Varying COI Policies or Requirements Among Sponsors

Florida Research Administration Conference

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- **USF**
  - $458.5 million in contracts and grants in FY 2016
  - 2,027 instructional faculty, 1,455 adjuncts and 50,000+ students
  - USF System includes: USF St. Petersburg, USF Sarasota-Manatee and USF Tampa (USF Health and Morsani College of Medicine)
  - One of 49 public research universities nationwide with very high research activity (RU/VH) that is designated as "community engaged" by the Carnegie Foundation
  - USF ranks fifth among American public universities and 11th among universities worldwide in generating new U.S. patents
COI regulations and climate

- U.S. Public Health Service
  - 42 CFR Part 50, Subpart F and 42 CFR Part 94 - Promoting Objectivity in Research
- National Science Foundation
  - Proposal and Award Policies and Procedures Guide, Chapter IX, A. Conflict of Interest Policies
- Some other federal agencies such as CMS, NIJ, DoE
- A few non-federal sponsors use NIH standards (e.g. PCORI, American Cancer Society)
- Increased public scrutiny and Congressional attention
- Litigation related to research conflicts
Regulatory Framework for PHS and NSF

- Individual financial conflicts of interest (including immediate family)
- Disclosure required for actual financial interests (within specified timeframes)
- Disclosure prior to proposal submission and annually
- Investigators (“anyone responsible for design, conduct or reporting”) must disclose, including subrecipients and consultants
- Specific thresholds for what is considered a Significant Financial Interest
- Reporting obligations to the sponsor (varies by sponsor)
- Manage, reduce or eliminate
December of 2014, Implementation of Uniform Guidance

- Uniform Guidance - General Provisions, 200.112 Conflict of Interest

  “The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy.”

COFAR FAQ 200.112-1

Q> Does this policy refer to scientific conflicts of interest that might arise in the research community?

A> No, however Federal agencies may have special policies or regulations specific to scientific conflicts of interest, such as HHS’s policy at 42 CFR Part 50. The conflict of interest policy in 2 CFR 200.112 refers to conflicts that might arise around how a non-Federal entity expends funds under a Federal award. These types of decisions include, for example, selection of a subrecipient or procurements as described in section 200.318.
Varying terms include three types of conflicts:

- **Individual**
  - In the context of research, an individual conflict of interest exists when an investigator’s private interests may compromise, or have the appearance of compromising, an investigator’s professional judgment in the design, conduct or reporting of the research.

- **Institutional**
  - In the context of research, an institutional conflict of interest may exist when the institution or one of its senior officials has a financial interest related to research.

- **Organizational**
  - Government is typically concerned about three things: unequal access to information, biased ground rules and impaired objectivity.
COI Terms and Conditions

- The COI Program reviews COI-specific terms and conditions in various requests for proposals (RFPs) and Agreements
- This COI language varies and can include different requirements in several areas:

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<td>Definition of COI</td>
<td>Actual, potential or apparent (appearance)</td>
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<td>Individual COI</td>
<td>May include all personnel, not just investigators</td>
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<td>Not just immediate family - inclusions “childhood friends,” siblings, in-laws, etc.</td>
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<td>Institutional COI</td>
<td>Uncommon, but may be included with organizational COI terms (e.g. PCORI)</td>
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<td>Timing of activities/interests for more than past 12 months</td>
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<td>Organizational COI</td>
<td>May ask for Institutional bias or conflicts</td>
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<td>Timing</td>
<td>If a +/- certification is required and whether it’s at proposal or award</td>
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<td>Reporting</td>
<td>Differences as whether external reporting is required ever or during the life of the award</td>
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State Funding

- Florida Department of Health research programs have COI terms and conditions that must be reviewed by COI Program at proposal and award
  - Examples:
    - James and Esther King Biomedical Research Program
    - Bankhead-Coley Cancer Research Program
    - Zika Research Grant Initiative Funding
    - Ed and Ethel Moore Alzheimer’s Disease Research Program FOA

