SRS Quarterly BA Meeting
June 14, 2016
Welcome
UG! Uniform Guidance creates divergent COI standards

HOLLY BANTE, PHD
CONFLICT OF INTEREST OFFICE, OFFICE OF RESEARCH
Circular A-81
2 CFR Chapter I, Chapter II, Part 200 et al

“Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards” collectively referred to as “Uniform Guidance”

Effective Date: December 26, 2013
Implementation Date: December 25, 2014 and thereafter

Three sections specifically address COI

- 200.112 General Provisions
- 200.318 (c)(1)* Procurement Standards
- 200.318 (c)(2)* Procurement Standards

*thereafter implementation date
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.

- Requires Federal awarding agencies to establish a conflict of interest policy for Federal awards
- Requires a disclosure to the awarding agency of potential conflicts of interest in accord with that agency's policy
- Institutions should monitor agencies implementation
§ 200.318(c)(1) Procurement Standards

Based on A-110 Procurement Standards. Requires written standards of conduct. Expands COI definition to include a tangible personal benefit.

Tangible personal benefit??

§ 200.318(c)(2) Procurement Standards

If the non-Federal entity has a parent, affiliate, or subsidiary organization, requires written standards of conduct covering organizational conflicts of interest. “Unable or appears to be unable to be impartial conducting a procurement action”.

How is “affiliate organization” defined?

Implementation date initially July 2016

Delayed in September 2015 to July 2017
Chaos started in Spring/Summer 2015

- 200.112 Some federal departments are implementing their own COI policies as required
- Include provisions of 318(c)(1) and (c)(2)
- Differing definitions as to individual and organizational COI
- In UG, it is unclear whether the COI policies should apply to the research in grants or only to procurement actions
  - OMB FAQ: procurement only
  - Different agencies applying to research in RFPs or policies

RESULT: Some federal agencies are implementing standards NOW on research PROPOSALS or AWARDS
Types of COI

- **Individual**: Entity maintains policies on financial interests of researchers and/or staff responsive to federal or other needs.

- **Institutional**: No federal definitions. Understood to be when entity owns equity, intellectual property, and could receive financial gain.

- **Organizational**: Varies according to federal department. Initially FAR clauses. Some recently seen definitions:
  1. The existence of conflicting roles that might bias judgment
  2. Access to nonpublic information that will give the offeror an unfair competitive advantage
  3. Situation where an organization would appear to be evaluating the effectiveness of its own prior work
Many agencies have formally implemented or communicated their implementation of the COI aspects of the UG into final regulations or policy documents, including (but not limited to):

1. **EPA**: Government wide Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
2. **NEA**: General Terms and Conditions for Grants and Cooperative Agreements to Organizations
3. **DOE**: EDGAR 80.36(b)(3)a
4. **DOJ**: DOJ Grants Financial Guide
Lack of updated agency-wide policy/regulation specifically implementing the UG, but COI terms and conditions consistently creeping up in proposal solicitations and broad agency announcements; for example:

ARPA-E Business Assurances Form FAQ

“Potential Conflicts of Interest within Project Team:
The applicant is required to disclose potential conflicts of interest within the Project Team. An apparent or actual conflict of interest may exist where an individual or entity has different, and potentially conflict, duties or relationships with respect to other individuals or entities within the Project Team...Examples of potential conflicts of interest include, but are not limited to:
The PI for the Prime Recipient has an equity stake in a Subrecipient; the PI for a Subrecipient has a consulting arrangement with the Prime Recipient; or a Subrecipient is a subsidiary of or otherwise affiliated with the Prime Recipient.”
And other agency examples...

| Department of Energy | “At the time of submission, the applicant shall include information identifying potential, apparent, or actual organizational and individual conflicts of interest and proposed mitigation. This shall include the applicant, their team members, and senior/key personnel named in the application. Negative responses are also required. Prior to award, DOE reserves the right to require the submission of a Conflict of Interest Management Plan describing the applicants approach to managing conflicts of interest.” |
| Office of Naval Research, DARPA | “All facts relevant to the existence or potential existence of organizational conflicts of interest must be disclosed. The disclosure shall include a description of the action the offeror has taken or proposes to take to avoid, neutralize, or mitigate such conflict. Proposals that fail to fully disclose potential conflicts of interest will be rejected without technical evaluation and withdrawn from further consideration for award.” |
## How do reviews differ?

