

AMERICAN COLLEGE OF SURGEONS
Policy and Procedure

Title: Conflict of Interest Policy — Officers, Officers-Elect, Board of Regents, Board of Governors Executive Committee, the Chief Executive Officer, Editor-in-Chief of the Journal of the American College Surgeons and its affiliated organizations.

Approved by: Board of Regents

Effective Date: June 7, 2002- Revised February 8, 2013

Purpose: To define, identify, and resolve potential conflicts of interest on the part of officers, board members and other leadership of the American College of Surgeons ("the College") and its affiliated organizations.

I. Applicability

A. This policy shall apply to the Officers, Officers-Elect, Board of Regents and Directors, Board of Governors Executive Committee, Editor-in-Chief of the Journal of the American College of Surgeons ("leadership," "member of leadership").

B. The Board of Regents shall adopt this policy by appropriate resolution pursuant to its Bylaws. The resolution shall be recorded in full in the minutes of the Board of Regents with the complete policy attached.

II. Rationale

The American College of Surgeons is a nonprofit organization dedicated to the advancement of knowledge through service, research, and education. It is the College's policy and its affiliated organizations that its leadership conducts the business of the College and its affiliated organizations in accordance with the highest legal, ethical, and moral standards. This policy statement is designed to reinforce a standard of conduct that is proper for the College or its affiliated organizations and that protects the reputation, financial well-being, and legal obligations of the College and its affiliated organizations.

III. Definitions

Conflict of Interest. A **conflict of interest** may arise whenever a member of the College's or its affiliated organizations leadership has any of the following: (1) a direct financial relationship with a company; (2) a significant financial interest in an actual or proposed transaction or arrangement that may be of some business interest to the College or its affiliated organizations; (3) the receipt of significant gifts or other favors; (4) participation in Satellite CME Symposia as a faculty member, presenter, chair, consultant, or in any role other than that of an attendee who receives no honoraria or reimbursement; or (5) participation as a leader or presenter in company promotional/marketing events held in exhibit space. Any conflict of interest on the part of a member of leadership must be disclosed and acted on as prescribed in this policy.

Company. A **company** is a for-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients.

Direct Financial Relationship with a Company. A **direct financial relationship with a company** is a relationship held by an individual with a company that results in wages, consulting fees, honoraria, or other compensation (in cash, in stock or stock options, or in kind), whether paid to the individual or to another entity at the direction of the individual, for the individual's services or expertise. The term direct financial relationship with a company does not mean stock ownership or intellectual property licensing arrangements.

Satellite CME Symposium. A **Satellite CME Symposium** is a company-supported CME program held as an adjunct to a medical specialty society meeting where CME credit for the Symposium is provided by a third party CME provider, and for which the society receives a fee.

Significant Financial Interest. **Significant financial interest** means anything of monetary value, including, but not limited to, salary or other payments for services (for example, consulting fees or honoraria); equity interests (for example, stocks, stock options or other ownership interests); and intellectual property rights (for example, patents, copyrights and royalties from such rights). The interest of the leadership may be direct or indirect, including, but not limited to, an interest of an immediate family member or of any other person having a substantial personal relationship to the member. Significant financial interest includes direct and indirect remuneration as well as gifts or favors that are substantial in nature.

The term does not include

- (1) Salary, royalties, or other remuneration from the College or its affiliated organizations.
- (2) Income from seminars, lectures, or teaching engagements sponsored by public or not-for-profit entities.
- (3) Income from service on advisory committees or review panels for public or not-for-profit entities.
- (4) An equity interest that, when aggregated for the member and the member's spouse and dependent children, meets both of the following tests:
 - Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
 - Does not represent more than a five percent ownership interest in any single entity.
- (5) Salary, royalties or other payments that, when aggregated for the member and the member's spouse and dependent children over the next 12 months, are not expected to exceed \$10,000.
- (6) Gifts or other favors of substantial value.

