Frequently Asked Questions about Cornell’s implementation of the PHS new rules on COI

For a short summary of the requirements and Cornell’s implementation, go to http://www.oria.cornell.edu/COI/

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**Applicability**

1. **What is the “New Rule”?**
   Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) published revised regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors (commonly known as the Financial Conflict of Interest (FCOI) regulations). These regulations establish new standards and clarify previously established standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. It is called 42 CFR Part 50 Subpart F. Details of the rules and the entire text of the notice are available here: http://grants.nih.gov/grants/policy/coi/index.htm

2. **Which funding agencies are included in “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).
3. When is Cornell required to comply with the 2011 revised regulation?
   An Institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than August 24, 2012. Therefore Cornell must demonstrate that it is in compliance with the new rules no later than August 24, 2012.

4. Is the 2011 revised regulation retroactive? In other words, does it apply to ALL active PHS awards?
   No. Cornell University has decided that the revised regulation will apply to a PHS grant or cooperative agreement with an issue date of the Notice of Award (including noncompeting continuations) of August 24, 2012 and after.

5. Does the PHS regulation apply to all Cornell researchers?
   No. Cornell University has decided that the revised regulation will apply only those researchers who are identified as key personnel on PHS funded awards with issue dates on or after Aug 24, 2012.

6. Who is covered by the regulation?
   The regulation is applicable to each Institution that is applying for, or that receives, NIH research funding by means of a grant or cooperative agreement and, through the implementation of the regulation by the Institution, to each Investigator who is planning to participate in, or is participating in, such research. At Cornell, “key personnel” on PHS awards are subject to this regulation:
   • Principal investigators, co-investigators, and any other individual named in a sponsored project key personnel list,
   • anyone else who, as determined by the PI and Co-PIs, has independent responsibility for the design, conduct and reporting of research,
   • Anyone who during the course of a sponsored project assumes a role synonymous with the roles above.

7. What must researchers do so that their proposals to the PHS funding agencies can be submitted and awards accepted?
   In order to meet the requirements of the regulation, Cornell must implement the following conditions for proposal submission and award acceptance. We encourage you to be mindful of these requirements when you are planning your grant related activities. Please contact coi@cornell.edu with questions. OSP and the COI office are partnering to assist you in meeting these requirements.

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Visit [http://www.oria.cornell.edu/COI/](http://www.oria.cornell.edu/COI/). Contact coi@cornell.edu
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For questions, assistance, call 254-8878, 255-2214 or email coi@cornell.edu

### Requirements under the new Rule

#### 8. What is the most significant difference between the 1995 regulation and the 2011 revised regulation?

The 2011 revised regulation includes comprehensive changes, focusing on these areas in particular:

- Definition of Significant Financial Interest
- Extent of Investigators’ disclosure of information to Institutions regarding their Significant Financial Interests;
- Institutions’ management of identified Financial Conflicts of Interest
- Information reported to the PHS funding component (e.g., NIH);
- Information made accessible to the public (i.e., Institutional FCOI policy and FCOIs of senior/key personnel); and
- Investigator training.

#### 9. What is the revised definition of a Significant Financial Interest?

The regulation covers all financial interests that have monetary value, whether or not the value is readily ascertainable. Consistent with the regulations, Cornell’s definition of “Significant Financial Interest” is described below:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s domestic partner and dependent children) that reasonably appears to be related to the Investigator’s Cornell responsibilities:
• With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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;

• With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

• Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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, or a research institute that is affiliated with an institution of higher education. The details of this disclosure include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Cornell’s COI office and FCOI Committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

10. What is excluded from the definition of a Significant Financial Interest?

The exclusions are:
• salary, royalties, or other remuneration paid by Cornell to the Investigator if the Investigator is currently employed or otherwise appointed by Cornell;
• intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
• income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
• income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
• income from service on advisory committees or review panels for a federal, state, or local government agency, or an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
• Unlike in the 1995 Financial Conflict of Interest regulation, income from non-profit entities other than federal, state, or local government agencies, Institutions of higher education, academic teaching
hospitals, medical centers, or research institutes that are affiliated with an Institution of higher education for the types of activities described above would be subject to the Significant Financial Interest definition.

11. **Is income from all non-profit institutions excluded from the definition of Significant Financial Interest?**

   No. The 2011 revised regulation states that income from seminars, lectures, or teaching engagements sponsored by 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, or a research institute that is affiliated with an Institution of higher education is excluded from the definition of Significant Financial Interest. Such income from all other sources is included in the definition of Significant Financial Interest and, accordingly, must be disclosed.

12. **What information must Cornell obtain from Investigators and when should it be collected?**

   Under the 2011 revised regulation, Investigators are required to disclose their Significant Financial Interests (and those of the Investigator’s domestic partner and dependent children) that reasonably appear to be related to the Investigator’s Cornell responsibilities:
   - no later than at the time of application for NIH-funded research; Use the form available on the Cornell COI website t http://www.oria.cornell.edu/COI/)
   - within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
   - at least annually, in accordance with the specific time period prescribed by Cornell, during the period of award.