- COIs need to be disclosed at proposal
- Proposal package includes a COI disclosure form
- Award cannot be set up until management plans are provided to Florida Department of Health
- New disclosures must be reported within 48 hours throughout the award
Example of State of Florida terms:

“The Grantee must report to the Department any reportable interests, regardless of any conflict of interest procedures at Grantee’s institution, at the time of the application and before the grant starts. Grantee must have in place an administrative process to identify and resolve financial conflicts of interest that may affect the objectivity of the proposed research. Grantee must inform the Department of any conflict of interest management plan required by Grantee’s institution prior to starting research. The Department may require an additional management plan if the plan developed by Grantee’s institution is not acceptable to the Department. If a reportable interest as defined by the Department arises after the grant starts, Grantee must immediately notify the Department within 48 hours.”
Federal Funding

- Uniform Guidance implementation led to a variety of agencies incorporating varying COI terms and conditions.

- Many federal RFPs, Broad Agency Announcements (BAAs), Funding Opportunity Announcements (FOAs), contracts, etc. include COI terms and conditions that must be reviewed by the COI Program.

- Requirements vary among agencies and solicitations and require case-by-case reviews by the COI Program.

- Examples of variations:
  - Timing of disclosure (proposal or award)
  - External reporting to sponsor
  - Types of COIs that must be reviewed (individual, institutional and/or organizational)
## Federal Funding

### Examples:

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<th>Category</th>
<th>Requirements</th>
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<td>NSF SBIR/STTR proposals</td>
<td>No one with an interest in the company can be paid on the university subcontract.</td>
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<td>Department of Transportation</td>
<td>Varying terms incorporated into contracts.</td>
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<td>NSF PFI:AIR-TT</td>
<td>Management must be reported to the NSF prior to award set-up for PIs and Co-PIs with an interest in a subrecipient.</td>
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<tr>
<td>NIJ research program</td>
<td>COI certification must be provided with the proposal application (requires gathering information from subs and university investigators).</td>
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<tr>
<td>Centers for Medicare and Medicaid Services</td>
<td>Requirements vary for grants and contracts and require review prior to proposal submission.</td>
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Federal Funding Terms

Examples of terms:

▶ “If an award is recommended and there is a subaward to a company with which a PI or co-PI has a Conflict of Interest, the University must submit the conflict of interest plan for that individual covering the proposed work before NSF funding will be released. - (The Conflict of Interest plan is not required at the proposal stage, only upon recommendation of award.)” (NSF 16-583, program solicitation)

▶ a. It is the National Highway Traffic Safety Administration’s (NHTSA) policy not to award contracts to Offerors whose objectivity may be impaired because of any related past, present or currently planned interest, financial or otherwise, in organizations regulated by NHTSA or in organizations whose interests may be substantially affected by NHTSA activities. Based on this policy:

b. The Offeror shall provide a statement in its technical proposal which describes in a concise manner all past, present or currently planned organizational, financial, contractual or other interest(s) with an organization regulated by NHTSA or with an organization whose interests may be substantially affected by NHTSA activities, and which is related to the work under the request. The interest(s) described shall include those of the Offeror, its affiliates, proposed consultants, proposed subcontractors and key personnel of any of the above. Past interest shall be limited to within one year of the date of the Offeror’s technical proposal. Affected organizations shall include, but are not limited to, the insurance industry. Key personnel shall include any person owning more than a 20% interest in the offering firm, and the Offeror’s corporate officers, its senior managers and any employee who is responsible for making a decision or taking an action on this contract where the decision or action can have an economic or other impact on the interests of a regulated or affected organization.

(National Highway Traffic Safety Administration (NHTSA) - DoT)
Federal Funding Terms

- Department of Energy

Previously...

“Consultants may not be employees of either the SBC or any subcontractor. SBC personnel cannot be reimbursed with DOE funding as a consultant, or as an employee of a subcontractor under the project.” (DE-FOA-0001646, CFDA 81.049)

Now...