**Case study: PHS and Dept. of Justice**

<table>
<thead>
<tr>
<th></th>
<th>PHS</th>
<th>DOJ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Individual Disclosure</strong></td>
<td>$5,000, any private equity</td>
<td>Personal or financial</td>
</tr>
<tr>
<td>Threshold</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>$ from Non-Profits in SFI</strong></td>
<td>Yes—excludes academic, research orgs</td>
<td>All inclusive</td>
</tr>
<tr>
<td><strong>Organizational COI</strong></td>
<td>Not required</td>
<td>Requires Analysis</td>
</tr>
<tr>
<td><strong>Subrecipient Rule</strong></td>
<td>Own policy or prime’s</td>
<td>Must be included in response to DOJ</td>
</tr>
<tr>
<td><strong>Training Required</strong></td>
<td>Yes</td>
<td>Not stated</td>
</tr>
<tr>
<td><strong>Report to Sponsor</strong></td>
<td>If FCOI, at award and annually</td>
<td>At time of PROPOSAL—certify yes or no individual and organizational COI. MUST include written description of process, including identifying future COIs.</td>
</tr>
</tbody>
</table>
How do reviews differ?
Case study: PHS and Dept. of Defense

<table>
<thead>
<tr>
<th></th>
<th>PHS</th>
<th>DOD*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual Disclosure Threshold</td>
<td>$5,000, any private equity</td>
<td>Thresholds not specified; but organization required to disclose COIs, “organizational or otherwise”</td>
</tr>
<tr>
<td>Organizational COI</td>
<td>Not required</td>
<td>Referenced but not defined</td>
</tr>
<tr>
<td>Subrecipient Rule</td>
<td>Own policy or prime’s</td>
<td>Not specified</td>
</tr>
<tr>
<td>Training Required</td>
<td>Yes</td>
<td>Not specified</td>
</tr>
<tr>
<td>Report to Sponsor</td>
<td>If FCOI, at award and annually</td>
<td>At time of PROPOSAL—certify yes or no, if yes, provide details on proposed mitigation</td>
</tr>
</tbody>
</table>

*This example specifically from ONR FOA, but we are seeing this language consistently from DOD agencies.
How do reviews differ?
Case study: PHS and EPA

<table>
<thead>
<tr>
<th>Disclosure Requirements</th>
<th>PHS</th>
<th>EPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Include Interests of Immediate Family (definition)</td>
<td>Individual, Spouse, Dependent Children</td>
<td>Spouse (&amp; parents); Children (&amp; spouses); Parents (&amp; spouses); Siblings (&amp; spouses); Grandparents/children (&amp; spouses); Domestic partner (&amp; parents), including DPs of above individuals; Any individual related by blood or affinity whose close association with employee is equivalent of a family relationship.</td>
</tr>
<tr>
<td>“Competitive Advantage” Assistance from Agency Personnel</td>
<td>Silent</td>
<td>Unfair competitive advantage includes an EPA employee who reviewed and commented on or drafted all or part of an applicant’s proposal.</td>
</tr>
</tbody>
</table>

Investigators complete project specific form; then individual emails sent to investigators to answer: 1) all questions again with EPA “immediate family” definition and 2) competitive advantage assistance question. **TIME OF AWARD**
Adjusting Procedures: COI Office

- Typically, our processes provide for COI reviews to occur at JIT or award time.

- In certain situations given terms and conditions referenced in previous slides, proposal-stage reviews are needed (before a proposal is submitted!)
Adjusting Procedures: COI Office

- Work closely and communicate with COI Office to proactively identify and notify (with as much lead time as possible prior to proposal submission!) any pre-proposal terms and conditions requiring COI review/certification prior to proposal submission.

- COI Office is developing template language for negative and positive certifications per agency as well as templates for subawards:
  - Letter of intent
  - Subrecipient commitment form
  - Agency specific sub-recipient forms
Promoting (Actual!) Uniformity

- Comment submitted* in OMB’s “National Dialogue” forum
  - *Comment submitted by Clint Schmidt, J D, Assistant Director, Office for Research Protections, Penn State University.
- COGR: harmonizing COI regs
  - OMB
  - US Army Medical Research and Material Command

Make Conflict of Interest policies consistent across agencies

Since the publication of the Uniform Guidance UG, institutions have seen various Conflict of Interest (COI) terms and conditions embedded within broad agency announcements and proposal solicitations, despite the lack of formal agency-wide policies or guidelines in most cases. The specific requirements for what financial interests and relationships need to be disclosed, the nature and timing of reviews, and even definitions such as “conflict of interest” and “immediate family member” are unclear and/or vary slightly from one agency to another, making it more complex to administratively handle and more difficult to ensure compliance in each case. Additionally, many of these terms and conditions require COI certifications at the time of proposal submission as to whether or not a COI exists and if so, how the COI will be mitigated if the proposal is funded.

