INDIVIDUAL CONFLICTS OF INTEREST AND COMMITMENT

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I. INTRODUCTION AND PURPOSE

Consistent with Sherman College of Chiropractic's (the "College's") research, teaching and public service missions, the College encourages faculty, staff and students to engage in appropriate outside relationships with private industry and the nonprofit sector. But members of the College community are expected to avoid conflicts of interest or commitment that have the potential to directly and significantly affect the College's interests, compromise objectivity in carrying out College responsibilities, or otherwise compromise performance of College responsibilities, unless such conflicts are disclosed, reviewed, and managed in accordance with this Policy. This Policy on Individual Conflicts of Interest and Commitment (hereinafter, the "Policy") describes the College's approach and process for identifying, reviewing, and managing such relationships to help assure the integrity of College academic and administrative endeavors.

A member of the College community --faculty, staff, student or trainee-- may be deemed to have a conflict of interest when he or she or any of that person's family possesses a personal or financial interest related to an activity that involves his or her College responsibilities.

Through this Policy the College seeks to minimize the most obvious and avoidable conflicts of interest that have potential for serious negative effects on performance of its missions. The

requirement that an individual's potential conflicts of interest be disclosed and evaluated by others is not a reflection or assessment of the integrity of the individual.

As members of a scientific and intellectual community, we recognize that objectivity about one's own situation and credibility with external observers requires an evaluation external to oneself. Moreover, the fact that an individual may be determined to have a conflict does not imply that the conflict is unethical or impermissible; it means simply that the relation of the conflict to the individual's institutional responsibilities must be carefully examined and in some cases managed, because conflicts – real, potential or perceived - may impair performance of the missions of teaching, research, and public service, as well as jeopardize public trust and support.

II. DEFINITIONS OF SELECTED TERMS

"Conflict of Interest" (COI) relates to situations in which financial or other personal considerations, circumstances, or relationships may compromise, may involve the potential for compromising, or may have the appearance of compromising a **Covered Individual**'s objectivity in fulfilling their College duties or responsibilities, including research, and teaching activities and administrative duties. The bias that such conflicts may impart can affect many College responsibilities, including decisions about personnel, the purchase of equipment and other supplies, the selection of instructional materials for classroom use, the collection, analysis and interpretation of data, the sharing of research results, the choice of research protocols, the use of statistical methods, and the mentoring and judgment of student work.

"Covered Individual" refers to any College employee, student or trainee who is performing teaching, research, public service, administration and business operations of the College.

"Executive Position" refers to any position that includes responsibilities for a material segment of the operation, management or oversight of a business, including Board membership.

"Family" of a **Covered Individual** includes his or her spouse and dependent children. For the purposes of this Policy, "spouse" includes a person to whom one is married or with whom one lives together in the same residence, shares responsibility for each other's welfare and shares financial obligations.

"Financial Conflict of Interest" (FCOI) means a **Financial Interest** that could directly and significantly affect the design, conduct, or reporting of research.

"Financial Interest" means one of more of the following interests of a **Covered Individual** (and **Family**) that appear to be reasonably related to a **Covered Individual's Institutional Responsibilities.**

Financial Interest of a **Covered Individual** includes:

(1) Salary external to the College, royalties (including royalties distributed to a **Covered Individual** or his or her **Family** through the College), or other payments, including consulting fees or **Honoraria** (except as excluded below), received by a **Covered Individual** or his or her **Family** in the twelve months preceding disclosure or anticipated in the twelve months following disclosure;
(2) Equity interest held by a **Covered Individual** or his or her **Family** in publicly-traded or non-publicly traded entities), in the twelve months preceding or anticipated in the twelve months following disclosure;
(3) Intellectual Property rights and interests (including inventorship) held by a **Covered Individual** or his or her **Family** in the twelve months preceding or anticipated in the twelve months following disclosure; and
(4) Gifts that have been made to the College for the direct benefit of the research or other professional activities of a **Covered Individual** in the twelve months preceding or anticipated in the twelve months following disclosure**.**

"Financial Interest" does not include:

(1) Salary or other remuneration (not listed above) from the College;
(2) Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education;
(3) Income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education;
(4) Income from investment vehicles, such as mutual funds or blind trusts, where a **Covered Individual or Family** has no control over the selection of holdings.

Note that **Financial Interests** of an **Investigator** include **Financial Interests** of the **Investigator's Family**, as defined above.

"**Honoraria**" means a payment made to a person for services rendered in a volunteer capacity, or situations where the giver does not have legal obligations, or for services where fees are not traditionally negotiated or expected.

"**Human Subjects Research**" means any systematic investigation (1) that is designed to develop or contribute to generalizable knowledge and (2) that obtains data through intervention or interaction with living individuals and/or obtains identifiable private information about living

individuals, including by means of the observation or recording of behavior. Intervention includes both physical procedures and manipulations of the subject or subject's environment that are performed for study purposes. Interaction includes communication or interpersonal contact between an investigator and a subject. Private information includes information that individuals can reasonably expect will not be made public. This definition also encompasses any experiment that involves a test article and one or more human subjects (i.e., a "clinical investigation" per FDA regulations).

"Institutional Responsibilities" for employees means teaching, research, clinical practice, service and administrative duties for the College. For Students or Trainees, these institutional responsibilities mean adherence to the rules or guidelines in their School or Program.

"Investigator" means the principal investigator, project director, key personnel and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of a **Project**. **Investigators** may also include research study coordinators, research assistants, graduate students or others. For the purposes of this Policy, research collaborators or independent consultants may also be considered **Investigators** depending upon their activities on the **Project**.

The term **Investigator** is not intended to apply to individuals who primarily provide technical support, administrative support, or who are purely advisory, such that these individuals have no influence over the research results (e.g. control over its collection, analysis or reporting). Further information is provided in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment.*

"Personal interest" means an external executive, consulting or advisory position related to an activity that involves or is related to a **Covered Individual's Institutional Responsibilities**. These activities may or may not be uncompensated.

