

Kaiser Permanente policy on conflicts of interest in research

Our policy on Financial Research Conflicts of Interest (FCOIs) can be found on this page. Questions may be directed to NCRSP@kp.org.

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1.0 Policy Statement

Kaiser Permanente (KP) is committed to conducting research in a manner that ensures the integrity of the research process and its research programs. Kaiser Permanente requires its employees, physicians, and any other person who is responsible for the design, conduct or reporting of research being conducted within KP to promptly disclose significant financial interests and other situations that present a conflict of interest or the appearance of a conflict of interest. Kaiser Permanente identifies financial conflicts of interest and other situations that may give rise to conflicts of interest, and addresses such situations to ensure research decisions made are in the best interests of KP, its research participants, patients, and members. Kaiser Permanente operates in accordance with federal regulations addressing research financial conflicts of interest. The [Principles of Responsibility](#) (PDF), Kaiser Permanente's code of conduct, addresses the subject of conflicts of interests for all of KP.

2.0 Purpose

The purpose of this policy is to describe minimum requirements for identifying and managing financial conflicts of interest in the conduct of research. These requirements apply to all research being conducted in whole or in part in Kaiser Permanente, regardless of the research sponsor,

except for the reporting requirements in sections 5.11 to 5.13. The requirements in sections 5.11 to 5.13 incorporate and expand upon federal regulations designed to promote objectivity in research funded by the U.S. Public Health Service (PHS).

3.0 Scope/Coverage

This policy applies to Kaiser Foundation Health Plan, Inc. and its subsidiaries and their employees; Kaiser Foundation Hospitals and its subsidiaries and their employees; and the Permanente Medical Groups, and their physicians and employees. Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, and the Permanente Medical Groups are collectively referred to in this policy as "Kaiser Permanente" or "KP."

4.0 Definitions

4.1 Conflict of Interest (COI): A conflict of interest arises when personal or financial interests influence professional judgment or decision-making. Anything that creates a divided loyalty or the appearance of a divided loyalty between the investigator and either KP or research participants may be a conflict of interest. A potential conflict of interest exists when an investigator has the potential for personal financial or other non-financial benefit from the outcome of a study, including an equity, or other financial interest in the company that is sponsoring research in which s/he participates.

4.2 Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stock, stock options or other ownership interests); and intellectual property rights (patents, copyrights and royalties from such rights) from companies that are sponsoring the research. Financial interest does not include the following:

4.2.1 Salary, royalties, or other remuneration paid by KP to the investigator if the investigator is currently employed or otherwise appointed by KP, including intellectual property rights assigned to KP and agreements to share in royalties related to such rights;

4.2.2 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;

4.2.3 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

4.2.4 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.

4.3 Financial Conflict of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct or reporting of research.

4.4 Institution: Kaiser Foundation Research Institute, the entity that receives PHS funding on behalf of Kaiser Permanente.

4.5 Investigator: The investigator means the physician or employee who is the project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed research. This may include collaborators or consultants. For research funded by the PHS, the term investigator includes, but is not limited to, all key personnel.

4.6 Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of the investigator and those of the investigator's immediate family that reasonably appears to be related to the investigator's institutional responsibilities:

4.6.1 For 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.

4.6.2 For 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 the investigator or a member of the investigator's immediate family holds:

4.6.2.1 Any equity interest, stock option, or other ownership interest, regardless of value;

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

4.7 See Appendix 1: Glossary of Policy Terms for definition of additional policy terms.

5.0 Provisions

5.1 Investigators may not accept enrollment bonuses from research sponsors or any other special payments related to achieving targets or meeting timeframes established by the sponsor.

5.2 Unless otherwise agreed to in writing by the KP entity in question, any inventions, intellectual property, or proprietary information developed as a result of research conducted while on KP work time, or using KP information, equipment, or facilities is owned by the KP entity by which the investigator is employed.

5.3 Investigators may not publish, formally present, or provide expert commentary on research without disclosing a significant financial interest in any company that sponsored the study being reported.

5.4 Appearance of Conflict. Investigators must avoid other situations, not specifically described in this policy that may create a financial conflict of interest or the appearance of a financial conflict of interest.

5.5 In-kind (non-cash) Support. Investigators may not accept in-kind support from research sponsors, with the exception of payment of travel expenses as noted in section 5.6. Immediate families of investigators may not accept in-kind support.

5.6 Travel. Investigators may receive in-kind support from sponsors such as airline tickets, to attend meetings related to the conduct or review of research. All in-kind support must be disclosed.