Can employees or owners of a small business be paid as project team members on a sub-award budget of a university subcontractor? If so, does the small business or the university need any type of pre-approval from DOE for this to occur?

Yes. Employees or owners of the SBC may be employees of the subcontractor when the subcontractor is a research institution.

Per the Funding Opportunity Announcement (FOA), applicants must be aware of potential conflicts of interest in the event their SBIR or STTR application includes a subcontract to a research institution (e.g., a National Laboratory, University, etc.) and the applicant’s employee(s)/ownership is (are) also an employee(s) of the research institution.

Any conflict of interest related to a subcontracted effort shall be addressed prior to award by providing (to DOE) a statement from the DOE Contracting Officer at the Laboratory Site Office, that he/she confirmed that the Laboratory is aware of the ownership (or dual employment) and that the Laboratory has conducted a conflict review in accordance with its approved conflict procedures. A similar statement should be obtained from the Sponsored Program Office or similar business office in the event the subcontract is with a University or other research institution. In addition, the small business SBIR/STTR recipient shall provide to DOE prior to award, a document detailing how it will exercise both financial and managerial control over the project and how the recipient will isolate the Research Institution, and its employee(s), from influencing financial and managerial control of the project.
Private Funding

- There are private entities that follow the PHS regulation (look to NoA or institution’s compliance office for details)
- Some private foundations that do not follow the PHS regulation incorporate varying COI terms and conditions, for example:
  - Alfred P. Sloan
  - National Fish and Wildlife Foundation
- PCORI follows the PHS regulation and has additional COI requirements that require particular review by the COI Program.
Private Funding Terms

Example of terms:

- “The proposal should include as an appendix a disclosure of potential conflicts of interest or sources of bias on the part of the primary investigator, all key project staff, and the grantee institution. If no such conflicts exist, the appendix should include a statement to that effect.” (Alfred P. Sloan Foundation)
Private Funding Terms

Example of terms:

B. Conflicts of Interest

In the interest of maintaining objectivity in research, PCORI must ensure that its funded research and processes are free from conflicts of interest, consistent with its legislative mandate.

Recipient is expected to have established policies about, and safeguards against, conflicts of interest. Recipient shall have protection in place that prevents Recipient and its employees, consultants, subcontractors from using their positions for personal gain (for themselves, or for other individuals—friends, business associates, family members, or others), financially or via gifts, favors, or other similar actions. Recipient is also responsible to ensure that all aspects of PCORI-funded research are not influenced by conflicts of interest, financial or otherwise. Recipient is required to have written guidelines to prevent such conflicts of interest, reflecting Recipient’s policy and that meet the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service (http://grants.nih.gov/grants/policy/col/).

Additionally, PCORI is required by law to make available to the public and disclose through its website the identity of each research entity and the investigators conducting such research and any conflicts of interest of such parties, including any direct or indirect links to industry.

Recipient must notify PCORI promptly if any conflicts arise during the term of this Contract. PCORI may review and require periodic certifications of Recipient’s Conflicts of Interest disclosures during the term of this Contract.

Recipient certifies that, as of the Effective Date:

a) Recipient has established policies about, and safeguards against, conflicts of interest that meet the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service;

b) Recipient has reported the existence of any conflicting financial interests, using the Conflicts of Interest Disclosure Form provided by PCORI in Attachment C and has provided a mitigation plan to address identified conflicts (acceptable mitigation strategies include, but are not limited to, a letter on institutional letterhead certifying that the financial interest does not constitute a conflict); and

c) Recipient has fully disclosed any direct or indirect links to industry that have the potential to bias PCORI research, using the Conflicts of Interest Disclosure Form provided by PCORI in Attachment C.

The Conflicts of Interest Disclosure Form and any attachments must be completed and returned to PCORI even if the Recipient and/or Key Personnel have no conflicts or industry links to disclose.