Immediate Family Member. Immediate family member includes spouse and dependent children as well as other family members residing in the same household.

IV. Members of Leadership

A. All leadership of the College or its affiliated organizations shall exercise the utmost good faith in all transactions touching upon their duties and responsibilities to the College and its property or its affiliated organizations. In their dealings with and on behalf of the College or its affiliated organizations, members of leadership shall be held to a strict rule of honesty and fair dealing among themselves and with the College or its affiliated organizations. They shall not use their positions, or knowledge gained from their leadership role, in such a way that a conflict might arise between the interests of the College, its affiliated organizations or that of the member.

B. All acts of members related to the conduct of the business of the College or its affiliated organizations shall be for the best interest of the College or its affiliated organizations.

C. Although it is recognized that a degree of conflict of interest may exist from time to time, such conflicts shall not be permitted to adversely influence the decision-making process of the College or its affiliated organizations. To this end, the member shall promptly report in writing the possible existence of a conflict of interest for himself or herself or any other member subject to the policy. The report shall be made to the Treasurer described in paragraph V or to his or her delegate.

D. A full disclosure of all facts pertaining to any transaction that is subject to any doubt concerning the possible existence of a conflict of interest shall be made before consummating the transaction. Disclosure shall be made in writing to the Treasurer or to his or her delegate.

E. Leadership shall be required to disclose all conflicts of interest to the Treasurer or to his or her delegate utilizing the Disclosure Statement form attached as Exhibit A. The Disclosure Statement shall be filed annually not later than January 31. The procedures to be followed in filing Disclosure Statements shall be established by the Treasurer or by his or her delegate.

V. Treasurer

The Treasurer shall provide oversight of all leadership conflicts of interest matters in the College or its affiliated organizations pursuant to its conflict of interest policies; recommend changes in conflict of interest policies when appropriate; conduct an annual review of policies and procedures implemented for the purpose of identifying and handling conflicts of interest matters in the College or its affiliated organizations; and take such actions and perform such duties as are otherwise specified for the Treasurer.

VI. Examples of Conflicts of Interest

For purposes of guidance in applying this policy, the following are examples of conflicts of interest.

A. Financial Interests

The following are prohibited activities unless specifically approved by the Conflict of Interest Committee:

(1) Participation by a member of leadership in a decision by the College or its affiliated organizations (including making a recommendation) to enter into a contract or transaction for the acquisition of goods or services with an entity in which the member or his or her immediate family or any other person having a substantial personal relationship to the member has a significant financial or ownership interest. Ownership in a mutual fund or similar investment that may have holdings in an entity that does business with the College or its affiliated organizations will not constitute a significant financial ownership interest that creates a conflict of interest.

(2) Having a direct financial relationship with a company.

(3) Use of employees of the College or its affiliated organizations to perform services for a company or other organization in which the member has a significant financial interest.

(4) Use of the College's or its affiliated organizations' supplies or equipment to support the activities of a company or institution in which the member has a significant financial interest.

(5) Use of the name of the College, its seal, or its letterhead for other than official business. Use of the name, seal or letterhead of an affiliated organization for other than official business.

(6) Participating in the negotiation of or approval of contracts between the College or its affiliated organizations and a company or organization in which the member has a significant financial interest.

(7) Use of information acquired as a result of the member's relationship with the College or its affiliated organizations for personal purposes or benefit.

(8) Participating in a Satellite CME Symposium as a faculty member, presenter, chair, consultant, or in any role other than as an attendee who receives no honoraria or reimbursement.

(9) Participating as a leader or presenter in a company promotional/marketing event held in exhibit space.

(10) Offering or giving something of value beyond what is permitted by law for the purpose of influencing the action of an official in the discharge of his or her public or legal duties.

B. Gifts and Other Favors

(1) The acceptance of bribes is prohibited under all circumstances.