"Project" means any research, testing, evaluation, training, and/or instructional plan conducted under the auspices of the College.

"Public Health Service" (PHS) means the section of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration. Funding overseen by the financial conflict of interest regulations is issued by the Department of Health and Human Services (DHHS) and

administered by the National Institute of Health (NIH).

"**Reimbursed or Sponsored Travel**" means any travel that is not covered directly through the College and for which an **Investigator** either receives direct reimbursement from, or is covered by, an external entity. For the purposes of this Policy, reimbursed or sponsored travel is only applicable to **PHS** funded **Investigators**.

"Senior/Key Personnel" means the Principal Investigator/Project Director and any other person identified as senior/key personnel by the College in a grant application, progress report, or any other report submitted to a **PHS** awarding component.

III. APPLICABILITY

This Policy applies to **Covered Individuals**, which is defined in this Policy to include any College employee, student, or trainee in the performance of the teaching, research, public service, administration and business operations of the College.

Under this Policy, the interests of a **Covered Individual's Family** are considered to be the "same as" the **Covered Individual** and should be disclosed as applicable.

IV. CONFLICT OF COMMITMENT

The term "conflict of commitment" relates to an employee's distribution of effort between College Duties or **Institutional Responsibilities** (primary and secondary), and external professional activities.

All Faculty and non-Faculty employees of the College are expected to devote their primary professional loyalty, time and energy to their **Institutional Responsibilities.** Accordingly, outside professional activities and outside financial interests must be arranged so as not to interfere with the primacy of **Institutional Responsibilities**.

Primary duties consist of assigned teaching, scholarship, research, institutional service requirements, administrative duties and other assigned employment duties.

Secondary duties may include professional affiliations and activities traditionally undertaken by College employees outside of the immediate College employment context. Secondary duties may or may not entail the receipt of honoraria, remuneration or the reimbursement of expenses. A list of these duties would include:

- membership in and service to professional associations and learned societies

- membership on professional review or advisory panels
- presentation of lectures, papers, concerts or exhibits
- participation in seminars and conferences
- reviewing or editing scholarly publications and books without receipt of compensation
- service to accreditation bodies

These activities, which demonstrate active participation in a profession are encouraged, provided they do not conflict or interfere with the timely and effective performance of the employee's primary **Institutional Responsibilities** or College policies.

Faculty and non-Faculty employees of the College may participate in activities for compensation outside of their **Institutional Duties**. Employees are required to receive approval in advance for External Professional Activities for Pay (EPAP), except for contract employees performing such activities for pay entirely outside the months of their College contract employment.

College policy does not provide that any faculty or non-faculty employee is entitled to engage in any EPAP for any specific or set percentage of time. Rather, an employee's supervisor always has the discretion to determine whether a proposed external activity is appropriate in scope and duration or constitutes excessive time away from **Institutional Responsibilities**.

While EPAPs may convey some implied benefit to an employee's position or, in general, to the College, such activities are not considered part of any employee's **Institutional Responsibilities;** however, they may be considered related to **Institutional Responsibilities** and should be disclosed as **Personal or Financial Interests** as applicable**.**

Employees may not use any College resources in support of these type of activities except as provided in Section V. C. below. While not inclusive of all resources, some examples of College resources which may not be used as part of, or in support of, an EPAP include an application to the Institutional Review Board or the assignment of student work. Please see Section V. C., Use of College Resources, in this Policy for further guidance.

Required Action:

Any potential Conflicts of Commitment between primary and secondary duties are subject to review by the employee's supervisor, department Chair or unit head.

A faculty or non-faculty employee who intends to engage in an EPAP is must submit a written request to participate to the employee's supervisor at least ten (10) days before engaging in the activity.

A faculty or non-faculty employee who is a College inventor seeking to engage in external professional activity, compensated or uncompensated, with an entity that proposes to license, has licensed or has otherwise acquired rights to his or her invention should include this information in the request so that the supervisor is notified of this relationship and the supervisor can consult with the Research Department. (See section "Intellectual Property Transactions" below).

The supervisor, chair or department head is required to respond with approval or disapproval of the EPAP request within 10 days of the submission of the request to participate.

V. CONFLICT OF INTEREST

A. Acceptance by Individuals of Gifts, Favors from External Entities

Generally, College employees may neither accept nor offer, either directly or indirectly, any personal gift or favor or loan to or from an organization, entity or person that is conducting or seeking to conduct business with the College, unless the gift is nominal.

A "nominal" gift occurs where the fair market value of all payments, gifts or favors from the same or related source within a single calendar year is less than forty dollars ($40.00). Cash gifts of any size are not considered nominal.

However, meals, texts, or customary honoraria may be provided to faculty or non-faculty employees in connection with secondary duties as listed above. Although customary honoraria and reimbursement for actual costs generally are not considered to be gifts, if reimbursements or **Honoraria** are significantly in excess of fair market value or customary amounts (e.g. expensive resort sojourns, coverage of family member expenses, etc.), they are defacto gifts.

College employees also may not accept any financial or other favors in exchange for privileged access by current or potential College vendors to College facilities or employees. Any personal compensation a **Project** sponsor pays to or for the benefit of a **Covered Individual** outside of contracted project support to the College must be reported by the **Covered Individual** as applicable under this Policy.

A College employee may not receive compensation from an external source for performance of College work except through a College contract or grant.

B. Gifts to the College or an Affiliated Foundation for the Benefit of a Covered Individual

For purposes of this Policy, gifts and donations that have been made to the College or to a College-affiliated foundation for the benefit of the professional activities of a C**overed**

Individual are considered to be a **Financial Interest** of the intended beneficiary, even though such gifts or donations are not the legal property of the beneficiary.

Such gifts and donations, where they coincide with College activities undertaken by the beneficiary that relate to the entity making the gift or donation, may create a **Conflict of Interest**, and they shall be disclosed by that individual as required under this Policy as for any other **Financial Interest** when the C**overed Individual** completes an applicable Conflict of Interest Disclosure form.

