Conflict of Interest: Who Decides and How?

NCURA
Western and Rocky Mountain Regional Meeting
Park City, Utah
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Compliance Director for Conflicts of Interest/Commitment
University of Colorado at Boulder
Meet Your Colleagues
Please indicate your gender:

1. Female
2. Male

76% Female
24% Male
<table>
<thead>
<tr>
<th>Percentage</th>
<th>Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>68%</td>
<td>NCURA Region VI - Western</td>
</tr>
<tr>
<td>28%</td>
<td>NCURA Region VII - Rocky Mountain</td>
</tr>
<tr>
<td>4%</td>
<td>Other NCURA Region</td>
</tr>
<tr>
<td>0%</td>
<td>Outside United States</td>
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</table>
What type of organization do you represent?

1. College or university with a medical school
2. College or university without a medical school
3. Private research firm
4. Governmental agency
5. Other
What type of position do you have:

1. Senior Level Administration
2. Grants and Contracts Officer
3. Study Coordinator
4. Faculty / PI
5. Other
How long have you worked in your current position?

1. 0 - 2 years: 35%
2. 3 - 5 years: 15%
3. 6 - 10 years: 38%
4. More than 10 years: 12%
Purpose of CoI Policies & Procedures:

- Identify potential conflicts of interest and manage them to the satisfaction of our funders
- Provide protection to the institution and to the disclosers from allegations of misconduct
- Provide protection to human subjects from inappropriate conduct of research
- Protect students and other subordinates from inappropriate use of their time and energy
Conflict of Interest Compliance

- Identify*
- Manage, Reduce, Eliminate
- Notify
Mechanisms for Identifying Conflicts:

- **Event-based**: some University activity requires the employee to disclose information relevant to potential conflicts of interest.
- **Annual**: employees disclose information relevant to potential conflicts of interest on an annual form.
- **When a conflict is identified**: the person with a potential conflict discloses to someone in authority when the discloser thinks s/he has a conflict.
Who decides when disclosure takes place?

- Annual: institution
- Event-based: institution
- When conflict identified: individual*
Do you know what kind of CoI identification process your institution uses?

1. Yes, I do know
2. No, I do not know

88% Yes, I do know
12% No, I do not know
Is your institution’s CoI identification...

1. Event-based?
2. Annual?
3. Discloser-driven?
4. Do not have one
5. I do not know

- Event-based: 48%
- Annual: 44%
- Discloser-driven: 0%
- Do not have one: 0%
- I do not know: 8%
Which is the “best” way to identify potential conflicts of interest?

• What is the “ideal” conflict of interest system?
• What should it do (or not do)?
Characteristics of an “ideal” system:

- Identify **every** possible conflict
- Require **minimal** paperwork/user friendly
- Be timely - **not interfere** with submissions/funding
- Get **all** the information needed
- Be **well-coordinated** with all research compliance offices (IRB, OSP, IACUC, etc.)
- Other? What do you think should be included?
## Event-based:
### Advantages and Disadvantages

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>- only folks with events do</td>
<td>- risk of missing potential conflicts</td>
</tr>
<tr>
<td>- accepted readily</td>
<td>- difficult to get all required</td>
</tr>
<tr>
<td>- easy to track to event</td>
<td>- greater risk to institution</td>
</tr>
<tr>
<td>- easy to coordinate</td>
<td>- other?</td>
</tr>
<tr>
<td>- all that is required by funders</td>
<td></td>
</tr>
<tr>
<td>- other?</td>
<td></td>
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</table>
## Annual: Advantages and Disadvantages

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>- ID all potential conflicts</td>
<td>- ID non-conflict situations</td>
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<tr>
<td>- everyone has one on file at any time</td>
<td>- has to be updated every year</td>
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<tr>
<td>- most protection for the institution</td>
<td>- even non-conflicted must submit</td>
</tr>
<tr>
<td>- other?</td>
<td>- have to relate to events somehow</td>
</tr>
<tr>
<td></td>
<td>- other?</td>
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</table>
What is the “Ideal System” for:

Identifying Every Possible Conflict

1. Annual
2. Event-based
What is the “Ideal System” to:
Minimize “paperwork” / user friendly

1. Annual
2. Event-based
What is the “Ideal System” for being:

Timely - not interfere with submissions/funding

1. Annual
2. Event-based

92%

8%
What is the “Ideal System” to:

Get all information needed to identify a conflict

1. Annual
2. Event-based
What is the “Ideal System” to be:
Well coordinated with other compliance offices

1. Annual
2. Event-based
What is the “Ideal System” for:

Other Considerations

1. Annual
2. Event-based
What did we decide is the “Ideal System”?

- Identify every possible conflict
- Minimize “paperwork” / user-friendly
- Timely – not interfere with submissions / funding
- Get all necessary information
- Well coordinated with other compliance offices
- Other considerations
Reality: Which are Most Important?