13. **What are Cornell duties or responsibilities?**

   These include an Investigator’s professional responsibilities on behalf of the Institution, including activities such as research, research consultation, teaching, administrative responsibilities, professional practice, Institutional committee memberships, and service on internal and external panels.

14. **Does the regulation require Investigator training?**

   Yes. Each Investigator (as defined by the regulation), including subrecipient Investigator(s), must complete training:
   - prior to engaging in NIH-funded research and
   - at least every four years, and
   - immediately under the designated circumstances:
     - Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
     - An Investigator is new to an Institution
     - An Institution finds that an Investigator is not in compliance with the Institution’s Financial Conflict of Interest policy or management plan.

15. **How can I complete training requirements?**

   - Cornell investigators may access the online required training by following this link http://www.oria.cornell.edu/COI/training/.
• At the time of submission of the Annual report of external interests, investigators are required to certify that they have read and understand the Cornell Policy 1.7 on fCOI. Please ensure that you complete this requirement before certifying completion of your annual report.
• Once your training is complete, the COI office will, within one (1) business day, update your profile in the eCOI system to reflect your complaint status.

16. **Do I need to disclose the occurrence of any reimbursed or sponsored travel related to my institutional responsibilities? How should I submit my report?**
Yes. The regulation requires Investigators to disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the Investigator’s institutional responsibilities. However, the 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, or
- a research institute that is affiliated with an Institution of higher education.

The details of this disclosure include the following:
- purpose of the trip,
- the identity of the sponsor/organizer
- the destination, and
- the duration.

Investigators must report travel that meet the criteria above, by completing the forms available on the Cornell COI website http://www.oria.cornell.edu/COI/

17. **Am I required to disclose all financial interests received from a foreign Institution of higher education or the government of another country?**
Yes. In each case when the regulation refers to exclusions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency, the reference is made to a United States (U.S.) Institution of higher education or a federal, state or local government agency within the U.S.

18. **What must you disclose for your financial disclosure?**
• Investigators who are planning to participate in PHS-funded research must disclose their SFIs over the previous twelve-month period to their Institution no later than at the time of application for PHS-funded research.
• Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.
• Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI.
19. **When is a Significant Financial Interest related to the NIH-funded research?**

   In accordance with the 2011 revised regulation, a Significant Financial Interest is related to the research when the Significant Financial Interest could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research.

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20. **Is pre-award spend on PHS awards allowable, prior to identifying an FCOI and submitting the FCOI report to the NIH?**

   Institutions may, at their own risk, incur pre-award costs. If the PHS awarding agency determines that the COI was not managed effectively during the period before the report was submitted, the agency reserves the right to take corrective action including not allowing the funds to be charged to the account.

   Therefore, Cornell has determined that if an investigator has declared a significant financial interest related to the PHS award, pre-award spending on the award will not be allowed until after the review of the SFI has been completed, and if needed, a management plan has been implemented and reporting to the NIH has been completed.

   Cornell must submit the FCOI report to the NIH through the eRA Commons FCOI Module prior to expenditure of NIH funds authorized under the award, that is, after the Notice of Award is issued and before the specific amount is charged to an NIH award.

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21. **What does “prior to the Institution’s expenditure of any funds” mean?**

   After NIH issues a grant or cooperative agreement award, “prior to the Institution’s expenditure of any funds” is the period of time before an expense is recorded in the official records of the Institution.

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22. **Does the regulation apply to subrecipients, subgrantees and collaborators (e.g., subcontractors or consortium members)?**

   Yes. A subrecipient relationship is established when federal funds flow down from or through an awardee Institution to another individual or entity and the subrecipient will be conducting a substantive portion of the NIH-funded research project and is accountable to the awardee institution for programmatic outcomes and compliance matters. Accordingly, as a recipient of federal funds from an awardee Institution, the Financial Conflict of Interest regulation applies to subrecipients (e.g., subcontractors or consortium members). See 42 CFR 50.604 (c).

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23. **What are Cornell’s responsibilities for subrecipients?**

   The awardee Institution is responsible for ensuring any subrecipient’s compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH. Awardee institutions must incorporate as part of a written agreement with subrecipient terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.

