UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

Research Compliance and Integrity Hot Topics Session April 19, 2023

<u>UC San Diego</u>

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 Good Clinical Practices (GCP) and Responsible Conduct of Research (RCR) Compliance
- Foreign Engagements
- General Research Compliance Activities

Website: RCI.UCSD.EDU Helpline: (858) 822-4939 Email: rci@ucsd.edu



Conflict of Interest (COI): Navigating Kuali COI and COI Disclosure Requirements for Research

Jennifer J. Ford Director, Conflict of Interest Office April 19, 2023



AGENDA

- Role of the Conflict of Interest (COI) Office
- Why Does Disclosing COI Matter?
- Research COI Policies
 - Sponsored Research and other related activities disclosures
 - Essential information for understanding and completing disclosures
 - Guidance on areas of concern
- Kuali COI
- Questions and Answers



WHAT IS THE ROLE AND SERVICES OF THE CONFLICT OF INTEREST (COI) OFFICE?



THE ROLE OF THE CONFLICT OF INTEREST (COI) OFFICE



The UC San Diego Conflict of Interest Office, also known as the COI Office, role is to provide faculty and staff assistance in assessing circumstances under which their outside activities or financial interests may inappropriately conflict with their responsibilities to the University.

CONFLICT OF INTEREST (COI) OFFICE SERVICES

- Reviews disclosures of financial interests from
 University faculty, students and staff
- Ensures compliance with all applicable regulations
- Serves as a resource to University faculty, students, staff and institutional offices
 - Starting Companies
 - Consulting
 - Dual appointments



WHY DOES DISCLOSING COI MATTER?

BESIDES COMPLYING WITH FEDERAL AND STATE LAWS AND UC POLICY



COI IN THE NEWS



In December of 2019, Propublica requested all Financial Conflicts of Interests (FCOIs) submissions by Awardees to National Institute of Health

COI IN THE NEWS

PROPUBLICA DOLLARS FOR PROFS

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Dollars for Profs

Dig Into University Researchers' Outside Income and Conflicts of Interest

By Sisi Wei, Annie Waldman and David Armstrong, ProPublica. Published December 6, 2019.

Professors' outside income can influence their research topics and findings, policy views and legislative testimony. But these conflicts of interest have largely stayed hidden — until now. This unique database allows you to search records from multiple state universities and the National Institutes of Health for outside income and conflicts of interest of professors, researchers and staff.



Then December 2019, Propublica created "Dollars for Profs" a searchable database of the details for researcher's financial interest(s) of all FCOI submission from National Institute of Heath

WHY AND WHEN CHANGES TO COI STARTED?

NIH Investigating Foreign Influence on Research

By Andrew Kreighbaum // August 24, 2018

D COMMENTS Q

National Institutes of Health director Francis Collins said Thursday that the agency is investigating multiple research institutions where researchers failed to disclose improper support from foreign governments.

In a letter to grant recipient institutions, Collins said foreign entities had mounted "systematic programs" to influence NIH research. The agency's concerns include the sharing of information on grant applications with foreign entities as well as failures to disclose financial support from foreign governments.

Collins also spoke about those research issues at a hearing of the Senate Health, Education, Labor and Pensions Committee, which oversees the agency.

NIH is responding by working with other government agencies and professional organizations to push for better reporting on sources of research support and improve intellectual property.

The letter also encouraged research institutions to reach out to the FBI about information involving grant applications or awards.

August of 2018, Foreign Influence NIH Director Francis Collins

CONCERNS NOT LIMITED TO NIH

- The National Defense Authorization Act, signed in August 2018, included Sec. 1286, which stated that "The Secretary of Defense shall . . . establish an initiative to work with academic institutions who perform defense research and engineering activities . . . to limit undue influence, including through foreign talent programs, by countries to exploit United State Technology ... "
- The National Science Foundation issued a statement on "Security and Science" dated October 23, 2018, stating that US universities must "embrace transparency and rigorously adhere to conflict of interest and conflict of commitment policies."
- The Department of Energy issued a notification on February 1, 2019, stating that DOE plans to implement a policy, which will mandate that "federal and contractor personnel fully disclose and, as necessary, terminate affiliations with foreign government-supported talent recruitment programs."

CONFLICT OF INTEREST (COI) UPDATES: NSPM-33 AND DOE

- In January of 2022, the Office of Science and Technology Policy (OSTP) released implementation guidance for <u>NSPM-33</u> which requires all federal funding agencies harmonize/standardize COI disclosures and other requirements
 - Department of Energy (DOE) requires implementation PHS FCOI regulations
- PHS/DOE Investigators must complete the UCOP's Ethics and Compliance Briefing for Researchers (ECBR)
 - It satisfies the federal PHS/DOE training requirements
- Investigators must submit COI Disclosures in Kuali COI
- More federal agencies may have or will change COI policy



Summary of NSTC Guidance for Implementing National Security Presidential Memorandum 33: Provisions Regarding DPIs, Consequences, Information Sharing and Research Security Programs

On January 14, 2021, the White House issued "Presidential Memorandum on United States Government – Research and Development National Security Policy" (NSPM-33"). NSPM-33 tasked the heads of U.S. research funding agencies with establishing policies on various aspects of research security, including:

- Researcher disclosure requirements
- Use of digital persistent identifiers (DPIs)
- Appropriate consequences for disclosure violations
- Sharing of information about violators, as consistent with applicable laws
- Standards for research security programs

https://www.cogr.edu/sites/default/files/final%20NSPM%2033%20guidance%20re%20research%20security%20programs%20etc%20jan%2010%202022.pdf

