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 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
In December of 2019, Propublica requested all Financial Conflicts of Interests (FCOIs) submissions by Awardees to National Institute of Health
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 Kreigbaum // August 24, 2018

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.”
In January of 2022, the Office of Science and Technology Policy (OSTP) released implementation guidance for NSPM-33 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

https://www.cogr.edu/sites/default/files/final%20NSPM%2033%20guidance%20research%20security%20programs%20etc%20jan%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 Act). This historic legislation is a critical step toward strengthening the United States' competitiveness in science, technology, and innovation. In addition to an unprecedented investment in U.S.-based semiconductor manufacturing, CHIPS Act 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 underpins the development of advanced technologies. The bill also includes key policy provisions to help end sexual harassment in STEM, diversify and fortify the U.S. scientific workforce, and thoughtfully steward our nation's supply of helium, a critical, non-renewable 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 Act 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

FACT SHEET: CHIPS and Science Act Will Lower Costs, Create Jobs, Strengthen Supply Chains, and Counter China

AUGUST 09, 2022

In President Biden’s first year in office, the Biden-Harris Administration has implemented an industrial strategy to revitalize domestic manufacturing, create good-paying American jobs, strengthen American supply chains, and 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, and innovation.

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?**

<table>
<thead>
<tr>
<th>Category</th>
<th>Agency</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsored Research</td>
<td>Federal</td>
<td>National Health Institute (NIH)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National Science Foundation (NSF)</td>
</tr>
<tr>
<td></td>
<td>Non-Federal</td>
<td>For-Profit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-Profit*</td>
</tr>
<tr>
<td>Other Related Activity</td>
<td>Non-Federal</td>
<td>Gifts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Material Transfer Agreements (MTA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Service</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unfunded</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Human Subject Research</td>
</tr>
</tbody>
</table>

* There are sponsors exempt from the disclosure requirement
**WHAT CONSTITUTES A POTENTIAL RESEARCH COI?**

<table>
<thead>
<tr>
<th>Type of Interests*</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income/Payments</td>
<td>Salaries, Consulting, Honoraria</td>
</tr>
<tr>
<td>Position</td>
<td>Founder, Partner, Board of Directors, Scientific Advisory Board, Employee</td>
</tr>
<tr>
<td>Equity / Ownership Interest</td>
<td>Stocks, Bonds, Stock Options</td>
</tr>
<tr>
<td>Gifts</td>
<td>From outside entity</td>
</tr>
<tr>
<td>Loans</td>
<td>Money loaned to outside entity</td>
</tr>
<tr>
<td>Travel Reimbursement/Payments</td>
<td>From outside entity</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Non-UC royalties</td>
</tr>
</tbody>
</table>

*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
## WHEN AND WHO MUST DISCLOSE FOR 700-U?

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

*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?

<table>
<thead>
<tr>
<th>Funding Entity Sponsor</th>
<th>Income Compensation</th>
<th>Ownership Position</th>
<th>Investment Equity</th>
<th>Travel paid for by / Reimbursement</th>
<th>Loans</th>
<th>Gifts</th>
<th>Intellectual Property</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Federal 700-U</td>
<td>&gt;$500</td>
<td>Any</td>
<td>&gt;$2,000</td>
<td>≥ $0</td>
<td>≥ $500</td>
<td>≥ $50</td>
<td>Any &gt;$500 (Excludes UC)</td>
</tr>
</tbody>
</table>

**Important:** Update of Financial Interests for Sponsored Activities within 30 days
## 700-U Determination

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

* Includes research and other related activities (gifts, service agreements, MTAs, unfunded projects, etc.)
### WHEN AND WHO MUST DISCLOSE FOR FEDERAL NON-PHS?

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

There are federal sponsors that do NOT require COI disclosure, such as, DOD, NOAA, and other federal agencies.
## Thresholds for Federal Non-PHS Disclosure?

