by requiring original material remain in the lab and/or on secure, shared servers, and back up frequently
- Do consider location of work assignment as some federal contracts and grants may restrict use of funds for work performed in foreign countries
- Don't pass along IFSO visa processing fee to foreign postdocs as CBA requires department/PI to cover this cost
- Don't charge visa processing fees to grants when expenses are not associated with initial recruitment as it is an unallowable charge

UCSanDiego RESEARCH COMPLIANCE AND INTEGRITY

Export Control

Brittany Whiting



EXPORT CONTROL OFFICE

- Identifies and manages export risks for U.S. national security & foreign policy to facilitate university research
 - Export Controls
 - Dual Use Research of Concern (DURC)
 - Facility Security
- Advises on and obtains export licenses for:
 - International payments, shipments, travel and collaborations
 - Sanctioned country activities with Cuba, Iran, North Korea, Syria & Sudan
 - Restricted parties
- Develops technology control plans with researchers for export restricted items



SYSTEMS FOR EXPORT REVIEWS

People Foreign Visiting Scholars & Grads Foreigner access to export restricted technology Foreign shipments Places Foreign payments • Sanctioned countries transactions • Travel pre-authorization alerts Procurement- Purchasing Contracts and Grants systems Things Biohazard Use Authorizations Chemical Hazard Use Authorizations

PEOPLE: RESTRICTED OR PROHIBITED PERSON OR ENTITY?

- The US Government issues various lists of individuals & entities both in the U.S. & abroad that have committed export violations or other serious offenses.
 - Terms & conditions require no debarred, disqualified or ineligible persons
 - Part of funding awards, procurement and service agreements
- Financial dealings or export transactions with Restricted or Prohibited parties is prohibited.
 - Terrorists
 - Weapons Proliferators
 - Export Violators
 - Drug Traffickers
- Visual Compliance Screening Tool





RESTRICTED ENTITY EXAMPLES (NOT COMPREHENSIVE)

- BEIJING UNIVERSITY OF AERONAUTICS AND ASTRONAUTICS (BUAA) AKA BEIHANG UNIVERSITY
- NORTHWEST POLYTECHNICAL UNIVERSITY
- SICHUAN UNIVERSITY
- UNIVERSITY OF ELECTRONIC SCIENCE AND TECHNOLOGY OF CHINA
- NATIONAL UNIVERSITY OF DEFENSE TECHNOLOGY
- MALEK ASHTAR UNIVERSITY OF TECHNOLOGY
- BAQIYATTALLAH UNIVERSITY OF MEDICAL SCIENCES
- IMAM HOSSEIN UNIVERSITY
- BEN GURION UNIVERSITY (BGU)



UCSanDiego RESEARCH COMPLIANCE AND INTEGRITY

Conflict of Interest (COI) and Conflict of Commitment (COC)

Jennifer J. Ford

WHEN ARE CONFLICT OF INTEREST (COI) DISCLOSURES REQUIRED?

COI Research and Other Related Activity Disclosures			
Category	Agency	Examples	
Sponsored Research	Federal	National Health Institute (NIH) National Science Foundation (NSF)	
	Non-Federal	For-Profit Non-Profit*	
Other Related Activity	Non-Federal	For-Profit or Non-Profit*	

^{*} There are non-profit sponsors exempt from the disclosure requirement

^{**} Disclosure may be required for internal University clinical research projects when Human Subjects are involved

WHAT CONSTITUTES A POTENTIAL RESEARCH COI?

Type of Interests*	Examples
Income / Compensation	Salaries, Consulting, Honoraria
Ownership / Position	Founder, Partner, Board of Directors, Scientific Advisory Board, Employee
Equity / Ownership Interest	Stocks, Bonds, Stock Options
Gifts	From outside entity
Loans	Money loaned to outside entity
Travel Expenses / Reimbursement	Paid from outside entity
Intellectual Property / Patent	Non-UC royalties

^{*}Applies to the Employee, Spouse, Registered Domestic Partner, and Dependent Children

WHICH COI DISCLOSURE FORMS AND WHEN TO SUBMIT?

PHS Form submitted at time of proposal and PHS supplement at NOA 9510 and 700U must be completed, signed and dated at time of proposal

Funding Entity / Sponsor	Disclosure Form Required with Initial Submission	Additional Form Required if Positive	When does COI Office review?
Public Health Services (PHS) (NIH and those who have adopted PHS)	PHS Form	Supplement	Notice of Award
Federal Non-PHS (NSF, CIRM, UC Programs)	9510	Addendum	Proposal submission
Non-Federal (For-Profit or Non-Profit)*	700U	Addendum	Proposal or equivalent

^{*} There are non-profit sponsors exempt from the disclosure requirement

THRESHOLDS FOR DISCLOSURE?