AFTER NSPM-33 ENACTMENT OF CHIPS AND SCIENCE ACT



APS Applauds Passage of CHIPS Act

July 29, 2022

The American Physical Society (APS) is delighted that Congress has passed the CHIPS and Science Act of 2022 (CHIPS+). This historic legislation is a critical step toward strengthening the United States's competitiveness in science, technology, and innovation. In addition to an unprecedented investment in US-based semiconductor manufacturing, CHIPS+ provides significant increases in authorized funding for the National Science Foundation, Department of Energy Office of Science, and other federal science agencies. Federal investment in science bolsters the economy and ensures our national security by supporting the cutting edge physical science research that underprins the development of advanced technologies. The bill also includes key policy provisions to help end sexual harassment in STEM, diversify and fortify the US scientific workforce, and thoughtfully steward our nation's supply of helium, a critical, nonrenewable natural resource. APS is grateful for the bipartisan support of these issues and their inclusion in the bill, which represents the culmination of years of sustained advocacy efforts by APS members. CHIPS+ is, without a doubt, the most significant piece of science legislation in more than a decade.



Frances Hellman APS President

https://aps.org/policy/analysis/chips-act.cfm

accelerate the industries of the future. These policies have spurred an historic recovery in manufacturing, adding 642,000 manufacturing jobs since 2021. Companies are investing in America again, bringing good-paying manufacturing jobs back home. The construction of new manufacturing facilities has increased 116 percent over last year.

Today, President Biden will sign into law the bipartisan CHIPS and Science Act of 2022, which will build on this progress, making historic investments that will poise U.S. workers, communities, and businesses to win the race for the 21st century. It will strengthen American manufacturing, supply chains,

https://www.whitehouse.gov/briefing-room/statementsreleases/2022/08/09/fact-sheet-chips-and-science-act-will-lower-costscreate-jobs-strengthen-supply-chains-and-counter-china/

EXAMPLES OF POTENTIAL COI AND FOREIGN ENGAGEMENT



- Affiliation with foreign University
- Students visiting from their home foreign institution, and investigator has a formal affiliation with the home foreign institution and/or is performing research at foreign institution
- Co-authorship with foreign collaborator on federal sponsor publication that also lists investigators affiliation
- Patent filings with foreign entity
- Travel paid for by or reimbursed by a foreign entity
- Member of a talents program or equivalent

RESEARCH CONFLICT OF INTEREST (COI)



WHAT TYPES OF ACTIVITIES REQUIRE RESEARCH COI DISCLOSURE?

COI Sponsored 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	Gifts Material Transfer Agreements (MTA) Service Unfunded Human Subject Research			

* There are sponsors exempt from the disclosure requirement

WHAT CONSTITUTES A POTENTIAL RESEARCH COI?

Type of Interests*	Examples
Income/Payments	Salaries, Consulting, Honoraria
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 Reimbursement/Payments	From outside entity
Intellectual Property	Non-UC royalties

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

EXAMPLES OF OUTSIDE INTERESTS AND POTENTIAL COI DOMESTIC AND FOREIGN



- Being a founder of a company
- Being on the board of a company or non-profit
- Consulting as a Scientific Advisory Board Member
- Affiliation with a university
- Travel paid for by or reimbursed by a university, company or association

700-U DISCLOSURE



CALIFORNIA'S FAIR POLITICAL PRACTICES COMMISSION (FPPC) NON-FEDERAL 700-U

CALIFORNIA 700-U FORM FAIR POLITICAL PRACTICES COMMISSION Please type or print in ink.	STATEMENT OF ECONOMIC INTERESTS FOR PRINCIPAL INVESTIGATORS A Public Document			Date Received Campus Use Only Campus: ID No:
NAME (LAST)	(FIRST)		(MIDDLE)	TELEPHONE NUMBER
ACADEMIC UNIT OR DEPARTMENT		MAIL CODE		() E-MAIL ADDRESS
1. Information Regarding (Use a separate Form 700-U for Name of Entity:		D. Have y the bal		from the entity in Part 1 for which 00 during the reporting period?
Address of Entity:		\$50 \$10	0 - \$1,000 ,001 - \$100,000	<pre>\$1,001 - \$10,000 Exceeded \$100,000</pre>

WHEN AND WHO MUST DISCLOSE FOR 700-U?

Funding Entity Sponsor	Common Sponsors	When to Disclose	Who Must Disclose
Non-Federal*	Non-Profit For-Profit	Initial submission, Additional funding,	Principal Investigator (PI)
		Change in financial interest	Studies involving <u>human subjects</u> , PI and any study personnel with a financial interest in an entity that would reasonably appear to be affected by the research
Unfunded Projects Clinical Research	Internal unrestricted	Initial submission to IRB	PI with a financial interest in an entity that would reasonably appear to be affected by the research

*There are sponsors exempt from the disclosure requirement: all non-profit tax-exempt educational institutions, and those on the list (on COI Website).

THRESHOLDS FOR 700-U DISCLOSURE?

Funding Entity Sponsor	Income Compensation			Travel paid for by / Reimbursement	Loans	Gifts	Intellectual Property
Non-Federal 700-U	>\$500	Any	>\$2,000	≥\$0	≥ \$500	≥\$50	Any >\$500 (Excludes UC)

Important: Update of Financial Interests for Sponsored Activities within 30 days

700-U DETERMINATION

Who is the Sponsor?	Which Regulation?	What to Disclose?	Who decides if the research and the interests are related?
Non-Federal (For-Profit or Non-Profit)*	700-U from the Fair Political Practices Commission (FPPC)	Disclose any interest(s) that meet the applicable threshold with the <u>specific</u> sponsor(s) supporting the project	Institution

* Includes research and other related activities (gifts, service agreements, MTAs, unfunded projects, etc.)