We strongly urge the federal agencies to harmonize COI requirements, particularly relative to policy scope, definitions, timing of COI reviews and determinations, and reporting requirements, in order to provide consistency across agencies and thereby reduce administrative burden. Given that the vast majority of research proposals are not funded, we specifically urge federal agencies to adopt the Public Health Service (PHS) timing for COI reviews and determinations (at the time of award/prior to expenditure of funds), rather than prior to proposal submission. A review of every potential COI for each research proposal submitted rather than a review relative to each research project actually funded constitutes a much higher burden on applicant institutions. Allowing COI reviews and determinations to occur at time of award would be more consistent with the policies and procedures institutions have already had to implement to comply with PHS’s 42 CFR § 50, an implementation that cost an average of $318,000 per institution according to the Association of American Medical Colleges COI Metrics Project*.

Finally, the UG calls for each agency to promulgate COI policies related to procurement, not research integrity. However, there is a lack of both clarity and consensus among institutions as to the focus of the COI provisions of the UG, and it appears these two types of COI have been conflated by agencies and institutions in the process of implementation. We request that federal agencies clearly establish and specifically articulate what types of terms and conditions or policies are required, and provide clarification to institutions on whether such requirements apply only to procurement arrangements and actions or are meant to address the potential for research integrity considerations as well.
Questions?

Contact COI Office
Holly Bante, PhD
COI Officer
556-5501

Carol Ann Taylor
Research Compliance Coordinator
558-4160

http://research.uc.edu/home/officeofresearch/COI.aspx
Open discussion with Deborah Galloway, Associate Vice President Research
## CoSAP Update

### Grant Account set-ups by FY and Month

<table>
<thead>
<tr>
<th>Month</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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<tbody>
<tr>
<td>July</td>
<td>64</td>
<td>67</td>
<td>89</td>
</tr>
<tr>
<td>August</td>
<td>64</td>
<td>87</td>
<td>90</td>
</tr>
<tr>
<td>September</td>
<td>75</td>
<td>78</td>
<td>84</td>
</tr>
<tr>
<td>October</td>
<td>65</td>
<td>65</td>
<td>48</td>
</tr>
<tr>
<td>November</td>
<td>47</td>
<td>40</td>
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<td>December</td>
<td>37</td>
<td>42</td>
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<td>February</td>
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<td>March</td>
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<td>April</td>
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<td>May</td>
<td>41</td>
<td>56</td>
<td>66</td>
</tr>
<tr>
<td>June</td>
<td>74</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Total Accounts:</td>
<td>664</td>
<td>694</td>
<td>710</td>
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<table>
<thead>
<tr>
<th>CoSAP Year to Date</th>
<th>2016 YTD</th>
<th>25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoSAP May</td>
<td>16</td>
<td>24%</td>
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</tbody>
</table>
Payroll Certification

- By budget period - Once a year at various times
- By project - PI approves everyone
- Electronic
- GCC currently working with Business Core Systems to make this a reality 😊
NIH Notice NOT-OD-15-105
Transition to Subaccounts in FY2016

- Identified with a Code type 4 - Extension (Example: 4 R01 ES00669-23)
- SRS Accounting has been proactively setting up both current grant year and the next year to make transition as smooth as possible
  - Allows for PCR’s to be completed early
  - Transition PO’s & other items as soon as possible
  - Department will still need to make sure all items are in place in order for expenses to hit the newest year (Protocols, Conflict of Interest etc.)
- New grants will allow pre-award costs
Closeout Reminders

- Remember only NIH has given us 120 days to complete FFR.
- Other agencies remain at 90 days.
- All are turning funding off after 120 days per OMB.
- Final expenses MUST BE TIMELY!
- Payroll adjustments and final invoices need to be in the system so we can draw the money down for them!
Any additional Questions?