Yana Pekarski, DDS
Financial Conflict of Interest (FCOI) Policy

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1) Introduction

The purpose of this policy is to ensure that research funded by the National Institutes of Health (NIH) is designed, conducted and reported objectively and without bias resulting from Investigator financial conflicts of interest (FCOI). It implements the 2011 revised regulation at 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research," which sets requirements for promoting objectivity in Public Health Service (PHS)–funded research under grants and cooperative agreements.

Yana Pekarski, DDS ("the Institution"), a general dental practice in Carmichael, California, adopts this policy for all Investigators, as defined below, engaged in PHS/NIH-funded research. It establishes processes to identify, disclose and manage Investigator financial conflicts of interest in order to protect research integrity, protect the safety of research participants, and maintain public trust in PHS/NIH-supported research.

2) Applicability

This policy implements the regulatory requirements of 42 CFR Part 50, Subpart F for grants and cooperative agreements issued by the NIH. It applies to every individual who meets the definition of "Investigator" below and who is planning to participate in, or participates in, PHS/NIH-funded research at the Institution, from the time an application is prepared through the close-out of any resulting award.

3) Definitions

Financial Conflict of Interest (FCOI): A significant financial interest that the Institution's Designated Official determines is related to the PHS/NIH-funded research (that is, the SFI could be affected by the research, or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the PHS/NIH-funded research.

Financial Interest: Anything of monetary value, whether or not its value is readily ascertainable.

Institutional Responsibilities: The professional responsibilities an Investigator performs on behalf of the Institution. At this Institution they include: clinical dental care of the practice's patients, including diagnosis, treatment planning and delivery of orthodontic and preventive care; clinical research and research consultation, including the design, conduct, measurement, analysis and reporting of studies carried out in the practice; development and testing of clinical procedures, protocols and patient education materials; teaching, training and supervision of practice staff, trainees and students who shadow in the practice; publication and presentation of research results; preparation of grant applications and other fundraising for the Institution's research; practice administration and management; and service, on behalf of the Institution, on committees and panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Designated Official (DO): The individual appointed by the Institution to solicit and review disclosures of significant financial interests, determine whether an FCOI exists in accordance with 42 CFR 50.604(f) and this policy, and develop management plans for identified FCOIs. The Designated Official is identified in Section 5.

Independent Reviewer: The individual appointed under Section 5 to review the disclosures of the Designated Official.

Institution: Any public or private organization, domestic or foreign (excluding a federal agency), that is applying for or receives PHS/NIH research funding. In this policy, "the Institution" means Yana Pekarski, DDS.

Investigator: The Project Director (PD) or Principal Investigator (PI), and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by PHS/NIH or proposed for such funding, which may include, for example, collaborators or consultants. The Institution determines who is responsible for the design, conduct or reporting of the research by considering each individual's role, rather than title, and the degree of independence with which the individual carries out the work.

Manage: 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.

Research: 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 includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement.

PHS: 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: The organizational unit of the PHS that funds the research, including NIH and its Institutes and Centers.

Senior/Key Personnel: The PD/PI and any other individual identified as senior/key personnel by the Institution in a grant application, progress report or other submission to PHS/NIH. In this policy the term applies specifically to the public accessibility requirement in Section 9.

Significant Financial Interest (SFI):

1.) A domestic or foreign (non-United States) 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 appear to be related to the Investigator's Institutional Responsibilities:

- **i.** **Publicly traded entity:** an SFI 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. 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.** **Non-publicly traded entity:** an SFI 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).
- **iii.** **Intellectual property rights and interests** (e.g., patents, copyrights): an SFI exists upon receipt of income greater than $5,000 in the twelve months preceding the disclosure related to such rights and interests, including royalties and agreements to share in royalties related to licensed intellectual property rights.

2.) **Reimbursed or sponsored travel:** Investigators must disclose any reimbursed or sponsored travel related to their Institutional Responsibilities in excess of $5,000 in the twelve months

preceding the disclosure. Such travel includes trips paid on behalf of the Investigator rather than reimbursed directly, where the exact cost may not be known. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor or organizer, the destination and the duration. This requirement does not apply to travel that is reimbursed or sponsored by a federal, state or local government agency located in the United States; a United States institution of higher education; or a United States academic teaching hospital, medical center or research institute affiliated with a United States institution of higher education.

3.) **Exclusions.** The term "significant financial interest" does not include, and Investigators are therefore not required to disclose, the following:

- 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 those rights.
- Any ownership interest in the Institution held by the Investigator, since the Institution is a commercial, for-profit organization.
- Income from investment vehicles, such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions made in those vehicles.
- Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency located in the United States; a United States institution of higher education; or a United States academic teaching hospital, medical center or research institute affiliated with a United States institution of higher education.
- Income from service on advisory committees or review panels for a federal, state or local government agency located in the United States; a United States institution of higher education; or a United States academic teaching hospital, medical center or research institute affiliated with a United States institution of higher education.