FEDERAL NON-PHS DISCLOSURE



WHEN AND WHO MUST DISCLOSE FOR FEDERAL NON-PHS?

Funding Entity Sponsor	Common Sponsors	When to Disclose	Who Must Disclose
Federal Non-PHS (formerly 9510)	NSF, CIRM and UC Programs	Initial submission, Change in funding, Change in financial interest	Principal Investigator (PI) and ALL other individuals who have the responsibility for the design, conduct or reporting of research

There are federal sponsors that do NOT require COI disclosure, such as, DOD, NOAA, and other federal agencies

THRESHOLDS FOR FEDERAL NON-PHS DISCLOSURE?

Funding Entity Sponsor	Income Compensation	•		Travel Paid for by / Reimbursement	Intellectual Property
Federal Non-PHS (formerly 9510)	> \$10,000	Any	> \$10,000 or > 5% owner	≥\$10,000	Any > \$10,000 (Excludes UC)

Important: Update of Financial Interests for Sponsored Activities within 30 days

FEDERAL NON-PHS DETERMINATION

Who is the Sponsor?	Which Regulation	What to Disclose?	Who decides if the research and the interests are related?
Federal Non-PHS (i.e., NSF, CIRM, UC Programs)	NSF Grants Policy	Disclose any interest(s) that meet the applicable threshold and is related to the work to be conducted under the proposed project	Discloser

Sponsors: National Science Foundation (NSF), California Institute for Regenerative Medicine (CIRM), some UC Programs

FEDERAL PUBLIC HEALTH SERVICES (PHS) DISCLOSURE



WHEN AND WHO MUST DISCLOSE FOR FEDERAL PHS?

Funding Entity Sponsor	Common Sponsors	When to Disclose	Who Must Disclose
Public Health Services (PHS) including DOE*	NIH, DOE, or those non-profits that have adopted FCOI	Initial submission, Change in funding, Addition of new personnel, Change in financial interest, No cost extension, At least annually	Principal Investigator (PI), Project Director, Senior/Key Personnel, and Others who direct or can materially influence the research, or who are responsible for the design, conduct, and reporting of such research

- PHS phase I STTR/SBIRs are exempt from a PHS disclosure requirement
- Mandatory PHS training is required by all senior key before funds can be released
- *Sponsors: Public Health Services (PHS) Agencies (e.g., NIH, FDA, CDC, etc.), Department of Energy (DOE) effective June of 2022, and other non-federal sponsors that adopt the PHS policy, (e.g., American Heart Association and the American Cancer Society)

THRESHOLDS FOR FEDERAL PHS DISCLOSURE

Funding Entity Sponsor	Income Compensation	Investment Equity	Travel paid for by / Reimbursement	Intellectual Property
Public Health Services (PHS), DOE	publicly traded > \$5,000	publicly traded > \$5,000	> \$5,000	Any (\$0) (Excludes UC)
DOL	non-publicly traded > \$5,000	non-publicly traded ≥ \$0	-	

Important: Update of Financial Interests for Sponsored Activities within 30 days

FEDERAL PHS DETERMINATION

Who is the Sponsor?	Which Regulation?	What to Disclose?	Who decides if the research and the interests are related?
Public Health Services (PHS) (i.e., NIH, DOE, and those who have adopted PHS)	PHS FCOI Regulation	Disclose all interest(s) that meet the applicable thresholds and are related to the discloser's Institutional Responsibilities*	Institution

* Reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities

COI DISCLOSURES WITH INCOMING SUBAWARDS

- For subawards more than one COI disclosure may be required:
 - PHS and 700-U (i.e., STTR/SBIR prime funding from NIH awarded to a company to UCSD)
 - Non-PHS and 700-U (i.e., STTR/SBIR prime funding from NSF awarded to a company to UCSD)
 - Two 700-Us (i.e., prime funding from a for-profit to non-profit to UCSD)



SUMMARY RESEARCH COI DISCLOSURES



- Three COI disclosure regulation based on sponsor
 - PHS
 - Non-PHS (formerly 9510)
 - Non-Federal (700-U)
- Each COI disclosure regulation has different requirements, timing, and thresholds
- Researchers need to provide updates of financial interest within 30 days

Submit in Kuali COI

ESR Enterprise Systems Renewal

Kuali COI:

IT System of Record for COI at UC San Diego




Kuali COI: How to Know when to Access



Click Kuali COI link in Email

Log in with AD and Duo

Email is from: Kuali Notifications at <u>no-reply@kuali.co</u>

- Once a record in is created, Kuali
 COI will e-mail the Researcher and their assigned Delegate(s)
- The email contains a direct link to Kuali COI
- Researcher will receive emails at proposal and award
 - Enhancement planned to minimize emails

FLOW AND TIMELINE OF DISCLOSURE IN KUALI COI



Legend: Kuali Research (KR) and Proposal Development (PD)

Kuali COI How to access without an email from Kuali COI

https://ucsd.kuali.co/coi

In order to submit COI disclosure(s) in Kuali COI:

There must be a record recently saved (after 1/21/2020) from either

- Kuali Research (for sponsored research) OR
- Manual project (for other related activities)