C. Use of College Resources, including Privileged Information

Confidential or privileged information acquired by the College may not be used by a **Covered Individual** for personal gain, nor may any **Covered Individual** permit unauthorized access to such confidential or privileged information. Insider trading is just one form of impermissible use of privileged information for personal gain. **College faculty and staff should be wary of consulting arrangements through which they may risk sharing confidential proprietary information acquired through sponsored Projects**.

Covered Individuals may not use for non-College purposes any College-funded or supported resources, including but not limited to College facilities, administrative offices, work product, results, materials, property records, or information developed with College funding or other College support except as otherwise allowed under College policy.

This prohibition includes the use of the College's name in a manner that may imply that the College is associated in some way with the **Covered Individual's** external activity or interest. One context in which this situation might occur for a faculty or non-faculty employee is an External Professional Activity for Pay. Mere identification of the College as one's employer and of one's position at the College is permitted, provided that such identification is not used in a manner that implies sponsorship or endorsement by the College.

Use of College facilities and resources must be in accord with the College's *Policy 3018 Facilities Usage and Charges*. Examples of acceptable use, which include but are not limited to, are minimal use of the telephone, support staff, or computer equipment. Please see the referenced policies for additional details.

Use of College facilities or resources that are governed by a facility use agreement entered into between a third party and the College must be undertaken in accordance with the terms of that Agreement. Such agreements are also subject to a conflict of interest review by the chief operating officer/chief financial officer. Any **Covered Individual** who is named in a facility use agreement will be deemed to have a **Conflict of Interest** under this Policy.

D. Purchasing, Contracting, Other Business Transactions on behalf of the College

A College employee generally may not participate in awarding, negotiating, reviewing or approving a financial transaction (including but not limited to purchases, contracts, and subcontracts) involving the College and an entity in which the employee has a personal financial interest without prior review and approval as described immediately below. Where an employee is involved in the design, conduct or reporting of College research related to that employee's **Financial Interest**, that potential conflict of interest is governed by the sections below entitled "Intellectual Property Transactions" and "Research and Sponsored Projects." In addition, an employee may assist in the negotiation of license agreements for College intellectual property.

Required Action:

College employees routinely involved in the negotiation, approval or administration of College contracts with external entities must file the applicable Conflict of Interest Disclosure form with the College's chief operating officer/chief financial officer. See the section below entitled "Exercise of College Administrative Responsibilities."

If a College employee has not filed an applicable Conflict of Interest Disclosure form disclosing **Personal** and/or **Financial Interests** but is prospectively involved in awarding, negotiating, reviewing or approving a financial transaction involving the College and an entity where there is **Personal** and/or **Financial Interest** of that individual, the potential conflict of interest must be reported to the employee's supervisor. The supervisor shall reassign that transaction to another employee with prior approval and such management as is deemed appropriate by the chief operating officer/chief financial officer.

E. Intellectual Property Transactions

The College's mission includes fostering the invention and development of new patentable and non-patentable technologies, methodologies or copyrights. The College may attempt to license these innovations to commercial entities so that College research results may reach the market for the public good. The College must be protected from both real and perceived inappropriate "pipelining" of College innovations to entities in which College inventors have **Personal** or **Financial Interests**. The College's facilities and resources must not be used to the advantage of the licensee entity without advance and specific authorization consistent with applicable College policy and procedures.

Required Action:

All **Covered Individuals** who are College inventors are required to disclose their **Personal** or **Financial Interests** and those of their **Family** in the course of the licensing process.

Covered Individuals who are College inventors of technologies licensed or otherwise made available through contract by the College to a third party must complete and submit an applicable Conflict of Interest Disclosure form before execution of the license or other agreement by the Research Department. Any **Covered Individual** who is an inventor and who holds equity in, is an officer or director of, or provides consultative services to an entity that has licensed or otherwise acquired rights to College invention(s) or copyrights will be deemed to have a **Conflict of Interest** under this Policy.

Updated Conflict of Interest Disclosure forms must be submitted to the College's chief operating officer/chief financial officer promptly when changes arise that may either: (a) give rise to a reportable **Personal or Financial Interest**; (b) eliminate a previously reported **Personal or Financial Interest**; or (c) result in an affirmative answer to any question previously answered in the negative.

Additionally, external consulting relationships between a **Covered Individual** who is College inventor and the holder of a College license for the inventor's technology are not permitted unless reviewed and approved in advance both as detailed in the Conflict of Commitment section above.

F. College Administrative Roles

By virtue of their role, individuals in administrative positions may have substantial influence in professional appointments, promotions, tenure decisions, allocations of space, determinations of salary, staffing decisions, execution of business contracts, etc., and must take particular care to avoid relationships that have the potential to advantage the individual but adversely affect the College's interests or inject inappropriate considerations into administrative decisions. They must be vigilant in ensuring that their exercises of administrative decisions are not, and do not appear to be, colored by their personal financial interests. (Such relationships may also be prohibited under the *Policy on Institutional Conflicts of Interest*.)

Required Action:

All College Vice-Presidents, Directors, Managers, Development personnel and any other employee deemed by his or her supervisor or the Conflict of Interest Officer to be routinely involved in decisions regarding professional appointments, promotions, tenure, allocations of

space, determinations of salary, staffing decisions or the review, award, or administration of College contracts must complete an applicable Conflict of Interest Disclosure form.

Updated Conflict of Interest Disclosure forms must be submitted promptly when changes arise that may either: (a) give rise to a new **Personal or Financial Interest**; (b) eliminate a previously reported **Personal or Financial Interest**; or (c) result in an affirmative answer to any question previously answered in the negative.

Further information on disclosure requirements is included in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment.*

G. College Review Panels

There are also important conflict of interest responsibilities for individuals participating on panels providing administrative review and evaluation on behalf of the College. Such panels include but are not limited to Administrative Council, Institutional Review Board, and Strategic Planning Committee.