(2) The following are prohibited activities unless specifically approved by the Finance Committee: acceptance of gifts or excessive entertainment from any outside concern that does, or is seeking to do, business with the College or its affiliated organization under

circumstances from which it might be inferred that such action was intended to influence or possibly could influence the individual in the performance of his or her duties.

Any gifts accepted by a member of leadership from suppliers, research sponsors, organizations, corporations, or persons who have business dealings with the College or its affiliated organizations should not be of substantial value.

(3) Except as otherwise prohibited in this policy, acceptance of reimbursement for travel expenses or other expenses related to a conference or meeting is prohibited except in those instances in which the member is making a presentation or providing a similar contribution at the meeting or conference.

It is customary for companies in the medical/health care industry to underwrite medical conferences or other professional meetings that permit academic institutions, professional associations, and health care organizations to provide continuing education. Subsidies from industry, however, should not be accepted to pay for the costs of travel, lodging, or other personal expenses of the members who are merely attending conferences or meetings, nor should subsidies be accepted to compensate for their time. Subsidies for hospitality should not be accepted outside modest meals or social events held as a part of a conference or meeting.

Except as otherwise prohibited in this policy, it is appropriate for members who are participating in a conference or meeting as presenters or panelists to accept reasonable honoraria and reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for members who supply genuine consulting services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses.

The giving of a gift directly to a member from a company's sales representative may create a personal relationship that could influence the use of the company's goods or services. Accordingly, when a company contributes funds for conferences that are sponsored by academic or other educational institutions, the funds should be given by the company to the conference sponsor who, in turn, can use the money to reduce the registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the member attending the conference.

VII. Disclosures Required

In order to identify and to resolve any potential conflict of interest situations, the following disclosures are required:

A. All members of leadership of the College or its affiliated organizations will be required to file a Disclosure Statement annually or more frequently if changes arise that may either give rise to a conflict of interest or eliminate a previously reported conflict of interest.

B. Disclosure Statements will be reviewed by the Treasurer or his or her delegate, and any suspected conflicts of interest shall be reported promptly to the Finance Committee of the Board of Regents.

C. Members whose Disclosure Statements have been referred to the Finance Committee will be notified by the Treasurer or his or her delegate.

D. The Treasurer or his or her delegate will verify annually that Disclosure Statements have been filed and approved and will file a report with the Finance Committee annually of the results of the review of these statements.

VIII. Administrative Action in Response to Identified Conflicts of Interest

The Finance Committee, when appropriate, shall rule on the propriety of transactions referred to it involving a possible conflict of interest. Prior to any such ruling, the member of leadership will be provided an opportunity to communicate with the committee concerning the transaction in question. The committee shall recommend to the Board of Regents Executive Committee of the College the administrative action required to avoid a conflict of interest.

The Board of Regents Executive Committee shall take action on any presumed or potential violation of this policy by a member of leadership to ensure that a conflict of interest does not arise or does not continue. In addition to any legal penalties, such action may include, but shall not be limited to, oral admonishment, written reprimand, resignation, and restitution.

A member of leadership who disagrees with the findings or recommendations of the Finance Committee or the action of the Board of Regents Executive Committee may appeal the decision to the Board of Regents.

IX. Distribution of the Policy

All members of leadership of the College or its affiliated organizations shall be given a copy of this policy.

AMERICAN COLLEGE OF SURGEONS
Conflict of Interest

Title: PUBLIC HEALTH SERVICE FUNDED RESEARCH
ADDENDUM TO CONFLICT OF INTEREST POLICY AND
PROCEDURE

Approved by: Board of Regents

Effective Date: January 17, 2013

Purpose: To comply with the federal regulations (42 CFR part 50, Subpart F and 45 CFR Part 94) concerning the responsibility of investigators and institutions for promoting objectivity in research funded by the Public Health Service, so that the design, conduct, and reporting of such research will be free from bias resulting from Investigator financial conflicts of interest.