Kuali COI Log in at <u>https://ucsd.kuali.co/coi</u>

• Select the blue "Update Disclosure" button

Last action date	Disclosure Status Expiration Date	Ó- O Ver
Oct 7, 2022 3:28 PM	Up to Date Oct 7, 2023 3:28 PM	Ø Vier
isclosure History (1)		Shaw ~

C		00-U Form for N projects	lew
Annual Disclos	ure		+ Back
ORMS alidate/Submit Gating Question	Reporter	Buchura Bana Iti Program	
Project Declaratio	Projects For assistance on your 700-U projects please review 700-U instructions		0% Complete → Next ✓ Save

If the Discloser has 700-U projects and interests to report, then additional screens may populate

Kuali COI: Return Portfolios Submitted for Approval to COI Office

Request COI Office to Send Back Portfolio to Investigator

CONFLICT OF INTEREST Kuali				CHANG, LILIAN	
Update Annual Disclosure				← Back	interest(s) is submitted, the portfolio is locked to
Reporter	Disclosure Status	Submitted Date		🖶 Print	ensure changes cannot be made during the COI
CHANG, LILIAN ljchang@ucsd.edu 000167 - Temporary Employment Services	Submitted for Approval	Apr 24, 2020 2:22 PM		Print Management Plan	Office's review
	fy the administrator. view 700-U Instructions your new 700-U forms.		R	equest Edit	×
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To unlock, click th the <mark>red bar</mark> to sub to return Researc	mit a request to		T	ANCEL Click	Request Edit

Kuali COI: System Behaviors Order of Screens through left Navigation Bar

CONFLICT OF INTEREST

Update Annual Disclos

1. 700-U Forms

- Always appears, even if there are no 700-U projects
- Must complete ALL 700-U forms before moving to the next screen
- 2. 700-U Validate/Submit**
 - Appears after Researcher completes questions for 700-U projects
- 3. Supplemental Questions
 - Appears if Researcher marks "Yes" to Role (3a), Equity (3b) or Income (3c) of 700-U
- 4. Federal Gating Question
 - Appears for Federal PHS and Non-PHS Project(s)
- 5. Federal Financial Entities
 - Appears if Researcher marks interest(s) = "Yes" to gating question
- 6. Federal Project Declaration
 - Questions answered only when <u>award</u> is created in Kuali Research
- 7. Federal Certification**
 - Always appears, even if Researcher only has 700-U projects

**Delegate cannot complete/submit on these screens

700-U Forms

- 700-U Validate/Submit
- Supplemental Questions
- FEDERAL GATING QUESTI...
- Federal Financial Entities
- Federal Project Declaratio...
- Federal Certification





- Click arrow or "Expand All" button to expand the project record to complete answers
- 2. Once the necessary answers are completed, projects will be marked as completed and moved to "All Projects"
- 3. Search for previously submitted 700-U disclosures to provide updates to interest(s)

Kuali COI: 700-U Form Project Expanded

700-U FORMS	Reporter	Disclosure Status				
• 700-U Validate/Submit	FORD, JENNIFER jjford@ucsd.edu	In Progress				
Federal Gating Question						
Federal Project Declaratio	Projects					
Federal Certification	For assistance on your 700-U projects please review 700-U Instructions					
	Click on all projects outlined in red to complete your new 700-U forms.			0% Complete		
		(✓ Expand All	→ Next		
	Implementation of new COI systems and impact on normal rese	earch process	\bigcirc	✓ Save		
					Scroll	
	Title Implementation of new COI systems and impact on normal research process	Project Type Proposal			down to	
	Project Number 25594	Principal Investigator FORD, JENNIFER			answer 700-U	
	Project Role Principal Investigator, PI/Contact	Start Date February 28, 2020			questions	
	Sponsor Name and Code ASTRAZENECA PLC: 1676	End Date January 1, 2022				
	Prime Sponsor Name and Code	Sponsor Project ID				
	Notice of Opportunity	Project Link View project				

- Researcher expands the 700-U project record that requires answers completed
- When the user scrolls down, the 700U COI Disclosure questions will display

Kuali COI: 700-U Complete Form – FPPC (state of CA agency) COI disclosure

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Title	Title				
Title	Title			osition of management in the entity listed in Part 1?	
Title	Title	<u>is</u>			
		-			

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- FPPC requires the discloser to enter every Part of the 700-U (i.e. Parts 1, 2 and 3)
- Recommend the Delegate complete Parts 1 and 2
 - Then notify Researcher to complete Part 3
- Estimates on amount of funding and date of funding
- If Income or Equity received for active consulting, mark "Yes" to Position (3a)

Kuali COI: 700-U Verify and Sign

• 700-U Forms	Reporter	Disclosure Status		
• 700-U VALIDATE/SUBMIT	FORD, JENNIFER jjford@ucsd.edu	In Progress		
Federal Gating Question				
Federal Project Declaratio	700-U Verification			25% Complete
Federal Certification	The Reporter listed above must verify and s	ubmit the 700-U forms listed below. The verify and subm	nit button is inactive for delegates.	→ Next
	Please verify that the information	in these forms is correct:		+ Previous
	,			✓ Save
	25594 IMPLEMENTATION OF NEW CO ON NORMAL RESEARCH PROCESS: ASTRAZENECA PLC	I SYSTEMS AND IMPACT	DOWNLOAD UNSIGNED FORM	
	✓ FORM PREVIEW			
	I verify that the information on this form is	s correct.		
erify and Sign	Signature			
	This is your digital signature			
			VERIFY & SUBMIT	

Researcher must verify and sign for each 700-U form

Delegate cannot complete or sign on this screen; however, can move to the next screen