5.7 Receipt of Research Funds. Investigators must place all revenue from sponsors in accounts as specified by the region. These funds must be used only for approved research-related expenses. Grants to investigators for educational or other non-research purposes must also be placed in accounts as specified by the region.

5.8 Training. KP provides investigators and others who participate in research education about this policy, including what constitutes a financial conflict of interest and required reporting of significant financial interests.

5.8.1 KP must train investigators prior to investigators engaging in research, every four years thereafter, and immediately when:

5.8.1.1 This policy is revised in a manner that affects the requirements for investigators;

5.8.1.2 An investigator is new to KP; or

5.8.1.3 An investigator is not in compliance with the policy or in compliance with a plan to manage a financial conflict of interest.

5.9 Investigator Disclosure. Prior to engaging in research, or before submitting an application for PHS-funded research, as applicable, investigators are required to disclose in

writing any significant financial interest(s) and the nature and scope of those interest(s). If an investigator has significant financial interests, the investigator must declare this in writing. Investigators must disclose all in-kind travel support, regardless of value.

5.9.1 Investigators are required to submit an updated disclosure annually, in accordance with the procedure adopted by the specific KP entity. Such annual disclosure must correct any information submitted previously that is no longer accurate.

5.9.2 Investigators must immediately disclose any new significant financial interests that arise during the course of research. This may occur in situations including, but not limited to, the acquisition of a financial interest through purchase, marriage, or inheritance.

5.9.3 Investigators who are notified of the requirement to complete a research conflict of interest disclosure form must promptly complete the form and respond to requests for clarification or additional information regarding their disclosure.

5.9.4 All disclosures and actions taken with respect to this policy must be maintained for at least 4 years from the date the final expenditure report for a study is submitted.

5.10 Review of Disclosures. Each region designates a conflict of interest officer (CIO) to receive and review disclosure statements from investigators. The CIO may not review disclosures relating to the CIO's own research or those of the CIO's immediate family. The CIO determines whether there is a financial conflict of interest to report and manage. Such review must occur before the expenditure of any funds under PHS-funded research, or for ongoing PHS-funded research, within 60 days of an investigator's disclosure of a significant financial interest.

5.11 Reporting to the Public Health Service

5.11.1 Reporting Required. KP reports a financial conflict of interest if it is related to PHS-funded research and the significant financial interest identified could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. A significant financial interest is related to PHS-funded research if KP reasonably determines that the significant financial interest could be affected by the PHS-funded research, or is in an entity whose financial interest is affected by the research.

5.11.2 Timing of Reporting. KP reports to PHS before KP's expenditure of any funds under a PHS-funded research project. If KP identifies a financial conflict of interest and eliminates it before its expenditure of PHS-awarded funds, KP does not submit an FCOI report to PHS. If KP identifies a financial conflict of interest during ongoing PHS-funded research, KP reports to PHS within 60 days of identifying the financial conflict of interest.

5.11.3 Method of Reporting. KP provides to the PHS Awarding Component an FCOI Report regarding any investigator's significant financial interest found by KP to be a financial conflict of interest.

5.11.4 Information to Include in Report. An FCOI report must include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict of interest, and to assess the appropriateness of KP's management plan. The requirements for what the FCOI report must contain are detailed in Appendix 2 of this policy, Reporting Requirements to PHS.

5.11.5 Annual Reporting. For any financial conflict of interest reported by KP, with regard to an ongoing PHS-funded research, KP provides 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. The annual FCOI Report specifies whether the financial conflict of interest is still being managed or explains why the financial conflict of interest no longer exists. KP provides these annual reports in the time and manner specified by the PHS Awarding Component.

5.11.6 Corrective Action. If an investigator's failure to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, KP promptly notifies the PHS Awarding Component of the corrective action taken or to be taken.

5.12 Management of Financial Conflicts of Interest. The CIO develops and implements a plan to manage any financial conflict of interest. What such a plan should include is detailed in Appendix 3 of this policy, Content Requirements of Plans to Manage Financial Conflicts of Interest. If the financial conflict of interest involves clinical research, KP requires the investigator 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. KP must develop and implement a management plan before the expenditure of any funds under PHS-funded research, or for ongoing PHS-funded research within 60 days of an investigator's disclosure of a significant financial interest. KP monitors the investigator's compliance with the management plan.

5.13 Retrospective Review

5.13.1 If 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 KP to constitute a financial conflict of interest, failure by KP 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), KP, within 120 days of KP's determination of noncompliance,

completes 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.