II. Applicability

This Public Health Service Funded Research Addendum to Conflict of Interest Policy and Procedure (“Addendum Policy”) applies to all persons responsible for designing, conducting, or reporting Public Health Service-funded research under the auspices of the American College of Surgeons (the “College”) or designing, conducting, or reporting research under contract with the Public Health Service.

III. Rationale

The College is a nonprofit organization dedicated to the advancement of knowledge through service, research, and education. It is the College’s policy that its employees and consultants conduct the business of the College in accordance with the highest legal, ethical, and moral standards. This Addendum Policy is designed to implement the legal standards that apply to the College.

IV. Definitions

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution, for example, the College.

Financial conflict of interest (“FCOI”) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, Public Health Service (“PHS”) research funding, including the College.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the College, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels and boards such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this Addendum Policy.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this Addendum Policy.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this Addendum Policy, the term includes any such activity for which research is performed under contract with PHS or where funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the College in the grant application, progress report, or any other report submitted to the PHS by the College.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the College to the Investigator if the Investigator is currently employed or otherwise holds an appointment by the College, including intellectual property rights assigned to the College 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 Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this Addendum Policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

V. Maintenance and Publication of Policy

The College shall maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with 42 CFR Part 50, Subpart F, and will make such policy available on the College's publicly accessible Web site.

VI. Inform and Train Investigators

The College shall inform each Investigator of the College's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of the applicable regulations, and require each Investigator to complete training regarding the policy and regulations prior to engaging in research related to any PHS-funded research and at least every four (4) years, and immediately when any of the following circumstances apply:

- (1) The College revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- (2) An Investigator is new to the College; or
- (3) The College finds that an Investigator is not in compliance with the College's financial conflict of interest policy or management plan.

VII. Designation of an Official to Solicit and Review the Disclosures

The College will designate a College official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

VIII. Disclosures Required

A. Initial Disclosures

Each Investigator who is planning to participate in the PHS-funded research must disclose to the College's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The disclosure must be made on a form provided by the College and shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In addition, a College official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

B. Annual Disclosures

Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests at least annually, not later than July 31, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the College pursuant to Section VIII.A of this Addendum Policy, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

C. Updated Disclosures

Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

IX. Designated Official Review of the Disclosures

A. Before the College disburses any funds for a PHS-funded research project, the designated official will obtain and review the Investigator Disclosures to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. The determination will be performed in accordance with guidelines developed by the College and consistent with this Addendum Policy and applicable federal law. An Investigator's significant financial interest is related to PHS-funded research when the College, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The College may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the College, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

B. If, during the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the College, the designated official(s) of the College shall, within sixty (60) days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan, as set forth below, that shall specify the actions that have been, and will be,

taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, 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 of disclosure and the completion of the College's review.

C. In the event the College identifies a significant 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 research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty (60) days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(1) Implement, on at least an interim basis, a management plan as set forth below that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(2) (a) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the College to constitute a financial conflict of interest; failure by the College to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the College shall, within 120 days of its 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.

(b) The College will document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- (i) Project number;
- (ii) Project title;
- (iii) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (iv) Name of the Investigator with the FCOI;
- (v) Name of the entity with which the Investigator has a financial conflict of interest;
- (vi) Reason(s) for the retrospective review;
- (vii) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (viii) Findings of the review; and
- (ix) Conclusions of the review.

(3) 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 financial conflict of interest going forward. If bias is found, the College will 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 FCOI reports annually, as specified in Section XII of this Addendum Policy. Depending on the nature of the financial conflict of interest, 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 financial conflict of interest or the Investigator's noncompliance is determined and the completion of the College's retrospective review.

X. Management of Financial Conflicts of Interest

If a financial conflict of interest is identified, the College will take such actions as necessary to manage such financial conflict of interest, including any financial conflicts of a subrecipient Investigator pursuant to Section XI of this Addendum Policy. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to Section IX of this Addendum Policy. The management plan shall specify the actions that have been, and shall be, taken to manage the financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- (1) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (2) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (2) 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 conflict of interest;
- (4) Modification of the research plan;
- (5) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (6) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (7) Severance of relationships that create financial conflicts.

