



Procedures

Disclosure Review and Management Process for USF System Research Projects (General)

University of South Florida
Office of Research & Innovation
Research Integrity & Compliance
Conflict of Interest Program

USF CONFLICT OF INTEREST PROGRAM

<p>USF Conflict of Interest Program Disclosure Review and Management Process</p>	<p>Revision 3: January 2015</p>
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Approved by:

Date:

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PART I GENERAL INFORMATION

1. Overview

A

Introduction

This is the Disclosure Review and Management Process to be used by the Conflict of Interest Program (COI Program), Research Integrity & Compliance (RIC).

B

Purpose

The purpose of this document is to provide guidance to the COI Administrator, administrative staff of the COI Program, and the COI Committee regarding the receipt, assignment, review, distribution and maintenance of Significant Financial Interests and Relationships disclosures submitted to the COI Committee for review and adjudication.

PART II RECEIPT OF DISCLOSURE

2. Receipt and Notification to COI Administrator

A Disclosure Receipt The disclosure review and management process begins when a disclosure is received in the COI Administrator’s inbox in the eCOI System (“Disclosure”).

PART III PRELIMINARY ADMINISTRATIVE REVIEW

3. Establish Jurisdiction

A Analysis and Determination The COI Administrator will review the Disclosure to determine whether review by the USF COI Committee is appropriate in the judgment of the COI Administrator. If review is not appropriate, the COI Administrator will notify the administrative staff to redirect the Disclosure to the appropriate review body or to handle in some other manner as directed by the COI Administrator.

4. Notification and Assignment to Review Process

A Sufficiency of Information

If the Disclosure is incomplete, the COI Administrator will contact the Interested Person to request the missing information or will delegate this task to the administrative staff. The request will be repeated to the Interested Person until the information is received, alternative arrangements are made with the Interested Person, or the Disclosure is withdrawn due to divestiture of the interest or discontinuation of the Interested Person in the research.

B Disclosure Assignment to Review Process

Once the Disclosure is deemed complete by the COI Administrator, the COI Administrator will review the Disclosure and determine whether the Disclosure will be reviewed/approved by:

- Administrative Approval (Part IV.6)
- Expedited Committee Review (Part IV.7)
- Convened Committee Review (Part IV.8).

Upon initial evaluation by the COI Administrator, if there is any question about the qualification of the Disclosure for administrative approval based on the review criteria or other circumstances that the COI Administrator believes would be pertinent to the Committee, the COI Administrator will submit the Disclosure to the Committee for a full Committee review.

(See “USF COI Committee Operating Procedures” regarding criteria for administrative approval and expedited review by Committee.)

5. Preparation of a Management Plan

A Preparation of Management Plan

The COI Administrator will prepare a Proposed Management Plan based on the information provided in the Disclosure and any other information received from the Interested Person or from other sources, and will present the Proposed Management Plan to the Interested Person for review and comment.

Once the Interested Person has reviewed the Proposed Management Plan and made any corrections or modifications, the Proposed Management Plan will either be:

- approved by the COI Administrator in accordance with the criteria established for administrative approvals (Part IV.6.B.); or
- will be presented to the COI Committee with the Disclosure to be reviewed by the Committee.

(See “USF COI Committee Operating Procedures” regarding criteria for administrative approval by COI Administrator.)

PART IV SUBSTANTIVE REVIEW OF DISCLOSURE

6. Administrative Approval

**A
Analysis and
Determination** The COI Administrator will analyze the elements of the Disclosure to determine whether approval by administrative review is appropriate in the judgment of the COI Administrator.

If administrative approval is not appropriate, the COI Administrator will assign the Disclosure to a Committee meeting in the eCOI System.

**B
COI
Administrator
Approval**

If approval by administrative review is appropriate, the COI Administrator will:

- prepare a Final Management Plan;
 - upload the Management Plan to the eCOI System; and
 - approve the Disclosure in the eCOI System .
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7. Expedited Committee Review

**A
Determination
of Meeting
Process**

If the Disclosure has been assigned to an Expedited Committee Review Process, the COI Administrator will determine whether a telephonic committee meeting (via conference call) or an in-person meeting would be most appropriate. Factors that the COI Administrator may consider include, but are not limited to:

- the time frame within which the review must occur;
- the availability of a quorum of voting members to meet simultaneously in person; and
- the nature and complexity of the disclosure.

**B
Telephonic
Meeting**

Notification of members. The COI Administrator will advise the COI Committee members via the eCOI System of the need for a telephonic Committee meeting and the justification for the expedited review.

