

**2015 Annual disclosure of external
financial interests and
commitments
OSP Roundtable**

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** Primary contact for system and status inquiries*

March 2015

Outline

1. Cornell COI requirements
2. 2015 Annual Reporting process/timeline
3. Sanctions for non-compliance
4. e-COI System administrative features
5. Requirements for PHS (NIH) and non PHS funded PI, Co-PI or KP
6. Resources

Cornell Policies on Conflict of Interest

- Cornell Policy 1.7, Financial Conflicts of Interest Related to Research:
 - Managed by the Office of Research Integrity and Assurance
 - Compliance with federal and other sponsor requirements
 - Applies to Cornell academic staff and research personnel
 - Defines reporting requirements
 - Identification of real or apparent conflicts
 - Management of such conflicts
 - Faculty Committee on COI implements the policy
- Cornell Policy 4.14, Conflicts of Interest and Commitment:
 - Managed by the Counsel's office and the Dean of Faculty
 - University principles and practices
 - Applies to all Cornell persons and functions
 - University Conflicts Committee, ad hoc when needed
- Cornell Faculty Handbook

Conflict of Interest, defined

“ An individual is considered to have a conflict of interest when he or she, a member of his or her family, or an associate (to his or her present knowledge) either (1) has an existing or potential significant financial interest or other material interest or relationship that impairs or might appear to impair the individual's independence and objectivity in the discharge of his or her responsibilities to the university; or (2) may receive a financial or other material benefit from information confidential to the university.

Typically, a conflict of interest may arise when an individual has the opportunity to influence the university's business, administrative, academic, or other decisions in ways that could lead to personal gain or advantage of any kind.*

**http://www.dfa.cornell.edu/cms/treasurer/policyoffice/policies/volumes/governance/upload/vol4_14.pdf, pp 4*

Financial Conflict of Interest (fCOI) Related to Research, defined

“ A real fCOI arises when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research.

An apparent fCOI arises when there is a reasonable apprehension, which reasonably well-informed persons are likely to have, that an individual’s opportunity for personal financial gain could compromise or influence the design, conduct, reporting, or direct administration of research.” *

**<http://www.dfa.cornell.edu/treasurer/policyoffice/policies/volumes/academic/financialconflict.cfm>, pp6*

Reason and Purpose

Ensure that there is no reasonable expectation that research results are biased by the external commitments and financial interests of persons who are responsible for university research.

Promote academic freedom with responsibility:

- assure open publication of research results
- encourage a spirit of entrepreneurship
- maintain integrity of the research process
- adequate protection for students
- protect the public's investment
- protect the institution
- maintain the public trust in the integrity of the university's research and education mission

Cornell Research

Defined in the Policy 1.7, includes:

- Sponsored research
- Non sponsored research
- Extension activities

Who is required to report?

All academic appointees and research personnel:

- All Cornell academic appointees
- Limited set of Administrators- with decision making authority for the direct management of research

Not:

- Students, technical or administrative staff, unless named as KP on sponsored projects

Who is required to report?

For sponsored projects:

Any research personnel planning to participate in or participating in Cornell research:

- PI, Co-PIs and all key personnel
- Anyone else **identified by the PI and/or Co PIs** as having independent responsibility for the design, conduct or reporting of research
- No students, unless specifically identified by the PI, Co-PIs as “key personnel”

2015 Annual Reporting Cycle

Policy 1.7 requires that all required personnel disclose their external financial interests and commitments at least annually and throughout the year, if there is a significant change in their financial interests.

- 2015 reporting starts April 7
- Staggered emails for reporting, sent over 4 days
- Reports must be submitted using the online tool e-COI
- Approximately 5 weeks to complete the report (last day- May 15)
- College contacts will be sent status reports
- OSP will send out proposals even if not all KP have completed the annual disclosure
- Sponsored awards will not be released until annual reporting is complete

Sanctions for non-compliance

- Will be implemented on May 18
 - Deans and Department Chairs informed
 - Letter from SVPR will be included in the employee record
- On and after May 18:
 - Proposals will not be submitted, awards will not be accepted
 - Spending on existing awards will be frozen
 - Modified (visiting, adjunct, courtesy) appointments terminated
 - Individuals cannot be paid on grant money
 - For PHS funded investigators, sponsor will be notified
 - SIP for salaried employees will be withheld

COI Requirements after May 18

Non- PHS funded research personnel:

Requirements	Proposal submission	Award acceptance
Annual Report of external interests	Required	Required
Resolution of any COI and implemented management plan	Recommended	Required

