

Research Financial Conflict of Interest

Palmer College of Chiropractic (College) acknowledges the importance of and complying with requirements detailed in 42 CFR Part 50, Subpart F designed to maintain the objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research will be biased by any conflicting financial interest.

The College is committed to the principle of free, open and objective inquiry in the conduct of its teaching, research and service missions. In the fulfillment of these missions, it is natural that opportunities arise for faculty, staff and students to develop relationships with external entities and to explore commercial activities. The College encourages such endeavors as they enhance personal competency, enrich instruction, and benefit the community and the institution.

These interactions, however, create the potential for financial conflicts of interest where an individual's financial or personal considerations may affect or appear to affect College activities related to externally sponsored programs. The existence of a real or apparent financial conflict does not necessarily mean that the activity at issue must be avoided or discontinued.

It is through disclosure of Significant Financial Interests (as defined below in this policy under "Definitions") to the College that such activities may be reviewed and, if warranted, managed. This Research Financial Conflict of Interest policy (Policy) establishes the process of disclosure, review and management.

PURPOSE

This document sets forth the College's Policy on the disclosure, review, management and resolution of Significant Financial Conflicts of Interest and pertains to Principal Investigators and their designated Senior/Key Personnel.

This Policy is required by, and is intended to establish compliance with, the US Public Health Service (PHS), National Institutes of Health Regulation (42 CFR Part 50, Subpart F) "Promoting Objectivity in Research." It is also intended to establish compliance with the National Science Foundation (NSF) and other granting agencies' policies on Conflict of Interest.

SCOPE

This Policy applies to the entire College community, which is defined as including the Davenport campus (Palmer College Foundation, d/b/a Palmer College of Chiropractic), West campus (Palmer College of Chiropractic West) and Florida campus (Palmer College Foundation, Inc., d/b/a Palmer

College of Chiropractic Florida) and any other person(s), groups, or organizations affiliated with any Palmer campus who are involved with externally sponsored programs and meet the definition of “Investigator” or “Senior/Key Personnel” as defined below in this Policy under “Definitions”.

DEFINITIONS

For the purposes of this Policy, the following terms shall have the meanings specified below:

- > The term “**College**” refers to the employer doing business as Palmer College of Chiropractic, Palmer College of Chiropractic Florida and Palmer College of Chiropractic West.
- > The term “**conflict of interest**” (COI) refers to any circumstance in which the employee’s judgment (or any other individual as defined in the Scope of this Policy) in exercising any College duty or responsibility is, or may appear to be, affected by the employee or relative’s personal, professional, financial or other interest.
- > The term “**financial interest**” refers to anything of monetary value, whether or not the value is readily ascertainable.
- > The term “**Financial Conflict of Interest**” (FCOI) refers to a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research.
- > The term “**Investigator**” refers to 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 funded or proposed research, which may include, but is not limited to, students, sub-awardees, contractors, consortium participants, collaborators or consultants.
- > The term “**Institutional Official**” refers to the individual in charge of this Policy and associated processes is the Associate Vice Chancellor for Academics.
- > The term “**investigator’s institutional responsibilities**” refers to an investigator’s professional responsibilities on behalf of and as defined by the College, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as institutional review boards or data and safety monitoring boards.
- > The term “**management plans**” refers to any actions taken by the institution to address any FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

- > The term “**Senior/Key Personnel**” refers to the program director/principal investigator (PD/PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. Key personnel are listed on grant application, progress report, or any other report of a proposed or funded research project.
- > The term “**Significant Financial Interest**” (SFI) refers to anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (patents, copyrights, and royalties from such rights) held by an investigator or the investigator's immediate family, individually or in aggregate, when such interest involves:
 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:
 - a) 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 a fair market value;
 - b) 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 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, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education. Disclosure information must include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Institutional Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes any conflict with the research.

3. Significant Financial Interest does not include the following types of financial interest: salary, royalties, or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights; any ownership interest in the institution held by the Investigator, if the institution is a commercial or for profit organization; 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, 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- > **The term “New Significant Financial Interest”** (SFI) refers to a different type or nature of SFI (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a “new” SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) from a different source (e.g., company A versus company B).

ADMINISTRATIVE RULES

Required and Annual Disclosure to Palmer College of Chiropractic

Principal Investigators must complete a PI Financial Conflict Of Interest (FCOI) Disclosure Form prior to the submission of a grant application. They must list all other Investigators and Senior/Key Personnel on their project and ensure that required disclosures have been submitted

to the College from all listed persons. The PI is responsible for reporting any SFI to the Financial Conflict of Interest Officer no later than 30 days of discovering or acquiring a new SFI.

Investigators will submit an Investigator FCOI Disclosure Form to the Financial Conflict of Interest Officer (FCOI Officer) annually. Notifications to the college community of this annual requirement will be coordinated by the Palmer Center for Research.