Foreign financial interests. The exclusions above apply only to the United States entities named. Investigators must disclose foreign financial interests, including income from seminars, lectures or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel, received from any foreign entity, including a foreign institution of higher education or a foreign government (including local, provincial or equivalent governments of another country), when the interest meets the threshold for disclosure.

4) Significant Financial Interest (SFI) Disclosure Requirements

Investigators disclose their SFIs that are related to their Institutional Responsibilities as defined in this policy. Disclosure is not limited to an Investigator's research responsibilities or to the PHS/NIH-funded research, as that would be too narrow and inconsistent with the 2011 regulation. Investigators do not decide whether an SFI is related to the PHS/NIH-funded research; that determination is made by the Institution under Section 6.

Disclosures are made on the Institution's SFI Disclosure Form and are retained by the Institution under Section 15. Investigators disclose their SFIs at the following times:

A. At the time of application. The PD/PI and all other individuals who meet the definition of Investigator disclose their SFIs to the Designated Official no later than the time of application for PHS/NIH-funded research. Any new Investigator who joins a project after the application has been

submitted, or during the course of the research, discloses SFIs promptly and before participating in the project.

B. Annually during the award. Each Investigator participating in research under an NIH award submits an updated disclosure at least annually, on or before July 1 of each year during the award period. The annual disclosure includes any information not previously disclosed and updated details for any previously disclosed SFI, such as a change in the value of an equity interest.

C. Ad hoc during the award. Each Investigator submits an updated disclosure within 30 days of discovering or acquiring a new SFI (e.g., through purchase, marriage or inheritance). Disclosure of reimbursed or sponsored travel that meets the requirement in Section 3 is submitted within 30 days of each occurrence.

5) Review of SFI Disclosures

The owner of the Institution, Yana Pekarski, DDS, serves as the Designated Official responsible for reviewing SFI disclosures and making determinations of FCOI.

Because the Designated Official is also an Investigator, she does not review her own disclosure, and the co-PD/PI, being also an Investigator, does not review it either. The Institution appoints an Independent Reviewer — a qualified individual who is not an Investigator, is not employed by the Institution and holds no financial interest in it — who reviews the Designated Official's disclosures, and any disclosure in which the Designated Official has a financial or personal interest, and makes the determinations required by this policy. Each such referral is documented.

Each SFI is evaluated in relation to every PHS/NIH research application or award on which the Investigator is responsible for the design, conduct or reporting of research. Disclosures are reviewed as follows:

A. Before the issuance of a new award or any expenditure of funds (e.g., at the Just-in-Time stage): the Designated Official reviews the Investigators' SFIs before NIH issues a new award. If an FCOI is identified, an FCOI report is submitted to NIH through the eRA Commons FCOI Module before any expenditure of funds.

B. Annual disclosure: the Designated Official reviews updated information on previously disclosed SFIs to determine whether changes to an existing management plan are needed. Any change is reflected in the next annual FCOI report, if applicable.

C. Ad hoc during the award: when a new Investigator joins a project, or an existing Investigator discovers or acquires a new SFI, the Designated Official, within 60 days: (1) reviews the disclosure; (2) determines whether the SFI is related to the PHS/NIH-funded research; (3) determines whether an FCOI exists; and, if so, (4) implements, at least on an interim basis, a management plan. An FCOI report is submitted to NIH within 60 days of identifying the FCOI.

Each review and determination, whether or not an FCOI is found, is documented in writing and retained under Section 15.

6) Relatedness of SFIs to PHS/NIH-Funded Research and FCOI

The Designated Official (or the Independent Reviewer, where Section 5 applies) assesses whether an SFI is related to PHS/NIH-funded research and whether it constitutes an FCOI.

Relatedness test. An SFI is related to the research when it is reasonably determined that:

- the SFI could be affected by the PHS/NIH-funded research; or
- the SFI is in an entity whose financial interest could be affected by the PHS/NIH-funded research.

Investigator involvement. The Investigator may be consulted when assessing whether an SFI is related to the research.

FCOI determination. An FCOI exists when it is reasonably determined that the related SFI could directly and significantly affect the design, conduct or reporting of the PHS/NIH-funded research ("significantly" meaning that the financial interest would have a material effect on the research).

