

FINANCIAL CONFLICT OF INTEREST POLICY

Yana Pekarski, DDS — Carmichael, California

Promoting Objectivity in Research — 42 CFR Part 50, Subpart F
Unique Entity Identifier SM6FTLZ47ZW9 · eRA Commons IPF 10097000
Effective 1 October 2026 · Version 1.1

1. Purpose and Scope

This policy establishes the standards and procedures by which Yana Pekarski, DDS (the “Institution”) promotes objectivity in research funded by the Public Health Service (PHS), including the National Institutes of Health, by ensuring that the design, conduct and reporting of such research are not biased by any conflicting financial interest of an Investigator. It is adopted to comply with 42 CFR Part 50, Subpart F.

This policy applies to every Investigator, as defined below, who is planning to participate in or is participating in PHS-funded research conducted by or through the Institution, and to any subrecipient of PHS funds awarded to the Institution. It applies from the time an application is prepared through the close-out of any resulting award.

2. Definitions

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 PHS-funded research, or of an application for such funding. This includes collaborators, consultants and subrecipient personnel where applicable, and is not limited to salaried employees of the Institution.

Institutional Official means the individual designated in Section 5 to solicit and review disclosures of significant financial interests and to make the determinations required by this policy.

Significant Financial Interest (SFI) means a financial interest of an Investigator, or of the Investigator's spouse or dependent children, that reasonably appears to be related to the Investigator's institutional responsibilities, consisting of one or more of the following:

- With regard to a **publicly traded entity**, the aggregate value of any remuneration received from the entity in the twelve months preceding disclosure and the value of any equity interest in the entity as of the date of disclosure, when that aggregate value exceeds **\$5,000**. Remuneration includes salary and any payment for services such as consulting fees, honoraria and paid authorship. Equity interest includes stock, stock options and other ownership interests.
- With regard to a **non-publicly traded entity**, remuneration received from the entity in the twelve months preceding disclosure exceeding **\$5,000**, or **any** equity interest in the entity of any value.
- **Intellectual property rights and interests**, such as patents and copyrights, upon receipt of income related to those rights and interests.
- **Reimbursed or sponsored travel** related to the Investigator's institutional responsibilities, which must be disclosed regardless of value so that the Institutional Official may determine whether it constitutes an SFI.

Significant Financial Interest does *not* include: salary, royalties or other remuneration paid by the Institution to the Investigator; income from investment vehicles such as mutual funds and retirement accounts in which the Investigator does not directly control investment decisions; income from seminars, lectures, teaching engagements or service on advisory 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 affiliated with an institution of higher education.

Financial Conflict of Interest (FCOI) means a significant financial interest that the Institutional Official reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-funded research.

3. Training

Each Investigator must complete training on this policy, on the Investigator's responsibilities regarding disclosure, and on the requirements of 42 CFR Part 50 Subpart F:

- prior to engaging in research related to any PHS-funded grant;
- at least every four years thereafter; and
- immediately when the Institution revises this policy in a manner that affects Investigator requirements, when an Investigator new to the Institution begins work, or when the Institution finds that an Investigator has not complied with this policy or with a management plan.

The Institution accepts completion of the NIH Financial Conflict of Interest tutorial, or an equivalent course, as satisfying this requirement. Certificates of completion are retained by the Institution.

4. Investigator Disclosure

Each Investigator must submit a written disclosure of all significant financial interests to the Institutional Official:

- **No later than the time of application** for PHS-funded research;
- **At least annually** during the period of the award, on a schedule set by the Institution; and
- **Within thirty days** of discovering or acquiring a new significant financial interest.

Disclosure is made on the Institution's Significant Financial Interest Disclosure Form. An Investigator with no significant financial interests to report must so state affirmatively; a blank or unreturned form does not satisfy this requirement.

5. Designation of the Institutional Official and Review of Disclosures

The **Institutional Official** for the purposes of this policy is the owner of the Institution, Yana Pekarski, DDS, acting in her capacity as Signing Official.

5.1 Review and determination

Upon receipt of a disclosure, the Institutional Official reviews it and determines whether any disclosed significant financial interest is related to PHS-funded research and, if so, whether it constitutes a financial conflict of interest. A significant financial interest is related to the research when the Institutional Official reasonably determines that it could be affected by the research, or is in an entity whose financial interest could be affected by the research. Review is completed, and any determination documented in writing, before the expenditure of funds under the award and within sixty days of the disclosure of any new significant financial interest during the award period.

5.2 Disclosures made by the Institutional Official

The Institution is a sole proprietorship whose owner is also an Investigator on PHS-funded research. The Institution recognizes that the Institutional Official cannot objectively review her own disclosure, and that the co-Principal Investigator, being himself an Investigator, cannot do so either.