Each Investigator who is planning to participate in the PHS-funded research will submit to the designated official(s) a listing of their known Significant Financial Interests (and those of their spouse and dependent children) by the time an application is submitted to PHS.

Required Submission of Revised Forms to Palmer College of Chiropractic

If there is a material change (an acquisition of a Significant Financial Interest) to the information provided on the FCOI Annual Disclosure Form and/or the FCOI Addendum Form, a new form must be submitted to the Vice Chancellor for Academics within 30 days of that change.

Outside Employment Forms

Investigators and Senior/Key Personnel who are required by this Policy to complete the Financial Conflict of Interest Detail Disclosure form will also be required to submit a copy of their Outside Employment Form.

Review and Management Process

1. The Vice Chancellor for Academics (or designee) shall appoint a Financial Conflict of Interest Officer (FCOI Officer) who will appoint an ad hoc Financial Conflict of Interest Committee (FCOI Committee) as necessary.
2. The FCOI Officer will review disclosures of financial interests and determine if disclosure alone is adequate or if FCOI Committee review is required.
3. If the FCOI Officer determines that no conflict exists or that disclosure only is required, he or she will notify the individual who filed the disclosure and the Vice Chancellor for Academics.
4. Disclosures of financial interests that require the development of a management plan will be forwarded to the FCOI Officer.

5. Upon receipt of the FCOI Officer and College official's recommendations, these recommendations and the investigator's disclosure materials will be provided to the FCOI Committee for review if a SFI has been identified.
6. The FCOI Committee will consider the nature of the research, the magnitude of the interest and the degree to which the conflict is related to the research, the extent to which the interest could be directly and substantially affected by the research and any conflict management strategies proposed or already in place. The FCOI Committee will develop a management plan (which may involve elimination of the conflict prior to initiating the activity) and notify the FCOI Officer of its recommendation.
7. The Vice Chancellor for Academics (or designee) will review the recommendations of the FCOI Officer and FCOI Committee and make a final determination regarding the management plan. This final determination will be forwarded to the Investigator and copied to the FCOI Officer and director or dean. In the case of research involving human participants, a copy of the determination will be forwarded to the Institutional Review Board.
8. The investigator must agree in writing to accept the management plan prior to initiating the research.
9. No individual who holds an SFI in a project may participate in the review of its management strategy.
10. FCOI Committee meetings are closed to the public and documentation/records are confidential personnel records.
11. Any investigator may appeal the decision of the Vice Chancellor for Academics (or designee) regarding the management plan for a conflict of interest in research to the President/Provost of the College, and thereafter to the College Chancellor.
12. Records of all disclosures made pursuant to this Policy and of any action taken to resolve, manage, or eliminate any interest required by this policy to be disclosed shall be retained for at least three years from the submission of the final expenditures report (in the case of grants or cooperative agreements) or at least three (3) years from the final payment (in the case of research contracts), or until the resolution of any external funding agency action involving those records, whichever is longer.

- 13.** Failure to file a complete and truthful disclosure as required by this Policy or to comply with the conditions or restrictions imposed in the resolution, management, or elimination of interests required to be disclosed, constitutes a violation of College policy and may violate state and/or federal law. In such cases, the investigator will be subject to appropriate sanctions consistent with College policies relating to faculty, staff, or other applicable disciplinary policies. In addition, the College may suspend an ongoing research project or technology transfer activity to prevent continued violation of this Policy. In any case in which the investigator does not comply with any applicable conditions or restrictions imposed pursuant to this Policy, the College shall withdraw any affected applications for funding if the project cannot otherwise be completed without the services of the investigator.
- 14.** In the event the College discovers that a failure to comply with this Policy has biased the design, conduct, or reporting of the research, the College will promptly notify the sponsor funding the research and describe the corrective action(s) taken or to be taken, consistent with applicable law and/or policy.
- 15.** Institutional officials holding a significant financial interest in an externally funded research project may not participate in the solicitation, negotiation of terms and conditions, oversight of the research (unless named as a member of the research team), or the management of any conflict of interest held by members of the research team.
- 16.** Any collaborator from another institution or organization who will share responsibility for the design, conduct or reporting of research results is required to comply with the policies and procedures of the institution/organization relating to disclosure and review of any significant financial interest(s) held by that collaborator. The collaborator's institution/organization is required to provide the College adequate assurances of its review and of its ability to manage, reduce, or eliminate such conflict(s). In the event a collaborator is employed by an institution or organization that does not have a conflict of interest policy and procedures in place, that institution or organization is required to provide the College adequate assurances of its review of a significant financial interest as defined by this Policy and of its ability to manage, reduce, or eliminate such conflict consistent with this Policy.

When A Significant Financial Interest (SFI) Exists:

1. College investigators holding a significant financial interest as defined above must disclose this interest in writing to the appropriate College official prior to submission of a grant application.
2. Any change in the nature or amount of the interest must be reported within 60 days.
3. Investigators who have submitted an initial disclosure will receive an annual request to update or confirm the status of their financial interest.
4. All conflicts of interest arising from a significant financial interest must be reviewed and a management strategy fully developed and in place prior to initiation of the research or expenditure of funds.
5. The research may not begin until the College has reviewed the disclosure and all parties have agreed to put into action necessary management strategies.

