

COI FAQs (June 1, 2018)

1. Who is required to complete a COI disclosure? Will research staff, graduate students, subcontractors, and post-doc fellows be required to complete a disclosure?

All faculty members and other academic appointees, as described in University Statue 11, must complete a disclosure. Individuals that have independence in decision making in the design, conduct, or reporting of research must also disclose. An individual listed on a PHS-funded grant that has submitted a biosketch with the grant must submit a COI Disclosure. This may include research staff and subcontractors if they have independence in decision making in the design, conduct, or reporting of research. If you are unsure if you should complete a COI Disclosure, please contact University Research Administration at coi@lists.uchicago.edu.

2. As a subrecipient, do I have to complete a disclosure with The University?

No, you may complete an assurance stating that your institution/organization is PHS compliant. You must inform the University of Chicago of your decision to do so at the time of proposal submission. If your institution/organization does not already have a PHS compliant policy, you will need to complete the University of Chicago Disclosure Form.

3. What should be disclosed?

All Significant Financial Interests must be disclosed, regardless of value or amount, which could reasonably appear to affect the design, conduct, or reporting of your research, or your performance of Institutional Responsibilities.

Significant Financial Interests include but are not limited to:

- Salary from employment or other payments for services such as:
 - Consulting fees
 - Data safety monitoring boards
 - Scientific advisory boards
 - Editorial compensation
 - Guest Speaking
 - Speaker's Bureau
 - Board of Directors compensation
- Royalties from the University of Chicago or outside companies

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- Gifts
- Equity in companies (stock, stock options, shares)
- Intellectual property rights (patents, patent applications, copyrights, licenses)
- Travel sponsored or reimbursed by industry

If you are unsure if an interest should be disclosed, always err on the side of disclosure. If you have any questions, please contact University Research Administration at coi@lists.uchicago.edu.

4. What does not need to be disclosed?

The following does not need to be disclosed:

1. Income from seminars, lectures, or teaching engagements sponsored by governmental or nonprofit entities
2. Income received for participating on advisory committees or review panels for governmental and nonprofit entities
3. Investments from mutual funds, retirement funds, and blind trusts that you do not directly control

5. Does the University of Chicago have a threshold for disclosure reporting?

Yes, The University has established a zero threshold for disclosure reporting both in dollar value and in percentage (%) of equity holding, meaning that if the financial interest could *reasonably be perceived* to directly and significantly affect the design, conduct or reporting of research, it must be reported even if its dollar value or percentage is de minimus.

6. How frequently will I have to disclose?

You are required to complete an annual disclosure at the beginning of the academic year. You may continue to update or modify your disclosure throughout the academic year. Any changes must be reported within 30 days.

7. What is the reporting period?

The reporting period is July 1st – June 30th.

8. If I have a new financial interest or outside activity to disclose, how soon do I need to report that?

Any changes to your disclosure, including additions, must be reported within 30 days.

9. Are there other organizations who have adopted the new PHS requirements?

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Yes. The following organizations have adopted the updated PHS requirements:

PUBLIC HEALTH SERVICE AGENCIES

- Administration on Aging (AoA) Indian Health Service (HIS)
- Administration for Community Living (ACL) National Institutes of Health (NIH)
- Administration for Children and Families (ACF) Office of the Assistant Secretary for Health (ASH)
- Administration on Children, Youth and Families (ACYF) Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Agency for Healthcare Research and Quality (AHRQ) Office of Minority Health Resources Center (OMH)
- Agency for Toxic substances & Disease Registry (ATSDR) Office of Population Affairs (OPA)
- Biomedical Advanced Research and Development Authority (BARDA) Office of Research on Women's Health (OWH)
- Centers for Disease Control and Prevention (CDC) Office of Global Affairs (OGA)
- Centers for Medicare & Medicaid Services (CMS) Substance Abuse and Mental Health Services Administration (SAMHSA)
- Health Resources and Services Administration (HRSA) U.S. Food and Drug Administration (FDA)

SPONSORS FOLLOWING PHS COI REGULATIONS

- American Heart Association (AHA)
- American Cancer Society (ACS)
- Alliance for Lupus Research
- Arthritis Foundation
- American Lung Association (ALA)
- California Breast Cancer Research Program (CBCRP)
- California HIV/AIDS Research Program (CHRP) Lupus
- Foundation of America (LFA)
- Juvenile Diabetes Research Foundation (JDRF)
- Susan G. Komen Foundation
- Patient-Centered Outcomes Research Institute (PCORI)
- CurePSP (Society for Progressive Supranuclear Palsy)
- Donald Danforth Plant Science Center
- Cooper Institute

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10. If I am involved in a start-up company, SBIR, or STTR grant, do I need to report this activity?