Staff duties. Administrative staff will:

- coordinate the conference call with the voting members (and any others who wish to attend) and set the call for the earliest available time when a quorum of voting members can attend;
- update the public schedule on the COI Program website to provide the requisite public notice for the meeting at least seventy-two (72) hours in advance of the meeting, with the conference call information included;
- arrange the conference call with the service provider; and
- notify the attendees of the time and date of the call and the conference call number and other pertinent information.

Telephonic meeting. At the appointed time, the members and the COI Administrator will attend the conference call and, upon establishing a quorum, will discuss and take action on the agenda.

8. Convened Committee Review

A Regularly Scheduled Meeting

Notification of members. The regular meeting schedule of the COI Committee is posted on the COI Program website.

Additionally, the COI Administrator will notify the COI Committee members of the upcoming meeting date, time and location prior to the meeting and will create the agenda for the meeting via the eCOI System.

Convened meeting. The meeting will begin upon obtaining a quorum of voting members. The Chair will conduct the meeting and the action of the Committee on the agenda will constitute the official Committee action.

B Specially Convened Meeting

Where the situation warrants, and in the determination of the COI Administrator, a specially convened meeting may be called to discuss and/or take action on an agenda item.

Notification of members. The COI Administrator will notify the COI Committee members of the upcoming meeting date, time and location prior to the meeting and will create the agenda for the meeting via the eCOI System.

Convened meeting. The meeting will begin upon obtaining a quorum of voting members. The Chair will conduct the meeting and the action of the Committee on the agenda will constitute the official Committee action.

PART V COMMITTEE ACTION

9. Approval

A Analysis and Determination

The COI Committee will analyze the elements of the Disclosure to determine:

- whether approval by the Committee is appropriate; and
- whether the Proposed Management Plan is effective to reduce or eliminate bias in the design, conduct or reporting of the research.

B Approval of a Management Plan

The COI Committee will review and discuss the Disclosure, including the Proposed Management Plan prepared jointly by the Interested Person and the COI Administrator. If the Committee action is to approve the Disclosure and Management Plan, the approval may or may not require modifications to the Management Plan:

Management Plan Approved without Modifications. If this is the action elected by the Committee, the COI Administrator will prepare a Final Management Plan and upload it to the eCOI System.

Management Plan Approved with Modifications. If this is the action elected by the Committee, the COI Administrator will:

- notify the Interested Person of the Committee's comments; and
- prepare the proposed modifications; or
- request and incorporate the information from the Interested Person, or ask the Interested Person to incorporate the requested information into the Proposed Management Plan; and
- prepare a Final Management Plan.

The COI Administrator will then upload the Final Management Plan to the eCOI System.

10. Deferral

A Analysis and Determination

If the COI Committee determines that it cannot approve the Proposed Management Plan based on the information provided, and:

- the issues presented cannot be resolved at the currently convened meeting due to lack of required information or for any other reason; and
- the issues involved require further discussion by the full Committee,

then the Committee may elect to defer the matter for discussion at a future meeting.

B Deferral

After the meeting, the COI Administrator will identify the issues resulting in the deferral and initiate resolution of the issues via communication with the Interested Person or other sources.

Prior to the next regularly scheduled meeting for the COI Committee, the COI Administrator will forward the requested information pertaining to the deferred disclosure to the Committee members via e-mail, if appropriate. If the requested information is not conducive to communication via e-mail, the COI Administrator will present the information at the next regularly scheduled COI Committee meeting.

The COI Administrator will then record the deferred Management Plan in the eCOI System and assign the Management Plan to the next regularly scheduled COI Committee meeting.

11. Requiring Divestiture or Non-Participation

A Analysis, Determination and Action

If the COI Committee determines that the financial interest disclosed is not manageable and the only resolution of the conflict of interest would be for the Interested Person either to divest the financial interest, or not to participate in the related USF System Research Project, then following the Committee meeting, the COI Administrator will draft correspondence to the Interested Person.

Such correspondence to the Interested Person shall include:

- the date of the Committee meeting;
- a summary of the Committee's discussion leading to the decision that divestiture or non-participation is required in order for the study to proceed;
- a request that the Interested Person notify the COI Administrator of his/her decision.

Once the COI Administrator receives notification from the Interested Person of his/her decision, the COI Administrator will Administratively Withdraw the Interested Person's disclosure in the ARC system and include a notation as to the reason for withdrawal (e.g. the Interested Person opted to divest so a conflict of interest no longer exists; the Interested Person did not wish to divest so the USF System Research Project cannot proceed, etc.).