Whenever the College implements a management plan pursuant to this Addendum Policy, the College shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

XI. Subrecipients

If the College carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the College will take reasonable steps to ensure that any subrecipient Investigator complies with this Addendum Policy by:

(1) Incorporating as part of a written agreement between the College and the subrecipient terms that establish whether the financial conflicts of interest policy of the College or that of the subrecipient will apply to the subrecipient's Investigators.

(a) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the applicable federal regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the College for disclosing significant financial interests that are directly related to the subrecipient's work for the College;

(b) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the College. Such time period(s) shall be sufficient to enable the College to provide timely FCOI reports, as necessary, to the PHS as required by this Addendum Policy;

(c) Alternatively, if the subrecipient's Investigators must comply with the College's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the College. Such time period(s) shall be sufficient to enable the College to comply timely with its review, management, and reporting obligations under this Addendum Policy.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this Addendum Policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

XII. Reports to PHS

The College will provide initial and ongoing FCOI reports to the PHS as required herein.

A. Prior to the College's expenditure of any funds under a PHS-funded research project, it shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the College to be conflicting and ensure that the College has implemented a management plan in accordance with this Addendum Policy. In cases in which the College identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, it shall not submit an FCOI report to the PHS Awarding Component.

B. For any significant financial interest that the College identifies as conflicting subsequent to the College's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the College shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the financial conflict of interest and ensure that the College has implemented a management plan in accordance with this Addendum Policy. Pursuant to Section IX.C(2) of this Addendum Policy, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the College (e.g., was not timely reviewed or reported by a subrecipient), the College also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to Section IX.C(3) of this Addendum Policy, if bias is found, the College is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

C. Any FCOI report required under paragraphs A or B of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the College's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (1) Project number;
- (2) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (3) Name of the Investigator with the financial conflict of interest;
- (4) Name of the entity with which the Investigator has a financial conflict of interest;
- (5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (6) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- (7) 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; and
- (8) A description of the key elements of the College's management plan, including:
 - (a) Role and principal duties of the conflicted Investigator in the research project;
 - (b) Conditions of the management plan;
 - (c) How the management plan is designed to safeguard objectivity in the research project;

(d) Confirmation of the Investigator's agreement to the management plan;

(e) How the management plan will be monitored to ensure Investigator compliance; and

(f) Other information as needed.

D. For any financial conflict of interest previously reported by the College with regard to an ongoing PHS-funded research project, the College shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The College shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

XIII. Publically Available Information

A. Prior to the College's expenditure of any funds under a PHS-funded research project, the College shall ensure public accessibility, on its publicly accessible Web site or written response to any requestor within five (5) business days of a request, of information concerning any significant financial interest disclosed to the College that meets the following three criteria:

(1) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this Addendum Policy;

(2) The College determines that the significant financial interest is related to the PHS-funded research; and

(3) The College determines that the significant financial interest is a financial conflict of interest.

B. The information that the College makes available on its publicly accessible Web site or written response to any requestor within five (5) business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

C. If the College uses a publicly accessible Web site for the purposes of this Addendum Policy, the information that the College posts shall be updated at least annually. In

addition, the College shall update the Web site within sixty (60) days of the College's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the College determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the College's identification of a new financial conflict of interest. If the College responds to written requests, it will 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 College's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

D. Information concerning the significant financial interests of an individual subject to the above requirements shall remain available, for responses to written requests or for posting on the College's publicly accessible Web site, for at least three (3) years from the date that the information was most recently updated.

XIV. Documentation Maintenance

The College will maintain records relating to all Investigator disclosures of financial interests and the College's review of, and response to, such disclosures (whether or not a disclosure resulted in the College's determination of a financial conflict of interest) and all actions under the College's policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b), relating to records retention.