<table>
<thead>
<tr>
<th>Funding Entity Sponsor</th>
<th>Income Compensation</th>
<th>Ownership Position</th>
<th>Investment Equity</th>
<th>Travel Paid for by / Intellectual Property Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal Non-PHS (formerly 9510)</td>
<td>&gt; $10,000</td>
<td>Any</td>
<td>&gt; $10,000</td>
<td>Any &gt; $10,000 (Excludes UC)</td>
</tr>
</tbody>
</table>

Important: Update of Financial Interests for Sponsored Activities within 30 days
## FEDERAL NON-PHS DETERMINATION

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

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?

<table>
<thead>
<tr>
<th>Funding Entity Sponsor</th>
<th>Common Sponsors</th>
<th>When to Disclose</th>
<th>Who Must Disclose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Services (PHS) including DOE*</td>
<td>NIH, DOE, or those non-profits that have adopted FCOI</td>
<td>Initial submission, Change in funding, Addition of new personnel, Change in financial interest, No cost extension, At least annually</td>
<td>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</td>
</tr>
</tbody>
</table>

- 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

<table>
<thead>
<tr>
<th>Funding Entity Sponsor</th>
<th>Income Compensation</th>
<th>Investment Equity</th>
<th>Travel paid for by / Reimbursement</th>
<th>Intellectual Property</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Services (PHS), DOE</td>
<td>publicly traded &gt; $5,000</td>
<td>publicly traded &gt; $5,000</td>
<td>&gt; $5,000</td>
<td>Any ($0) (Excludes UC)</td>
</tr>
<tr>
<td>non-publicly traded</td>
<td>non-publicly traded &gt; $5,000</td>
<td>non-publicly traded &gt; $0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Important:** Update of Financial Interests for Sponsored Activities within 30 days
# FEDERAL PHS DETERMINATION

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

* 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-U (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
Conflict of Interest (COI)

Annual Portfolio Disclosure

Public Health Services
Non-Public Health Services

Support Staff Delegates

Researcher

Disclosure Per Project

700-U

Federal Research
Non-Federal Research
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 no-reply@kuali.co

- 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

700-U Projects: Non-Federal Sponsors

Notification will be sent to **ONLY** PI once PD record is created with a sponsor and the PI is added in the Key Personnel tab. 700-U is reviewed at time of proposal submission in Kuali COI

**Proposal (PD in KR)**

**Award (Award in KR)**

PHS/Non-PHS Projects: Federal Sponsors

Notification will be sent to Key Personnel **ONLY** if Investigator has never disclosed in Kuali COI

The Award must be created in KR before COI can be completed in Kuali COI. Notification will be sent to **ALL** Key Personnel only if the Investigator(s) have Interest(s). COI is reviewed at time of Award

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 https://ucsd.kuali.co/coi

- Select the blue “Update Disclosure” button

Complete 700-U Form for New projects

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

Once a Portfolio with interest(s) is submitted, the portfolio is locked to ensure changes cannot be made during the COI Office’s review.

To unlock, click the hyperlink “request to edit” in the red bar to submit a request to the COI Office to return Researcher’s portfolio.
Kuali COI: System Behaviors
Order of Screens through left Navigation Bar

CONFLICT OF INTEREST

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 award 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
Kuali COI: Non-Federal (700-U)

- Complete 700-U at time of proposal or submission to central office
- Minimum Requirements:
  - Need a draft project title and draft SOW in KR or to central office

** Non-Kuali Projects are:
- Gifts, HS Business Contracting, Unfunded Human Subject, etc.
- Continue to submit paperwork to the applicable central office
Projects Need Attention and Searching

1. Researcher lands on the “700-U Forms” screen, the Researcher can only answer 700-U questions “Needs Attention” and highlighted in pink identifies to the Researcher which projects requires action on this screen. 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

- 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**

- 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

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.
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

