

1 **USF Conflict of Interest in Research Committee**
2 **Operating Procedures**

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4 **Effective: July 2007**
5 **Revised: March 2020**
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8 **COMMITTEE COMPOSITION & TERM**
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11 **Members**

At least nine voting members, including

- 12 1. Three faculty members representing the USF Health Core
- 13 facilities (College of Medicine, College of Nursing, College
- 14 of Public Health, College of Pharmacy).
- 15 2. Three faculty members from other Colleges.
- 16 3. Two faculty member clinicians who conduct human
- 17 subjects research.
- 18 4. One faculty member who conducts basic sciences
- 19 research.
- 20 5. The Director of the USF Health Office of Faculty Affairs.
- 21 6. One community representative.

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24 Members can serve in more than one category. For example,
25 a member of the USF College of Medicine can also serve as a
26 member who conducts human subjects research.

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28 Members are appointed by the Sr. Vice President for
29 Research, Innovation & Knowledge Enterprise or designee.
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32 **Ex Officio**
33 **(Non-Voting)**

- 34 1. The USF Conflict of Interest in Research Program
- 35 Administrator.
- 36 2. A representative from USF Research & Innovation,
- 37 Sponsored Research.
- 38 3. A representative from the Office of the General Counsel.
- 39 4. A representative from USF Research & Innovation,
- 40 Research Integrity & Compliance
- 41 5. *Ad Hoc*: A representative from any affiliate or school for
- 42 which the Committee reviews a COI disclosure.

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46 **Alternates**

One or more alternates may be identified to serve by the Sr.
47 Vice President for Research, Innovation & Economic
48 Development or designee and will be invited to attend when it
49 is anticipated that the number of voting members in
50 attendance at a convened meeting of the Committee will not
51 constitute a quorum of the voting membership.
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Chair Appointed by the Sr. Vice President for Research, Innovation & Economic Development or designee.

Term Voting members shall serve for a one year term, which may be renewed. Ex-officio members shall serve for the duration of the term of office.

PRINCIPLES, ROLES & RESPONSIBILITIES

Charge

Primary **Financial Conflict of Interest (FCOI) Review & Management.** To review federally-funded project-specific disclosures submitted through the e-COI system and related documents of USF employees who have a financial interest or external commitment related to a USF Research Project funded by a federal agency or Certain Agencies & Extramural Sponsors¹, and to develop appropriate safeguards and/or review proposed FCOI management plans to ensure that the disclosing person’s (“Interested Person’s”) financial interest will not bias the design, conduct or reporting of the USF Research Project.

General COI Review & Management. To review potential Institutional Conflicts of Interest and individual Significant Financial Interest and Relationships Disclosures submitted through the e-COI system and related documents of USF employees who have a financial interest or external commitment related to a USF Research Project and to develop appropriate safeguards and/or review proposed management plans to ensure that the Institutional Conflict of Interest or Interested Person’s financial interest will not bias the design, conduct or reporting of the USF Research Project.

Secondary To implement, oversee and enforce the individual conflict of interest in research provisions of USF Policy 0-309, *Individual Conflicts of Interest in USF Research Projects and USF Financial Conflict of Interest (FCOI) Policy* and USF Policy 0-317, *Institutional Conflicts of Interest in Research (“Policies”)* and to recommend modifications of such provisions as needed to accomplish the objectives of the Policies and the requirements of the federal regulations.

¹ Certain Agencies & Extramural Sponsors is the term used to denote those non-PHS entities that have adopted the PHS regulation regarding objectivity in research. For a current list of such Agencies & Extramural Sponsors, please see the COI website: <https://www.usf.edu/research-innovation/research-integrity-compliance/ric-programs/conflict-of-interest/coi-terms.aspx>

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In cooperation with the USF IRB, to fulfill the University’s ethical obligation to identify and consider institutional and individual conflicts of interest that might affect the relationship with human subjects participants in research or the outcome of the research, and to manage such conflicts.

To review justifications by an Interested Person to rebut the presumption that he or she may not conduct human subject research.

To monitor the management of identified conflicts of interest in research during the conduct of the research.

To monitor federal requirements governing the conflict of interest in research and to respond to internal and external inquiries pertaining to conflicts of interest in research and any policies or practices of the Committee.