COI Requirements after May 18

PHS funded research personnel: COI requirements for investigators funded on PHS funds and other agencies in Appendix A

Requirements	Proposal submission	Award acceptance
Annual Report of external interests	Required	Required
fCOI online training	Recommended	Required
Travel report (past 12 months) and every 30 days	Recommended	Required
Proposal/Award specific report	Recommended	Required
Resolution of any COI and implemented management plan	Recommended	Required

Using the e-COI system to support your unit

If you are responsible for managing grants and proposals for your unit, we recommend that you request limited administrative rights to the online eCOI system. This will allow you to:

1. Add reporters who need to submit their annual report
2. Check the status of reports
3. Check COI training for PHS funded reporters

You will not have permission to see the actual disclosure.

Managing access to sensitive data

The eCOI database contains sensitive information about people. Access to it is provided when needed to meet job responsibilities. Admins have “Global view” access, but are trusted to only look for information relevant to their units and their jobs.

Before you leave today:

- Please check with Bridget if you have access and confirm that you need continued access.
- If you don't have access and need it, please request it with Bridget.
- If there are people on the list for your department who don't need access, please mark them for removal.

Add a New Reporter

1. From your Home Page, click on "Administration" and select "Add Reporter"
2. Click on the binoculars icon
3. When the "Find a user" box opens, enter the new reporter's netID in "Verify a User"
4. Click "Find"
5. Select the Reporter's department
6. Check "PHS/42 CFR 50 Agency" if the reporter is PHS funded
7. Click on "Create Reporter" to add this profile to the database.

Search COI Reports (Test)

My COI Reports View Reports Administration Help

Add Reporter

Create A New Reporter

* Required fields

1

NetID*  2

Middle name

Title

First name

Last name

5 Department* --- Select A College/Dept ---

Email*

6 PHS/42 CFR 50 Agency (For ORIA office use only) Completed NIH Training

Funded

After step 1, the "Find a User" box will appear

Find A User

Last Name: equals startswith contains endswith

First Name: equals startswith contains endswith

Affiliation:

- Any
- Student
- Staff
- Academic
- Alumni
- Retiree

Verify A User

3 Netid: 5

Find Cancel

7

Create Reporter Cancel

Search for Reports

Search COI Reports (Test)

My COI Reports View Reports Administration Help

Search COI Reports

Search all reports

1

- From your Home page, Click on "View Reports" and then "Search COI Reports".
- Search:
 - For a reporter: Enter the reporter's netID and go to Step 3.
 - For reporters in certain statuses: select a status from "Report Status"
 - For reporters in certain college or department: select a "College" or "Department"
- Click on "Find (List)", or simply click "enter" on your keyboard.
- Search results will look like this. Click on the name to see the details of the report.

Search Criteria

Reset Search Find (List) Find (Count)

NetID

2A

Last Name

Report Status

- Administrator Pulled Back
- Appeal Submitted
- Assigned to Committee
- Disclosable Interest Eliminated
- Disclosable Interest Managed
- Disclosable Interest Unmanageable

2B

Department

- AGRICULTURE & LIFE SCIENCES - AMERICAN INDIAN PROGRAM [172]
- AGRICULTURE & LIFE SCIENCES - ANIMAL SCIENCE [127]
- AGRICULTURE & LIFE SCIENCES - APPLIED ECONOMICS & MGMT [121]
- AGRICULTURE & LIFE SCIENCES - BIO & ENVIRONMENTAL ENGINEER [123]
- AGRICULTURE & LIFE SCIENCES - BIO STATISTICS & COMP BIOLOGY [150]
- AGRICULTURE & LIFE SCIENCES - BIOMETRICS [151]

First Name

3

PHS/42 CFR 50 Agency All (For ORIA office use only)

Report Year

- 2012
- 2011

College

- AGRICULTURE & LIFE SCIENCES
- ARCHITECTURE, ART & PLANNING
- ARTS & SCIENCES
- COMPUTING AND INFORMATION SCIENCE
- ENDOWED PROGRAMS
- ENGINEERING

2C

Report Type

- Annual Report
- Event-based update

Review Type

- Appeal
- Exempt
- Exempt and Unit Review
- Expedited
- Expedited and Unit Review
- Full Board

Entity Name

A/B Reporter All

Award Number

Reporter Status All

Excused Status All

4

Reporter	COI Report ID	Event	Submitted Date	Review Type	Status	Status Changed
Verma Amita	27805	Annual Review			In Work	

Check the status of reporters in your unit

1. Click on “Search COI Reports” under the “View Reports” tab.
2. The “Search COI Reports” page will load. Enter or select the information which you would like to search for. Multiple colleges or departments can be selected by holding Ctrl + Alt while clicking on a selection.
3. Click “Enter” or “Find (List)”.
4. This is how your results will appear. The status is indicated by the red arrow.