- Identify every possible conflict
- Minimize “paperwork” / user friendly
- Be timely – not interfere with submissions / funding
- Get all the information needed
- Be well-coordinated with all research compliance offices (IRB, OSP, IACUC, etc.)
- Other considerations
Please select the following items in rank order from Most Important to Least Important.

1. Identify every possible conflict
2. Minimal “paperwork”/ user-friendly
3. Timely - not interfere with submissions / funding
4. Get all necessary information
5. Well coordinated with other compliance offices
6. Other considerations
## Summary

<table>
<thead>
<tr>
<th></th>
<th>Annual</th>
<th>Event-based</th>
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<tbody>
<tr>
<td>Identify every possible conflict</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Minimize “paperwork”</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Timely – not interfere</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Get all necessary information</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Well coordinated with offices</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Other considerations</td>
<td></td>
<td>(was not determined)</td>
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So ... which system is right for your institution?

There is no one “right” answer – institution specific.

Consider the strengths and limitations of each identification system, then evaluate your institution’s needs, resources, values, etc.

Be flexible!
Training and Educational Outreach
Goals and Objectives

- to educate faculty and staff about University Conflict of Interest policies
- to support and maintain policy compliance
- to develop a standardized body of knowledge for all members of the research community
Discussion Item: Mandatory or Voluntary Participation

- Implementation and Enforcement Strategy
- Duty of Care and Responsibility
- Subject Matter Expert (SME) Recruitment
- Hiring Decisions / Conditions of Employment
- Compensation Issues
- Documentation, Records and Statistics
Should participation in CoI policy training be:

1. Mandatory
2. Voluntary

- 67% for Mandatory
- 33% for Voluntary
The majority has selected **mandatory participation.** Official records of attendance should be maintained by:

1. Human Resources
2. Research Education
3. College / Department
4. Both 1 & 3
5. All of the above
Discussion Item: Method of Delivery

- Identify and understand all target audiences
- Conduct detailed Needs Assessments
- Prepare “Feature / Benefit” tables for each proposed method of delivery
- Marketing and Promotional Strategies
- Evaluation Processes
- Administration Costs
Case Scenario:  
Method of Delivery

Options:
- Policy Letters, Emails & Web Postings
- Online Training Courses
- Classes, Workshops and Meetings

Desired Outcomes:
- Effective learning and retention (Program Quality)
- Broad-based attendance (Level of Outreach)
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<th>High</th>
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<td>1</td>
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<td>2</td>
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<tr>
<td>8</td>
<td>15%</td>
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</table>
Policy Letters, Emails & Web Postings: Level of Outreach

1. Low
2. ...
3. ...
4. ...
5. ...
6. ...
7. ...
8. High
Online Training Courses: Program Quality

1. Low
2. ...
3. ...
4. ...
5. ...
6. ...
7. ...
8. High
Online Training Courses:

Level of Outreach

1. Low
2. ...
3. ...
4. ...
5. ...
6. ...
7. ...
8. High
Classes, Workshops & Meetings: Program Quality

1. Low
2. ...
3. ...
4. ...
5. ...
6. ...
7. ...
8. High
Classes, Workshops & Meetings: Level of Outreach

1. Low
2. ...
3. ...
4. ...
5. ...
6. ...
7. ...
8. High
Take Home Points

- Focus on training program content and educational outreach objectives
- Evaluate and implement methodologies based upon your unique institutional culture
- Consider incorporating interactive technologies for instruction, data collection and assessment purposes
Any Questions?
What is your opinion ..... 

1. Strongly Agree
2. Agree
3. Disagree
4. Strongly Disagree
Reminder ..... 

Please return your ResponseCard®

Thank You!