Streamlining COI

New Annual Conflict of Interest Procedure

(Public Health Service Investigators)

Nadia Wong
COI Administrator
Agenda

- Main Changes
- KC COI
- New Annual Form 810
- Getting Ready
- Resources & Contacts

Note: These procedures also apply to agencies and organizations that have adopted the PHS Regulations.
Main Changes for PHS Investigators

<table>
<thead>
<tr>
<th>Type of Disclosure</th>
<th>Current Process</th>
<th>New Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative</strong> (no financial interests)</td>
<td>Project A: 800, Project B: 800, Project C: 800, Project D: 800</td>
<td>All Projects: Annual Disclosure (KC COI)</td>
</tr>
<tr>
<td></td>
<td><strong>Total Forms: 4</strong></td>
<td><strong>Total Forms: 1</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Total Forms: 10</strong></td>
<td><strong>Total Forms: 4</strong></td>
</tr>
</tbody>
</table>
Benefits

• Less forms
• Less questions
• Less travel disclosures
• Disclosure tracking
• Automated email reminders
KC COI Disclosures

Investigator: An individual responsible for the design, conduct, or reporting of the funded research project

- Annual Disclosure
- Add a New SFI
- PHS Travel Log
- Master Disclosure
Change: Annual Disclosure (replaces Form 800)

New section in Zot!Portal under the Research tab for KC COI

Click “Create/Update Annual Disclosure”
Question 1- Disclosure transaction type

Investigators primarily select “No”

- “Yes” indicates: A “new SFI” that requires additional COIOC review
  - New SFI includes:
    - A different type of SFI (e.g. royalty payment vs. income) from previously disclosed entity
    - A SFI from a new entity
Question 2- Disclosure of significant financial interests excluding travel

- Income (honoraria, consulting income, etc.)
- Equity interests (stock, stock options, and other ownership interests)
- Royalty Payments (from intellectual property not assigned to UC Regents)
Question 3- Disclosure of sponsored or reimbursed travel

3. Have you received any travel reimbursement or been sponsored for travel (i.e. travel expenses paid on behalf of Investigator and not reimbursed to Investigator), in the past 12 months, by any entity related to your institutional responsibilities? This does not include travel sponsored or reimbursed by a federal, state, or local government agency, a US institution of higher education or an affiliated research institute, an academic teaching hospital, or a medical center.

- Yes
- No

• Remember to consider the listed travel exclusions
• Disclose the details of travel in the KC COI Travel Log
Click “submit.”

You completed your Annual Disclosure!

Note: Only the Investigator can complete their own Annual Disclosure.
Change: Update SFIs electronically

To update or report a new SFI excluding travel, select “Yes” to the first question of the Annual Disclosure.

The Annual Disclosure Questions 2 and 3 should reflect all of your current financial interests in addition to the new SFI.
Change: Disclose sponsored or reimbursed travel electronically

Click “Create New Travel Disclosure”
Complete the required fields marked with an asterisk (*), click “add” and then click “submit.”

<table>
<thead>
<tr>
<th>Event Type:</th>
<th>Travel Disclosure</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Destination/Location of Travel:</td>
<td></td>
</tr>
<tr>
<td>* Travel Sponsor:</td>
<td></td>
</tr>
<tr>
<td>Estimated Value of Travel:</td>
<td></td>
</tr>
<tr>
<td>* Purpose of Travel:</td>
<td></td>
</tr>
<tr>
<td>* Start Date:</td>
<td></td>
</tr>
<tr>
<td>* End Dates:</td>
<td></td>
</tr>
</tbody>
</table>

[Image of the interface with highlighted fields and buttons for adding and submitting.]
Jun 2016
- First Annual Disclosure completed (disclosed Merck equity interests)

Jul 2016
- New sponsored travel: PHS Investigators create entry in PHS Travel Log and do not need to update Annual Disclosure

Jan 2017
- Receive $10,000 (a new SFI type) from Merck- Update Annual Disclosure by selecting “Yes” for Question 1 in the Annual Disclosure

Nov 2017
- Notified Annual Disclosure about to expire (11 months after last Annual Disclosure)- Submit a new Annual Disclosure and select “No” for Question 1 since this is a standard Annual Disclosure
Change: Master Disclosure

Master Disclosure: View all of your completed past disclosures
New Proposals
Change: List all UCI Investigators on the project.

- List all individuals that previously would have completed a Form 800 for this project
- Listed Investigators will be notified if they have not completed the necessary disclosures.
To add an individual- click the magnifying glass icon

Search the name/UCInetID and click “return value”
- Select the Proposal Role
- Click “add person”
- Repeat until all Investigators have been added

Change: Updated two COI Questions

If yes:

- **Subrecipient** - Upload the PHS Form 800SRs in subrecipient package

- **Non-UCI Investigators** - Upload PHS Form 800SRs as separate labeled file
**Change: Ability to track disclosure statuses**

All disclosures must be completed before proposal is submitted to sponsor.

### Proposal Summary tab

<table>
<thead>
<tr>
<th>Person</th>
<th>Role</th>
<th>Proposal Person Certification</th>
<th>Annual Disclosure</th>
<th>NSF Disclosure</th>
</tr>
</thead>
<tbody>
<tr>
<td>MARY ANTEATER</td>
<td>Principal Investigator</td>
<td><img src="Incomplete" alt="view" /></td>
<td>Incomplete</td>
<td>Incomplete</td>
</tr>
<tr>
<td>PAUL ANTEATER</td>
<td>Investigator</td>
<td></td>
<td>Incomplete</td>
<td>Incomplete</td>
</tr>
</tbody>
</table>

### Personnel tab

- **MARY ANTEATER**
  - ![show](Person Details)
  - ![show](Proposal Person Certification (Incomplete))
  - ![show](Annual Disclosure (Incomplete), NSF Disclosure (Incomplete))

- **PAUL ANTEATER**
  - ![show](Person Details)
  - ![show](Certify)
  - ![show](Annual Disclosure (Incomplete), NSF Disclosure (Incomplete))
Change: Request Annual Disclosure email (optional)

Personnel tab: Click “request annual disclosure” to send an email to Investigators with incomplete Annual Disclosures

Note: Template email will include all Investigators so please delete those Investigators who have already completed their disclosures
Transition Period

Proposals created before June 23rd (KC COI Implementation) will have a choice:

Complete the old (current) process
- Must NOT update the KC Questionnaire when prompted after June 23rd (ignore prompt)
- Must upload disclosure forms labeled as “PHS Financial Disclosure Form 800” and answer old COI questions before June 23rd

Use the new KC COI process
- Updated the KC Questionnaire
- Disclosure forms not labeled and uploaded and/or old COI questions not completed before June 23rd
- Process:
  - Update the KC Questionnaire when prompted to answer the updated COI questions
  - Add all Investigators in the Personnel tab and have Investigators complete the Annual Disclosures

NOPE
Update

Update
Continuing Awards
Change: Personnel Doc

- The Personnel Doc is the list of UCI Investigators who need to disclose for the active award (similar to the list on the Personnel tab for new proposals).
- The Personnel Doc is completed by the PI or the PI with the support of his/her PI Assistant.
- If the last Personnel list was created in KC, then KC will create a copy for you to edit.
After the annual progress report has been submitted, you will receive an email with a link when a Personnel Doc needs to be updated for a continuing award. Click on the link to start the process.

Alternatively, go to Zot!Portal and select “Update Personnel for Continuing Awards.”
Click on the “Document Id” for the Personnel Doc you want to update.
Similar to Personnel tab for new proposals
Add: Search by name or UCInetID, click “return value”, select their Project Role, and then click “add”
Delete: Click “delete” in the individual’s row
Similar to Question tab for new proposals

If you check either or both boxes, you must collect and submit the PHS Form 800SRs through email labeled with the UCI Proposal Number to coioc@research.uci.edu for the subrecipients following UCI’s COI policies and/or the non-UCI Investigators.
Click “approve” after the Personnel Doc has been updated.

By clicking approve below, I certify as the Principal Investigator of this project that this is an accurate and complete list of all UCI Investigators on this project. I also acknowledge by clicking approve below, that as the Principal Investigator, it is my responsibility to identify the Investigators on this project and collect the required financial disclosures (when applicable) to comply with the PHS regulations regarding financial conflict of interest.
Change: Created a new role, PI Assistant

PI Assistant (optional) is an individual granted access by the PI to update the Personnel Doc for continuing PHS awards. The PI Assistant reviews and updates the Personnel Doc for the PI to review and approve.

- To have access to the Personnel Doc, PI Assistants must be approved prior to SPA initiating the continuing award process
- PI Assistant does not have access to an Investigator’s PHS Travel Log or Annual Disclosure
Click “KSAMS” to request access as the PI Assistant
Click “Access Request”

Grantee UCInetID: UCInetID of person requesting the PI Assistant role

Make sure to click “search” after typing the name/UCInetID
Role Name Lookup:

- Type “Kuali Coeus” and click “search”
- Select the “+” next to the “Kuali Coeus – PI Assistant”
UCInetID: UCInetID of the Principal Investigator you are assisting

Reason/Justification: Provide a brief description
Chart Code: Two letters at the beginning of the Lead Unit code
Organization Code: Four numbers in the second part of the Lead Unit code

- If the original submitted in KC, then open that proposal and find the information under the Lead Unit (XX-####)
- If not submitted in KC, contact eRA support team, era@research.uci.edu
Click “Submit Request”

If you assist multiple Principal Investigators (PIs) and/or your PI submits proposals through multiple departments, you should submit multiple KSAMS requests, one for each PI for each department.
After PI Assistant has requested the role, you will receive an email requesting your approval of the PI Assistant. Click the link and submit approve.