   Awardee Institutions are responsible for monitoring subrecipient’s compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.
24. **How is Cornell implementing Subrecipient requirements?**

Since the NIH places the responsibility for subrecipient compliance on the awardee institution, and requires timely reporting of any identified fCOI at the subrecipient institution, Cornell has implemented the following requirements in order to assure compliance. Visit the OSP website http://www.osp.cornell.edu/Policies/sub-proc.html for details and links to documents:

- A sub-recipient commitment form must be signed and returned to Cornell’s OSP indicating the compliance status of the sub-awardee institution.
- The sub-recipient terms and conditions include additional language regarding identification, management and reporting of fCOI to Cornell University
- Subrecipients who indicate that they do not currently, and are not able to independently certify compliance with the NIH rules, may be deemed ineligible to be awarded the sub-award. This determination will be made on a case by case basis. A list of all the institutions who have declared compliance with the new NIH rules is available at the FDP Clearinghouse website http://sites.nationalacademies.org/PGA/fdp/PGA_070596

25. **Is Cornell required to make its policy on Financial Conflict of Interest publicly accessible?**

Yes. Cornell is required to make its policy on Financial Conflict of Interest publicly available via a publicly accessible Web site.

26. **Is Cornell required to make information on Financial Conflict of Interest of senior/key personnel publicly accessible?**

Yes. Prior to Cornell’s expenditure of any funds under a NIH-funded research project, we must ensure public accessibility, via a written response within five business days of a request, of information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:

- The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- The Institution determines that the Significant Financial Interest is related to the NIH-funded research; and
- The Institution determines that the Significant Financial Interest is a Financial Conflict of Interest.

Cornell must make available, at a minimum, the following:

- Investigator’s name;
- Investigator’s title and role with respect to the research project;
- Name of the entity in which the Significant Financial Interest is held;
- Nature of the Significant Financial Interest; and
- Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
27. Is an FCOI related a PHS award is identified, what must the management plan include?

The regulation requires that the FCOI report contain a description of the key elements of the Institution’s management plan including the following:

- The role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator’s agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Updated or annual FCOI reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the NIH.

Reporting to the NIH

28. When must annual FCOI reports be submitted to the NIH?

- **Initial Reports:** Prior to the Institution’s expenditure of any funds under a NIH-funded research project, the Institution must provide to the NIH an FCOI report regarding any Investigator Significant Financial Interest found by the Institution to be a Financial Conflict of Interest in accordance with the regulation.

- **Submission of Initial FCOI reports during an Ongoing NIH-funded Research Project:** The Institution must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award.

- **Annual FCOI Report:** For any Financial Conflict of Interest previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan.

29. What must the FCOI report include?

The regulation provides key elements that must be included in the FCOI report to NIH including but not necessarily limited to:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the Financial Conflict of Interest;
- Name of the entity with which the Investigator has a Financial Conflict of Interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;
• A description of the key elements of the Institution’s management plan

30. **What actions may NIH take after the receipt and review of a FCOI report?**

- NIH staff will evaluate the information provided by the Institutions as specified in the regulation, as well as other information that may be requested from an Institution during the review process.
- NIH may inquire at any time (i.e., before, during, or after award) into any Investigator disclosure of financial interests and the Institution’s review of, or response to, such disclosure, whether or not the disclosure resulted in the Institution’s determination of a Financial Conflict of Interest. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with the regulation.
- If NIH decides that a particular Financial Conflict of Interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the Financial Conflict of Interest in accordance with the regulation, NIH may determine that imposition of special award conditions, or suspension of funding or other enforcement action is necessary until the matter is resolved.

**Non compliance/Corrective Actions**

31. **What is a retrospective review and when is it required?**

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;
- the Institution shall, within 120 days of the Institution’s determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

32. **What are the key elements for documenting the retrospective review?**

The Institution shall document the retrospective review which must include at least the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- Findings of the review; and
- Conclusions of the review.
33. **What actions should be taken in the event that an Investigator fails to comply with Cornell’s Financial Conflict of Interest policy or management plan?**

When an Investigator fails to comply with the Cornell’s Financial Conflict of Interest policy or the management plan, Cornell must, within 120 days:

- complete a retrospective review of the Investigator’s activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research;
- document the retrospective review consistent with the regulation; and
- document Cornell’s determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator’s non-compliance with Cornell’s Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research.

If bias is found, Cornell must notify the NIH promptly and submit a mitigation report to the NIH that shall address the following:

- impact of the bias on the research project and
- Cornell’s plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Cornell shall submit FCOI reports annually, in accordance with the regulation. Depending on the nature of the Financial Conflict of Interest, Cornell may determine that additional interim measures are necessary with regard to the Investigator’s participation in the NIH-funded research project between the date that the Financial Conflict of Interest is identified and the completion of the Institution’s independent retrospective review, 29.

34. **What are the penalties/fines for failure to comply with the 2011 revised regulation?**

Depending on the severity and duration of the noncompliance, NIH may take one or more actions. For example, NIH may impose special conditions on a grant to allow the grantee to take corrective action. In addition, if a grantee has failed to materially comply with the terms and conditions of award, NIH may take action to wholly or partly suspend the grant, pending corrective action, or may terminate the grant. The regulatory procedures that pertain to suspension and termination are specified in 45 CFR parts 74.61 and 74.62, and in part 92.43.