Required Action:

If any individual member of a College review panel has a financial or personal interest (including **Family** member interests) in a matter subject to the panel's review, that individual must report the potential conflict of interest to the panel's chair. If the panel chair deems the conflict to be material to the matter under review, the panel member shall recuse himself or herself and shall not participate in the related review process. The recusal shall be documented in the panel's minutes. The offices which provide oversight over such panels may provide further guidance to their panels.

H. Research and Sponsored Projects

The following sections of this Policy contain requirements applicable to all **Projects**, regardless of level or source of funding. Certain provisions apply to all **Covered Individuals**, while others are limited to **Investigators,** or further limited to **Investigators** engaged in **PHS**-funded research. It is the responsibility of each **Covered Individual** to understand which of the following provisions and associated required actions are applicable in the performance of his or her **Institutional Responsibilities**.

1) Training

Training is required of all **Covered Individuals** prior to involvement in any **Project** and at least every four years thereafter. Such training will inform the **Covered Individual** of the College's Policy, an **Investigator's** disclosure responsibilities and federal regulations on financial conflict of interest.

Required Action:

All **Covered Individuals** involved in a **Project** will need to complete the COI training modules through the intranet. Training completion will be reflected in the individual's personnel file as well as in the Conflict of Interest compliance files. Funding for any sponsored **Project** may not proceed until all of the **Covered Individuals** involved in these activities have completed the COI training.

For **Covered Individuals** new to the College, training will be completed prior to involvement in any **Project**. **Investigators** are also subject to re-training when either of the following circumstances occurs: (1) the College determines that an **Investigator** is not in compliance with the College Policy or his/her specific management plan or (2) the College revises its Policy in a manner that affects the requirements of **Investigators**' responsibilities.

Alternative training options for those **Covered Individuals** with special circumstances may be proposed by a principal investigator and approved on a case by case basis by the chief operating officer/chief financial officer. Further information is included in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment*.

2) Disclosure

Disclosure is required from all **Investigators** involved in any **Project** that is submitted through the Department of Research. **Investigators** are required to complete any applicable Conflict of Interest Disclosure form and provide details regarding their **Personal** or **Financial Interests** as necessary in the conflict of interest review process. Disclosure must include any **Personal** or **Financial Interest**, regardless of level or type of compensation, and any uncompensated position, board membership, or consultancy with or for an external entity involved in the **Project** in any way, including as a sponsor, subcontractor, subrecipient, or as an owner or licensee of any product, process or technology studied in the **Project**.

For the purpose of this Policy, **Investigator** includes the principal investigator, project director, key personnel and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of a **Project**. **Investigators** may also include research study coordinators, research assistants, graduate students or others. For the purposes of this Policy, research collaborators or independent consultants may also be considered **Investigators** depending upon their activities on the Project.

The term **Investigator** is not intended to apply to individuals who primarily provide technical support, administrative support, or who are purely advisory, such that these individuals have no influence over the research results (e.g. control over its collection, analysis or reporting).

The Principal Investigator on each **Project** is responsible for ensuring that each individual who qualifies as an **Investigator** has completed a Conflict of Interest Disclosure form as required under this Policy.

Further information is detailed in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment.*

Required Action:

All **Investigators** are required to complete and submit a Conflict of Interest Disclosure form annually and for each **Project**. Any **Investigator** new to the College must complete any applicable Conflict of Interest Disclosure form upon request related to a **Project** submission or an annual form within 60 (sixty) days from the commencement of employment.

For the purposes of this Policy, research collaborators or independent contractors who are determined to be **Investigator**s will need to comply with this Policy if not covered by a conflict of interest policy at their own organization or institution. A letter of assurance signed by an authorized official at their own organization indicating policy coverage must be provided by these individuals.

Investigators are responsible for updating their Conflict of Interest Disclosure forms within 30 (thirty) days when changes arise that may either: (a) give rise to a **Personal** or **Financial Interest**; (b) eliminate a previously reported **Financial Interest**; or (c) result in an affirmative answer to any question on any Conflict of Interest Disclosure form previously answered in the negative.

3) **Review**

Conflict of Interest Disclosure forms are submitted to the College's chief operating officer/chief financial officer and processed as specified in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment.* Such review will determine whether there is a **Conflict of Interest** of any level or type and a specific review to determine if a **Financial Conflict of Interest** (**FCOI**) exists.

Potential conflict of interests includes any **Financial** or **Personal Interest**, regardless of level

or type of compensation, and any uncompensated position, board membership, or consultancy with or for an external entity involved in the **Project** in any way, including as a sponsor, subcontractor, sub-recipient, or as an owner or licensee of any product, process or technology studied in the **Project.**

The review will include an analysis of the **Investigator's Personal** and **Financial Interests** and relatedness to his/her **Institutional Responsibilities**. Whether the interests are determined to be an actual **Conflict of Interest** will depend upon the nature of the **Personal** and/or **Financial Interests,** the relatedness of the responsibilities and the nature of the activities potentially affected by the disclosed **Personal** or **Financial Interest**. Specific review will be conducted to determine if the disclosed interests meet the federal definition of being a **FCOI**.

Subject to special provisions regarding particular types of College relationships (such as SBIR or STTR Agreements, *see below*), the following guidelines are generally applicable:

(A) Where an **Investigator** proposes to be engaged in the design, conduct or reporting of College research other than **Human Subjects Research**, his or her **Conflict of Interest** or **FCOI** may be allowed with College approval and appropriate management.

(B) Where an **Investigator** proposes to be involved in the design, conduct or reporting of College **Human Subjects Research**, he or she may not have a **Personal** or **Financial Interest** of any level or value reasonably judged to be significantly and directly related to the outcomes of such research, absent a showing by the **Investigator** of compelling circumstances justifying continuation of involvement in the **Project** notwithstanding these **Interests**.

Compelling circumstances are those facts that convince the reviewer that an **Investigator** who has a **Personal** or **Financial Interest** judged to be significantly and directly related to the research 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 interest and the degree to which it is related to the research,
(3) the extent to which the **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 **Investigator** is uniquely qualified to perform a research study with important public benefit, and
(6) the extent to which the **Personal** or **Financial Interest** is amenable to

effective oversight and management.

