

## Part 1

### Section I: Financial Conflict of Interest Program Review: Reporting Procedures

NOTES:

1. Each question or issue is drafted in a manner to allow the institution to document the existence of policies and procedures.
2. The term “investigator” is used here to include all personnel required to report under the institution’s policy. The institution’s meaning of investigator may include individuals considered “key personnel” and/or research staff with design, conduct and reporting responsibilities as well as administrative staff.
3. The questions are designed to guide the process and are not intended to be a full “audit”.

#### Section I.A. Policies

1. Policies and Procedures to follow when reporting financial interests and relationships have been written and distributed or communicated to investigators

Yes

No

Some are written

1.a. If you have different policies/procedures for different units, e.g., the medical center, the policies and procedures to follow when reporting financial interests and relationships have been written and distributed or communicated to investigators

Yes (USA hospitals have some SOPs on COI... need one comprehensive COI policy)

No

Some are written

Note: If you have different policies and procedures for different units, you may want to complete a survey and related sampling for each set of policies and procedures.

2. The delineation or definition of who reports is clearly defined in policy.

Yes

No

2.a. The terms "investigator" is defined in policy

Yes (defined under PHS/NSF reporting requirements)

No

2.b. the term "key personnel" is defined in the policy.

Yes (referred to as other persons responsible for the design, conduct or reporting of the research)

No

3. A threshold, if any, for reporting has been clearly defined in policy.

Yes

No

3.a. If the definition relies on "a significant financial interest," the meaning is clearly defined in policy.

Yes

No (not defined in COI policy.... definition specified on University Transmittal Form)

3.b. If the definition refers to "potential" or "perceived" benefits, these terms are clearly defined in the policy.

Yes

No

4. The policy provides for penalties or sanctions for nondisclosure and/or inaccurate disclosure of financial interests and relationships.

Yes (COI policy, pg 11)

No

4a. If Yes, the circumstances that would justify a penalty or sanction as well as the type of penalties or sanctions that might be imposed are defined.

Yes

No

4b. Provisions for penalties and sanctions are in writing.

Yes

No

Some are written

## Section I.B. Procedures

5. Processes are in place to make investigators aware of the reporting procedures and their responsibility for following them at the outset of a project.

Yes

No

5.a. Processes are in place to make investigators aware of the reporting procedures and their responsibility for following them during the conduct of a project when/if their financial interests and relationships change.

Yes

No

6. Standard, formal financial disclosure form(s) and procedures are made available to the investigators to report their financial interests and relationships.

Yes

No

6.a. If No, how do investigators disclose financial interests and relationship?

7. Investigators are required to submit additional documentation or information with their financial disclosure forms.

Yes

If Yes, the other documentation collected includes: If applicable,

- Attachment A: Categories of Employee Activities, Category B
- Attachment B: Categories of Employee Activities, Category C

No

8. Additional information regarding investigators' financial disclosures (i.e., follow-up information, supporting documentation, etc.) is routinely asked for and collected.

Yes

If Yes, the following additional documentation is routinely collected:

No

(Note: Not sure how this is routinely being handled at the departmental level)

9. The designated official(s) who solicits and reviews financial disclosure information from investigators is clearly identified.

- Yes  
 No

It is (by job title): Dept Chairs/Supervisors review annual disclosure forms  
Office of Research Compliance receives PHS/NSF disclosures

9a. The designated official(s) have clearly delegated responsibilities to other staff regarding the solicitation and review of financial disclosure information.

- Yes  
If Yes, what responsibilities are delegated and to whom (by job title):

No

10. Procedures for investigating allegations of nondisclosure and/or inaccurate disclosure of financial interests are in writing.

- Yes  
 No  
 Some are written

11. Over the most recent five years, are there any instances in which an investigator did not disclose or inaccurately disclosed a significant financial interest?

- Yes  
If Yes, the circumstances of, and the way in which, these instances were handled is documented.  
 Yes  
 No  
 No (Not that I'm aware of)

## Section II: Identifying Financial Conflicts of Interest

12. The process for reviewing financial disclosure information and criteria used for determining if a financial conflict of interest exists are clearly written and known to all involved in the process (e.g. administrator, Committee Members, Responsible Official)

Yes

No

Some are written

12.a. The criteria address "Relatedness" of conflicts to research activities.