To serve in an advisory capacity, as may be requested by USF administrators, on matters pertaining to conflicts of interest in research.

Scope of Review

The USF Conflict of Interest in Research Committee (“the COI Committee” or “the Committee”) reviews financial interest and relationships disclosures of persons who are employees of USF and who have a financial interest or external commitment related to a USF Research Project. The Committee reviews disclosures of the institution’s interests (those held by USF and its Covered Officials) related to USF Research Projects.

**Jurisdiction to
Address
Noncompliance**

The COI Committee may take action to monitor compliance with the terms of an approved management plan, may communicate with the Interested Person regarding the terms or implementation of the management plan, may notify or refer noncompliance matters to other appropriate committees or persons, and may withhold or withdraw the COI Committee’s approval of a management plan to address a disclosed conflict of interest in research, requiring that the Interested Person may not participate in the research study unless the conflicting interest is divested.

The COI Committee may not impose any disciplinary action or otherwise take any action against the terms of the Interested Person’s employment.

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**PRELIMINARY
ADMINISTRATIVE
REVIEW**

Jurisdiction to Review

Upon receipt of a disclosure of financial interests, the COI Administrator will review the information provided and ensure that the requested review falls within the jurisdiction of the COI Committee.

Information Check

If the disclosure of financial interests falls within the COI Committee’s jurisdiction, the COI Administrator will review the disclosure and related materials to ensure that adequate information has been provided to enable a meaningful review of the disclosure:

- ✓ A description of the research study.
- ✓ A detailed description of the Interested Person’s role in the research study (i.e., what aspects of the study are under the Interested Person’s control)
- ✓ The nature and amount of the Interested Person’s or institution’s financial interest or relationship.

Optional:

The Protocol, sponsor information on the study, or other available description of the research procedures and details of the study.

A copy of the research agreement with the sponsor, if applicable.

**Interested Person
Contact**

The COI Administrator will arrange to meet with the Interested Person if necessary to assist the Interested Person with the development of a management plan. The COI Administrator will communicate with the Interested Person as needed to ensure that he/she is aware of the process and time frame for the review and management of the disclosed interests. If additional information or documents are necessary to perform a meaningful review, the COI Administrator will request this information.

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3 **Administrative**
4 **Approval**

5 If the study qualifies for administrative approval, the COI
6 Administrator will conduct an administrative review of the
7 Interested Person’s disclosure.

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9 A disclosure of an individual interest will qualify for
10 administrative approval if:

- 11 1. The study at issue is not a USF Research Project
12 Funded by the NSF or PHS or Certain Agencies or
13 Extramural Sponsors; and
- 14 2. the study at issue does not involve an institutional
15 conflict of interest; and
- 16 3. the interest disclosed is not an intellectual property
17 interest in an article being evaluated in or otherwise
18 significant to the research study; and
- 19 4. the value of the Interested Person’s interest is less
20 than \$10,000 and the Interested Person owns less than
21 5% ownership equity; or
- 22 5. the interest disclosed is greater than \$10,000 or a
23 greater than 5% equity interest, but the Interested
24 Person’s role in the study is tangential or very minimal
25 (e.g., performing injections on the study).
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28 The COI Program will administratively review Institutional
29 Conflicts of Interest when the following three criteria are met
30 and it is determined that formal management is not
31 necessary:

- 32 1. The research project being conducted is not
33 human subjects research; and
- 34 2. A Covered Official’s equity interest is in a publicly
35 traded entity. Additionally, if the Covered Official is on
36 the Board of Trustees, the interest is the salary from
37 their primary place of employment and the Covered
38 Official does not also have an equity interest; and
- 39 3. The Covered Official has no responsibility for oversight
40 of the research (e.g. CO is Dean of College of
41 Education and research is being conducted in USF Health).
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43 A disclosure may also qualify for administrative approval if it
44 is very similar to an existing, Committee-approved disclosure,
45 and the management plan would be the same.
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47 Upon initial evaluation by the COI Administrator, if there is
48 any question about the qualification of the disclosure for
49 administrative approval based on these criteria or other
50 circumstances that the COI Administrator believes would be
51 pertinent to the Committee, the COI Administrator will consult

1 the Chair to determine whether to submit the disclosure to the
2 Committee for a full Committee review.

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4 All disclosures reviewed and approved by administrative
5 procedures will be reported to the convened COI Committee.
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9 **EXPEDITED REVIEW**

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12 **Criteria**

A disclosure may qualify for expedited review (i.e. review prior to the next convened meeting) by the COI Committee if:

- 13 1. there is a legitimate business need or other good cause
14 to review the study on an expedited basis rather than
15 on the Committee's regularly scheduled meeting date
16 (e.g. a disclosure has been deferred pending
17 substantive changes or clarifications, a quorum was
18 not achieved at the regular meeting, etc.); and
19 2. the Interested Person or PI of a study with a related
20 institutional interest requesting the review is not
21 primarily responsible for the circumstances
22 necessitating the expedited review.
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26 Review of disclosures by expedited review is subject to a
27 request by the Interested Person or PI of a study with a
28 related institutional interest and at the discretion of the COI
29 Administrator and COI Chairperson.
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32 **Determination of
33 Meeting Format**

If a disclosure qualifies for expedited review, the COI Administrator will determine whether a telephonic Committee meeting (via conference call) would be appropriate. Factors that the COI Administrator may consider include, but are not limited to,

- 34 • the time frame within which the review must occur;
- 35 • the availability of a quorum of voting members to meet
36 simultaneously in a conference call; and
- 37 • the nature and complexity of the disclosure.
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44 **Committee Action**

The official action of the COI Committee will be the action of a quorum of the voting members via telephonic vote on an agenda item or, if warranted, a subsequent electronic mail response following the voting members' review of information requested during the conference call.
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2 **CONDUCT OF MEETING**
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5 **Quorum**

The minimum number of members of the COI Committee necessary to conduct the business of the Committee is half of the total voting members plus one (or, the majority).

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9 ***Electronic or Telephonic Meetings.***

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11 *Telephonic attendance by members at convened meeting.*
12 While a member's presence at a regularly scheduled meeting
13 is preferred, a member attending a meeting telephonically will
14 be counted in the quorum for that meeting.

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16 *Electronic or telephonic meeting of Committee.* The action of
17 a quorum of the voting members via telephonic vote on an
18 agenda item will constitute official Committee action on the
19 agenda item.
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24 **Conflict of Interest**
25 **of a Committee Member**

26 Recusal of the member from voting is required whenever any
27 member has an actual or apparent conflict of interest with
28 regard to any matter under review. Conflicts of Interest of
29 Committee members may include personal conflicts,
30 professional conflicts or financial conflicts. The member may
31 remain on hand prior to discussion and voting to answer
32 questions pertaining to the Committee's review, at the option
33 of the Committee. Pursuant to Florida Statutes §286.012,
34 members are prohibited from abstaining from a vote unless
35 there is, or appears to be a conflict of interest as defined by
36 the Florida Code of Ethics for Public Officers and Employees
37 (Florida Statutes §112.313).
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40 **Procedure for**
41 **Review of Disclosures**

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1. As stated previously, the COI Administrator will identify whether all necessary information has been provided by the Interested Person or appropriate departments (for institutional interests) for adequate Committee review. If not, the review must be postponed until such information has been provided.
 2. The COI Administrator will identify whether the USF Research Project involves human subjects or whether the results of the research will be used to support the design/conduct of a subsequent clinical study. If so, the COI Committee should, as a first principle, determine whether there are compelling circumstances to permit the activity.

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Compelling circumstances are those facts that convince the COI Committee that an Interested Person should be permitted to conduct human subjects research, taking into account **the following factors:**

1. the nature of the research,
2. the magnitude of the **significant financial interest** and the degree to which it is related to the research,
3. the extent to which the **significant financial interest** could be directly and substantially affected by the research,
4. the degree of risk to the human subjects involved that is inherent in the research protocol,
5. the extent to which the Interested Person is uniquely qualified to perform a research study with important public benefit, and
6. the extent to which the interest is amenable to effective oversight and management.

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3. When an Interested Person is permitted to conduct human subjects research, the interest must be subject to appropriate management controls so that the interest does not adversely affect human subjects. If there are reasonable and/or compelling circumstances to permit the activity, the Committee should determine:
 - a. whether the financial interest will adversely affect the protection of participants in terms of the criteria for IRB approval; and
 - b. whether the financial interest will adversely affect the integrity of the research.
4. The COI Administrator, in consultation with the Committee, is responsible for designing and implementing a management plan for the conflict as well as appropriate monitoring procedures, if required by the Committee [see **Evaluating Compelling Circumstances, Developing a Management Plan** and **Monitoring Mechanisms** in this Section].

An appropriate management plan may include disclosure of the interest to the participants in the research, but

1 *disclosure alone is not sufficient to manage the interest.*
2 Additional management controls for human subjects
3 research can include disqualifying the Interested Person
4 from discussing the research study and/or consenting
5 potential subjects. For institutional interests, referral to an
6 external IRB may be an appropriate management control.

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10 5. The COI Committee must identify whether the financial
11 interest will have a direct effect and/or substantial impact
12 on the design, conduct or reporting of the USF Research
13 Project. If the USF Project is funded by PHS or Certain
Agencies or Extramural Sponsors, *then the COI
Committee must determine whether the interest is an
FCOI.*

Direct effect occurs where the outcome of the research will be directly relevant to the development manufacturing or improvement of products or services of the business entity (secondary interest).

Significant impact occurs where the value of the business entity its earnings or the sales of its products (or it is a proposed subcontractor or participant in the federally funded project) will be materially affected by the outcome of the research.

E.g., a direct effect/significant impact should be presumed in circumstances where the purpose of the research is to test the safety or efficacy of a product or invention in which the Interested Person has a stake either as the inventor of the product or as an owner or investor in the business entity licensing or manufacturing the product. Also, the COI Committee should consider less obvious impacts such as the influence of the research study on the allocation of lab space and resources.

- 14 6. If an Interested Person's interest is confirmed as (based on
15 the determination of the RFD Committee) or independently
16 determined by the Committee to be an FCOI, the
17 Committee must implement an FCOI Management Plan.

The FCOI Management Plan will include, at minimum, the following specific elements, which elements shall also be included in the FCOI Report to the PHS or Certain Agencies, Foundations & Extramural Sponsors as required under Section III, 11., below:

- (i) Project Number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- (vii) A description of how the financial interest relates to the PHS-funded research and the basis for USF's determination that the financial interest conflicts with such research; and
- (viii) A description of the key elements of USF's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the research project;
 - (B) Conditions of the management plan;
 - (C) How the management plan is designed to safeguard objectivity in the research project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and
 - (F) Other information as needed.

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7. The COI Committee must identify whether other conditions exist that suggest close ties between the research and the related financial interest. For example,

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- The research is performed jointly with an investigator representing the business entity;
- The research is conducted at the facility of the business entity;
- The Interested Person has a significant ownership interest in the entity;
- The Interested Person has the opportunity to receive substantial financial benefits from the entity (e.g., bonuses, stock options); or
- The Interested Person has a long-term or ongoing consulting relationship with the entity.

8. The following situations may merit advisory consideration by the Committee (and possible referral to the administrative entity responsible for oversight of such matters):

- Any indications that the arrangement may not be an “arm’s length” transaction (e.g., grants of an equity interest to an individual that provide disproportionate compensation relative to 1) the standard share of royalties a faculty member might receive for technology licensed to an unrelated company, or 2) the services provided (compensation should be fair market value for the services provided));
- Licensing of inventions covering basic research that may cause the licensee to compete with the institution for grant funding;
- Any limits on the freedom to publish, other than short delays allowing a sponsor to comment or to permit filing of patent applications (or disclosures).
- Whether University facilities and other resources will be used to support the secondary interest, and, if so, whether costs are being fully recovered by the University;
- Whether the private sponsorship/financial interest could affect students' academic progress, and/or whether there is an employment relationship between students working on the project and the sponsor, and/or whether there is free exchange of information and technical interaction between personnel working on the sponsored project and related USF Research Projects on campus; and/or whether there is an open research environment for the project;
- Whether all technology has been disclosed to Technology Transfer Office, Patents & Licensing; and /or whether the Interested Person is involved in setting terms of licensing the technology.

1 9. The COI Committee must consider whether the
2 management controls proposed are sufficient to eliminate or
3 reduce the Interested Person and/or institution’s influence in
4 the **design** and/or **conduct** of the research study and/or the
5 **reporting** of the research results. If no formal management
6 plan has been proposed, the COI Committee may determine
7 that the research may proceed based on the management
8 controls proposed in the disclosure, may require that a formal
9 management plan be developed by the COI Administrator and
10 the Interested Person, or may determine that the research
11 may not proceed. As a general rule, an Interested Person
12 should not be directly engaged in aspects of the research
13 project that could be influenced inappropriately. If a formal
14 management plan is required or proposed, the Committee will
15 determine:

- 16 a. (if human participants are involved) whether the
17 financial interest will adversely affect the protection of
18 participants in terms of the criteria for IRB approval;
19 and
 - 20 b. whether the financial interest will adversely affect the
21 integrity of the research;
- 22 and determine whether a management plan is adequate
23 based at minimum on these criteria.

24 10. Finally, the COI Committee will take action on the
25 disclosure (approve, approve pending modifications or defer).

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27 **Evaluating**
28 **“Compelling**
29 **Circumstances”**

30 It is the University’s policy that an Interested Person may not
31 participate in a research study involving human subjects
32 absent “compelling circumstances”. Whether the
33 circumstances are deemed compelling will depend in each case
34 upon the nature of the science, the nature of the conflict of
35 interest, how closely the conflict of interest is related to the
36 research, the degree to which the conflict of interest, specifically
37 any significant financial interests attributable to the real or
38 perceived conflict of interest may be affected by the research, the
39 degree of risk to the human subjects, the extent to which the
40 Interested Person is uniquely qualified to perform the research
41 study, and the extent to which the conflict of interest is amenable
42 to effective oversight and management.
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45 **Developing**
46 **a Management Plan**

47 Some circumstances of a research study provide inherent
48 management controls that can be considered by the

1 Committee as part of the management plan. These include,
2 but are not limited to:

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- 4 ▪ Objective outcomes that cannot be manipulated by the
- 5 Interested Person (e.g., an objective read-out of a
- 6 device);
- 7 ▪ Multi-center trials in which the site of the Interested
- 8 Person does not provide a disproportionate percentage of
- 9 the research results;
- 10 ▪ Peer review or independent testing of research results
- 11 prior to further dissemination of results or influence of the
- 12 results on the secondary interest;
- 13 ▪ Interested person will be blinded;
- 14 ▪ Multiple non-interested investigators taking part in the
- 15 study.
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17 Beyond the inherent management controls that may be
18 present in a research study, useful criteria and principles for
19 developing a management plan include:

20 ***Disclosure***

- 21 ▪ The Interested Person makes disclosures to the
- 22 research sponsor.
- 23 ▪ The Interested Person makes disclosures to potential
- 24 publishers of the research findings.
- 25 ▪ The institution's interests are disclosed to potential
- 26 publishers of the research findings.
- 27 ▪ The Interested Person discloses to students and
- 28 research associates his or her financial interests or
- 29 relationships.
- 30 ▪ The Interested Person discloses his or her financial
- 31 interests or relationships and/or the institution's
- 32 interests are disclosed to human subjects in the
- 33 research informed consent document (subject to
- 34 review and approval of the IRB of such disclosure and
- 35 any suggested language).

36 ***Oversight***

- 37 ▪ An ad hoc oversight committee reviews the USF
- 38 Research Project on a periodic basis to be
- 39 determined by the Committee.
- 40 ▪ Research data are managed by independent
- 41 investigators or an existing multi-center data oversight
- 42 committee.
- 43 ▪ Certain aspects of the research study conducted by the
- 44 Interested Person are monitored by an independent
- 45 party.
- 46 ▪ Re-review of the research study by the COI Committee
- 47 at intervals to be determined by the COI Committee.

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Divestiture or Removing the Situation

- The Interested Person is replaced as principal investigator by an independent investigator with no relevant financial interest.
- Research plans are modified or portions of the research are transferred to independent investigators.
- The Interested Person removes himself or herself from supervision of non-interested individuals conducting the research.
- The Interested Person resigns from a board or executive position.
- The Interested Person recuses himself or herself from board deliberations involving his or her own research.
- The Interested Person divests equity in a company that is sponsoring his or her research.

Committee Action

Following review and discussion of a disclosure, the Committee may take any of the following actions:

1. **Approval.** By approving a disclosure/management plan, the Committee is stating that the design, conduct, and reporting of the research will not be subject to bias due to the Interested Person’s secondary interest or that the management plan presented is sufficient to protect the integrity of the research from bias due to the Interested Person’s secondary interest. No further action by the Interested Person is necessary, except to comply with the notification requirements of USF Policy 0-309, to comply with the management plan, and to follow any additional instructions by the Committee for subsequent periodic review of the research study. Upon approval by the Committee, the research may proceed in accordance with any conditions imposed by the management plan, *following approval of the USF Research Project by all other required compliance review committees or subsequent reviewing bodies with final authority in the matter.* For studies involving human subjects: the reviewing IRB will have the final authority to determine whether the conflicting interest has been adequately managed and whether the research may proceed notwithstanding approval by the COI Committee. Additionally, the reviewing IRB can impose additional management controls regarding the Interested Person’s financial interests: however, the reviewing IRB cannot take away from the management controls implemented by the COI Committee. Any concerns by the reviewing IRB regarding the management controls applied by the COI Committee should be communicated in writing to the COI Administrator and COI Committee Chairperson.

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- 2. **Approval, pending minor changes or clarifications.** The Committee may approve the disclosure/management plan pending minor changes or clarifications, which may be reviewed and approved by the Chair or COI Administrator without further action by the Committee. Upon approval by the Chair or COI Administrator, the research may proceed in accordance with any conditions imposed by the revised management plan, *following approval of the USF Research Project by all other required compliance review committees or subsequent reviewing bodies with final authority in the matter. For studies involving human subjects:* the reviewing IRB will have the final authority to determine whether the conflicting interest has been adequately managed and whether the research may proceed notwithstanding approval by the COI Committee. Additionally, the reviewing IRB can impose additional management controls regarding the Interested Person’s financial interests: however, the reviewing IRB cannot take away from the management controls implemented by the COI Committee. Any concerns by the reviewing IRB regarding the management controls applied by the COI Committee must be communicated in writing to the COI Administrator and COI Committee Chairperson.

- 3. **Deferral.** The Committee may defer action on the disclosure until a future meeting if the revisions or clarifications needed are so substantive as to require review by the full Committee before approval may be granted. A deferred disclosure means that the research may not proceed until the disclosure has been reviewed and approved by a quorum of the Committee at a subsequent meeting.

**Documentation of
Committee Action**

The COI Committee will document its findings and the basis for any recommendations to permit or to recommend against permitting an Interested Person to conduct the proposed research activity via ARC, or to allow or disallow a study with a related Institutional Conflict of Interest to be conducted. The requirement of documentation shall be met by the Review Complete function in the e-COI system and, if required, a final management plan prepared by the COI Administrator and uploaded to the e-COI system, which document shall describe the proposed research study, the role of the Interested Person, the nature and amount of the financial interest (individual or institutional), the Committee’s recommendations, the approved management controls and conditions and a summary of the Committee’s discussion. This final management plan will be provided to the reviewing IRB.

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ACTION SUBSEQUENT TO MEETING/REVIEW

Notifications

The following notifications will be made regarding the COI Committee’s final action:

1. **To the Interested Person.** Notification of the COI Committee’s action will be made to the Interested Person, or to the PI in the case of a study with a related Institutional Conflict of Interest.
2. **To the Institutional Review Board (IRB).** Notification of final action, for research studies involving human subjects, will be made to the IRB by the COI Committee Chair or other administrator as appropriate, with all requested modifications incorporated into the management plan. Notification will include access to the approved management plan (if any).
3. **Agency notifications (NSF and PHS & Certain Agencies & Extramural Sponsors only).** If an FCOI is identified at the time a NSF-, PHS- or Other Agency-funded proposal is submitted, and that proposal is subsequently awarded, or if a potential conflict is identified subsequent to the award of the project, the COI Administrator will submit an FCOI Report via *eraCommons* for PHS-funded studies, or as otherwise directed by the sponsor for studies funded by Certain Agencies & Extramural Sponsors. For NSF-funded projects, notification to the NSF Office of General Counsel will be made when an identified conflict of interest cannot be managed or eliminated and research will proceed without the imposition of controls.
4. **To the Sr. Vice President for Research, Innovation & Economic Development.** The Committee will notify the Sr. Vice President for Research, Innovation & Economic Development regarding Institutional Conflict of Interest determinations.