(C) The training experience and academic progress of College students and trainees must not be subordinated to the **Personal** or **Financial interest** of an **Investigator** or commercial interests of research sponsors.

Where a **Conflict of Interest** or **FCOI** poses the risk that College activities may be inappropriately affected, the conflict must be managed, reduced or eliminated.

Required Action:

The **Investigator** will be contacted at the sequential stages of the process to indicate the status of the review. Any Conflict of Interest Disclosure form submitted by an **Investigator** will be processed as specified in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment.*

When the need for a Conflict of Interest Disclosure form is indicated through the review processes of the Office of Sponsored Research, any of the Institutional Review Boards, or any other College office, the research or other contract for which the form is indicated or the initiation of **Human Subject Research** may not proceed until the Conflict of Interest Disclosure form has been disclosed, evaluated and approved or resolved. Violation of this provision by any **Covered Individual** may lead to disciplinary action, up to and including dismissal from employment or enrollment.

4) SBIR/STTR

Of special concern are federally sponsored SBIR or STTR research projects that involve association with small business entities. Due to the potential for either the actual or the appearance of a **Conflict of Interest**, a **Covered Individual** may not conduct research or administrative activities in conjunction with a SBIR or STTR project on behalf of both the College and the grantee or sub-grantee company without compelling evidence to support execution of both roles. Approval must be received through the conflict of interest review in accordance with the standards in this Policy prior to the commencement of any activities arising from such collaboration.

5) Compliance with External Sponsors

The College will be compliant regarding conflict of interest standards as required by the terms of its agreement with external sponsors.

The College will submit reports to federal sponsors as required under applicable federal

regulations. Reports on **FCOIs** for those **Investigators** with **PHS** funding shall be submitted to the **PHS** awarding component as required ("FCOI Reports"). FCOI Reports shall be submitted prior to the College's expenditure of funds under the **PHS** funded project and annually thereafter. In addition, the College must submit an FCOI Report within sixty (60) days of the identification of any new **FCOIs** (e.g., upon the participation of an **Investigator** who is new to the research).

For **Projects** funded by the National Science Foundation ("NSF"), the College will inform the NSF's Office of General Counsel if the College is unable to satisfactorily manage an **FCOI**.

Required Action:

FCOI Reports shall include a statement that the College has implemented a management plan, as well as key elements of the management plan and other information regarding the nature and value of the **Financial Interest** as required under **PHS** regulations. Further guidance on the information required to be reported pursuant to federal regulations is included in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment*.

6) Provisions Specific to Research Funded by Certain Federal Sponsors

The following sections contain requirements that apply to research funded by certain Federal sponsors. Accordingly, the following sections have a more narrow application than the prior sections that apply to all **Projects**.

a) Travel and Paid Authorship

As detailed in the **PHS** regulations, **Investigators** who receive **PHS** research funding are also required to disclose 1) reimbursed or compensated travel and 2) paid authorship. **PHS** funded **Investigators** must disclose any **Reimbursed or Sponsored Travel** related to their **Institutional Responsibilities**. The College will determine if any travel disclosure requires further review, including but not limited to the disclosure of the monetary value of the travel. Additionally, **PHS** funded **Investigators** must disclose any income received from any paid authorship, including textbooks.

Required Action

PHS funded **Investigators** must disclose the occurrence of any **Reimbursed or Sponsored Travel**, with exclusions, related to their **Institutional Responsibilities** through a specific Conflict of Interest travel disclosure form which will capture the sponsor or organizer, purpose, destination and duration of the travel. Generally, exclusions from disclosure include any travel paid directly by the College, a US public entity or a US academic institution. The Conflict of Interest travel disclosure form should be submitted prior to the travel but must be submitted no

later than 30 days after the occurrence of the travel.

Disclosure for paid authorship can be submitted on any applicable Conflict of Interest Disclosure form, and must be submitted no less than annually.

Further information about specific exclusions from the necessary disclosure and processing of the COI disclosure forms are specified in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment.*

b) Public Accessibility

In accordance with the federal regulations, the College will make information available to the public regarding **FCOIs** for those **Senior/Key Personnel** in conjunction with a specifically **PHS** funded research project either through responding to a written request or web posting.

Required Action

More specific information on public accessibility to the **FCOI** information is set forth in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment.*

c) Subcontracts

If the College carries out research funded by the **PHS** or the NSF through sub recipients, contractors, or collaborators, the College must take reasonable steps to ensure that **Investigators** working for such entities either (1) comply with this Policy or (2) the entity has its own policy that meets applicable federal requirements on financial conflicts of interest.

Required Action

For research sponsored by the **PHS**, the College's Office of Sponsored Research requires that a sub-recipient provides an indication during the application process of contractual assurance of its compliance with **PHS'** policy on conflict of interest or the intent to comply with the College's Policy.

If the sub-recipient provides assurance of its own policy, there is a contractual obligation that includes a requirement that the sub recipient report to the College's Office of Sponsored Research the following information for any **FCOI** of sub recipient **Investigators**: (a) sub recipient contract number; (b) name of the sub recipient **Investigator** with the **FCOI**; (c) name

of the entity with which the **Investigator** has a **FCOI**; (d) nature of the financial interest (e.g., equity, consulting, etc.); (e) value of the financial interest; (f) a description of how the financial interest relates to the **PHS**-funded research and the basis for the sub-recipient's determination that the financial interest conflicts with the **PHS** funded research; and (g) a description of the management plan.

The Office of Sponsored Research will forward a copy of each such sub recipient report, identified by **PHS** grant number, with a copy to the Principal Investigator and the Conflict of Interest Officer for reporting to the **PHS** awarding component.