Search all reports

Reset Search Find (List) 3 Submit

NetID

Last Name

Report Status
Administrator Pulled Back
Appeal Submitted
Assigned to Committee
Disclosable Interest Eliminated
Disclosable Interest Managed
Disclosable Interest Unmanageable

Department
ARTS & SCIENCES - ENGLISH [A64]
ARTS & SCIENCES - ETHICS AND PUBLIC LIFE PROGRAM [A51]
ARTS & SCIENCES - FEMINIST, GENDER & SEXUALITY [A97]
ARTS & SCIENCES - GERMAN STUDIES [A69]
ARTS & SCIENCES - GOVERNMENT [A70]
ARTS & SCIENCES - HISTORY OF ART [A73]

First Name

PHS/42 CFR 50 Agency All

Funded

Report Year
2015
2014

College
AGRICULTURE & LIFE SCIENCES
ARCHITECTURE, ART & PLANNING
ARTS & SCIENCES
COMPUTING AND INFORMATION SCIENCE
ENDOWED PROGRAMS
ENGINEERING

Report Type
Annual Report
Event-based update

Entity Name

Award (OSP) number

Reporter	COI Report ID	Event	Submitted Date	Review Type	Status	Status Changed
MacRae Bridget	34126	Event			No Conflict Exists	03/18/2014

Look for Training for PHS reporters

1. **View Reports**

2. **NetID** bm483

3. **Find (List)**

Report Status: Administrator Pulled Back, Appeal Submitted, Assigned to Committee, Disclosable Interest Eliminated, Disclosable Interest Managed, Disclosable Interest Unmanageable

Department: AGRICULTURE & LIFE SCIENCES - AMERICAN INDIAN PROGRAM [172], AGRICULTURE & LIFE SCIENCES - ANIMAL SCIENCE [127], AGRICULTURE & LIFE SCIENCES - APPLIED ECONOMICS & MGMT [121], AGRICULTURE & LIFE SCIENCES - BIO & ENVIRONMENTAL ENGINEER [123], AGRICULTURE & LIFE SCIENCES - BIO STATISTICS & COMP BIOLOGY [150], AGRICULTURE & LIFE SCIENCES - BIOMETRICS [151]

Report Year: 2015, 2014

Report Type: Annual Report, Event-based update

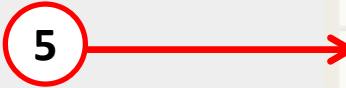
1. Click on "Search COI Reports" under the "View Reports" tab.
 2. The "Search COI Reports" page will load. Enter the netID for the reporter.
 3. Click "Enter" or "Find (List)".
 4. Your results page will load. Click on the reporter's name.
 5. The reporter's profile will load. To see if the reporter has completed NIH Training, please refer to the "yes/no" indicator in the "NIH Training Complete" section.
- To view a list of all training completion records, please visit:
<http://www.oria.cornell.edu/COI/lookup/>

4. **Reporter** ↑

Reporter	COI Report ID	Event	Submitted Date	Review Type	Status
MacRae Bridget	34126	Event			No Conflict Exists

Latest Report for Bridget MacRae (bm483)

Report No.	2015-bm483-E.1
Event	Event
Submitted Date	
Status	No Conf Exists
Review Type	
Last Update	03/18/2014
NIH Training Complete	NO Take the Training View Training Records



Who to call for help?

Generally this is the order in which we advise that you contact us for help. For urgent requests or escalation of an issue, contact any of us and we will make sure we engage the right people to find a resolution.

coi@cornell.edu- mailbox is closely monitored at all times

- System issues (access, navigation, how to..)
- Who should report using eCOI
- Can a proposal be submitted, award accepted
 - Bridget bm483, 4-8878
 - Amita av234, 5-2214
 - Guilaine gds64, 5-8994
- Advice on whether some activity should be reported
 - Guilaine gds64, 5-8994
 - Bridget bm483, 4-8878
 - Amita av234, 5-2214
- Advice on whether a relationship could be a conflict of interest and how to manage it
 - Guilaine gds64, 5-8994
 - Amita av234, 5-2214
 - Bridget bm483, 4-8878

Requirements: PHS funded research personnel

NIH in 2012 imposed new requirements for investigators funded on PHS funds. Several other agencies have adopted these rules (See Appendix A).