Appeal of Committee Final Actions

For individual interests: Should the COI Committee make a decision regarding non-human subjects research that the Interested Person believes to be unduly restrictive, the Interested Person may appeal the Committee’s decision to the

1 Sr. Vice President for Research, Innovation & Economic
2 Development. If the Sr. Vice President for Research,
3 Innovation & Economic Development has an apparent or
4 perceived personal or professional conflict of interest and thus
5 cannot consider the appeal, the Assistant Vice President for
6 Research Compliance will appoint a disinterested Vice
7 Presidential level individual within USF Research & Innovation
8 to consider the appeal. Appeals of Committee decisions must
9 be made within thirty (30) days of the Interested Person's
10 receipt of written notice of the Committee's decision. All
11 appeals must be in writing, addressed to the COI Committee
12 Chair or COI Administrator and must include detail regarding
13 the reason(s) for appeal. Once an appeal is received by the
14 COI Committee Chair or COI Administrator, it will be
15 forwarded to the appropriate person for consideration. If the
16 research involves human subjects, the IRB must also approve
17 the research and the more stringent determination will be
18 dispositive. The reviewing IRB will have the final authority to
19 determine whether the conflicting interest has been
20 adequately managed and whether the research may proceed
21 notwithstanding approval by the COI Committee.
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23 **For institutional interests:** For both human and non-human
24 subjects research, if the principal investigator of the project
25 believes the Committee's determination to be unduly
26 restrictive, an appeal may be made to the Sr. Vice President
27 for Research, Innovation & Economic Development. If the Sr.
28 Vice President for Research, Innovation & Economic
29 Development has an apparent or perceived personal or
30 professional conflict of interest and thus cannot consider the
31 appeal, the USF President will have the final decision
32 regarding the appeal.
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36 **Monitoring of
37 Management Plans**

38 At the discretion of the COI Committee, periodic monitoring of
39 the Interested Person's (or the PI, in the case of an
40 Institutional Conflict of Interest) compliance with the
41 management plan may be required as part of the COI
42 Committee's oversight. **All FCOI Management Plans must
43 include a monitoring plan.**
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46 **INTERESTED PERSON
47 NONCOMPLIANCE**

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51 **Notification to
52 Interested Person
53 of Compliance**

1 **Requirements**

2 In the correspondence issued via the e-COI disclosure
3 system to the Interested Person and/or via
4 correspondence from the COI Program to the PI (in the
5 case of an Institutional Conflict of Interest), notification
6 will be made to the Interested Person or PI that the
7 Committee’s approval is contingent upon the
8 compliance of the Interested Person or PI with the
9 terms of the management plan, and that failure of the
10 Interested Person or PI to adhere to the terms may
11 result in the withdrawal of the Committee’s approval
12 and possible referral of the matter to other committees
13 and/or offices for appropriate remedial action.
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17 **Committee Action**
18 **Regarding**
19 **Noncompliance**
20 **of Interested Person**

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22 ***Nondisclosure/Inaccurate Disclosure***

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24 *Failure to File Disclosure Form*

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26 Failure of an Interested Person to file a disclosure prior to
27 initiating a research study represents noncompliance with USF
28 Policy 0-309, *Individual Conflicts of Interest in USF Research*
29 *Projects*. Failure of a PI or Covered Official to disclose an
30 Institutional Conflict of Interest of which s/he is aware prior
31 to conducting research represents noncompliance with USF
32 Policy 0-317, *Institutional Conflict of Interest in Research*.
33 Either of these circumstances of noncompliance requires an
34 appropriate progressive response which will be dependent
35 upon the circumstances. An “appropriate progressive
36 response” will generally be as follows:
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1. In the event that the COI Administrator receives information that would suggest that a disclosure may be required but has not been submitted for research that is known to be in progress, the COI Administrator will contact the potentially Interested Person or PI, evaluate the circumstances and advise the potentially Interested Person or PI regarding whether or not a disclosure should be completed and submitted in accordance with University Policy. If it is determined that a disclosure is required, the COI Administrator will notify other offices (e.g., DSR, the IRB, IACUC, Department Chair, etc.) as may be appropriate under the circumstances, and will also notify the Principal Investigator (PI), if the PI is not the Interested Person.
 2. The COI Administrator, with the COI Committee Chairperson and other appropriate administrators as

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needed, will evaluate the circumstances to determine whether the research may continue prior to review of the disclosure by the convened COI Committee. If the research involves human subjects, the COI Administrator will contact IRB Administration and a determination regarding continuation of the research will be made in consultation with the IRB. If the research is permitted to continue, interim management controls may be imposed by the COI Administrator (and the IRB, if applicable) if determined to be appropriate under the circumstances.

3. The Interested Person or PI will be advised to submit a disclosure for review.
4. Continued noncompliance with disclosure requirements will be referred to the Department Chair and other offices as appropriate (e.g., Sr. Vice President for Research & Innovation, Dean, Provost, etc.) for remedial action and oversight or suspension of the research activity.
5. If the USF Research Project is funded by PHS or Certain Agencies or Extramural Sponsors, then the following must occur for individual interests meeting the PHS regulation’s definition of Financial Conflict of Interest:
 - a. A retrospective review must take place within sixty (60) days of identifying a significant financial interest (SFI) and must be documented;
 - b. If it is determined that the interest constitutes an FCOI, an interim management plan must be implemented. In addition, the Interested Person must immediately submit to FCOI training and a report to PHS or other funding agency must take place in accordance with the “Notifications” section of this document.
 - c. If a retrospective review uncovers bias in the design, conduct or reporting of the research, a mitigation report will be submitted to the funding agency immediately.

Inaccurate or Incomplete Disclosure

Receipt of a disclosure that is incomplete will be handled in accordance with Section 4.A. of the *Disclosure Review and Management Process for USF Research Projects* of the COI Program.

If the COI Administrator receives a disclosure that the COI Administrator believes to be inaccurate, the COI Administrator will contact the Interested Person or PI, in the case of Institutional Conflicts of Interest, and seek clarification of the perceived inaccuracies. If the Interested Person persists in asserting the perceived inaccuracy, the COI Administrator will refer the matter to the COI Committee for a recommendation.

Failure to Comply with Terms of Management Plan

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Initially upon receiving information that an Interested Person or PI, in the case of Institutional Conflicts of Interest, has substantially failed to comply with the terms of an approved management plan, the COI Administrator or a Committee representative will contact the Interested Person or PI to ascertain the facts and circumstances related to the noncompliance. Upon reviewing the facts, the Committee may take appropriate action as follows:

1. Advise the Interested Person or PI in writing that compliance with the terms of the management plan is required for the Committee’s continued approval of the conduct of the research by the Interested Person and notify the PI, if the PI is not the Interested Person;
2. Meet with the Interested Person or PI to resolve any concerns of the Interested Person with the implementation of the approved management plan (including amendment of the management plan to assist the Interested Person with compliance in a manner that does not compromise the integrity of the study) in consultation with the Committee;
3. Notify the Department Chair, supervisor, IRB or other committees or offices (e.g., DSR, the IRB, IACUC, Department Chair, etc.) of the noncompliance;
4. Require monitoring of the study for compliance with the approved management plan; and/or
5. Withdraw the Committee’s approval of the management plan.
6. If the USF Research Project is federally funded and the interest disclosed is determined to be an FCOI, then the Interested Person must immediately submit to FCOI training as directed by the COI Administrator.

The Committee may elect to take any or all of these actions, or may take other reasonable actions based on the individual facts and circumstances to address the noncompliance. **Such actions must be consistent with the jurisdiction of the Committee** [See **Jurisdiction to Address Noncompliance**, under **PRINCIPLES, ROLES & RESPONSIBILITIES**]. Any action taken by the Committee will be communicated to all appropriate parties.

Pattern of Noncompliance

Repeated instances of failure to disclose, inaccurate or incomplete disclosures or failing to adhere to management plan requirements will be referred to the COI Committee for evaluation and recommendation.