Yes, all outside commercial activities need to be reported.

11. The new PHS regulations include travel, how does this affect me?

For individuals who receive PHS funding or funding from any of the aforementioned organizations, any externally supported travel must be reported within 30 days. This disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- A federal, state, or local government agency.
- An Institution of higher education as defined at 20 U.S.C. 1001(a)
- An academic teaching hospital
- A medical center
- A research institute that is affiliated with an Institution of higher education

12. For individuals reporting travel, what information do I need to report?


When reporting your sponsored industry travel, you need to report the following information:

- Dates and/or Duration of Travel
- Amount (i.e. hotel, travel, meals, honorarium, etc...if known)
- Destination
- Purpose of the trip
- Who funded the trip

13. Can I modify/update my disclosure at any time?

Yes, you can access your COI Disclosure in AURA COI at any time to make changes and updates to your disclosure. To modify your submitted disclosure, log into AURA COI (Auracoi-prod.uchicago.edu/COI) and click on the “My Submitted Disclosures” tab. Then click on the “Manage My Disclosures” button to modify your submitted disclosure.

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14. Will my current disclosure be accessible to me at any time?

Yes, you will be able to access your COI Disclosure at any time by logging into AURA COI (Auracoi-prod.uchicago.edu/COI) and clicking on your annual disclosure under the “My Inbox” tab.



15. If I am unable to complete my disclosure, can I return to it and complete it at a later date? Yes, you can exit the system and complete your disclosure at a later date. Your information will be saved.

16. Will I be able to view my previous disclosures submitted prior to September 2012 in AURA COI?

No, your previous disclosures will not be in the new AURA COI system. If you would like a copy of your previous disclosures, please contact University Research Administration at coi@lists.uchicago.edu.

17. Will you still be accepting COI Disclosures via email, fax, or mail?

No. All COI Disclosures must be submitted through the AURA COI System. If you are having problems logging into the system or submitting your disclosure, contact the AURA Help Desk at AURA-Help@uchicago.edu.

18. How can I print my COI Disclosure?

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You can print your COI Disclosure by opening your disclosure and clicking on the "Printer Version" button on the left side of the page.

19. How do I disclose recurrent payments?

If you have received recurrent payments, you can make one entry with the latest known date and the aggregated amount received. In the comment section, you should state the specifics.

For example, you received the following payments from Takeda throughout the year: \$400 (January), \$650 (March), \$ 700 (May). In AURA COI, you could enter the following:

Date: May 1, 2012

Amount: \$1750

The screenshot shows a web form titled "Edit UC Disclosure Details". At the top, there is a grey header bar with the title. Below the header, there is a paragraph of instructions: "Click OK when you have finished entering the information below for the current company. Click OK and Add Another if you have additional Consulting, Advisory, Data or Scientific Advisory Board information to enter for this company." The form contains four main sections, each with a red asterisk indicating a required field:

- * Date of Transaction:** A text input field containing "5/1/2011" and a calendar icon to its right.
- * Amount (Enter 0 if unknown):** A text input field containing "1750".
- * Relationship of the Recipient to You:** A dropdown menu with "Self" selected.
- * Comments:** A large text area containing the text "I consulted for Takeda on 4 different occasions." and a vertical scrollbar on the right side.

At the bottom of the form, there is a horizontal line. Below the line, on the left, is a red asterisk and the word "Required". On the right, there are three buttons: "OK" (highlighted in blue), "OK and Add Another", and "Cancel".

20. If only the month and year are known, how should I report the date of transaction?

You should select the 1st of the month if only the month and year are known (e.g. 7/1/2012).

21. If I am unsure which division of a company to choose when entering the external organization's name, what should I do?

You should select the most general entry.

For example, you work for Baxter as a consultant. You would select Baxter Healthcare Corp.

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Create New Disclosure

External organization: If you are not sure which division of the large multinational to choose, select the most general entry.

baxter

Organization	Org Parent
<u>Baxter</u> Healthcare Corp	
<u>Baxter</u> Int	
<u>Baxter</u> Travenol Fndn	

bove list, enter the name as text here: