

FCOI Procedures - PHS Subawards from Penn to Other Institutions

General Principles. As a rule, the University will require Subrecipient institutions to maintain and administer their own FCOI policies and will only in exceptional circumstances assume primary responsibility for directly soliciting and reviewing Subrecipient Investigator disclosures in order to determine whether a Subrecipient Investigator has an FCOI. The determination of whether an exception may be granted will be made by the Office of Research Services (ORS) in consultation with the PI and Research Integrity Office (RIO) with additional input from others with relevant information, if needed. In the event of a dispute as to whether compelling circumstances exist, the Vice Provost for Research will make the final determination.

- Generally, it is assumed that foreign Subrecipients will not have an FCOI compliant policy and thus may be covered under Penn's policy, depending on the circumstances. In addition, it is generally assumed that in circumstances where the Subrecipient is a physician's private practice or an affiliated legal entity through which the private practice conducts research, such entity will not have an FCOI compliant policy and thus may be covered under Penn's policy. In these situations, prior to submitting the subaward request in the Research Inventory System (RIS) or as soon as possible, the responsible School department must obtain written confirmation that both the Subrecipient and the Subrecipient Investigator(s) have no academic affiliation. The department should forward the written confirmation, as well as the Subrecipient PI's name and Institutional Official's (IO) contact information, to ORS.

Following submission of the subaward request in the RIS, the Subrecipient must indicate in the Request for Information (RFI) whether it has a compliant FCOI Policy. The following outlines the sequence of steps that must be taken by ORS, department BAs and the RIO based on the Subrecipient's response to the RFI.

I Subrecipient has a compliant FCOI Policy

1. Subrecipient will be deemed to have a compliant FCOI Policy if:
 - a. Subrecipient indicates "Yes" in RFI (has its own compliant FCOI Policy)
 - ORS will check the FDP Clearinghouse to confirm. However, Penn will not require the Subrecipient to register in the FDP Clearinghouse, as long as the Subrecipient is willing to certify in the subaward that it has a compliant FCOI Policy. If ORS has a question regarding whether to accept the Subrecipient's assertion that it has a compliant FCOI Policy, ORS will contact the RIO to discuss.
 - b. Subrecipient adopts FDP FCOI Policy
 - If Subrecipient indicates "No" in RFI (does not have its own compliant FCOI Policy), ORS will offer Subrecipient the option to adopt a compliant Policy based on the FDP model. If Subrecipient agrees, it must submit confirmation to ORS that the policy has been adopted.

2. Subrecipient must execute Standard Subaward (Subaward Attachment 2).
Subrecipient designates herein that the Subrecipient's financial conflict of interest policy will apply and by execution of this Subaward Agreement, Subrecipient Institution also certifies that its policy complies with 42 CFR Part 50.
 - In connection with execution of a standard PHS subaward, ORS will send Subrecipient *Subrecipient FCOI Report to the University of Pennsylvania* to be used to report any FCOIs
3. FCOI Reporting to NIH – Subrecipient has an FCOI compliant policy*

Initial reporting

- If an FCOI is reported to Penn, RIO will report the FCOI to NIH in eRACCommons. ORS will be copied on the notification.
- ORS should promptly forward any FCOI Reports received from Subrecipients to RIO.
- ORS will coordinate with RIO if additional information is needed for purposes of RIO reporting.

*RIO does not at this time contemplate managing any Subrecipient Investigator's FCOI where the Subrecipient does not have a compliant FCOI policy. Any exceptions will be handled on a case by case basis.