Yes

No

12.b. The criteria address "Actual" as opposed to "Potential" or "Perceived" benefits or conflicts.

Yes

No

13. The information disclosed by an investigator regarding their financial interests and relationships is verified for accuracy.

Yes

No (**Go to Question 14**)

13a. The type of information that is verified includes:

13b. The procedures followed to verify the accuracy of the information include:

13c. These procedures are in writing?

Yes

No

Some are written

14. There is a conflict of interest committee.

Yes

No (**Go to Question 15**)

14a. The role and responsibilities of the committee in reviewing financial disclosure information, and determining if a financial conflict of interest exists, are clearly defined.

Yes

No

14.b. The process for appointing members, including special members, to the committee is clearly defined.

Yes

No

14.c. On average, the Committee reviews (number) \_\_\_\_ of financial disclosures in a year. **(none at this time)**

14.d. If the Committee plays a role in the management of conflict of interest management plans, on average, the Committee manages (number) \_\_\_\_ of conflict of interest management plans in a year. **(none at this time.. the committee periodically reviews case studies as an exercise)**

15. The procedures that are followed to ensure that financial conflicts of interest are properly reported to a funding source include:

The department chair conducts the initial review. If the review indicates a potential for financial conflict of interest, then the chair notifies the applicant and the college dean. The department chair composes a management plan and forwards the applicant's information to the Office of Research Compliance whom is responsible for reporting to funding agency within 60 days of such identification.

15a. These procedures are in writing and distributed to parties who need to know.

Yes

No

Some are written

### Section III: Managing Financial Conflicts of Interest

<p>16. Policies and procedures for determining how to manage, reduce, or eliminate identified financial conflicts of interest are clearly defined:</p> <p><input checked="" type="checkbox"/> Yes (only provide management template for Human Subjects Research)</p> <p><input type="checkbox"/> No</p> <p>16a. These policies and procedures are in writing</p> <p><input checked="" type="checkbox"/> Yes (posted on website. The IRB application has a dedicated section on COI and provides information regarding management plans)</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Some are written</p>
<p>17. The roles of the designated official(s) and/or the conflict of interest committee in determining how to manage, reduce, or eliminate a financial conflict of interest have been clearly defined.</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>17a. The roles of other university academic and administrative leadership are identified.</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p>
<p>18. Methods used generally to <u>manage</u> financial conflicts of interest include: (e.g. specific examples):</p>
<p>19. Methods used generally to <u>reduce</u> financial conflicts of interest include: (e.g. specific examples):</p>
<p>20. Methods used generally to <u>eliminate</u> financial conflicts of interest include: (e.g. specific examples):</p>
<p>21. Investigator's role in the development of their own conflict management plans is defined.</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No (NOTE: Role is defined for human subjects research via IRB application materials)</p>

22. The procedures for ensuring that investigators are managing, reducing, or eliminating the financial conflicts of interest as outlined in the conflict management plan are defined.

Yes

No

22a. These procedures are in writing

Yes

No

Some are written

23. The role of the designated official(s) and/or the conflict of interest committee in ensuring that the financial conflict of interest is managed, reduced, or eliminated is clearly defined.

Yes

No

23.a.. The role of other university academic or administrative staff in monitoring compliance with management plan is clearly defined.

Yes

No

24. Investigators are required to certify that they have complied with the conflict management plan.

Yes

If Yes, institutional forms they must submit, and/or procedures that they must follow, in order to certify compliance with the conflict management plan are developed and used.

- Yes - PI certifies annual disclosure at time of grant proposal
- VP for Research conducts annual audits of College for reporting compliance

No

25. There are procedures for handling instances of noncompliance with the conflict management plan.

Yes

No

25a. These procedures are in writing

Yes

No

Some are written

26. Policies that provide for the imposition of penalties or sanctions for noncompliance with the conflict management plan are in place.

Yes

If Yes, the circumstances that would justify a penalty or sanction as well as the type of penalties or sanctions that might be imposed are well defined.

Yes

No

26a. These policies are in writing

Yes

No

Some are written

## Section IV: Information and Guidance

27. Clearly defined information or guidance is provided to investigators regarding financial disclosure and financial conflicts of interest; these include written materials, such as trainings, websites, etc.