Requirements	Proposal submission	Award acceptance
Annual Report of external interests	Required	Required
fCOI online training	Recommended	Required
Travel report (past 12 months) and every 30 days	Recommended	Required
Proposal/Award specific report	Recommended	Required
Resolution of any COI and implemented management plan	Recommended	Required

Travel reporting- Why, when and What?

Why? Travel paid for or reimbursed by an external entity could constitute a Significant Financial Interest that could be a COI.

When? Within 30 days of completion of the trip.

What? Any travel that contributes to or arises out of your teaching, research, outreach, publications, clinical practice, other scholarly pursuits or Cornell administrative duties

AND

Is reimbursed or paid for by any entity other than those listed in the next slide as "excluded entities".

Examples for reportable travel: Travel for conference presentations, lectures, keynote speeches, consulting activities arising out of your research or academic expertise associated with your Cornell appointment, expert witness testimonies, marketing, publicity or development efforts, etc. but not paid by your Cornell department account or your OSP award.

Travel reporting- what not to report

- (1) Travel that is **not related** to Cornell responsibilities or professional consulting activities;
- (2) Travel that is reimbursed or paid for by these "**excluded entities**":
 - Cornell University, or another US, non-profit Institution of higher education as defined at 20 U.S.C. 1001(a)
 - a US Federal, state, or local government agency (e.g.: NIH, NSF, New York State agencies, etc.)
 - an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Examples of what not to include:

- Vacations or other trips that you/your family paid for;
- Travel funded by the federal, state or local government agency or award sponsor,
- Travel for teaching or lectureships at non-profit, US Universities;
- Travel funded through your Cornell account

Award specific reports

Award acceptance- Key personnel on a PHS award must complete an award-specific disclosure of external interests.

Purpose- to identify if an investigator has a financial interest that is related to that specific award.

If there are any identified SFIs that are related to the PHS award, they **must be resolved** prior to “expenditure of PHS funds”.

Required COI training

- Online training available at <http://www.oria.cornell.edu/COI/training/>
- Check previous day's training completion records at <http://www.oria.cornell.edu/COI/lookup/>

Sub-recipients (subawards)

- Must be in compliance with the NIH regulations
- Cornell must report within 60 days any FCOI for a sub-recipient investigator related to the NIH award.
- If an institution does not have an NIH-compliant policy, Cornell assumes the risk of being responsible for individuals at the other institution- case by case determination based on risk.
- *If we are the sub-recipient, the grantee institution may ask for our researchers' reports, management plans etc. and choose to conduct duplicate review.*

Appendix A: Public Health Service (PHS) Agencies

Within the Department of Health and Human Services (HHS), eight agencies are designated components of the U.S. Public Health Service (PHS):

- (1) the Agency for Healthcare Research and Quality (AHRQ),
- (2) the Agency for Toxic Substances and Disease Registry (ATSDR),
- (3) the Centers for Disease Control and Prevention (CDC)
- (4) the Food and Drug Administration (FDA),
- (5) the Health Resources and Services Administration (HRSA),
- (6) the Indian Health Service (IHS),
- (7) the National Institutes of Health (NIH), and
- (8) the Substance Abuse and Mental Health Services Administration (SAMHSA).

Appendix A: sponsors that have adopted PHS rules

For complete list, see http://sites.nationalacademies.org/PGA/fdp/PGA_070596

Federal agencies:

- Administration on Aging (AoA)
- Administration for Children and Families (ACF)
- Agency for Toxic Substances & Disease Registry (ATSDR)
- Biomedical Advanced Research and Development Authority (BARDA)
- Centers for Medicare and Medicaid Services (CMS) [formerly HCFA]
- Office of Global Affairs (OGA)
- Office of the Assistant Secretary for Health (ASH)
- Susan G. Komen Foundation for the Cure of Breast Cancer

Non profit Organizations:

- California Breast Cancer Research Program (CBCRP)
- California HIV/AIDS Research Program (CHRP)
- Alliance for Lupus Research (ALR)
- American Cancer Society (ACS)
- American Heart Association (AHA)
- Arthritis Foundation (AF)
- Juvenile Diabetes Research Foundation (JDRF)
- Lupus Foundation of America (LFA)