The system retains and re-displays the answers for position, income or equity from the primary 700-U form onto the supplemental question screen.
Kuali COI: Federal PHS and Non-PHS

Portfolio means:
- Projects are added to a Researcher’s Portfolio
- Answers to questions are saved
- Financial Interest(s) are saved
- Each certification creates a new version
Kuali COI: Federal PHS/DOE Gating Question and Mandatory Training Data

This is a **four-part** question to answer the one PHS question:

1. Public Traded Entity Equity or Income **OR**
2. Privately Held Entity Equity or Income **OR**
3. Intellectual Property **OR**
4. Travel by Entity

Paid for by or Reimbursed

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 **OR** Federal PHS/DOE and Federal Non-PHS Disclosers
- Training Data from UC Learning linked in Kuali COI
Kuali COI: Federal Non-PHS (9510)

Non-PHS (9510) Gating Question (at proposal)

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

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

- 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

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)

The Reporter Comment is only required when the Financial Entity is 'related'.

<table>
<thead>
<tr>
<th>FINANCIAL ENTITY</th>
<th>DECLARATION</th>
<th>REPORTER COMMENTS</th>
<th>SUPPLEMENTAL QUESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>Related</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not Related</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amgen Inc.</td>
<td>Related</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not Related</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Declaration per Interest**

- Principal Investigator: [ID Number]
- Sponsor Name and Code: NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER: 3402
- Prime Sponsor Name and Code: [ID]
- Notice of Opportunity: [URL]
- Start Date: February 1, 2020
- End Date: January 31, 2025
- Project Link: [URL]
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) **before** staff can have access.
Kuali COI: Assign Delegates

Researcher ability to add support staff

For a Researcher to review their Delegates on the “My Delegates” Screen
Kuali COI: Remove Delegates
Researcher ability to remove support staff

For a Researcher to remove their Delegates on the “My Delegates” Screen

Click
Kuali COI: Delegate Access
Delegate’s ability to view and edit Researcher’s Portfolio

- 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 to choose which Researcher’s portfolio to review and edit.

- 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.

**Delegate Role:**
- 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 federal 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

<table>
<thead>
<tr>
<th>COI Annual Disclosure Status:</th>
<th>In Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>COI Project Status:</td>
<td>Update Needed</td>
</tr>
<tr>
<td>COI Project Disposition:</td>
<td>None</td>
</tr>
</tbody>
</table>

← 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

<table>
<thead>
<tr>
<th>Project Disposition Status</th>
<th>Project Status “Up to Date”</th>
<th>Project Status “Update Not Required”</th>
<th>Project Status “Update Needed”</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>COI Disclosure Incomplete*</td>
<td>COI Disclosure Complete</td>
<td>COI Disclosure Incomplete</td>
</tr>
<tr>
<td>No Conflict</td>
<td>COI Disclosure Complete</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approved/Managed</td>
<td>COI Disclosure Complete</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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
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

<table>
<thead>
<tr>
<th>Responsible Office</th>
<th>System</th>
<th>Conflict of Interest Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic Personnel Office</td>
<td><strong>UCOP APM 671 / APM 025</strong></td>
<td>Conflict of Interest Office&lt;br&gt;Part of the Research Compliance and Integrity (RCI) office</td>
</tr>
</tbody>
</table>

### Purpose
- Identify and manage outside professional activities to avoid conflicts of commitment
- Prior approval to engage in category 1 activities and annual reporting of time and earnings for category 1 and 2 activities
- Category I: Prior to Engagement<br>Category II: Annually
- Proposal and/or award stages and then dependent on funding

### Disclosure Requirements
- Dependent on outside funding entity or type of activity

### Questions
- info-coi@ucsd.edu
Background:
- UCSD faculty member served as a grant reviewer for a scientific Institute in the U.S. (a non-profit 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.
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-compliance-hot-topics.html
- To be added to the RCI list serv, please email rci@ucsd.edu