Retrospective Review

The College is required by federal regulation to conduct a retrospective review in those cases of non-compliance with the federal regulations. This must be done within 120 days of the College's determination of non-compliance. The College will notify the awarding agency promptly and submit a report to the awarding agency in cases where bias is found. The report will address the impact of the bias on a research project and the actions taken by or to be taken by the College to eliminate or mitigate the bias.

Disclosure of the FCOI must be reported in each public presentation of the results of the research; and to request an addendum to previously published presentations.

Monitoring

The College may conduct random and for-cause monitoring of FCOI Management Plans.

Non-Compliance

Failure to comply with this Policy or to follow an agreed upon Management Plan will result in a Retrospective Review (described above) and may result in the following actions:

1. Termination of Investigator's external funding project(s) at the College;

2. Termination of Investigator's ability to submit proposals for external funding through the College; and/or
3. Disciplinary action.
4. Violations of this Policy include, but are not limited to:
 - a) Failure to comply with the disclosure process (by refusal to respond; by deliberately responding with incomplete, inaccurate, or misleading information, or otherwise);
 - b) Failure to remedy significant financial conflicts of interest; and/or
 - c) Failure to comply with a prescribed Management Plan.

Training Requirement

Each Investigator and Senior/Key Personnel must complete Conflict of Interest training prior to engaging in research related to any externally-funded grant or contract and at least every four years. In addition, training must be completed immediately under the following circumstances:

1. The College FCOI policies change in a manner that affects Investigator requirements.
2. An Investigator is new to the College.
3. The College finds an Investigator noncompliant with the institutional policy or their Management Plan.
4. At the time of training, Investigator and Senior/Key Personnel shall provide acknowledgement that they have read and understand this Policy.
5. The following link will guide Investigators through the training. <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
6. The Certificate of Completion should be submitted to the Research Administrator.

Public Disclosure

The College will make this Policy available to the general public by posting it on the Palmer College of Chiropractic website and the Palmer IRB website.

The College is required by federal regulation to make certain information about significant financial interest (SFI) related to an externally-funded research by Senior/Key Personnel available to the public. The College will do so by responding to any request for information about these FCOI specifically covered SFIs within five business days. Information that must be made available includes:

1. Investigator's name;
2. Investigator's title and role with respect to a research project;
3. Name of the entity in which the SFI is held;
4. Nature of the SFI; and
5. Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,000; \$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 references of public prices or other reasonable measures of fair market value.

Additional Responsibilities

The College maintains this Policy and will implement the process to identify and manage, reduce or eliminate these conflicts.

The College shall, for any externally funding agency that imposes FCOI requirements:

1. Include in the Subaward agreement terms that Subaward Investigators are required to submit an FCOI Disclosure Form to Palmer along with proof of FCOI training from their institution;
2. Maintain the records of, and related to, disclosures and will be located in the Office of Strategic Development;
3. Report conflicting Significant Financial Interest to the awarding component of the funding agency prior to the expenditure of funds, within 60 days of the newly identified for existing Investigators and within 60 days for an Investigator who is new to the project;

4. Inform NIH or the appropriate awarding agency if it is unable to satisfactorily manage a Significant Financial Conflict of Interest;
5. Report to the NIH or the appropriate awarding agency the existence of any conflicting Financial Interests and assure that the interest has been managed, reduced, or eliminated in accordance with NIH regulations; and
6. Maintain records related to Investigator disclosures of Financial Interests and the institution's review of, or response to, such disclosures and all actions under this Policy or retrospective review for at least three years from the date of the final expenditure report.

STANDARD INSTITUTIONAL POLICY PROVISIONS

Institutional policies are supplemented by provisions that are applicable to all institutional policies. It is the responsibility of all employees and students to know and comply with these standards.

- > [Standard Provisions Applicable to All Institutional Policies](#)

Additional Information

ASSOCIATED POLICIES, PROCESSES AND/OR PROCEDURES

This Policy is supplemented below. It is the responsibility of all employees and students to know and comply with policies and procedures as supplemented.

POLICIES

- > [Confidential Information](#)

PROCESSES AND/OR PROCEDURES

- > [Research Policy Handbook](#)

FORMS/INSTRUCTIONS

- > Financial Conflict of Interest Disclosure Form

- > Financial Conflict of Interest Addendum Form

OTHER RELATED INFORMATION

- > Code of Federal Regulations – Title 42 CFR Part 50, Subpart F
(http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm)
- > NIH (<http://www.nih.gov/>)
- > NSF (<http://www.nsf.gov>)

CONTACTS

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HISTORY

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Responsible Officer: Dan Weinert, M.S., D.C., Ph.D.

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