

Procedures for Policy 216

Management of Research and Other Outside Interests and Activities for Faculty Members, Faculty Fellows, and Investigators

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Change History

Date	Summary of Changes
4/1/2017	Updated the following: references to OSR/ORC (now SPARC); references to R&A form (now Cayuse); deadlines; award acceptance procedures; Retrospective Review procedures; management plan template
12/5/2012	New Document

Summary

These procedures describe the specific processes relevant to Rice Policy 216: *Management of Research and Other Outside Interests and Activities for Faculty Members, Faculty Fellows, and Investigators* (collectively, Scholars). This policy applies to all Scholars.

The [overview section](#) of this document provides a synopsis of processes that allow Rice Scholars the flexibility to engage in Outside Interests and Activities responsibly. Specifically, the Conflict of Interest (COI) processes permit research and scholarship to occur without any actual or perceived COI. Many stakeholders (e.g. Faculty Members, deans and their staff, the Faculty Conflicts Committee (FCC), the Office of Sponsored Projects and Research Compliance (SPARC), the Vice Provost for Research (VPR), and the Provost) have important roles to play in identifying and managing the COI of Rice's Scholars. Federal regulations about COI for federally funded investigators are an important consideration in developing a university-wide set of procedures for COI identification and management.

The [stakeholder roles, responsibilities, and procedures section](#) provides detailed instructions specifically for each party involved in the COI reporting, review, and management process.

A glossary of terms and acronyms appearing in this document is available in [Appendix A](#). Specific guidance on the definition of Significant Financial Interests and the types of information that must be disclosed are provided in [Appendix B](#). Sample management plans as starting points are also provided in [Appendix C](#). Any interested party may submit additional examples for use by the Rice community. The FCC Charge is provided at [Appendix D](#).

Overview for COI procedures

A. The Disclosure Process: Gathering Essential Information From Scholars

Policy 216 requires that Scholars disclose Outside Interests and Activities:

- 1) At least annually in response to Provost's request for disclosure;
- 2) At any time during the year as new Outside Interests and/or Outside Activities arise, but no later than 30 days after discovering or acquiring a new Outside Interest;
- 3) Before a proposal is submitted to any funding entity; and
- 4) Before expenditures occur on an awarded grant.

With respect to disclosures required in C and D above, Scholars who have made complete, up-to-date disclosures and have no reason to add, or other otherwise make modifications to their existing disclosures, do not need to fill out additional paperwork. For proposal submission (C, above) Cayuse includes a question that triggers an interim disclosure only if there are changed circumstances. For award acceptance (D, above), the Principal Investigators will be instructed in their award notification from the Office of Sponsored Projects and Research Compliance (SPARC) to complete an interim disclosure if their Outside Interests and Activities have changed.

1. Annual COI Disclosure

Policy 216 requires that Scholars disclose Outside Interests and Outside Activities at least annually. To gather this information, all Scholars will be asked to complete an annual COI disclosure. The following provides a general timeline of this process:

- a) A master list of all Scholars is compiled by the Provost's office during the month of November.
- b) The Provost's office sends an email to all Scholars in early December. The Provost's email requests completion of an online form and specifies a deadline for completing the online form, which will be no less than 4 weeks.
- c) The Scholars will complete their annual disclosures by early February.
- d) The divisional deans' offices and SPARC will have approximately 30 days, or until the beginning of March, from the Scholars' reporting deadline, to provide preliminary assessments of the annual disclosures. Deans or their designees can begin their assessments as soon as Scholars complete their disclosures.
- e) Deans and Scholars will then have approximately 30 days, or until the beginning of April, to obtain additional information in order to ascertain a final assessment of the annual disclosures, and to draft management plans when necessary.
- f) By the beginning of April each year, management plans and any additional questions raised by SPARC will be forwarded to the FCC. The FCC assessment, revision of management plans, and finalization of recommendations to the Provost can take up to 30 days.

g) The finalized management plans and other issues will then be forwarded to the Office of the Provost by May 1. The Provost, or his or her designee, shall have until May 15 to approve management plans and COI assessments.

Note that the timeline above be modified to accommodate federal requirements and other university deadlines. For example, with regards to financial conflicts disclosed by grantees, Public Health Service (PHS) regulations require that submission of reports to the funding agency and the institution of a management plans must occur within 60 days of the disclosure. As such, the completion of the outlined process may occur on a shorter timeframe.



Figure 1: General timeline for the annual disclosure process for the annual reporting cycle with the responsibilities of key stakeholders outlined. If a deadline falls on a weekend or staff holiday, the deadline shall be the next business day.

2. Interim Disclosure: For New Travel, Gifts, and Changed Circumstances

Scholars are responsible for completing new disclosures as new activities and interests arise. Generally they have 30 days to complete and file their disclosures from the time they discover or acquire their Outside Interest. Once received, this interim disclosure should be handled in a time frame consistent

with Figure 2 below, so that dean, SPARC, and FCC review, and Provost approval of disclosures and any appropriate management plans shall occur no later than 60 days after the initial interim disclosure. However, the FCC chair shall have the authority to forward recommendations, on behalf of the FCC, to the Provost (or back to the deans, in the event that FCC chair recommends further revision of management plans) in lieu of holding a formal FCC meeting, especially with regards to meeting regulatory deadlines during, e.g., school breaks.

In accordance with University policy and federal regulations, PHS Investigators must, within 30 days (rather than annually), and regardless of the amount, disclose any sponsored travel or reimbursement paid on their behalf by domestic or foreign for-profit (e.g., industry) or certain nonprofit entities. Refer to Appendix B for an explanation of travel disclosure requirements. Such disclosures shall be made using the same reporting website as the interim disclosures.

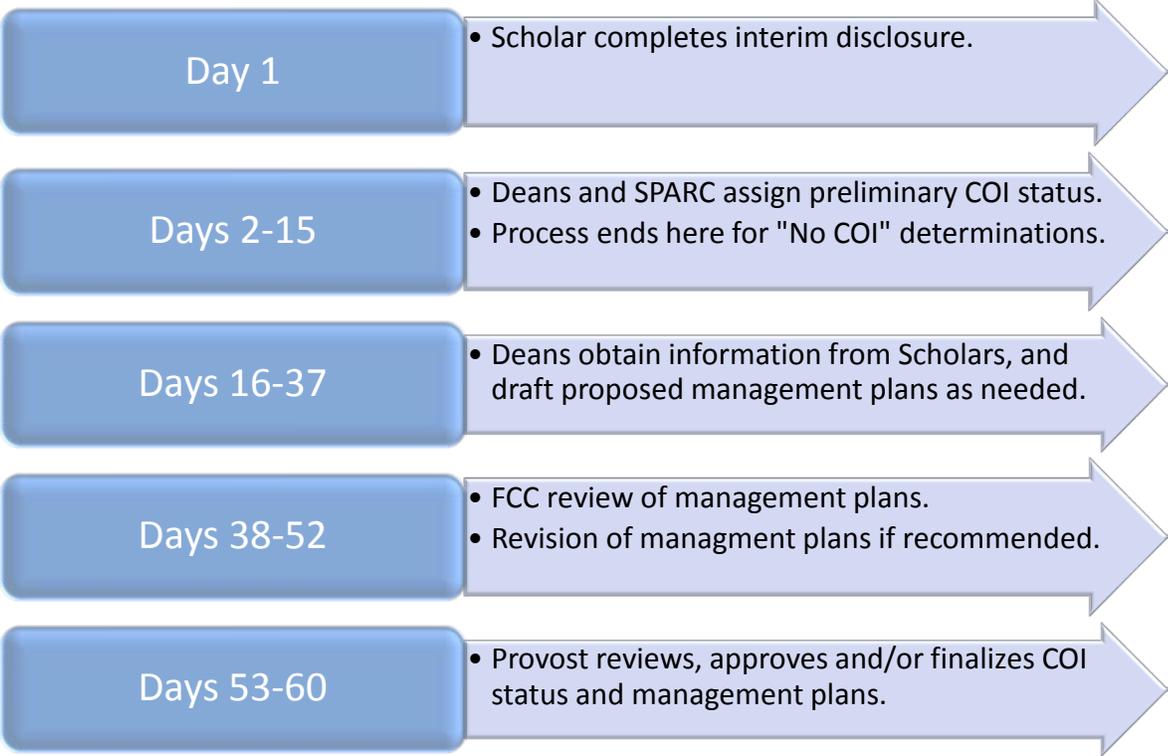


Figure 2: General timeline for the interim disclosure process with the responsibilities of key stakeholders outlined. If a deadline falls on a weekend or staff holiday, the deadline shall be the next business day.

3. Pre-Proposal Disclosures

During proposal submission, Cayuse requires that Investigators affirm that their and the project’s other Investigators’ (if any) annual disclosures are current and that there is not a change in circumstances. If they indicate that a change of circumstance has occurred, they must complete an interim disclosure prior to the time of application for the funded research.

SPARC and the Investigators’ deans review each disclosure and identify any possible COIs. This review, even if a potential COI is present, should not prevent SPARC from processing the proposal.

In determining whether there is a COI, the dean and SPARC may consult with the appropriate Investigator.

A management plan may need to be developed when a disclosed Outside Interest (a) is determined to be a COI, and; (b) the related research proposal is awarded funding.

Typically (a) is known before (b). To limit the possibility of developing management plans for proposals that are not ultimately funded, the development of a management plan does not need to commence unless and until the Scholar is relatively confident that the research proposal will receive funding. Scholars are encouraged to alert SPARC if they receive positive indications concerning the funding prospects for a proposal under consideration.

The above notwithstanding, it is important to note that work on a management plan need not be delayed until funding is imminent. For example:

- If no information is available, or expected to be available relevant to a proposal's funding prospects, then the Scholar and the Dean may opt to begin work on a management plan at any point after the disclosure has been submitted to SPARC; and/or
- If SPARC raises the possibility that an Outside Interest may present an unmanageable COI, then SPARC is expected to notify the Scholar and commence discussions within thirty days to trigger a broader process to assess manageability.

B. Classifying and Identifying Conflicts of Interest in Disclosures

1. Classifying COIs

The divisional dean's office reviews each annual and interim disclosure and evaluates whether there is a COI between the Outside Activities and Interests of a Scholar and his or her Institutional Responsibilities. Deans or designees have 30 days from the close of the annual disclosure reporting period, or 14 days from the receipt of the interim disclosure, to assign to each Scholar the following preliminary classifications:

- No COI
- Potential COI – Pending further information
- COI – Manageable
- COI – Unmanageable

Although the dean's office identifies COI, others within the University may provide input as well. In particular, Scholars are encouraged to identify, and bring to the attention of the dean's office their potential COIs. Also, any employee of the university concerned that a COI exists, but has not been reported, may report such instances under the provisions of Rice University Policy 813.

In determining whether there is a COI, the dean's office will review the disclosure and first determine whether the Scholar disclosed any Outside Interests or Activities. Scholars who do not disclose any Outside Interests and Activities, for example, will be unlikely to have a COI and will generally be classified as "No COI."

2. Identifying COIs

University policy defines COI as a situation in which a Scholar may be influenced by considerations of personal gain due to an existing or potential related Outside Interest or Activity. Such relationships may affect or might reasonably appear to affect his or her ability to make objective independent judgment in the pursuit of research results, scholarship, or creative work.

For those who do disclose potential related Outside Interests and Activities, deans must make a preliminary assessment of the relatedness of these interests and activities and the Scholar's Institutional Responsibilities. Note that, while the disclosure questions give Scholars the discretion to make this assessment, Scholars are encouraged to err on the side of the disclosure in the event that there is doubt as to the interest or activity's connection to Institutional Responsibilities. Figure 3 below provides a few examples of Outside Interests most likely related to Institutional Responsibilities.

Examples of Outside Interests Likely Related to Institutional Responsibilities

- The wife of a Faculty Member in the Computer Science department is a full-time employee of the Microsoft Corporation. The Faculty Member has a sponsored research agreement with Microsoft for his research at Rice.
- A Faculty Member holds \$10,000 worth of stock in Yamaha Corporation, producers of pianos and other instruments. The Faculty Member teaches piano at the Shepherd School.
- An oil and gas company reimburses the travel expenses of an Investigator's trip to seven out-of-state conferences a year. The last two were in Hawaii. The Investigator's research involves the environmental impact of natural gas extraction.

Should deans find that Outside Interests and Activities are related to Scholars' Institutional Responsibilities, deans must then assess whether there is a risk that the pursuit of personal gain related to the interest or activity could affect, or reasonably appear to affect, Scholars' ability to make objective independent judgment in the pursuit of research results, scholarship, or creative work, or otherwise compromise Scholars' Institutional Responsibilities. The outcome of this deliberation is a classification that a COI exists or does not exist.

In some cases the dean may not be able to get the information needed, or have the experience, to assign a preliminary finding for COI. In those limited cases, the divisional dean may elect to use the designation "Potential COI."

3. Identifying Manageable and Unmanageable COIs

After a COI is identified, a determination must be made as to whether the COI is manageable. Figure 4 below provides COIs that have traditionally been held to be unmanageable.

Examples of Potentially Unmanageable COIs

- Directing the purchase of equipment, instruments, materials, services, or other items from an Outside Entity in which the person making the disclosure or a Family Member has a significant or controlling interest;
- Orienting or performing sponsored research at Rice to benefit an Outside Entity that has not supported the research. This does not include discussions with potential sponsors about sponsoring research at Rice or potential commercial development, though discussions regarding commercial development of University-related research should be coordinated with the University's Office of Technology Transfer. See also University Policy No. 831-96 on personal use of University property;
- Consulting for a government agency on a subject that could benefit an Outside Entity in which he or she has an Outside Interest;
- Transmitting to an Outside Entity sponsored research products, results, materials, records, or information not available to the public. (This does not preclude appropriate consulting on the basis of sponsored research results where there are no conflicting relationships);
- Using for personal gain (or other unauthorized purposes) privileged information acquired in connection with sponsored research or other University activities;
- Accepting gratuities or special favors from an Outside Entity with which the University does (or may do) business, i.e. as may be specified in the first bullet point above;
- Being simultaneously involved in activities of Outside Entities within Rice that are competing directly for government and/or private funds;
- Making an academic or administrative decision that could result in his or her personal gain;
- Simultaneously receiving outside remuneration and university remuneration for the same services or activities; and
- Involving students and staff, over whom they exercise supervisory or academic responsibility at the University, in his or her Outside Activities.

For all other cases, Deans must consider (1) the adverse risks associated with the COI and (2) whether a management plan can minimize or significantly reduce these risks. A COI is not manageable if the adverse risks associated with the conflict cannot be minimized, or significantly reduced, through development of a management plan. An important adverse risk is the possibility that a Scholar's ability to make objective independent judgments in the design, conduct, and reporting of research may be, or might reasonable appear to be, affected by bias. Consequently, other adverse risks can include harm to the reputation of the University, the Scholar, and others on the Scholar's research team; harm to human subjects; and loss of sponsored research funding.

Upon identifying the adverse risks, Deans can then consider whether elements in a management plan can minimize or significantly reduce these risks. Traditional elements of a management plan include:

- Public disclosure of financial COI (e.g., when presenting or publishing the research; to staff members and/or students working on the project; to Institution's Institutional Review Board(s));

- For research projects involving human subjects research, disclosure of the financial COI directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial COI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., divestment of an equity interest); or
- Severance of relationships that create financial conflicts.¹

If the COI is manageable, then a management plan must be developed. Any COI that is not manageable must be eliminated by the Scholar within 90 days, by eliminating the COI or by terminating involvement in the conflicted research project.

In determining whether a COI is manageable, the dean's office is expected to consult with the appropriate Scholars and SPARC.

4. SPARC Review

Once the dean's assessment is received, SPARC will complete its own assessment of the COI of all Scholars using the following designations:

- A. Agree (SPARC is in agreement with the dean's office);
- B. Disagree (SPARC disagrees with the dean's office and puts case to the FCC to make its own assessment); and
- C. More information is needed.

C. Managing & Monitoring Conflicts of Interest

Once a manageable COI has been identified, deans will work with Scholars to draft a proposed COI management plan, and a schedule for monitoring the provisions of the plan. SPARC will submit the plan and schedule to the FCC. The FCC reviews each draft and decides whether to recommend the plan for Provost approval. It is the Provost or designee who ultimately approves of each plan.

1. Drafting the Management Plan

Although the dean's office typically drafts the management plan, the dean's office is expected to collaborate with the Scholar and SPARC. The dean's office may also consult with the Scholar's department chair.

¹ National Institute of Health, *Frequently Asked Questions for Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F) applicable to grants and cooperative agreements (2011 Revised Regulations)*, http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3203.

2. Management Plan Provisions

The provisions contained in management plans vary because COIs vary with regards to, e.g., the following factors:

- The percentage of equity, if any, held;
- Managerial or other positions held;
- Size of the entity with which there is a conflict;
- Involvement, if any, of graduate students; and
- Involvement in university personnel also associated with the entity.
- While COIs differ, certain elements of management plans do tend to appear somewhat routinely, including: Public disclosure of the COI, including disclosure in publications;
- Informing students about the existence of the conflict; and
- Annual review of the COI and compliance with the management plan.
-

There are additional examples in Section 2.C. above. An example of a management plan is included in Appendix D.

3. FCC Review and Provost Approval

Once a draft of the management plan and associated monitoring provisions is complete, the appropriate dean's office provides a copy of the proposed plan to SPARC. SPARC will then forward all management plans to the FCC. The FCC has responsibility for reviewing each management plan and the approach to monitor adherence to the plan's terms.

The management plan will then be forwarded to the Provost for approval. A plan must be approved, or the conflict eliminated, (1) prior to the University's expenditure of federal funds; or (2) within 60 days of disclosure of the new Outside Interest, whichever is earlier. Should the plan be approved, SPARC will notify the Scholar, dean, and the FCC of the Provost's approval or request for a management plan modification. Should the Provost disagree with the assessment of the FCC regarding the manageability of a COI, the Provost must meet face-to-face with the FCC to explain this decision.

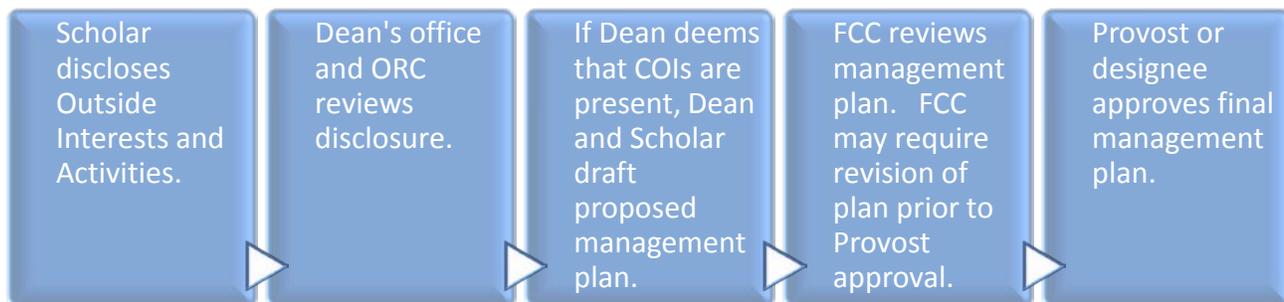


Figure 5: Process for the disclosure and approval of COI management plans.

D. Reporting Conflicts of Interest, Subcontracts and Training and Record Retention

1. Reporting Conflicts of Interest

PHS Reporting. SPARC notifies the PHS funding sponsor in accordance with federal regulations. When reports to the PHS funding components are filed, ORC notifies the PI in advance.

In particular, a Financial COI (hereafter, FCOI) Report shall be made when an award has a disclosed COI, management of which has been approved by the Provost. Such notice is made:

- Prior to the Institution’s expenditure of any sponsored research funds; and
- Within 60 days of identifying any COI subsequent to the initial FCOI Report during an ongoing PHS-funded research.

The FCOI Report includes the information below:

- Project number;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI.;
- Name of the entity with which the Investigator has FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 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 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;
- A description of how the financial interest relates to the PHS-funded research and the basis for the University’s determination that that financial interest conflicts with such research; and
- A description of the key elements of the University’s management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;

- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

SPARC shall also submit an Annual FCOI Report (with reference to the date of the initial FCOI report) during the duration of the PHS funded research's project period (including extensions with or without funds). The Annual FCOI includes the following information:

- Status of the potential FCOI and management plan;
- Status of FCOI (i.e., whether the FCOI is still being managed or why the FCOI no longer exists); and
- Changes to the management plan, if any.

Retrospective Review. Should SPARC or a Scholar identify a potential Outside Interest that was not disclosed timely by the Scholar, for whatever reason, or was not previously reviewed by Rice during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by the sub-recipient), a retrospective review will be conducted. First, SPARC will conduct a preliminary review of the situation with the Investigator and Investigator's dean's office. This preliminary review will examine reasons for the possible oversight and effect of the bias on the research, if any.

SPARC will draft a written report with information required under 42 C.F.R. § 50.605(a)(3)(ii)(B), which will include SPARC and the dean's office's preliminary determination as to the effect of the bias on the Scholar's Institutional Responsibilities. This report will be submitted to the VPR, and the VPR will indicate in the certification section of the report as to whether (a) the VPR agrees SPARC and the dean's office preliminary findings and (b) whether further review of the COI (via a committee review) is needed. A committee review may be required in complex cases, cases where the conflict may have biased research, or cases where the VPR disagrees with the SPARC and dean's offices preliminary determination. The VPR will determine appointments for this committee and may consult SPARC.

Depending on the results of the retrospective review:

- If no bias is found: SPARC will complete a review of the Outside Interest and file with the appropriate PHS awarding component an FCOI Report, which provides the information stated above. Thereafter, an Annual FCOI Report shall be filed.
- If bias is found: within 120 days of determining that noncompliance has occurred, SPARC shall file with the appropriate PHS awarding component an FCOI Mitigation Report. Thereafter, an Annual FCOI Report is filed. The FCOI Mitigation Report includes the following information:
 - Description of the impact of the bias on the project; and
 - Rice's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and

quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Public Reporting. SPARC shall respond within five business days to written requests for information concerning financial COIs held by senior/key personnel (defined by the PHS as Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation) of PHS-funded projects. SPARC shall note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new financial COI, which should be requested subsequently by the requestor. SPARC responds to such requests dated no later than three years from the date the senior/key personnel's conflicts were most recently disclosed.

SPARC shall provide such information as required under PHS regulations. When Rice responds to such requests, SPARC notifies the PI in advance, unless the requesting agency prohibits such advance notice.

2. Subcontracts

Investigator Disclosures. Rice requires that each individual at a subcontractor institution who is identified as an Investigator as defined in Rice Policy 216 complete either Rice's disclosure or a comparable form from the subcontractor institution at the time of proposal submission. Such COI certifications from other institutions must be received within 30 days of proposal submission.

Prior to issuing a new subcontract, SPARC sends an email to the Rice PI asking him or her to consult with the subcontractor Investigator(s) to verify that the information disclosed in the original review and approval forms or comparable form(s) is up-to-date. If no new Outside Interests or Activities need to be disclosed, the SPARC proceeds to issue the new subcontract. If new information needs to be disclosed, a new disclosure or comparable form will be required. SPARC reviews all forms received.

Certifications. One of the following two versions of the "Objectivity in Research" clause is included in all outgoing sub-awards and subcontracts.

OBJECTIVITY IN RESEARCH (Sub-recipient Institution's COI policy applies)

The SUBCONTRACTOR certifies that it has a written and enforceable conflict of interest policy that complies with the provisions of 42 CFR Part 50, Subpart F "Responsibility of Applicants for Promoting Objectivity in Research" and 42 CFR Part 94, "Responsible Prospective Contractors." The Subcontractor further certifies that to the best of their knowledge all financial disclosures required by its conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed, reduced or eliminated prior to the expenditures of any funds under this SUBCONTRACT in accordance with the SUBCONTRACTOR'S conflict of interest policy. In this regard, Subcontractor agrees to have each person serving as an "Investigator", as that term is defined in the above-referenced federal regulations, sign the certification form attached hereto as EXHIBIT __, and for those who have conflicts of interest requiring management, reduction or elimination, the following certification form attached as EXHIBIT __ also must be signed. SUBCONTRACTOR further agrees to notify Rice within 30 days of any financial agreement pertaining to this SUBCONTRACT that may arise during the course of the project.

OBJECTIVITY IN RESEARCH (Rice's COI policy applies)

The Subcontractor certifies that to the best of their knowledge all financial disclosures required by Rice's conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed, reduced or eliminated prior to the expenditures of any funds under this SUBCONTRACT in accordance with Rice's conflict of interest policy. In this regard, Subcontractor agrees to have each person serving as an "Investigator", as that term is defined in the above-referenced federal regulations, sign the certification form attached hereto as EXHIBIT __, and for those who have conflicts of interest requiring management, reduction or elimination, the following certification form attached as EXHIBIT __ also must be signed. SUBCONTRACTOR further agrees to notify Rice within 30 days of any financial agreement pertaining to this SUBCONTRACT that may arise during the course of the project.

SPARC ensures that as part of the written agreement with sub-recipient, there are terms establishing whether Rice's or the sub-recipient institution's COI policy will apply to the sub-recipient's Investigator.

3. Training

Scholars at Rice who receive sponsored research funding must complete a Rice COI training module prior to submitting a sponsored research proposal or receiving an award. This training must be repeated, at a minimum, every four years. SPARC notifies Scholars when it is time to repeat COI training.

Scholars are required to complete additional training immediately if: (1) Rice finds that they are not in compliance with Policy 216 or an existing management plan; (2) Rice, on its own or in response to changes in federal regulations, revises its institutional policies or makes material changes to its procedures related to COI in any manner that affects the requirements of Scholars.

Should a Scholar not complete the training in a timely and satisfactory manner, in addition to other potential sanctions, his or her dean's office will not be permitted to forward any of his or her proposals to SPARC for submission, and the SPARC will not process proposals for the individual until he or she satisfactorily completes the training.

4. Record Retention

SPARC retains electronic copies of the following for a period of 3 years from the latter of (1) the date the document was most recently updated; (2) the date the final expenditure report is submitted to PHS; or (3) the date of the submission of the final quarterly or annual financial report for Health and Human Services (HHS) awards that are renewed quarterly or annually:

- Annual and interim disclosures;
- Management and monitoring plans;
- Retrospective review records;

- Disclosures to PHS agencies;
- Responses to public requests for information;
- FCC minutes; and
- Other documents as required by law or regulation.

If any litigation, claim, negotiation, audit or other action involving the records has been started before the expiration of the 3-year period, the records must be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular 3-year period, whichever is later.

Stakeholder Roles, Responsibilities, and Procedures

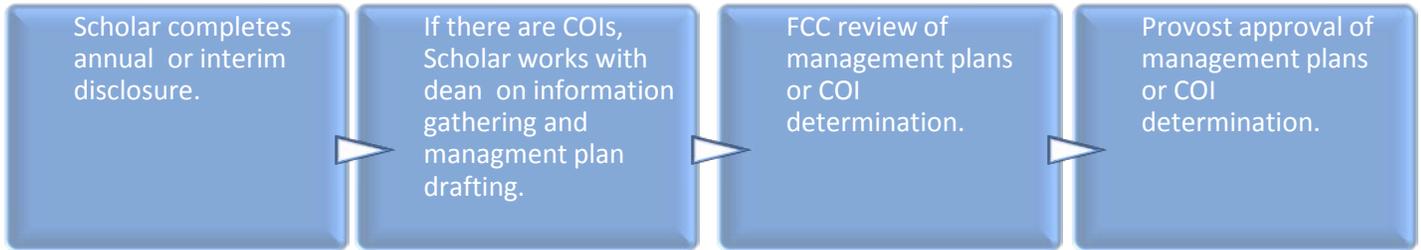
1. Scholars

BASIC QUESTIONS	ANSWERS	
Who discloses?	<i>SCHOLARS</i>	Includes, Faculty Members Faculty Fellows, and Investigators
How are disclosures made?	<i>DISCLOSE ONLINE at www.coi.rice.edu</i>	Complete initial disclosure and update subsequent disclosures
When are disclosures made?	<i>Annually</i>	Provost emails request (DEC) Disclosures due (FEB)
	<i>If New interest Arises</i>	Disclosures to be made within 30 days of travel or acquiring or discovering interest
	<i>Before</i>	Typically requires updating
	<i>Before Expenditures</i>	See "Before Proposal"
What financial interests must be disclosed?	<i>Income & Interests</i>	According to definitions provided under Policy 216
	<i>Gifts</i>	
	<i>Travel Expenses</i>	

Figure 6: A summary of Scholars’ disclosure obligations.

Annual and Interim Disclosure of Outside Interests and Activities. Figure 7 below provides a general overview of the procedures Scholars should follow in the completion of disclosures and any necessary management plans. After the submission of their disclosures, Scholars will work closely with their deans (and, if necessary, SPARC and their department chairs) to assist in the identification of conflicts and drafting of management plans. They will be informed along the way if more information is needed in the assessment of COIs or a management plan (or revision thereto). FCC review and Provost approval occurs thereafter.

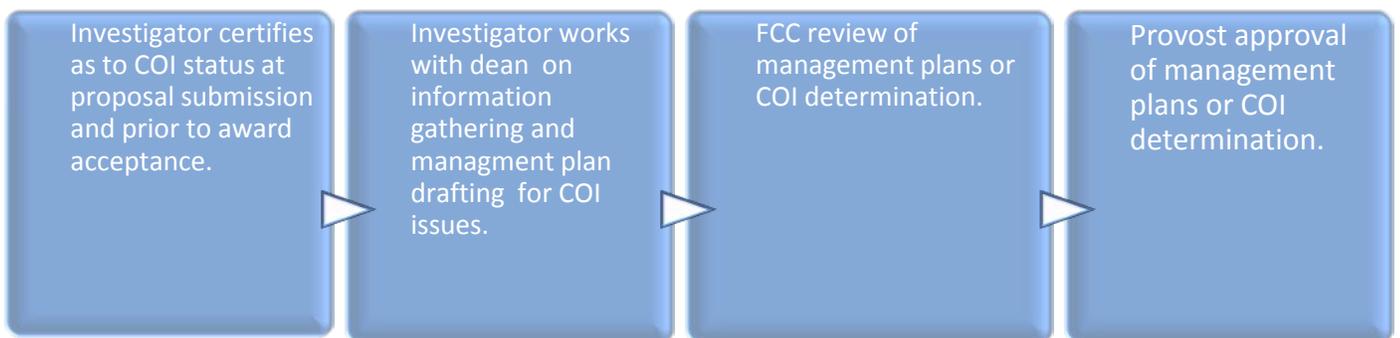
Plans not approved by the Provost are sent back to the Scholar, Dean, and FCC for revision, with an explanation of the Provost’s decision. If the Provost views the conflict as unmanageable, in conflict with the views of the FCC, then there must be a face-to-face meeting between the Provost and the FCC to explain this reasoning.



Pre-Proposal and Award Acceptance Disclosures. Figure 8 below is a summary of Investigators’ responsibilities at the time of submission for sponsored funding applications and prior to award acceptance. While University policy provides only that management plans must be in place before federal funds can be expended, the process for the compilation of additional information to make the COI assessment and the drafting of management plans may begin at any point after the proposal has been submitted to the funding agency.

At the time of proposal submission, Investigators are required to complete the COI certification in Cayuse and submit an interim disclosure if necessary. Subsequent to SPARC’s review of the disclosures and Cayuse certification, Investigators may be contacted to provide more information to more fully assess the presence of conflicts and/or, if necessary, to begin the drafting of management plans. Like the process with the annual and interim disclosures, management plans and other issues will be forwarded to the FCC for recommendation to the office of the Provost. The Provost or his or her designee will provide the final approval for management plans and COI determinations no later than prior to the expenditure of funds awarded by the funding entity.

SPARC will require Investigators to confirm that their COI disclosures are current at the time of award acceptance, prior to the expenditure of funds.



2. Departmental Chairs and Staff

When appropriate, Department Chairs or their designees will assist deans in determining whether a COI exists, whether it is manageable, and if so, the proper elements in a management plan.

3. Divisional Deans and Staff

The dean's office plays a pivotal role in refining the Provost's list of Scholars to be evaluated for COI; they will, in response to the Provost's initial list, check that all Scholars listed as members of their division have the correct name, title, and contact information. This information must be received by the Provost's office in early November.

If no COIs are present the Dean or his/her designee can assign the disclosure as "No COI."

When a potential COI is presented, the dean and or his/her designee consults with the Scholar about the conflict.

The dean's office, in consultation with the Scholar, the department chair, and SPARC, then begins to draft a management and monitoring plan for the conflict. This document and accompanying documents are sent to SPARC for tracking and records purposes. SPARC then forwards the documents to the FCC for review.

Once a management and monitoring plan has been approved by the Provost or his or her designee, the dean's office ensures the Scholar's on-going adherence to the plan, which must be specified in the management plan.

The dean's office ensures COI certifications in Cayuse are submitted with all sponsored research proposals and updated as TBN staff are added.

4. Office of Sponsored Projects and Research Compliance (SPARC)

SPARC is responsible for, among other things:

- Providing to the Provost a list of Scholars classified as 'PHS', 'Sponsored Research', 'other.'
- Expert level interpretation of University policy and federal regulations on COI;
- Maintaining standard operating procedures related to implementation of COI policies;
- Ensuring that the Rice COI system is functioning properly and that annual disclosures are distributed timely;
- Reviewing disclosures independently from the deans to ensure objectivity in the COI review and monitoring process, as Rice's institutional official required under PHS and regulations at 42 CFR Part 50;
- Notifying deans' offices of COIs that may need to be addressed;
- Assisting in the coordination of the development of management and monitoring plans;
- Ensuring that an annual review takes place for each approved management and monitoring plan;
- Ensuring that retrospective reviews take place for COIs not disclosed timely;
- Convening FCC meetings, recording FCC meeting minutes, and distributing and collecting meeting materials;
- Coordinating with the Office of the Provost for final signature;
- Ensuring that the any sponsoring agencies are appropriately notified of the management of COI;

- Providing within (5) business days, upon request, information about disclosed and managed COI; and
- Monitoring of compliance with University policies and procedures and management plans.

5. Faculty Conflicts Committee

The FCC is responsible for reviewing all management plans drafted by deans and Scholars, and recommending them to the Provost for approval. The FCC also assigns a COI status in cases that are complex, or where there is a disagreement between deans and SPARC, regarding a COI situation. The FCC is the body that forwards to the Provost the request for COI notification. For more information about the FCC's responsibilities, see Appendix D for a copy of the FCC Charge.

6. Provost and Staff

The Provost or his or her designee is responsible for first, starting the process to harmonize and agree on the institutional list of Scholars in the fall. Next, the Provost makes the formal request for annual disclosures. The Provost makes the final decisions regarding the status of COIs disclosed annually and on an interim basis, and also reviews management plans recommended by the FCC and provide final approvals thereto.

APPENDIX A

Definitions and Acronyms

Policy 216 contains a glossary of terms, many of which are used in this document. Definitions and full terms for acronyms used frequently herein are defined in the tables below,

Key Terms	Policy 216 Definitions
Conflict of Interest (COI)	a situation in which a Scholar may be influenced by considerations of personal gain due to an existing or potential Outside Interest or Activity. Such relationships may affect or might reasonably appear to affect his or her ability to make objective independent judgment in the pursuit of research results, scholarship, or creative work.
Faculty Conflicts Committee (FCC)	a committee composed of Faculty Members and staff, and chaired by the Vice Provost for Research (or his or her designee). The role of the FCC is to review, revise as needed, and recommend for approval management of any COI identified. The FCC also has responsibility for monitoring management plans.
Faculty Fellow	individuals holding research positions that are not tenure-eligible, under University Policy No. 327.
Faculty Member	includes all faculty members with tenure and tenure-track appointments, as well as benefits-eligible non-tenured or non-tenure track faculty members with the rank of Lecturer or above, under University Policy No. 201.
Family Member	the Scholar's spouse, domestic partner, or dependents with financial interests related to the Scholar's Institutional Responsibilities. However, since the integrity of the research and scholarship of Scholars is vital to the mission of the University, Scholars should also be sensitive to situations where other family members such as a parent, sibling, or non-dependent children may have a Significant Financial Interest reasonably related to the Scholar's Institutional Responsibilities (such as a significant investment in a start-up company that has licensed the Scholar's intellectual property). In such cases, to avoid the appearance of a financial COI, it may be prudent for the Scholar to disclose such additional interests of which he or she is aware.
Institutional Responsibilities	the professional responsibilities of a Scholar on behalf of the University. Institutional Responsibilities include, for example, activities such as teaching, preparing coursework, counseling students, service on

	departmental and University-wide committees, research, publishing scholarly work, and other work relevant to his or her academic field of endeavor, professional practice, and consultation.
Investigator	any university employee who is a Principal Investigator or co-investigator on a research project. This broader term includes all Rice professors of the practice, certain research faculty, and any individual to whom Principal Investigator or co-principal investigator status has been provided. It may also include other individuals, including significant contributors, collaborators, consultants and others regardless of position, title or compensation from an award, who are independently responsible for the development, design, conduct, or reporting of a sponsored research project.
Outside Activity	includes leadership participation in professional, community, or charitable activities; self-employment; participation in business partnerships; or employment or consulting arrangements with Outside Entities. An Outside Activity may be either compensated or uncompensated. In general, any service on any board (for-profit, non-profit, advisory, honorary, or otherwise) will constitute an Outside Activity.
Outside Entity	any corporation, partnership, sole proprietorship, or any other organized legal entity other than Rice University.
Outside Interest	the interests referenced in Policy 216 under the subsection titled “Outside Interests and Activities That Must Be Disclosed.” (see Appendix B for this subsection).

Acronym	Full term
COI	Conflict of Interest
FCC	Faculty Conflicts Committee
FCOI	Financial Conflict of Interest
SPARC	Office of Sponsored Projects and Research Compliance
PHS	Public Health Service

TBN	To Be Named
VPR	Vice Provost for Research

APPENDIX B

What Information Needs To Be Disclosed

Significant Financial Interests That Must Be Disclosed

It is, of course, impossible to predict the range of circumstances that may lead to a conflict of interest. Typically, a COI emerges as a result of one or more significant financial interests. For example, although not exhaustive, the following are considered significant financial interests and must be disclosed when they reasonably relate to a Scholar's institutional responsibilities:

- Scholars must disclose for themselves and their Family Members received income from a publicly-traded entity, if the value of income from the entity, when aggregated, has a value of more than \$5,000, including salary, payment for consulting fees, honoraria, paid authorship, and/or equity interest, including stock, stock ownership, stock option, or ownership interest. In the event that the value is not known, Scholars should report situations in which they have ownership or control more than 5% of the equity, stock, or stock options in a corporation or LLC.
- Scholars must disclose for themselves and their Family Members interests in a non-publicly traded entity in any form (e.g., corporation, LLC or partnership), if the value of any remuneration received from the entity, when aggregated has a value of more than \$5,000, or when the Scholar and/or their Family Members holds any equity interest (e.g., stock, stock option, or other ownership interest). In the event that the value of an entity is not known, Scholars should report situations in which they have ownership or control more than 5% of the equity, stock, or stock options in a corporation or LLC.
- Scholars must disclose for themselves and their Family Members income of more than \$5,000 from royalties on any single item from any non-Rice activity, including any income from intellectual property rights and interests not jointly owned by the University (such as patents, copyright, and licensing fees).
- Gifts larger than \$2,500 from any Outside Entity.

In identifying potential disclosure items, it is important to recognize that the value held by Family Members is aggregated. For example, if a Scholar earns \$2,500 from consulting services provided to the Board of Directors of a publicly traded corporation, and the Scholar's spouse earns \$3,000 from consulting services to a wholly-owned subsidiary of the same corporation, the income of each is added for disclosure purposes. Since the "aggregated" amount exceeds \$5,000, a significant financial interest may exist and the relationship must be disclosed.

Disclosure of Sponsored Travel and Travel Reimbursements

- Scholars must annually disclose sponsored travel or travel reimbursements that reasonably appear to be related to their Institutional Responsibilities and received from domestic or foreign for-profit (e.g., industry) or nonprofit entities not excluded in (a) below (e.g., foundations) if the amount exceeds \$5,000 per trip. Disclosure information would include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

- Scholars do not need to disclose: a) direct reimbursement or income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency; a U.S. institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education; b) income from service on advisory committees or review panels for a federal, state, or local government agency; or c) income from service on advisory committees or review panels for a federal, state, or local government agency, or for a U.S. institution of higher education.

Special Requirement for PHS Investigators: While the normal requirement is for Scholars to disclose sponsored travel and travel reimbursements annually, PHS Investigators must, within 30 days of receipt (rather than annually), and regardless of the amount, disclose any sponsored travel or reimbursement paid on their behalf by entities required to be disclosed in the travel and travel reimbursement disclosure requirement, as noted above. If upon evaluation SPARC feels that additional information is needed to determine whether the sponsored travel or travel reimbursement indicates a Significant Financial Interest, then additional information such as the estimated or actual cost of the travel may be requested.

Financial Interests That Do Not Need To Be Disclosed

The following forms of remuneration do not ordinarily need to be reported by Scholars:

- Salary, royalties, or other remuneration by the University if the Scholar or Family Member is currently employed or otherwise appointed by the University.
- Intellectual property rights assigned to the University and agreements to share in royalties related to such rights.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Scholar does not directly control the investment decisions made by these vehicles.
- Outside Interests that are not related at all to the Scholar's Institutional Responsibilities.

Outside Activities That Must Be Disclosed

- Scholars must disclose any leadership role they have in Outside Entities if that entity may be impacted by the outcome of the Scholar's work.
- Standard academic activities such as service on editorial boards, conference boards, and the like need not be disclosed under this policy. It is expected, however, that such activities be reported in a Scholar's annual report.

APPENDIX C

Sample Management Plan

[School letterhead]

To: Scholar

Subject: Conflict of Interest (COI) Management and Monitoring Plan

Date:

Re: [Entity name]

Dear Scholar:

You have disclosed the following potential COI between your role at the university and your personal activities:

[description]

In view of this potential COI, Rice has developed the following measures to eliminate the likelihood that actual conflicts will arise:

Technology Transfers.

- You will submit a completed invention disclosure form to the Office of Technology Transfer (OTT) regarding any future patentable inventions developed by Rice University resources.
- You further agree not to transfer any materials or proprietary information regarding such future inventions to [Entity name] prior to the consummation of a confidential disclosure agreement, sponsored research agreement, and/or a license agreement related thereto, if any.
- You also agree to assist OTT in obtaining such additional information as may be required to evaluate licensing opportunities for future inventions.
- The invention disclosure forms and related correspondence or agreements, as well as your compliance with the terms agreed to above, shall be reviewed by your dean's office for any potential conflicts of interests. Should your dean determine that a potential COI exists, the terms of any license agreement with the licensee may be modified accordingly or such other remedial action taken as would be in accordance with COI policies and corresponding provisions of the Rice's Intellectual Property Policy.

Publications and Presentations.

- In publications and academic presentations related to or utilizing any of the products or technologies associated with [Entity name], you must disclose your relationship with [Entity name] where disclosure

is possible. Such disclosure should clearly state that the relationship is covered by a management and monitoring plan.

- Your relationship with [Entity name] must not inhibit your, or your staff's, your students, or your postdoctoral fellows rights to receive, analyze, or interpret any data generated.
- Your relationship with [Entity name] may not restrict publications or presentations. Publications may be reasonably delayed for the purpose of prepublication review for a period consistent with Rice IP policies.

Interaction with Students, Personnel, and Human Subjects.

- You must inform, in writing, all personnel under your supervision, including students, of your relationship with [Entity name], and of their right to bring concerns about your relationship with [Entity name] to the attention of the Office of Sponsored Projects and Research Compliance (SPARC). Further, just as you disclose to current students and personnel, you must also disclose your relationship with [Entity name] to incoming graduate students who will be under your supervision prior to the students' commitment to do research in your laboratory. Attached is the recommended disclosure letter.
- If you expect to involve university employees or students in the activities of [Entity name] you must notify and obtain approval from the Dean before such involvement occurs. Involvement of university employees or students directly with [Entity name] may require a modification to this management plan.
- If human subjects are participating in research project(s) related to this potential conflict, you must disclose your relationship in the relevant sections of any Institutional Review Board (IRB) applications for each project and will, if required by the IRB, comply with any additional COI stipulations related to that protocol, such as disclosure of financial interests in the informed consent document. Contact Rice's IRB administrator at irb-io@rice.edu for guidance regarding your IRB obligations.

Sponsored Research Proposals and Awards

- When submitting a proposal for sponsored research funding involving a project related to this conflict, in the "Conflict of Interest" section of Cayuse you must answer "Yes" to indicate that you have reported a financial interest or activity related to the proposal.
- Should such proposals be awarded funding, SPARC may request from you updates regarding the status of your relationship with [Entity name]. You shall assist SPARC in providing information about this relationship to funding agencies, should such reports be required or requested by the agency.

Use of University Facilities and Services.

- Any activity involving the use of University facilities or services for the benefit of [Entity name] must be conducted in accordance with all relevant university policies pertaining to the use of university facilities. If you wish to use university facilities for the benefit of [Entity name], you must make arrangements through your department chair and your dean.

Change in Circumstances.

- Any time a significant change in relationships with, or compensation from [Entity name] occurs for you, you must update your COI disclosure. New compensation directly from [Entity name] (i.e. stocks or

consulting fees) to students or members of their immediate family must be reported directly in writing to SPARC and may require revisions to your management plan.

Annual Review.

- You will be asked to prepare an annual update to the Dean or his or her designee to review information related to your relationship with [Entity name], its influence on your institutional responsibilities to Rice, and compliance with the terms of this management plan. The assessment will then be forwarded to the Faculty Conflicts Committee and utilized in its annual review of the relationship between your university research and [Entity name].

Signature of agreement

Scholar _____

Date _____

Dean _____

Date _____

Cc: Office of Sponsored Projects and Research Compliance

APPENDIX D

Faculty Conflicts Committee Charge

Background

Rice policies on conflicts of interest (COI) and commitment stipulate that full-time faculty and staff owe their primary professional allegiance to the University. Outside interests and activities and must be arranged in ways that respect this relationship and that do not interfere with the Scholars' institutional responsibilities. Federal regulations in this area of compliance have been receiving enhanced scrutiny over the past few years and new federal rules for the PHS were announced in August 2011. These rules become effective on August 24, 2012. The changing requirements for regulatory compliance necessitated substantial changes to University policies and procedures pertaining to disclosure, review, and resolution of outside relationships and how any potential or actual COI identified via this process are managed.

Faculty Committee on Conflicts

The Provost determined that it was appropriate to establish a faculty committee whose role would be to ensure that the plans for managing, monitoring and/or eliminating COI be established.

Composition of the FCC

Committee members

The Faculty Committee on Conflicts (FCC) is faculty committee composed of at least seven members who are appointed by the Provost as outlined in Rice Policy 216: Management of the Research and other Outside Interests and Activities of Faculty Members, Faculty Fellows and Investigators. The faculty members will be selected to broadly reflect the research, academic interests, and activities of the University. The Vice Provost of Research shall, on behalf of the Provost, consult with the divisional deans and the Speaker of the Faculty Senate on appointments to the FCC. The Vice Provost of Research or his or her designee will serve as the FCC Committee Chair. The FCC Committee Chair may request, at his or her discretion, non-voting members to participate in the work of the FCC as required by the cases under consideration.

COI Institutional Official

The FCC is staffed by the Rice COI Official, from the Office of Sponsored Projects and Research Compliance (SPARC). This individual will: 1) provide expert level interpretation of University policy and federal regulations on conflict of interest; 2) convene meetings; 3) record committee minutes; 4) distribute and collect meeting materials; 5) coordinate with the Office of the Provost for final signature; 6) ensure that an annual review takes place for each approved management and monitoring plan; 7) ensure that the any sponsoring agencies are appropriately notified of the management of COI; 8) ensure that retrospective reviews take place for a COI not disclosed timely; 9) provide, within (5) business days of request, information about disclosed and managed COI; 10) ensure that the Rice COI system is functioning properly and that annual disclosures are distributed timely; and 11) maintain standard operating procedures related to implementation of COI policies.

Roles and Responsibilities of the FCC

As an independent faculty committee, the FCC will ensure that appropriate measures are taken to preserve the confidentiality of the disclosure, review, and resolution of any COI situations. The FCC is expected to resolve COI matters in a thoughtful, consistent, timely, and unbiased manner balancing the interests of the institution and the conflicted scholar with strict adherence towards compliance with federal regulations. The key charge for the committee is the preservation of academic integrity and the protection of those engaged in research at Rice as well as any human subjects involved.

The FCC will be responsible for: (a) affirming or disputing identifications of COIs; and (b) recommending whether COIs can be managed or must be eliminated. This standing committee will operate in a manner similar to the other research compliance committees.

In accordance with Policy 216, the FCC will review proposed management and monitoring plans for all COI cases and either approve the plan or send it back with recommended revisions to the Dean and the

Scholar. For changes in circumstances, or new COI disclosed outside of the annual disclosure process, the FCC may meet as required to evaluate COI cases and their proposed management and monitoring plan. The committee will meet no less than quarterly. No federal funds can be expended until a management plan is approved by the Provost. For conflicts that arise or relationships that change substantially during an active grant or contract must have an acceptable management and monitoring plan developed in a timely fashion and in accordance with federal and University guidelines. The final version of the management and monitoring plan shall be approved by the Provost.

The FCC may at its discretion request input from the Scholar. The FCC may also request that staff serve on the committee in an ex officio capacity or are invited to attend meetings as deemed appropriate to provide administrative information pertinent to the resolution of a particular case.