If the sub-recipient chooses to comply with the College's Policy, then a statement to this effect should be included in the letter of intent and will be included in the sub-award contract. All sub recipient **Investigators** known at the time of application must be identified and complete the necessary disclosure process and applicable training as detailed in this Policy. If additional **Investigators** are identified by the sub-recipient at the time of the sub-award contract, these **Investigators** must complete the applicable Conflict of Interest Disclosure form and applicable conflict of interest training before the sub-award can be granted. In these instances, the College will report to the **PHS**-awarding component **FCOIs** related to sub recipient **Investigators** in the same manner as it reports **FCOIs** related to its **Investigators**.

VI. RECORDS CONFIDENTIALITY AND RETENTION

A. Confidentiality

The Conflict of Interest Disclosure forms, review information and any related management plans containing information that may have a direct bearing on a **Covered Individual's** employment and are considered to be confidential personnel information that should be maintained in a secure and confidential file. Access to information disclosed in the COI review process, including management plans, will be limited to those with a need to know. This information is available only to individuals duly charged with the responsibility for review, the College's IRB, any central IRB under agreement with the College and other College offices with a business purpose and may be released only in accordance with and as required by federal regulation, South Carolina law or lawful court order.

B. Records Retention

All records relating to the reporting of potential conflicts of interest and commitment, and to the actions taken with respect to those disclosures, reports or plans, shall be maintained for three years following the expiration of their relevance, or as required by applicable government regulations, whichever is greater.

VII. POLICY IMPLEMENTATION

The President is responsible for overseeing the implementation of this Policy. Day-to- day responsibility for such implementation is delegated through the Director of Research to the chief operating officer/chief financial officer. The College will make this policy and the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment* available on its website.

In addition, the Administrative Council will be authorized to make recommendations to the President for appropriate changes to this Policy, along with such other recommendations regarding the disclosure, evaluation, approval and management of conflicts of interest as the Committee deems appropriate.

VIII. POLICY BREACHES

Possible sanctions for violation of this Policy, including furnishing false, misleading, or incomplete information, can range from administrative intervention to termination of employment or of enrollment, all in accordance with applicable College policies. The President, or the President's delegate, will review all alleged violations of this Policy, including the provisions of the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment.* Violations may include but are not limited to: (a) failure to comply with the process (by failure to disclose timely **Personal** or **Financial Interests** as required, by failure or refusal to respond to requests for additional information, by providing incomplete or knowingly inaccurate information, or otherwise); (b) failure to remedy conflicts; and (c) failure to comply with a prescribed management agreement or monitoring plan.

When the College identifies a **Financial Interest** that was not disclosed timely by an **Investigator** or, for whatever reason, was not previously reviewed by the College during an ongoing **PHS**-funded **Project** (such that it was not timely reviewed or reported by a subrecipient), the Conflict of Interest Officer will, within 60 days (1) review the **Financial Interest**, (2) determine whether it is related to the research, and (3) determine whether a **FCOI** exists. If a **FCOI** is determined to exist, the College will implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the **FCOI** going forward.

In addition, whenever a **FCOI** is not identified or managed in a timely manner due to (1) failure by the **Investigator** to disclose a **Financial Interest** that is determined by the College to constitute a **FCOI**, (2) failure by the College to review or manage a **FCOI**, or (3) failure by the **Investigator** to comply with a **FCOI** management plan, the College shall, within 120 days of the College's determination of noncompliance, complete a retrospective review of the **Investigator**'s activities and the **PHS**-funded research project to determine whether any **PHS**-funded research, or portion thereof, conducted during the time period of the

noncompliance, was biased in the design, conduct, or reporting of such research. Such reviews will be in accordance with federal regulation and documented as detailed in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment*.

If a determination of bias is made during the retrospective review, a mitigation report will be completed. Mitigation reports will include among other elements, a description of the impact of the bias on the **PHS**-funded **Project** and the College's action or actions taken to eliminate or mitigate the effect of the bias. In those instances where the Department of Health and Human Services determines that a **PHS**-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an **Investigator** with a **FCOI** that was not managed or reported by the College as required under **PHS** regulations, the College will require the **Investigator** involved to disclosure the **FCOI** in each public presentation of the results of the research and to request an addendum to previously published presentation.

SHERMAN COLLEGE OF CHIROPRACTIC

STANDARD OPERATING PROCEDURES FOR INDIVIDUAL CONFLICTS OF INTEREST AND COMMITMENT

I. Introduction
II. Committee Structure
III. Conflict of Commitment
IV. Conflict of Interest
V. Management of COI
VI. Investigation and Resolution of Policy Violations

I. Introduction

These Standard Operating Procedures ("SOPs") are based on the College's *Policy on Individual Conflicts of Interest and Commitment* ("the Policy") and are intended to provide effective and transparent processes for the disclosure, review, management, and reporting of potential conflicts of interest within the College community. The SOPs do not apply to situations arising under the *Policy on Institutional Conflicts of Interest* or to situations governed by the Ethics in Government Act.

Terms used in these SOPs shall have the meaning as under the Policy unless otherwise noted. The SOPs are maintained and executed, except as noted, by the chief operating officer/chief financial officer and the Director of Research who are part of the Research Compliance

Program. The chief operating officer/chief financial officer serves as the College's Conflict of Interest ("COI") Officer. These SOPs are subject to change.

II. Committee Structure

The Administrative Council serves as the College's Conflict of Interest Committee.

III. Conflict of Commitment

External Professional Activities for Pay (EPAP) requests should be submitted by the requesting employee 10 days prior to the activity to the employee's supervisor. Any EPAP request will be routed to the designated EPAP approver(s) for review. EPAP approvers can approve or deny the requests. The decision, with any available comments, is automatically routed back to the requesting employee.

For further information, please see the *Employee Handbook*.

IV. Conflict of Interest

The definition of a conflict of interest being situations where a Covered Individual's personal or financial interest:

- may compromise,
- may involve the potential for compromising, or
- may have the appearance of compromising

his or her objectivity in meeting College duties or Institutional Responsibilities, including research activities.