7) Management of SFIs that Pose an FCOI

When an FCOI is identified, the Designated Official determines and implements a written management plan to ensure the research is conducted objectively. Management conditions may include, but are not limited to:

- public disclosure of the FCOI (e.g., in publications or presentations, to study personnel, to the IRB or to the safety monitor);
- for human subjects research, disclosure of the FCOI to participants in the informed consent document;
- appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research from bias;
- modification of the research plan;
- change of personnel or personnel responsibilities, or removal from all or part of the research;
- reduction or elimination of the financial interest (e.g., divestiture of equity); or
- severance of relationships that create financial conflicts.

The Designated Official communicates the determination and the management plan to the Investigator in writing and requires the Investigator to agree in writing to comply with the plan. No funds under an NIH award are spent until the Investigator has met all disclosure requirements and agreed in writing to comply with any management plan. The Institution reports the FCOI to NIH through the eRA Commons FCOI Module under Section 10.

8) Monitoring Investigator Compliance

The Institution monitors Investigator compliance with each management plan for the duration of the NIH award. Where this policy applies to subrecipient Investigators, the Institution also monitors their compliance.

As part of monitoring, the Designated Official may request and review documentation demonstrating compliance with required FCOI disclosures, including publications, presentation materials, abstracts, posters and written communications to study personnel. Investigators provide copies of such materials to the Designated Official, and these records are retained to document compliance with the management plan and to support review and audit.

9) Public Accessibility of the FCOI Policy and FCOIs Held by Senior/Key Personnel

FCOI policy. The Institution makes this policy publicly available on its website at https://sacramentoholisticdentist.com/fcoi-policy, where it may be read and downloaded without registration or charge, as required by 42 CFR 50.604(a) and Section 4.1.10 of the NIH Grants Policy

Statement. The Institution also submits a copy of this policy to NIH through the eRA Commons Institution Profile Module.

Identified FCOIs held by Senior/Key Personnel. Before any funds are spent under an NIH award, the Institution ensures public accessibility by providing a written response, within five business days of a request, regarding any SFI that meets all three of the following criteria:

- the SFI was disclosed and is still held by Senior/Key Personnel;
- the Institution has determined that the SFI is related to the NIH-funded research; and
- the Institution has determined that the SFI is an FCOI.

The response includes at least: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI in the following ranges: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The written response notes 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 Institution's identification of a new FCOI, which the requestor should request subsequently. Information subject to public accessibility remains available for at least three years from the date of the most recent update.

10) Reporting Identified Financial Conflicts of Interest

Before spending any funds under an NIH award, the Institution submits an FCOI report to NIH for any Investigator SFI determined to be an FCOI, and ensures that the Investigator has agreed to, and begun implementing, the associated management plan.

The Designated Official serves as the FCOI Signing Official in the eRA Commons FCOI Module and is authorized to submit FCOI reports to NIH. FCOI reports are submitted only when an award is active and an FCOI has been identified: no award means no FCOI report, and no FCOI means no FCOI report. Reports are prepared following the eRA Commons FCOI Module User Guide.

Types of FCOI Reports Summary Chart for NIH:

Report	Content	When required
New (Initial) FCOI Report	Grant number; PD/PI; name of Investigator with the FCOI; name of entity; nature of the financial interest; value within the required ranges; how the financial interest relates to the research and the basis for the FCOI determination; key elements of the management plan (42 CFR 50.605(b)(3))	Before the expenditure of funds on a new award, or within 60 days of identifying any new FCOI during the award
Annual FCOI Report	Status of the FCOI (still managed or no longer exists) and any changes to the management plan	Each year at the same time as the annual progress report (RPPR) or multi-year progress report, and at the time of any extension; not required at close-out
Revised FCOI Report	Updates to a previously submitted report, describing actions that will be taken to manage the FCOI going forward	After a retrospective review that identifies noncompliance, if applicable

Mitigation Report	Project number and title; PD/PI; Investigator with the FCOI; name of entity; reason for the review; detailed methodology, findings and conclusions; impact of the bias and corrective plan	After a retrospective review that finds bias

11) Training Requirements for Investigators

Each Investigator is informed of this policy and trained on the Investigator's responsibility to disclose foreign and domestic SFIs under this policy and 42 CFR Part 50, Subpart F. Training is completed before an Investigator engages in PHS/NIH-funded research, at least once every four years, and promptly when:

- the Institution revises this policy or its procedures in a way that affects Investigator requirements;
- an Investigator is new to research at the Institution under an NIH award (training is completed before participating in the research); or
- the Institution determines that an Investigator has not complied with this policy or with a management plan (training is completed within 30 days, as directed by the Designated Official).

The Institution accepts either: completion of the NIH FCOI training module, with the certificate of completion provided to the Designated Official; or review of the NIH virtual seminar presentation on FCOI compliance, with the date of completion sent to the Designated Official by email. Training records are retained under Section 15.