XV. Enforcement

A. The College will enforce the requirements of this Addendum Policy which may include the imposition of employee sanctions or other administrative actions to ensure Investigator compliance.

B. If an Investigator fails to comply with this Addendum Policy, the College may develop a corrective action plan. The College may impose sanctions, which include suspension, denial of ability to engage in research, or other appropriate penalties. Such sanctions may also require giving notice to professional bodies or journals, or the public.

C. If an Investigator fails to comply with this Addendum Policy, a management plan, or a corrective action plan in a manner that could have biased the design, conduct, or reporting of PHS-funded research, the College shall promptly notify the PHS awarding component of the corrective action imposed or to be imposed (e.g, a mitigation report for the PHS-funded research, as further described in this Addendum Policy) and implement the corrective action plan.

D. In any case in which the HHS 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 financial conflict of interest that was not managed or reported by the College as required by this Addendum Policy, the College shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

E. The College will submit to HHS or applicable government agencies, or permit on-site review of, all records related to compliance with 42 CFR Part 50 Subpart F.

XVI. Certification

The College will certify, in each application for funding to which this Addendum Policy applies, that the College:

- (1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
- (2) Shall promote and enforce Investigator compliance with this Addendum Policy and the requirements of 42 CFR Part 50, Subpart F, including those pertaining to disclosure of significant financial interests;
- (3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with the requirements of 42 CFR Part 50, Subpart F;
- (4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the College's review of, and response to, such disclosure, whether or not the disclosure resulted in the College's determination of a financial conflict of interest; and
- (5) Shall fully comply with the requirements of 42 CFR Part 50, Subpart F.

DISCLOSURE STATEMENT

I have read the College's and its affiliated organizations' Conflict of Interest Policy and Public Health Service Funded Research Addendum. I understand its application to me and to members of my family, and agree to abide by the policy. Pursuant to the policy, I hereby state that, to the best of my knowledge and belief, I or members of my immediate family have the following interests and activities (check "None" where applicable):

1. OUTSIDE INTERESTS

Identify all positions (officers, director, trustee, etc.) and significant financial interests that you or your immediate family own or hold in any entity (i) that provides goods or services to the American College of Surgeons or its affiliated organizations; or (ii) that has made or is making any type of research grant or other award to the College or its affiliated organizations.

None

2. OUTSIDE ACTIVITIES

Identify any and all instances in which you or your immediate family render or have rendered services to any entity that to the best of your knowledge, (i) does business with the College or its affiliated organizations (ii) provides services similar to the services of the College or its affiliated organizations, or (iii) that provides services in competition with services of the College or its affiliated organizations:

None

3. DIRECT FINANCIAL RELATIONSHIP WITH COMPANIES

List all companies with which you have a direct financial relationship.

None

4. SATELLITE CME SYMPOSIA

Identify any instances where you have participated in Satellite CME Symposia as a faculty member, presenter, chair, consultant, or in any role other than that of an attendee who receives no honoraria or reimbursements.

None

5. COMPANY EXHIBIT SPACE

List all instances where you have participated as a leader or presenter in a company promotional/marketing event held in exhibit space.

()None

6. OTHER

List any other activities or transactions in which you or your immediate family are engaged that might be regarded as constituting a conflict of interest.

()None

7. GIFTS, GRATUITIES AND ENTERTAINMENT

If you or any member of your immediate family has knowingly accepted gifts, gratuities, or entertainment that might influence your judgment or actions concerning business of the College or its affiliated organizations, identify such items.

()None

INSIDE INFORMATION

I certify that neither I nor any member of my immediate family has knowingly disclosed or used information relating to the College's or its affiliated organizations' business for my personal profit or advantage or that of my immediate family.

I agree that I will advise the Treasurer in writing if there are any changes from the foregoing which should be disclosed under the policy.

DATED this _____ day of _____, 20__

Leadership Signature

Print Name

Approved: _____

Signature: _____

Disapproved: _____

Signature: _____