A. College Responsibilities Annual Administrative Role Disclosure

The COI Officer shall create a schedule of required submission dates for College employees specifically required by the Policy to submit a conflict of interest annual form. Such form will be designed by the COI Officer and shall be filed in the Business Office. Any employee who fails to file a required form on or before the date specified by the COI Officer other than for good cause (as determined by the COI Officer) shall be deemed to be in violation of the Policy and subject to disciplinary review by his or her supervisor.

The COI Officer will review all conflict of interest annual forms and determine whether or not the information disclosed in each represents a potential COI. Upon making the determination that there is a potential COI, the COI Officer will forward the applicable

disclosure form with a preliminary analysis and recommendation for resolution to the senior vice president for presidential affairs ("the reviewing officer").

The reviewing officer shall issue a decision regarding the disclosure within fourteen days of receipt of the conflict of interest annual form, provided that that deadline may be extended by the COI Officer for good cause. Where the reviewing officer agrees with the COI Officer's analysis, the employee will be required to recuse himself or herself from any College activities affected by his or her COI. In situations where recusal of the employee cannot be effected consistent with his or her Institutional Responsibilities, the employee will be required to resolve the COI by divestment of the personal financial interest causing the COI.

Where the reviewing officer disagrees with the COI Officer's conclusion that a COI exists, he or she shall set out the basis for that decision in a memorandum to the President, with a copy to the COI Officer and the employee. The President may accept or reject the reviewing officer's decision and order such further measures to resolve or manage the COI as the President deems appropriate.

B. Research and Sponsored Projects Conflicts of Interest

The following sections provide details on the procedures for complying with Section V.H of the Policy.

1. COI Training

As specified in the Policy, all Covered Individuals are required to complete Conflict of Interest training prior to involvement in a Project. The training requirement applies whether the Project is funded or unfunded. Administrative offices which support the research enterprise are encouraged to take this training as well.

The training modules are at sherman.edu under intranet resource documents. Except as detailed in the Policy, completion of training is valid for four years. Training status for an individual will be reflected in the individual's personnel file as well as the COI officer's compliance files. The Director of Research is responsible for ensuring that training has been completed prior to assigning a Covered Individual to a sponsored award account number.

Any principal investigator requesting use of alternative training should submit a written request to the COI officer and attach a proposed plan for the alternative training.

2. Disclosures

The College requires that all Investigators involved in a Project submitted through the Office

of Sponsored Research ("OSR") or the Office of Human Research Ethics ("OHRE") submit conflict of interest disclosure forms detailing their personal and financial interests. Investigators will also need to complete an annual conflict of interest disclosure form.

The requirement to complete a specific conflict of interest disclosure form is communicated through an email notification to the Investigator. The email provides a link to access the form.

Other conflict of interest disclosures are self-initiated by an Investigator. All conflict of interest disclosure forms can also be accessed through the intranet at sherman.edu.

A. Paid Authorship Disclosure

Investigators with PHS funding must disclose any compensation received from paid authorship which includes textbooks, book chapters, etc. This information will need to be disclosed in the conflict of interest annual disclosure form. The College will determine if any further information is needed from the Investigator to assess the disclosure.

B. Reimbursed or Sponsored Travel Disclosure Form

Investigators with PHS funding must self-disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities. To assist PHS funded Investigators in submission of this information, Investigators will receive a monthly reminder email to submit travel disclosures if appropriate. Such disclosure will include the sponsor or organizer, the purpose of trip, the destination, and the duration. Disclosure of reimbursed or sponsored travel is done through a specific travel disclosure form, separate from the annual and project-specific disclosures.

PHS funded Investigators are NOT required to disclose travel that is reimbursed or sponsored:

- directly through the College
- by a US federal, state, or local government agency, or
- by a US institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Reimbursed or sponsored travel from all other sources, including private entities, foreign governments, foreign universities, non-profits or NGO's must be disclosed.

The travel disclosure form should be submitted prior to the travel but must be submitted no

later than 30 days after the occurrence of the travel. PHS funded Investigators will receive a monthly reminder email to submit travel disclosures if appropriate. The College will determine if any travel disclosure requires further information, including but not limited to the disclosure of the monetary value.

3. Review

Upon completion of either the annual or project specific conflict of interest disclosure by an Investigator, the COI Officer checks for affirmative answers that might be an indication of a potential COI. If a potential COI is not indicated, the disclosure is finalized in the COI files.

If a potential COI is identified by the system, the disclosure is flagged and reviewed by COI officer, who will make a threshold determination of whether a potential COI exists. The Investigator may be contacted to gather additional or supplemental information necessary to evaluate the disclosure.

If the COI Officer determines that no potential COI exists, the COI Officer will inform the Investigator of the determination.

If the COI Officer determines that a potential COI exists, an alert is sent to the Administrative Council indicating that a review is necessary. The Vice President for Academic Affairs, with input from the COI Officer, will review the disclosure and make a determination regarding whether the case can be handled through expedited review or whether the case should be assigned to an agenda for full committee review. If the Vice President for Academic Affairs determines that expedited review is appropriate, he or she will make recommendations to the COI Officer on management of the conflict.

Taking into account any conclusion reached by the Vice President for Academic Affairs or Administrative Council, the COI Officer will determine whether a COI exists and, if so, whether it can be managed or must be resolved in order for the Project to proceed. The COI Officer may proceed to make a determination regarding the existence of a COI if no advice is provided by the Vice President for Academic Affairs or Administrative Council within fourteen (14) days of transmission of the need for a COI evaluation; this deadline may be extended by the COI Officer for good cause and where doing so will not jeopardize the proposed research relationship.

The COI Officer shall indicate in the COI files one of the following determinations and the will convey the decision to the Investigator:

(i) No COI exists;

(ii) A COI exists that is subject to administrative considerations by the College,

(iii) A FCOI exists that is subject to management by the College,

(iv) A COI or FCOI exists that cannot be managed.

Where a COI is deemed to be subject to administrative considerations, the COI staff will promptly contact the Investigator with the proposed details and will secure the Investigator's agreement to such administrative considerations.