12) Noncompliance With FCOI Policy and Corrective Actions

If the Institution identifies an SFI that was not disclosed, reviewed or managed in a timely manner, the Designated Official (or the Independent Reviewer, where Section 5 applies), within 60 days: reviews the SFI; determines whether it is related to the NIH-funded research; determines whether it constitutes an FCOI; and, if so, implements an interim management plan describing the actions that have been and will be taken to manage the FCOI going forward. The Institution also submits an FCOI report to NIH through the eRA Commons FCOI Module.

Whenever an FCOI is not identified or managed in a timely manner — including failure by the Investigator to disclose an SFI later determined to be an FCOI, failure by the Institution to review or manage an FCOI, or failure by the Investigator to comply with a management plan — the Institution, within 120 days of identifying the noncompliance:

1. completes a retrospective review of the Investigator's activities and the NIH-funded research to determine whether any part of the research was biased in its design, conduct or reporting; and
2. documents the retrospective review as required by 42 CFR 50.605(a)(3)(ii)(B) and, based on its results, updates the previously submitted FCOI report as appropriate, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, the Institution promptly notifies NIH and submits a mitigation report through the FCOI Module as required by 42 CFR 50.605(a)(3)(iii), including the impact of the bias on the research project and the plan of action or steps taken to eliminate or mitigate its effect. The Institution thereafter submits annual FCOI reports as required. Depending on the circumstances, the Institution may implement additional interim measures regarding the Investigator's participation in the research until the retrospective review is complete. If no bias is found, no further action is taken unless new information is discovered that must be reported to NIH.

If the failure of an Investigator to comply with this policy or with a management plan appears to have biased the design, conduct or reporting of the PHS/NIH-funded research, the Institution promptly notifies the PHS/NIH Awarding Component of the corrective action taken or to be taken.

13) Clinical Research Requirements

If 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 an FCOI that was not managed or reported by the Institution as required, the Institution requires the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

14) Subrecipient Requirements

The Institution currently has no subrecipients. If PHS-funded research is carried out through a subrecipient in future, the written agreement with the subrecipient will specify whether this policy or the subrecipient's own FCOI policy applies to subrecipient Investigators.

- If the subrecipient's policy applies, the subrecipient certifies in the agreement that its policy complies with 42 CFR Part 50, Subpart F, and reports identified FCOIs to the Institution in time for the Institution to meet its NIH reporting deadlines (before funds are spent, and within 50–55 days of the subrecipient identifying an FCOI).
- If the subrecipient cannot provide that certification, this policy applies, and subrecipient Investigators disclose to the Institution their SFIs related to the subrecipient's work for the Institution. The Institution reviews, manages and reports any resulting FCOIs and monitors compliance.

15) Maintenance of Records

The Institution maintains records of all Investigator disclosures of financial interests, the Institution's review of and response to those disclosures (whether or not they resulted in a determination of an FCOI), management plans, monitoring, training completions, and any actions taken under this policy or through retrospective review. Records are retained for at least three years from the date of submission of the final expenditures report, or for the longer periods specified in 2 CFR 200.334, for each competitive segment of an award. Management plans are retained in the Institution's records and are not submitted to NIH.

16) Enforcement Actions and Remedies for Noncompliance

Compliance with this policy is a condition of employment and/or participation for all Investigators. Failure to comply, including failure to disclose SFIs, failure to comply with a management plan, or failure to complete required training, may result in corrective or disciplinary action, including formal notification, restriction of participation in research activities or use of research funds, suspension or termination of employment or contractual relationship, or disqualification from participation in PHS/NIH-funded research. Corrective action concerning the Designated Official is determined by the Independent Reviewer.

The PHS/NIH Awarding Component and/or HHS may inquire at any time before, during or after an award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, whether or not the disclosure resulted in a determination of an FCOI. The Institution will submit, or permit on-site review of, all records pertinent to compliance with the regulation and this policy. The PHS/NIH Awarding Component may impose specific

award conditions under 2 CFR 200.208, or suspend funding or take other enforcement action under 2 CFR 200.339, until the matter is resolved.

17) Useful FCOI and NIH Resources

- NIH email address for FCOI inquiries: FCOICompliance@mail.nih.gov
- FCOI regulation, 42 CFR Part 50, Subpart F: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F
- NIH Financial Conflict of Interest webpage: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi
- NIH FCOI training: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training
- NIH Grants Policy Statement, Section 4.1.10 Financial Conflict of Interest: https://grants.nih.gov/policy/nihgps/index.htm

18) Point of Contact

If you have a question related to the FCOI Policy of Yana Pekarski, DDS, or would like to disclose a financial interest, contact us using the information below:

Contact:
Yana Pekarski, DDS
Owner and Designated Official
Yana Pekarski, DDS
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