Kuali COI: 700-U Download Completed Form



If Researcher marks "Yes" to 700-U questions about Position (3a), Equity (3b) or Income (3c) then Researcher will be presented the "Supplemental Questions" screen

Supplemental Questions after completing 700-U form

Answers on 700-U form transfer to separate supplemental questions screen

	3. Filer Information				
	 A. Are you a director, officer, partner, trustee, consultant, employee, or do you hold a plisted in Part 1? Yes No 	osition of m	nanagement in the entity Supplemental Questions		
	Title		Needs Attention (1)		
	Consultant		Usability of an Online COI system (FE36-GC	DOGLE INC.)	(^
			Project Title Usability of an Online COI system Are you a director, officer, partner,	Economic Interest FE36-GOOGLE INC. Do you, your spouse or registered	Have you received income of \$500 or
li	e system retains and re- splays the answers for position,		trustee, consultant, employee, or do you hold a position of management in the entity listed in Part 1? Yes	domestic partner, or your dependent children have an investment of \$2,000 or more in the entity listed in Part 1 above? No	more from the entity listed in Part 1 during the reporting period? No
or	come or equity from the imary 700-U form onto the		Title of Office Consultant		
bu	pplemental question screen		Non Federal Disclosure Questions	S	



Kuali COI: Federal PHS/DOE Gating Question and Mandatory Training Data This is a four-part question



Once submitted for review to COI Office:

- Negative = auto approved ("no conflict")
- Positive = interest(s) will be reviewed at NOA
- Gating Question for Federal PHS/DOE only Disclosers <u>OR</u> Federal PHS/DOE and Federal Non-PHS Disclosers
- Training Data from UC Learning linked in Kuali COI

to answer the one PHS question
1. Public Traded Entity Equity or Income <u>OR</u>
2. Privately Held Entity Equity or Income <u>OR</u>
3. Intellectual Property <u>OR</u>
4. Travel by Entity Paid for by or Reimbursed

Kuali COI: Federal Non-PHS (9510) Non-PHS (9510) Gating Question (at proposal)

CONFLICT OF INTEREST	kuali	WANG, X	UEMEI (impersonated by Victor Kinzer
Update Annual Disclos	sure		← Back
-	Reporter	Disclosure Status	
	WANG, XUEMEI xmwang@ucsd.edu	In Progress	
Gating Question	Do you, your spouse, or dependent children have any financial interests related to the work to be conducted on this project Ves	?	66% Complete
Ouestion • Project Declaration	No		→ Next ← Previous
Certification And Attachm			✓ Save

This gating question appears for Non-PHS only disclosers Once submitted for review to COI Office: Negative = auto approved ("no conflict") Positive = interest(s) will be reviewed at NOA

Kuali CO: Entering Federal Financial Entities

Select +Add Line and +Add Info to update financial entities

Financial Entities

1.Please provide information on each entity with which you have a financial or other interest during the past 12 months

2.If the relationship has not previously been disclosed, click on the "+ Add Line" button

3.If the relationship has been previously disclosed, to update the information click on the "Pencil" icon next to the name of the entity.

4.If the relationship is now more than 12 months in the past and you do not anticipate continuing a relationship with this entity, or if you entered an entity that was unnecessary and wish to delete it, set the Active indicator to No

A Significant Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, registered domestic partner and/or dependent children) that reasonably appears to be related to the Investigator institutional responsibilities:

Publicly-Traded Entity: Any income received from entity in 12 months preceding disclosure and value of any equity interests in entity as of date of disclosure exceeding \$5,000 when combined for an Investigator, Investigator's spouse, and dependent children from a single Entity (Business, Public or Nonprofit) including salary, consultant payments, honoraria, royalty payments, dividend, loan, or any other payments or consideration with value, including payments made to the University of California Health Sciences Compensation Plans during the prior twelve months. Equity Interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

Privately Held For-Profit Entity or Not-For-Profit Entity or Foreign Entity (including Foreign University and Foreign Government): Any remuneration received from entity in 12 months preveding disclosure, when combined, exceeds \$5,000; or when Investigator holds any equity interest (e.g., stock, stock option, or other ownership interest). Exclude income from semitiris, lectures, or teaching engagements sponsored by a Federal, state, or local government agency; a U.S. institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institution of higher education or a lederal, state, or local government agency within the US. Therefore, Investigators, Including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

Intellectual property rights and interests, upon receipt of ANY income (no dollar threshold), during the twelve months preceding disclosure from such rights and interests. However, Significant Financial Interests do NOT include royalties received from the University of California Regents.

Travel: Sponsored travel or reimbursements made to or on behalf of, the Investigator, exceeding \$5,000 during the twelve months preceding disclosure, from a for-profit or non-profit entity, including professional organizations, foreign universities and foreign governments, related to the Investigator's institutional Responsibilities. However, Significant Financial Interests do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher ducation, or 0.0. Screarch institution, a U.S. screarch institute, a U.S. academic that a U.S. institution of higher ducation.