II Subrecipient does not have a compliant FCOI Policy and will be covered by Penn's FCOI Policy

1. Subrecipient will be deemed not to have a compliant FCOI Policy if:
 - a. Subrecipient indicates "No" in RFI and unwilling to adopt FDP FCOI Policy.
 - b. Subrecipient unwilling to certify in the subaward that it has its own compliant FCOI Policy.
 - Subrecipient must execute Attachment 2, Research Subaward Agreement with the following term: *Subrecipient represents that it does not maintain an up-to-date, written, enforced policy on financial conflict of interest (FCOI) pursuant to 42 C.F.R. §50.604(a).*

III Procedure for obtaining and reviewing disclosures received from Subrecipient Investigators covered by Penn's FCOI Policy

1. ORS will send the Subrecipient via email (with a copy to the RIO) the following:
 - a) Penn Cover Sheet asking the Subrecipient to identify its IO and to provide a list of Subrecipient Investigators who will be disclosing to Penn.

b) *Financial Interests Disclosure Form for Investigators Not Affiliated with the University of Pennsylvania* (Non-Penn Affiliate Disclosure Form)

c) *University of Pennsylvania Policy on Conflicts of Interest Related to Research*, effective August 24, 2012

d) Financial Conflicts of Interest in Research – Investigator Training Course

2. The Subrecipient PI or IO will be responsible for obtaining all Investigator disclosures and submitting at one time to the RIO with a copy of the completed Penn Cover Sheet.
3. Once the RIO receives the Penn Cover Sheet identifying the Subrecipient Investigators, RIO will email a copy to department BAs to enter non-Penn Investigators into PHS-FITS Investigator Maintenance.
4. RIO will administratively review Subrecipient investigator Disclosures upon receipt.
 - If any FCOIs are identified:
 - RIO will send the Investigator a *Non-Penn Affiliate FCOI Determination Letter* indicating that his /her SFIs must be eliminated in order for that Investigator to participate. The determination will state that if the Investigator is willing to eliminate his SFIs, s/he must execute the certification included at the bottom of the letter and return to RIO.
 - If the Investigator is unwilling to eliminate his/her FCOI, the determination states that the Investigator may not participate in this research.
 - If SFIs identified but no FCOIs, or if no SFIs are identified:
 - RIO will send the Investigator a *Non-Penn Affiliate Determination Letter – SFIs but no FCOI or No SFIs* that must be accepted by the Investigator and returned to RIO.
5. RIO will copy the Subrecipient's IO and the PI on all determination letters.
6. For every Subrecipient Investigator disclosure, RIO will enter date of disclosure and attach a copy of the disclosure in PHS-FITS Investigator Maintenance.
7. RIO will email ORS once all disclosures and signed final determination letters received.
 - ORS will not execute the subaward until it has received confirmation by the RIO that every Subrecipient Investigator has returned a completed Non-Penn Affiliate Disclosure Form and a fully executed determination letter.

- ORS will confirm in PHS-FITS Investigator Maintenance that for every Subrecipient Investigator, the Non-Penn disclosure received field has a date entry and the disclosure is attached.

V Procedure for obtaining annual disclosures from Subrecipient Investigators covered by Penn's FCOI Policy

- ORS will notify the RIO at the time a subaward is about to renew so that RIO may obtain new disclosure forms to meet the PHS regulatory requirement that all investigators annually disclose their SFIs.
- RIO will send Subrecipient Investigators a new Non-Penn Affiliate Disclosure Form to complete.
- RIO will notify ORS upon receipt of all annual disclosures, including any material changes to the disclosure.
- ORS will not set up the next segment of the subaward until it has been notified by the RIO that all required annual disclosures have been received.

VI Procedure for Subrecipients for subawards that predate the RIS

Upon request to modify or otherwise amend a current subaward, ORS will:

- Confirm whether or not subrecipient has an FCOI compliant policy.
- Confirm that correct Subaward Agreement (with current, standard terms) has been executed. If an outdated version has been executed, ORS will require Subrecipient to execute an amended Subaward Agreement.
- If it is determined for the first time that Subrecipient will be covered by Penn's FCOI Policy, ORS will proceed to Step III (1).

For questions regarding the above procedure, please contact Richard Shellenberger, FCOI Program Coordinator, at (215) 898-3603 or by e-mail at rlshell@upenn.edu.