Funding Entity / Sponsor	Income / Compensation	Ownership / Position	Investment / Equity	Travel Expenses/ Reimbursement	Loans	Gifts	Intellectual Property / Patent
Public Health Services (PHS)	publicly traded > \$5,000 non-publicly traded > \$5,000	Any	publicly traded > \$5,000 non-publicly traded ≥ \$0	> \$5,000	> \$5,000	> \$5,000	> \$5,000 (excludes UC)
Federal Non-PHS 9510	> \$10,000	Any	> \$10,000 or > 5% owner	≥ \$10,000	> \$10,000	> \$10,000	Any royalties (excludes UC)
Non-Federal 700U	>\$500	Any	>\$2,000	≥ \$0	≥ \$500	≥ \$50	Any royalties (excludes UC)



EXAMPLES THAT MAY CREATE A CONFLICT OF INTEREST

- Starting a company
 - Founder and managerial position
- Employee position at a company
- Visiting appointment at a foreign University or foreign Government
- Being on a proposal or award for another entity
- Operating a lab at another entity
- Consulting for a company or foreign University
 - Being on the Scientific Advisory Board (SAB)
- Travel expenses or reimbursement paid by an outside entity



THE INTERSECTION BETWEEN CONFLICT OF INTEREST (COI) AND CONFLICT OF COMMITMENT (COC)?

CONFLICT OF COMMITMENT (COC) AND CONFLICT OF INTEREST (COI)

	Conflict of Commitment	Conflict of Interest
Policies	APM 025 / APM 671	UCSD PPM 200-13, APM 028, OP PHS and NSF*
Disclosure Forms	Category I (prior approval) and II	Dependent on outside funding entity**
Timing	Category I: Prior to Engagement Category II: Annually	Proposal and/or award stages and then dependent on funding
Responsible Offices	Academic Affairs	Conflict of Interest Office

Similarity: Engagement with outside activities

^{*} There are many COI policies, see http://blink.ucsd.edu/sponsor/coi/policies.html

^{**} Disclosure may be required for internal funding when Human Subjects are involved

COC AND COI SCENARIO FOREIGN ENGAGEMENT

Dr. Green, an active NIH grant recipient, has a visiting professor appointment at the Imperial College of London (Imperial). Dr. Green teaches and mentors students in a research lab at Imperial. Dr. Green receives compensation (\$6,000) and travel reimbursement (\$8,500).

Is COC reporting and PHS disclosure required?

Yes

What must be disclosed?

Visiting Professor appointment, income and travel

Which category type?

Category I

Prior approval required?

Yes, for the visiting professor appointment

- Will COI disclosure be reviewed by the IRC committee?
 - Yes, if the relatedness assessment by the COI Office determines that the interest and the scope of work are related
- What might be the COI IRC management strategies?

Disclose in Publications, Presentations, and to research team, disclose inventions, consult with OCGA to determine if foreign component prior approval is required

WHAT CAN WE DO TO PROTECT UC SAN DIEGO?

- Follow established UC and UC San Diego Procedures
- UC Policies on COI, COC and External Research outline responsibilities for reporting
 - For PHS, disclose Foreign Institutions and Governments:
 - Disclose financial interests including foreign Universities and foreign governments
 - Income OR travel expenses/reimbursement over \$5,000 (disclose within 30 days)
- Our existing procedures for proposals, agreements, purchasing and visiting scholars are in place to comply with regulations and alert us to address risks
- Use visual compliance for screening foreign collaborators, including visitors, funding entities, purchases or shipments
 - Restricted parties lists are being updated every few days by the USG
- Be transparent with UCSD and Federal Agencies
- Escalate any requests for information from federal authorities on national security or export controls



UC SAN DIEGO

- A Good Rule of Thumb
 - Any external support (whether financial or not) or engagement that you would acknowledge in public presentations or publications is something that you should also disclose in grant applications, annual reports and closeout summaries and in university-related COI and COC disclosure forms (as required).
- "Transparency and compliance with UC and federal requirements are mechanisms to support all investigators and faculty."
- Resources Online: https://blink.ucsd.edu/research/foreign-engagements.html

CONTACTS

Research Compliance and Integrity (RCI)	Angie McMahill
Export Control	Brittany Whiting
Conflict of Interest (COI)	Jennifer J. Ford
Office of Postdoctoral and Research Scholar Affairs (OPRSA)	Jennifer (Oh) Bourque
Office of Contract and Grant Administration (OCGA)	Linda Collins
Office of Innovation and Commercialization (OIC)	Paul Roben
Graduate Division	Paul Yu
Academic Senate and Council on Research	Andrew Kehler
	Robert Horwitz
Office of International Affairs (OIA)	Chip Schooley

UNANNOUNCED VISITS BY FEDERAL AND STATE AGENCIES

- UC San Diego can expect site visits by outside agencies as part of routine oversight activities and for specific ongoing investigations
- The University's practice is to cooperate with outside investigating agencies, while protecting the rights and privacy of the students, faculty, staff and research subjects
- Promptly contact Research Compliance and Integrity who will provide assistance or alert appropriate institutional offices

For additional information and FAQs, please see https://blink.ucsd.edu/research/policies-compliance-ethics/index.html

COMMUNICATIONS

- Research Compliance and Integrity Helpline: (858) 822-4939, rci@ucsd.edu
- Conflict of Interest Helpline: (858) 534-6465. info-coi@ucsd.edu
- Export Control Helpline: (858) 246-3300, export@ucsd.edu
- IACUC Helpline: (858) 534-6069, iacuc@ucsd.edu
- Hot Topics and Newsletters:





- Website: http://blink.ucsd.edu/sponsor/rci/news.html
- Research Compliance and Hot Topics Training Program
- To be added to the RCI list serv, please email rci@ucsd.edu