NEW ENTITIES: Click "+ Add Info" below to add new entities.
 ADDITIONAL ENTITIES: Click "+ Add Line" to insert additional entities.
 EXISTING ENTITIES: Select the Edit Pencil next to an existing entity to edit as needed

To change entity status to active or inactive, select the pencil icon to the left of the entity. At the top of the dialog box, select the toggle button to active or inactive, scroll down to bottom of dialogue box, and select done



If Researcher marks "yes" to the Gating Question, then Researcher enters their interest(s) This information is stored and saved in the Researcher's portfolio

Kuali COI: Federal Financial Entity Entry

Active		Add	>
If you cannot find your entity name search for MISCELLANEOUS SPONSORS and type in the entity name below. Entity Type Please describe any relationships you and/or your family member has with this entity. A description of ALL relationships with an entity is required. (Example, you are a paid consultant for this organization, your spouse volunteers with this organization one weekend a year at their annual gala. In this scenario, you have two relationships for this outside entity, one for 'self', and one for 'spouse'.) Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships due does and Member, etc.) Income or Other Payment for Services Equity Intellectual Property Rights and Interests (excluding UC Royalties) Travel Do you have any additional attachments related to your disclosure? Yes No		Active	
Please describe any relationships you and/or your family member has with this entity. A description of ALL relationships with an entity is required. (Example, you are a paid consultant for this organization, your spouse volumeers with this organization one weekend a year a brief annual gala. In this scenario, you have two relationships for this outside entity, one for 'self', and one for 'spouse'.) Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please interview Please		If you cannot find your entity name search for MISCELLANEOUS SPONSORS and type in the entity name	
relationships with an entity is required. (Example, you are a paid consultant for this organization, your spouse volunteers with this organization one weekend a year at their annual gala. In this scenario, you have two relationships for this outside entity, one for 'self', and one for 'spouse'.) Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Please indicate ALL types of relationships this individual has with this entity Income or Other Payment for Services Equity Intellectual Property Rights and Interests (excluding UC Royattles) Travel Do you have any additional attachments related to your disclosure? Yes No		Entity Type 🗢	
Vel Position/Role in Entity (Founder, Advisory Board Member, etc.) Income or Other Payment for Services Equity Intellectual Property Rights and Interests (excluding UC Royalties) Travel Do you have any additional attachments related to your disclosure? Yes No		relationships with an entity is required. (Example, you are a paid consultant for this organization, your spouse volunteers with this organization one weekend a year at their annual gala. In this scenario, you ha	
Vel Income or Other Payment for Services Equity Intellectual Property Rights and Interests (excluding UC Royalties) Travel Do you have any additional attachments related to your disclosure? Yes No			
Vel Equity Equity Cravel Do you have any additional attachments related to your disclosure? Yes No		Position/Role in Entity (Founder, Advisory Board Member, etc.)	
Vel Intellectual Property Rights and Interests (excluding UC Royalties) Travel Do you have any additional attachments related to your disclosure? Yes No		Income or Other Payment for Services	
Vel Travel Do you have any additional attachments related to your disclosure? Yes No		Equity	
Do you have any additional attachments related to your disclosure? Ves No		Intellectual Property Rights and Interests (excluding UC Royalties)	
○ Yes ○ No	vel	Travel	
O No		Do you have any additional attachments related to your disclosure?	
		O Yes	
X Cancel		○ No	
× Cancel ✓ Done			
		× Cancel	one

- Researcher enters each entity separately
- For each entity, click ALL applicable relationships:
 - Position/Role
 - Income
 - Equity
 - Intellectual Property
 - Travel
- If Income or Equity received for consulting, mark "yes" to Position/Role

Kuali COI: Federal Financial Entities with Interests

CONFLICT OF INTEREST

Update Annual Disclo	sure			
700-U Forms	Reporter	Disclosure St	atus	
700-U Validate/Submit	JOYCE, NICOLE njoyce@ucsd.edu	In Progress		
Federal Gating Question				
FEDERAL FINANCIAL ENT	Financial Entities			
Federal Project Declaratio	1.Please provide information on each entity with which you have a financial or other	interest during the past 12 months		
 Federal Certification 	2.If the relationship has not previously been disclosed, click on the "+ Add Line" butt	ton.		
	3.If the relationship has been previously disclosed, to update the information click o	in the "Pencil" icon next to the name of the entity.		
	4.If the relationship is now more than 12 months in the past and you do not anticipa	te continuing a relationship with this entity, or if you entered an entity that	was unnecessary and wish to delete it, set the Active indicator to No.	
	A Significant Financial Interest consisting of one or more of the following interests	of the Investigator (and those of the Investigator's spouse, registered dom	estic partner and/or dependent children) that reasonably appears to be related to the Inv	estigator's institutional responsibilities:
		valty payments, dividend, loan, or any other payments or consideration with	xceeding \$5,000 when combined for an Investigator Investigator's spouse, and depende value, including payments made to the University of California Health Sciences Compen ssures of fair market value;	
	(e.g., stock, stock option, or other ownership interest). Exclude income from semina	ars, lectures, or teaching engagements sponsored by a Federal, state, or loc tion of higher education; however, these references refer to a US Institution	om entity in 12 months preceding disclosure, when combined, exceeds \$5,000; or when al government agency, a U.S. institution of higher education as defined at 20 U.S. 0. 100 of higher education or a federal, state, or local government agency within the U.S. There hich includes local, provincial, or equivalent governments of another country).	1(a), a U.S. academic teaching hospital,
	Intellectual property rights and interests, upon receipt of income, exceeding \$5,000	during the twelve months preceding disclosure from such rights and inter	ests. However, Significant Financial Interests do NOT include royalties received from the	University of California Regents.
		do not include travel reimbursed or paid by a federal, state, or local govern	for-profit or non-profit entity, including professional organizations, foreign universities ment agency, a U.S. institution of higher education, or a U.S. research institute, a U.S. ac	
	To change entity status to active or inactive, select the pencil icon to the left of the e	entity. At the top of the dialog box, select the toggle button to active or inac	ive, scroll down to bottom of dialogue box, and select done.	
	Has anything changed with your entities since your last disclosure? If so click the pe	ncil icon to the left of the entity and make all appropriate changes.		
				Columns + Add Line
	ACTIVE	ATT ROME	⊤ RELATIONSHIPS	Ŧ
	Yes Yes	Pfizer	Equity	
terest(s)				

