Process for PHS funded Proposals and Awards with Subawards

OSP procedures:

- When CU receives a request to submit a proposal for a PHS funded project that includes subawards, if you have not received a completed Subcontractor Commitment Form (Form) for each subcontractor, please remind the PI, and the associated Department Administrator, that each subcontractor must complete the Form, which includes a section addressing Conflict of Interest, as required by PHS, before a proposal can be submitted.

- In addition, for the personnel from Cornell (PI, Co-PI and Key Personnel), please verify in eCOI that each person has completed their annual disclosure. If not, all each person, in addition to the PI and Co-PI(s), named on the proposal and identified as Key Personnel by the PI and Co-PI(s) as independently responsible for the design, conduct or reporting of research, must complete an annual disclosure before the proposal is submitted. If yes, the proposal can be submitted, once each subcontractor has completed the Form.

- Review the Subcontractor Commitment Form, Section 7 Conflict of Interest. If this is a PHS funded proposal, identify each subcontractor’s conflict of interest status within Section 7.A. The PI or Unit can use the clearinghouse found on the FDP website that provides a central location to document that they are in compliance with the PHS Financial Conflict of Interest rules and regulations (http://sites.nationalacademies.org/PGA/fdp/PGA_070596).
  - If a Subcontractor has selected the first box -- the subcontractor is compliant with the PHS requirement and the completed Form can be added to the Communication Document Set for the project.
  - If the second box is checked, the subcontractor has indicated they do not currently have a policy in place, but they plan to implement a policy and will notify us when this has been done. If this box is selected, please forward the Subcontractor Commitment Form to the Federal Team mailbox (OSP_Federal_Center@cornell.edu). Subcontractors with this status will remain in a pending certification folder within the Federal mailbox and once the subcontractor has notified us they have implemented the policy, the completed Form will be transferred to the Communication Document Set for that project. If awarded, the Subaward Team will know a subcontractor is compliant if the completed Form is in the Communication Document Set and not in the Federal Team mailbox.
  - If the Subcontractor marks the third box, they currently do not have a policy and they wish to comply with Cornell’s policy, the GCO notifies the Cornell COI office (coi@cornell.edu) and copies the PI, the Subcontractor and the Department Administrator, at the proposal stage using the standard email message (see attached), so ORIA can work with the Subcontractor to ensure compliance. The Cornell COI office will make the determination if it is possible for the Subcontractor to conform to the Cornell COI policy. The Cornell COI office will notify the OSP (OSP_Federal_Center@cornell.edu) and copy the Subcontractor, the PI and Department Administrator on their final decision. If not, the Subcontractor may need to implement its own policy, or it will not be permitted to serve as a Subcontractor on the PHS funded project. If the Subcontractor will adhere to the Cornell COI policy:
    - The Cornell COI office will send, to the individual or authorized representative at the subcontracting organization, the Financial Disclosure Requirements for Subrecipient Investigators Form that must be completed by each researcher engaged in the Cornell funded research.
    - The subrecipient investigators must send the completed forms to the Cornell COI office at coi@cornell.edu.

Version 01/15/13
The Cornell COI office will conduct its review of the disclosures and inform the researchers of any follow up action.

If the disclosure does not require any further review, the Cornell COI office will inform the Cornell OSP that COI requirements have been met.

If the disclosure indicates the presence of a significant financial interest, the Cornell COI office will work directly with the researcher to get more information. If it is determined that a conflict of interest with respect to the Cornell funded research exists, Cornell will make a decision on whether the researcher can participate in the Cornell research.

The subaward cannot be issued and PHS funds cannot be expended until compliance with all applicable COI requirements have been met and confirmed in writing by the COI office.

Upon notification of award, consistent with Cornell’s COI policy for any PHS funded award, before accepting it, please check in the eCOI system as to whether a project specific report exists for that OSP# for each Cornell person named.

If not, please advise PI and the Department Administrator, and copy the Cornell COI office, that compliances are pending. The Cornell COI office will follow up with the PI and the Department Administrator and inform OSP when required actions are complete. If time is of the essence, OSP will notify the Cornell COI office immediately and the Cornell COI office will provide guidance on whether to accept the award and hold it, or whether to decline the award immediately (rare but might happen). If no study-specific COI exists, the Cornell COI office will inform OSP. OSP can proceed with the award.

If study-specific COI exists, the Cornell COI office will inform OSP, and the Cornell COI office will work with the investigator to resolve it. An award cannot be accepted until this process is complete. When a management plan is implemented, the Cornell COI office will inform OSP.

For Subawards on the project when an award is received, review the status of the Subcontractor’s on the project.

If any Subcontractors on the project remain non-compliant, send the Subcontractor an email (see attached template for this purpose), and copy the Cornell COI office (coi@cornell.edu), indicating that before a subaward will be issued and before any work by the Subcontractor can begin, the Subcontractor must be in compliance with the requirement under 42 CFR Part 50, Subpart F, and that the matter is being transferred to the Cornell COI office (coi@cornell.edu) for further communication. Any questions from the Subcontractor regarding the COI should be directed to the Cornell COI office (coi@cornell.edu or 607-255-6439).
**Email templates:**

*To the Cornell COI office when Subcontractor chooses to comply with Cornell’s Financial Conflict of Interest Policy:*

To:  COI@cornell.edu  
cc: Subcontractor; Cornell PI; Department Administrator, OSP_Federal_Center@cornell.edu  
Subject:  Subcontractor – Cornell Conflict of Interest  

Dear COI Coordinator:

(Subcontractor’s Name), as a proposed Subcontractor on the project under OSP#XXXXX, entitled “XXXX YYYY” under the direction of (Cornell PI’s name),  has indicated that they do not have a conflict of interest policy and wishes to comply with Cornell’s policy. Please notify OSP (OSP_Federal_Center@cornell.edu) when the Subcontractor is compliant.

Any questions regarding this matter should be directed to the Office of Research Integrity & Assurance Conflict of Interest Coordinator (coi@cornell.edu or 607-255-6439).

Sincerely,

(GCO Name)

*To Subcontractor when Notice of Award received and Subcontractor not compliant:*

To:  Subcontractor  
cc:  COI@cornell.edu; Cornell PI; Department Administrator, OSP_Federal_Center@cornell.edu  
Subject:  Subcontractor Conflict of Interest compliance  

Dear (Subcontractor Authorized Representative):

Cornell University is in receipt of the Notice of Award for the project entitled “XXXX YYYY” under the direction of (Cornell PI’s name) in Cornell’s XXXXX Department. Our records indicate that we have not received notification regarding the implementation of a conflict of interest policy at your institution. All Subcontractors must be in compliance with the requirement under 42 CFR Part 50, Subpart F, before a subcontract will be issued and before any work by the Subcontractor can begin. This matter is being transferred to Office for Research Integrity & Assurance Conflict of Interest (the Cornell COI office) Coordinator (coi@cornell.edu) for follow-up and resolution. Any questions regarding this requirement should be directed to the Cornell COI office (coi@cornell.edu or 607-255-6439).

Sincerely,

(GCO Name)