After approved, all Personnel Doc update requests will be sent to you and your PI Assistant. Once the PI Assistant has submitted the updates, you will receive an email for your final approval of the Personnel Doc.
Alternatively, you can visit the Kuali Coeus Conflict of Interest section and click the “KSAMS” link. Then select the “Approval Queue” tab and open the access request by clicking the “Id.” Review the request and click “Approve.”
## Summary

<table>
<thead>
<tr>
<th>Proposals</th>
<th>Continuing Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>List all Investigators on the Personnel tab</td>
<td>Update/edit list of all Investigators in Personnel Doc</td>
</tr>
<tr>
<td>Completed by PI and/or Initiator</td>
<td>Completed by PI and/or PI Assistant</td>
</tr>
<tr>
<td></td>
<td>• PI Assistant requires KSAMS approval</td>
</tr>
<tr>
<td>Answer two COI questions related to subrecipients and non-UCI Investigators- upload necessary forms in KC</td>
<td>Check the boxes if there are subrecipients complying with UCI’s policies and/or non-UCI Investigators- email necessary forms to <a href="mailto:coioc@research.uci.edu">coioc@research.uci.edu</a> labeled with the UCI Proposal Number</td>
</tr>
</tbody>
</table>
New Annual Form 810
Change: Annual Form 810
(Add additional pages if necessary)

New option

Responses will be reviewed to determine if the financial interest is related to the PHS project.
Annual Form 810

Financial Disclosure Appendix for PHS-Funded Research (Annual Form 810)

Please type your responses

III. Reimbursed or Sponsored Travel
Please report all reimbursed or sponsored travel in the Kuaf Coors Conflict of Interest Travel Log (excluding travel that is reimbursed or sponsored by Federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with institution of higher education).

IV. Acknowledgment and Certification
I certify this is a complete disclosure of all my financial interests related to my institutional responsibilities and I have used all reasonable diligence in preparing this Financial Interest Disclosure, and to the best of my knowledge it is true and complete. I also acknowledge by signing my name below it is my responsibility to disclose, within 30 days, any new significant financial interests obtained during the term of my active PHS compliant projects.

Signature __________________________ Date ____________

The information provided herein may be released or transmitted to the sponsor, including Federal agency representatives, and according to the California Public Records Act, may also be released to the public upon request. These records may also be released to a new principal institutionalization if sponsored project or until resolution of any action by the sponsor. This Office of the Office of Research.

V. Definitions

- Income includes salary, consulting fees, honoraria, paid authorship, income received related to intellectual property rights and interests, etc., not paid by or assigned to the UC Regents.

- Institutional Responsibilities is defined as teaching/education, research, outreach, clinical service, training and University and public service, on behalf of UC and directly related to those credentials, expertise and achievements upon which the Investigator’s UC position is based.

- A new Significant Financial Interest (SFI) is a different type or nature of SFI (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a “new” SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) from a different source (e.g., company A versus company B).

Disclose all travel in PHS Travel Log
Update Annual Disclosure if acquire or discover a new significant financial interest.
Are you ready?
Startup Steps: Today

Principal Investigator
- (Optional) Your administrative staff can request the PI Assistant role to gain access to help you with your Personnel Doc
  - Approve the request(s) for PI Assistant access
  - Plan for transition period

PI’s Administrative Staff
- Request the PI Assistant role through KSAMS as soon as possible
- Plan for transition period
Startup Steps: Today

Transition Period: in progress proposal applications that will be completed after June 23rd

- **Old/Current Procedures**
  - Upload and label Form 800 disclosures and complete the current COI questions before June 23rd
  - Do NOT update the KC Questionnaire- ignore prompt

- **New KC COI Procedures**
  - Do NOT collect paper Form 800 disclosures
  - Update the KC Questionnaire after June 23rd when prompted, list all UCI Investigators on the Personnel tab, and answer the updated COI questions
Startup Steps: June 23rd (Day 1 of KC COI)

UCI Investigator
• Complete the Annual Disclosure
• If applicable, begin disclosing travel in Travel Log

Initiator
• Include all Investigators in the Personnel tab and answer the updated COI Questions when submitting a new PHS proposal
## KC COI Email Notifications

<table>
<thead>
<tr>
<th>KC COI Email Notification</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action Item/Action Required</td>
<td>Respond as soon as possible to avoid delays in processing your project</td>
</tr>
<tr>
<td>Reminder</td>
<td>Respond if applicable (ex. you need to update your financial interests or your Annual Disclosure is about to expire)</td>
</tr>
</tbody>
</table>
Training Opportunities

• KC COI Office Hours: June 2016
  – Sign up in UCLC, search “KC COI”
  – Opportunities to see KC COI up close in the computer lab and have more personalized training

• One-on-One Training (only by request: email eRA@research.uci.edu)
Resources

- KC COI Overview Video: https://www.youtube.com/watch?v=qpbiTiOfXs
Contacts

- KC COI Questions: era@research.uci.edu
- Conflict of Interest Questions:
  - Amy Green (COI Analyst), acgreen1@uci.edu
  - Nadia Wong (COI Administrator), nadiaw@uci.edu