Yes

No

## Section V: Staffing and Administration

28. The program has adequate staffing to manage the process (e.g. review financial disclosure information and determine if a financial conflict of interest exists, etc.) (Exclude conflict of interest committee members.)

Yes (decentralized review process - conducted by dept chairs)

No

29. On average each staff member reviews (number) \_\_\_??\_\_\_ financial disclosures in a year.

30. On average each staff member spends (number) \_??\_ hours reviewing each financial disclosure

31. Data collection and review is by means of:

a) All Electronic or web-based systems

Yes

No (Note: HCCS has a COI tool (COI-SMART) for the management of COI disclosures. The tool manages the disclosure process on the front end and also helps manage the conflicts that are uncovered through the review process)

b) All paper

Yes

No

c) Some of each

Yes

No

## Section VI: Documentation

<p><b>Program documentation includes:</b> Institutions may want to review individual investigator disclosure and/or conflict management files to ensure that required and/or appropriate documents are in each investigator's file.</p>	<p>Yes</p>
<p>o <b>Written policies and procedures</b> that meet the Federal and state regulations for any and all agencies that the institution regularly conducts business with including the PHS/NIH and NSF</p>	<p><input checked="" type="checkbox"/></p>
<p>o <b>Institutional forms or checklists</b> that investigators can use to disclose their financial interests and relationships and those used to certify compliance with conflict management plans</p>	<p><input checked="" type="checkbox"/></p>
<p>o <b>Written information or guidance</b> your institution provides to investigators with regarding financial disclosure and financial interest and relationships</p>	<p><input checked="" type="checkbox"/></p>
<p>o <b>Other institutional forms or checklists</b> used by designated official(s), committee members, or other staff to review and/or verify financial disclosure information and determine if a financial conflict of interest exists.</p>	<p><input checked="" type="checkbox"/></p>

## PART 2: Sample Review of Financial Conflicts of Interest Reported in FY 200X

This form can be used to evaluate a sample of a specific reported financial conflict of interest. This evaluation can help validate the effectiveness of the general self-assessment conducted in Part 1. Institutions can review all documents against the procedures described in Part 1 above to test the adequacy and workings of the established processes

<b>Grant Number:</b>	<b>Report Date:</b>
<b>Project Title:</b>	<b>Investigator With Conflict:</b>
<b>Principal Investigator:</b>	<b>Investigator With Conflict:</b>
<b>1. The nature of the financial conflict of interest.</b> Please also include whether the conflict involved activities with outside entities (e.g., consulting, teaching, writing, participating on boards, etc.)	
<b>2. Compensation received by the investigator,</b> [ <u>how much</u> and <u>what type</u> of compensation was received e.g., travel reimbursement, fee, honorarium, per diem, royalty, expenses, and stocks]	
<b>2a. Was this information verified?</b> <input type="checkbox"/> Yes If yes, how and who verified this information:  <input type="checkbox"/> No	
<b>3. The procedures followed by the investigator(s) to report this significant financial interest were the same as those outlined in Part 1.</b> <input type="checkbox"/> Yes <input type="checkbox"/> No If no, please describe how the procedures used to report this significant financial interest differed from the procedures outlined in Part I.	
<b>4. The procedures that the designated official or conflict of interest committee used to identify this financial conflict of interest were the same as those outlined in Part 1.</b> <input type="checkbox"/> Yes <input type="checkbox"/> No If no, please describe how the procedures used to identify this financial conflict of interest differed from the procedures outlined in Part I.	

**5. For this grant, other significant financial interests were disclosed that were determined not to be a conflict of interest and, subsequently, not reported**

Yes

If yes, please provide a brief description of these other significant financial interests:

No

Cannot determine (Please explain):

**6. After completion of the review:**

This financial conflict of interest was managed.

This financial conflict of interest was reduced.

This financial conflict of interest was eliminated.

**7. The details of how this financial conflict of interest was managed, reduced, or eliminated are well documented in the management plan.**

Yes

No

**8. The procedures used to determine how to manage this financial conflict of interest were the same as those outlined in Part 1.**

Yes

No

If no, please describe how the procedures used to determine how to manage this financial conflict of interest differed from the procedures outlined in Part 1:

**9. Document any additional information regarding this sample review here.**