Once Financial interest(s) are entered and saved in Researcher's portfolio Upon re-entry the Researcher will re-affirm the accuracy and/or update, accordingly Click pencil per entity to review, edit and update, accordingly



For those Researchers that have disclosed interests in their Federal Portfolio:

1. Records marked "Needs Attention" and highlighted pink identifies which federal projects requires action

Click arrow or "Expand All" button to expand the project record to **answer declaration questions** per project

- 2. Once the necessary answers are completed, projects will be marked as completed and moved to "All Projects"
- 3. Searching is available for previously submitted 700-U disclosures to provide updates to interest(s) on 700-U Forms Screen

Kuali COI: Federal Project Declarations (NOA)

	Principal Investigator 2c9034e73a1082cf013a4c9	7517503ea	Start Date February 1, 2	.020		
	Sponsor Name and Code NATIONAL INSTITUTES OF F	HEALTH CLINICAL CENTER: 3402	End Date January 31, 2	2025		
	Prime Sponsor Name and Co	ode	Sponsor Pro	ect ID		
	Notice of Opportunity		Project Link View project			
	Reviewer Recommender	d Disposition	Project Disp	osition		75% Complete
						→ Next
	This project includes PHS	The Reporter	Comment is	only required		← Previous
	Relationships FINANCIAL ENTITY	when the Fin	ancial Entity i		O Columns	✓ Save
Declaration per Interest	Pfizer	 Not Related Related 	Click Here to Add Text	Columns STUDENT + Add Info	+ Add Line	
	Amgen Inc.	 Not Related Related Required 	Click Here to Add Text	Columns STUDENT + Add Info	+ Add Line	
3					*	

Kuali COI: Federal Certification and Submission

Update Annual Disclo	osure	← Back
700-U Forms	Reporter Disclosure Status	
Federal Gating Question	In Progress	
Federal Financial Entities		
Federal Project Declaratio	Federal Certification	99% Complete
FEDERAL CERTIFICATION	By clicking submit, I certify to the best of my knowledge that this is a complete and accurate disclosure and I have used all reasonable diligence in preparing this financial interest disclosure. I also acknowled	ge that it is my responsibility to
	disclose within 30 days of discovering or acquiring a new reportable interest during the term of the federal project(s).	ge that it is my responsionity to Visite
	Department of Energy (DOE) Certification: For DOE Investigators by clicking submit, I understand that this Disclosure is required to obtain funding from the U.S. Government. I certify to the best of my knowledge and belief that the information containe true, complete, and accurate. I understand that any false, fictilitous, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrati statements, false claims, or otherwise. (18 U.S.C. §§ 1001 and 287, and 31 U.S.C. 3729-3730 and 3801-3812). I further understand and agree that (1) the statements and representations made herein are material decision, and (2) I have a responsibility to update the disclosures during the period of performance of the award should circumstances change which impact the responses provided above.	ve penalties for fraud, false
	The Reporter listed above must certify and submit this disclosure. The submit button is inactive for delegates.	

- Discloser must click "submit" (under pie chart) as e-signature certification for the ALL projects (federal and non-federal) in their Kuali COI portfolio
- Once Researcher has finished answering all questions, the final page of the disclosure is the federal certification screen
- Delegate(s) cannot certify to submit a Researcher's portfolio in Kuali COI

Kuali COI: Assign Delegates

Researcher Must Add Each Support Staff



Researcher must add Delegates (support staff) <u>before</u> staff can have access

Kuali COI: Assign Delegates

Researcher ability to add support staff

Mana	ge Delegates					
	MY DELEGATES	USERS DELEGATED TO ME				
User			Click	+ Add Delegate		
				Enter		
					- 1	

For a Researcher to review their Delegates on the "My Delegates" Screen

Kuali COI: Remove Delegates

Researcher ability to remove support staff

Manage Delegates					
MY DELEGATES	USERS DELEGATED TO ME	+ Add Delegate			
User CHANG, LILIAN		Click			

For a Researcher to <u>remove</u> their Delegates on the "My Delegates" Screen

Kuali COI: Delegate Access

Delegate's ability to view and edit Researcher's Portfolio

Disclosures		
MY DISCLOSURES	DISCLOSURES DELEGATED TO ME	Click
Crec lisclos :		
LAST ACTION DATE		
You have yet to submit a disclosure		

- At log in, Kuali COI defaults to "Disclosures" Screen and the "My Disclosures" Tab
 - Click "Disclosures Delegated To Me" Tab
- Do NOT click "Create Disclosure" button on "My Disclosures" tab, it is YOUR COI portfolio

Kuali COI: Disclosures Delegated to Me

Delegate's have the ability chose the Researcher to obtain access to Researcher's portfolio



- Delegate clicks to choose which Researcher's portfolio to review and edit
- Then click "create disclosure" or "update disclosure" button for access to the specific Researcher's Portfolio

If the Portfolio is not editable, the delegate can request the Portfolio to be unlocked

Kuali COI: System Behavior for Delegates

Researcher Role:

- Researchers must verify, review, certify, and submit/sign their COI disclosure(s) in Kuali COI
- Researchers can add as many Delegates as needed

<u>Delegate Role</u>:

- Delegates can:
 - Enter on the "700-U Verify/Submit" screen (can click "next")
 - Can be assigned to as many Researchers, as necessary
 - Communicate to the Researcher inside of Kuali COI when the Delegate has finished their portion of their review and data entry.
 - Then an email is sent to Researcher with the Delegates name in the subject line.
- Delegates cannot:
 - Certify and Submit ("700-U Verify/Submit" or "Federal Certification")
- COI Office does not have real-time access to view which Researcher has Delegates assigned



Definition of COI Statuses in Kuali Research

- There are three listed COI statuses listed for each researcher listed in Kuali Research record:
 - COI Annual Disclosure Status: refers to the overall Kuali COI status of the researcher's <u>federal</u> disclosure portfolio.
 - COI Project Status: refers to the Kuali
 COI status of the particular project being viewed
 - COI Project Disposition Status: refers to the status assigned by the COI office during the review process
 - Viewable only by the proposal creator and the PI of record

HOW TO REVIEW COI STATUS IN KUALI RESEARCH (KR) IN AWARD FEDERAL AWARDS

For Kuali Research (KR) Award Records

- Viewable for only Federal PHS and Federal non-PHS
- Go to "Contacts" tab in KR
- Must review COI statuses for every Researcher Individually

COI Annual Disclosure Status:	In Progress
COI Project Status:	Update Needed
COI Project Disposition:	None

 \leftarrow Update is Required by Researcher

Tutorial to read all Kuali COI Statuses in Kuali Research: https://blink.ucsd.edu/_files/coi/Kuali-COI/How%20to%20check%20COI%20status%20in%20KCOI.pdf

COI STATUSES IN KUALI RESEARCH

Project Disposition Status and Project Status

Project Disposition Status	Project Status "Up to Date"	Project Status "Update Not Required"	Project Status "Update Needed"
None	COI Disclosure Incomplete*	COI Disclosure Complete	COI Disclosure Incomplete
No Conflict	COI Disclosure Complete		
Approved/Managed	COI Disclosure Complete		

- If "Annual Disclosure Status" is "Submitted for Approval", then the Researcher's disclosure has been updated and submitted to include this particular project; however, the submission has not been reviewed by the COI office
 - A project disposition MUST be set by the COI Office in order for the COI disclosure to be complete
- *For federal projects only, the COI Disclosure is incomplete if the "Annual Disclosure Status" is "Expired"

Grey shading indicates that these combinations of status are not likely

Kuali COI Office Hours

We provide Kuali COI Office Hours on Wednesdays at 11:00 am via Zoom

Investigator's sign-up for office hours at: www.calendly.com/ucsdcoioffice



Conflict of Commitment	or	Conflict of Interest	
UNIVERSITY OF CALIFORNIA	System	kuali coi	
Academic Personnel Office	Responsible Office	Conflict of Interest Office Part of the Research Compliance and Integrity (RCI) office	
UCOP <u>APM 671 / APM 025</u>	Governing Policies	UCSD (<u>PPM 200-13</u>), UCOP (<u>APM 028</u>), Funding agencies (PHS/NIH, NSF)	
Identify and manage outside professional activities to avoid conflicts of commitment	Purpose	Protect the objectivity of research and comply with policies and regulations	
Prior approval to engage in category 1 activities and annual reporting of time and earnings for category 1 and 2 activities	Disclosure Requirements	Dependent on outside funding entity or type of activity	
Category I: Prior to Engagement Category II: Annually	Timing	Proposal and/or award stages and then dependent on funding	
Academic Personnel	Questions	info-coi@ucsd.edu	

QUESTION PROVIDED BEFORE TODAY'S PRESENTATION

Background:

- UCSD faculty member served as a grant reviewer for a scientific Institute in the U.S. (a nonprofit entity) on April 5 and 6, 2023
- This outside activity involved five hours of zoom on each day (10 hours total)
- UCSD faculty was paid \$6,000 for their outside activity with non-profit entity

Question: How does this UCSD Faculty member report this outside activity in Kuali COI and UCOATS?

- For COI and Kuali COI, does the faculty member have PHS/DOE funded research at UCSD? Yes, then given the \$ threshold (income amount) the faculty member must disclose within 30 days in Kuali COI. However, if the faculty member has only federal non-PHS funded research, then no disclosure required (below \$ threshold).
- For COC and UCOATS, in general, grant reviewing is considered category III and not required to be disclosed in UCOATS. For questions, consult their academic personnel analyst for assistance.

CONTACT CONFLICT OF INTEREST (COI) OFFICE



Email Questions: info-coi@ucsd.edu Telephone: (858) 534-6465

Kuali COI (access): <u>https://ucsd.kuali.co/coi</u> Kuali COI Tutorials: <u>https://blink.ucsd.edu/sponsor/coi/ku</u> <u>alicoi.html#Tutorials</u>

COI Website: http://coi.ucsd.edu

QUESTIONS AND ANSWERS



RCI COMMUNICATIONS

- Research Compliance and Integrity Helpline: (858) 822-4939, rci@ucsd.edu
 - RCI Office Hours, Tuesdays from 11-12: https://calendly.com/ucsdrcioffice
- 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
- Unannounced Governmental and Law Enforcement Hotline: (858) 246-4600
- Hot Topics Eblasts and Newsletters: http://blink.ucsd.edu/sponsor/rci/news.html



RCI Hot Topics Training Program: https://blink.ucsd.edu/sponsor/rci/research-compliancehot-topics.html

To be added to the RCI list serv, please email rci@ucsd.edu