Accordingly, where the disclosing Investigator is the Institutional Official, or where the Institutional Official has any financial or personal interest in the matter disclosed, the disclosure is referred for review to an **independent reviewer** retained by the Institution for that purpose: a qualified individual who is not an Investigator, is not employed by the Institution, and holds no financial interest in the Institution. The independent reviewer makes the determinations required by Section 5.1 and, where a financial conflict of interest is identified, recommends a management plan under Section 6. The independent reviewer's determination is binding on the Institution and is documented in the same manner as any other determination under this policy.

6. Management of Identified Conflicts

Where a financial conflict of interest is identified, the Institution develops and implements a written management plan before the expenditure of funds, specifying the actions taken to manage, reduce or eliminate the conflict and the monitoring by which compliance with the plan is verified. Measures may include one or more of the following:

- public disclosure of the financial conflict of interest, including in presentations and publications arising from the research, and disclosure to participants during the informed consent process;
- 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 of personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- reduction or elimination of the financial interest; or
- severance of the relationship that creates the conflict.

The Investigator is notified in writing of the determination and of the requirements of any management plan, and must acknowledge the plan in writing before participating further in the research.

7. Reporting to the PHS Awarding Component

The Institution submits FCOI reports to the PHS Awarding Component through the eRA Commons FCOI Module as follows:

Report	When submitted
Initial FCOI report	Prior to the Institution's expenditure of any funds under the award
FCOI report for a newly identified conflict	Within sixty days of identification, and before further expenditure related to that conflict
Annual FCOI report	For the duration of the award, at the time of and in the same frequency as the annual progress report, for each previously reported conflict, stating the status of the conflict and any change to the management plan
Report following retrospective review	Promptly upon completion of the review required by Section 8, together with any mitigation report

Each report contains the elements required by 42 CFR 50.605(b), including the project identifiers, the name of the Investigator, the name of the entity with which the Investigator has the conflict, the nature and value of the financial interest within the ranges specified by the regulation, and a description of how the conflict is being managed.

8. Non-compliance and Retrospective Review

If the Institution identifies a significant financial interest that was not disclosed in a timely manner or not previously reviewed, the Institutional Official, or the independent reviewer where Section 5.2 applies, reviews it within sixty days and determines whether it constitutes a financial conflict of interest. Where the Institution determines that a financial conflict of interest was not identified or managed in a timely manner — including any failure by an Investigator to disclose, to comply with a management plan, or by the Institution to review or report — the Institution completes a **retrospective review within 120 days** of that determination to assess whether the research conducted during the period of non-compliance was biased in its design, conduct or reporting. The review is documented, and where bias is found, the Institution notifies the PHS Awarding Component and submits a mitigation report.

9. Subrecipients

Where the Institution carries out PHS-funded research through a subrecipient, the written agreement with that subrecipient establishes whether this policy or the subrecipient's own policy applies to subrecipient Investigators, and specifies the time periods within which the subrecipient reports identified financial conflicts of interest to the Institution — in time for the Institution to meet its own reporting obligations under Section 7.

10. Public Accessibility

As required by 42 CFR 50.604(a), the Institution maintains this policy on a publicly accessible website, at <https://sacramentoholisticdentist.com/fcoi-policy>, where it may be read and downloaded by any member of the public without registration or charge. Each superseded version is retained together with the dates during which it was in effect. Should the website become unavailable for any period, the Institution provides a written copy of the policy to any requester within five business days of a request.

Prior to the Institution's expenditure of funds under a PHS award, the Institution also makes available, in writing and within five business days of a request, information concerning any significant financial interest that it has determined to be a financial conflict of interest and that is held by a senior or key person listed on the award, including the individual's name and title, the name of the entity, the nature of the interest and its approximate value within the ranges specified by the regulation. Such information remains available for at least three years from the date it was most recently updated.

Requests are addressed to the Institutional Official at the Institution's address of record.

11. Enforcement

Failure by an Investigator to disclose a significant financial interest, to complete required training, or to comply with a management plan is a violation of this policy. Sanctions are proportionate to the violation and may include a written warning, the imposition or modification of a management plan, suspension of the Investigator's participation in the research in whole or in part, and, where the violation is serious or repeated, termination of the Investigator's role in PHS-funded research at the Institution. Sanctions imposed on the Institutional Official are determined by the independent reviewer under Section 5.2.

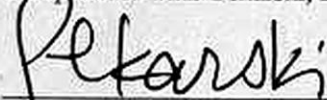
12. Records

The Institution maintains records of all Investigator disclosures, of all determinations, management plans, monitoring, retrospective reviews and reports made under this policy, and of all training completions, **for at least three years from the date the final expenditures report is submitted** to the PHS, or for the longer period required by 45 CFR 75.361 where litigation, a claim, or an audit has been started before the expiration of that period.

13. Review of This Policy

This policy is reviewed at least every three years, and whenever the governing regulations change. The Institution maintains each superseded version together with the dates during which it was in effect.

Adopted for Yana Pekarski, DDS:



Date: 10/01/26

Yana Pekarski, DDS — Owner and Signing Official