Where a FCOI is deemed to be subject to management, the COI Officer will promptly contact the Covered Individual to discuss the Management Agreement and will arrange necessary meetings with the Investigator to resolve any questions he or she may have prior to gaining the Investigator's agreement to abide by the created a Management Agreement.

The IRB retains final jurisdiction over Human Subjects Research and may decline to approve an application on grounds of COI notwithstanding a decision by the COI Officer that there is no COI or that a COI is present but capable of being managed.

V. Management of Conflicts of Interests

A. Management Principles

The COI Officer is responsible for designing appropriate management mechanisms for conflict of interest activities which have been determined to be capable of being managed. The COI staff will work with the Research Department on determining the management plan and tools. The COI Officer may seek advice from individuals outside as well as within the College in proposing such mechanisms.

Possible measures to be taken in managing a COI include, but are not limited to, any of the following:

- Public disclosure of financial interests
- Reformulation of the work plan
- Close monitoring of the project; independent review committee
- Substituting supervisors and/or any other personnel
- Divestiture of financial interests
- Termination or reduction of involvement in the relevant projects
- Termination of inappropriate student involvement in projects

- Severance of relationships that pose actual, potential or the appearance of conflicts
- Separation of the Covered Individual from involvement in human subject's research in the critical areas of recruitment, inclusion/exclusion evaluation, enrollment, and adverse event evaluation and reporting.

B. Reporting of FCOI for PHS Funded Investigators

As required by PHS regulations, the College shall report the following information regarding FCOIs related to PHS funded research to the funding agency through the eRA Commons:

- Project Number
- PD/PI or Contact PD/PI if multiple PD/PI model is used
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has a the FCOI
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- Value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value
- A description of how the financial interest relates to the PHS-funded research and the basis for the College's determination that the financial interest conflicts with such research
- A description of key elements of the College'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
    - Other information as needed or requested by the funding agency

C. Public Accessibility

In accordance with the federal regulations, the College will make information available to the public regarding **FCOIs** for those **Senior/Key Personnel** in conjunction with a specifically **PHS** funded research project. Requests must be submitted in writing to

Sherman College of Chiropractic, Business Office, Post Office Box 1452, Spartanburg, SC 29304-1452, Attention: COI Request. Request will be answered within five business days from the date of receipt at the Business Office. The request must identify the specific PHS project number for which the information is being requested and must include a named recipient. If the request is in writing, a return address with a physical street address must be included, P.O. Boxes are not acceptable.

The College will note in its written response that the information is current as of the date of the correspondence and is subject to updates at least annually and within 60 days of the College's identification of a new FCOI, which must be requested under separate cover by the requestor.

In accordance with PHS regulations, the following information will be provided:

1. Project Number
2. Name of the Investigator with a conflicted interest;
3. Investigator's title and role with respect to the PHS research project;
4. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); and Value of the financial interest (in ranges), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

VI. Investigation and Resolution of Policy Violations

Any time the COI Officer becomes aware of a potential violation of the Policy or of any other situation that could indicate that College research, education and training may have been affected inappropriately by a Conflict of Interest, the COI Officer shall conduct a preliminary investigation to determine whether the concerns appear to be warranted.

On receipt of such a report, the COI Officer shall notify the Executive Team. In consultation with those persons, the Conflict of Interest Officer may:

(1) Investigate the matter and make a written memorandum of his or her conclusions;

(2) Request that the person or committee assigned to monitor the activity conduct an investigation and file a written report of the results of that investigation; or

(3) Appoint another faculty member or a committee of faculty members to conduct an investigation and file a written report of the results of that investigation.

Any such investigation should, at a minimum, include a personal interview with the person bringing forth the allegations or concerns and a personal interview with the Covered Individual, who should be informed with specificity of the allegations or concerns that have arisen. While the Covered Individual has a right to know the identity of a person making such allegations, he or she should be informed that College policy prohibits retaliation against a person making such allegations in good faith.

Upon determination that a violation of this Policy has occurred or of the existence of a situation that could indicate that College research, education, training, business administration or other performance may have been affected inappropriately by a conflict of interest, the COI Officer should take any steps necessary to correct the situation, including and up to disapproval of the conflict of interest being managed. In addition, where appropriate the COI Officer must consider recommending to the relevant officials the imposition of disciplinary or other action under other appropriate College policies, including the Policies and Procedures on Ethics in Research and disciplinary policies for faculty, staff or students. Such possible actions or sanctions could include a letter of reprimand, increased monitoring of the conflict or other appropriate actions. The COI Officer, in consultation with the Vice President for Academic Affairs, shall have the authority to direct that the research activities of the Covered Individual affected by the COI be suspended pending conclusion of an investigation or, on conclusion of an investigation, that they be suspended pending amelioration of the Policy violation.

Upon a determination that no violation of the Policy has occurred, or otherwise at the conclusion of any investigation conducted under this Policy, all materials generated in the course of such investigation should be placed with the Covered Individual's personnel file or, if a student, with the vice president for student affairs, marked as "confidential" and stored in a secure manner, in order to ensure the confidentiality of these records.

For PHS funded studies, the College and Investigators are subject to the following additional procedures when a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a financial interest that is determined by the College to constitute a FCOI; failure by the College to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI Management Plan.

(1) The College must implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward;
(2) Within 120 days of the College's determination of noncompliance, the College must complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design,

conduct, or reporting of such research.

(3) The College must document the retrospective review and include, at minimum, the following information:
(a) Project number
(b) Project title
(c) D/PI or contact PD/PI if a multiple PD/PI model is used
(d) Name of the Investigator with the FCOI
(e) Name of the entity with which the Investigator has a FCOI
(f) Reason(s) for the retrospective review
(g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
(h) Findings of the review
(i) Conclusions of the review

Based on the results of the retrospective review, if appropriate, the College shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If the retrospective review team members find bias, the College is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the College'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).

Thereafter, the College will submit to the PHS Awarding Component FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the FCOI, the College may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research project between the date that the Investigator's noncompliance is determined and the completion of the College's retrospective review.