Recipient acknowledges and agrees that any conflicts of interest and/or any direct or indirect links to industry provided to PCORI may be disclosed to the public via the PCORI website, in its Annual Report, or in some other format that may be released to the public. Recipient acknowledges and agrees to cooperate should PCORI investigate further any identified conflicts of interest.
2.1 Completing the COI Form (PI)
1. On your project record, navigate to the COI & Expertise section.
2. Click the ‘New COI & Expertise’ button.
3. You will be brought to a new COI & Expertise form page. The first two fields, Name of Recipient (Awardee Institution) and Name of PCORI-Funded Research Project will automatically populate with information from your project.
4. The next section requests that you confirm the names and institutions of the PI and other Key Personnel on your project. Review the populated information to confirm that it is correct.
5. If the PI & Key Personnel information are correct, select the checkbox next to the ‘Above Key Personnel Names are validated’ field.

6. Once you have verified that this information is accurate, the page will expand with questions for you to answer. Begin by answering the first question, which asks whether or not the recipient has a COI Policy or Guidelines that meet the requirements of the federal financial COI regulations. Use the drop-down menu to select ‘Yes’ or ‘No.’
   a. If ‘Yes,’ continue to the second question on the form.
   b. If ‘No,’ the page will expand to include an additional question. Enter your answer in the box provided. Once you have answered the first question, continue to the next question in the form.

7. Answer the remaining questions on the COI form using the boxes provided.
8. After entering all information, click ‘Save.’

9. After saving, you will be navigated back to the project page. To review the COI or make further edits, scroll down to the COI & Expertise section and click the applicable COI & Expertise Number to navigate back to the COI form. Until you submit the COI form for approval, you can return to the COI form and edit any of the information.

Note: If the information in this section is incorrect, please reach out to help@pcori.org. Please note that all changes to Key Personnel require PCORI approval.

Note: You have not yet submitted the COI form to the AO for approval. Complete the steps in section 2.2 in order to submit the COI form to the AO.
2.2 Submitting the COI Form for AO Approval (PI)
1. To submit the COI form for AO approval, scroll down to the COI & Expertise section.
2. Click the COI & Expertise Number to navigate to the form.
3. After reviewing the answers provided, scroll down to the Approval History section to submit the COI form to the AO for approval.
4. Click the ‘Submit for Approval’ button.
5. In the pop-up box, confirm that you would like to submit the form by clicking ‘OK.’

Note: After clicking ‘OK’, the form is no longer editable by the PI.

6. The page will refresh and an email notification will be sent to the AO indicating that a COI form has been submitted for their review and approval.

Note: The PI can scroll down to the Approval History section of the COI form to view the status of the approval.

2.3 Approving the COI Form (AO)
1. Once submitted for approval by the PI, the AO can now review and approve the COI form.
2. As the AO, navigate to the COI & Expertise section of the Project details page.
3. Click the applicable COI & Expertise Number in order to navigate to the COI form.

Note: Prior to approving the COI form, the AO can provide any updates, if necessary, by following steps 6-9 in section 2.1.
USF COI Program Processes

Organizational COIs
- Refer to Sponsored Research for standard review process

Training
- Sponsored Research Administrator training

COI Referral
- Sponsored Research refers specific RFPs and agreements to COI program via email

Reports for High Risk Areas
- COI Program conducts monthly SBIR/STTR report

Risk Assessment
- Conducted annually - includes a review of select Department of Defense projects
Addressing COI requirements

- Request modifications for certain agreements, if possible
- Review and request Interest Inventories, including USF Subrecipient Forms A/B from subrecipients, consultants, etc.
- Email investigators with specific requirements for proposal/award
- Draft letters/statements from COI Program templates
- Determine specific requirements for terms and conditions (e.g. reporting to sponsor or local management), and if external reporting is required, how to track ad hoc requirements
- Email request to notify COI office and/or hold setup if the proposal is awarded, including updates if any changes are made throughout the award
Questions?
Contacts

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• Ivana Neff: isehovic@usf.edu, 813-974-1596