5.13.2 KP documents the retrospective review. Such documentation will include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the investigator with the financial conflict of interest; (5) Name of the entity with which the investigator has a financial conflict of interest; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.

5.13.3 Based on the results of the retrospective review, if appropriate, KP updates the previously submitted financial conflict of interest report to PHS, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, KP notifies the PHS Awarding Component promptly and submits 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 KP'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, KP submits financial conflict of interest reports annually.

5.13.4 Depending on the nature of the financial conflict of interest, KP 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 KP's retrospective review.

5.14 Sanctions. Failure to comply with this policy will result in institutional sanctions to the investigator, which may include loss of research privileges. Investigators who fail to comply with this policy are subject to disciplinary action, up to and including termination.

5.15 Documentation and Retention of Documentation. KP maintains records relating to all investigator disclosures and KP's review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a financial conflict of interest), and all actions under this policy, for a period of 4 years from the date of submission of the final expenditures report for the PHS-funded research.

5.16 Regional Policy and Procedure. Each region and Permanente Medical Group may adopt a stricter research conflict of interest policy. Each region and Permanente Medical Group

maintains a written standard operating procedure (SOP) describing its processes for adhering to this policy, which must comply with the federal regulations. The SOP is made widely available within the region and Permanente Medical Group. The SOP addresses the following:

5.16.1.1 Designation of a Conflicts of Interest Officer;

5.16.1.2 Procedures for the review of all disclosures;

5.16.1.3 Standards for the determination of whether a significant financial interest is a financial conflict of interest that must be reported to the PHS; and

5.16.1.4 Standards for the development and implementation of plans to manage and remediate identified financial conflicts of interest.

5.17 Posting on a Publicly Accessible Web Site. In accordance with federal regulations, this policy must be available via a publicly accessible website. Publishing this policy on this website fulfills that requirement.

5.18 Public Accessibility

5.18.1 Prior to KP's expenditure of any funds under a PHS-funded research project, KP ensures public accessibility, via a publicly accessible website, of information concerning any significant financial interest disclosed to KP that meets the following three criteria: (1) The significant financial interest was disclosed and is still held by the investigator; (2) KP determines that the significant financial interest is related to PHS-funded Research; and (3) KP determines that the significant financial interest is a financial conflict of interest.

5.18.2 The information KP provides on the publicly accessible website is detailed in Appendix 4 of this policy, FCOI Information Provided on the Publicly Accessible Website. [View the FCOI information provided to the Federal Government.](#)

5.18.3 KP maintains this information on the publicly accessible website for 4 years from the date the information was most recently updated.

5.19 Subcontracts. When KP subcontracts PHS-funded research to another institution, KP takes reasonable steps to ensure that the other institution's investigators comply with either this policy or, if the other institution's policy complies with federal regulations, complies with the other institution's policies. KP includes the following terms in its subcontracts:

5.19.1 If the subcontractor's investigators will comply with the subcontractor's financial conflicts of interest policy, the subcontractor will certify as part of the agreement that its policy complies with the 42 Code of Federal Regulations Part 50, Subpart F (the "Federal

Regulations”). Additionally, the agreement will specify time period(s) for the subcontractor to report to KP all identified financial conflicts of interest, as defined by the Federal Regulations, which time period(s) will be sufficient to enable KP to provide FCOI reports before the expenditure of funds, and within 60 days of any subsequently identified FCOI.

5.19.2 If the subcontractor will not provide such certification, the agreement will state that subcontractor investigators are subject to KP’s policy for disclosing significant financial interests that are directly related to the subcontractor’s work for KP. The agreement will specify time period(s) for the subcontractor to submit all investigator disclosures of significant financial interests to KP, and which time period(s) will be sufficient to enable KP to comply in a timely manner with its review, management, and reporting obligations under the Federal Regulations.

6.0 References/Appendices

6.1 Appendix 1: Glossary of Policy Terms

6.2 Appendix 2: Reporting Requirements to PHS

6.3 Appendix 3: Content Requirements of Plans to Manage Financial Conflicts of Interest

6.4 Appendix 4: FCOI Information to be Provided on the Publicly Accessible Website

6.5 Federal Register/Vol.76, No. 165/Thursday, August 25, 2011

6.5.1 CFR Part 50

6.5.2 CFR Part 94

7.0 Approval

This policy was approved by the following representatives of Kaiser Foundation Hospitals, Kaiser Foundation Health Plan, Inc., and their subsidiaries and the Permanente Medical Groups.

Name	Title	Organization	Date of Approval
Raymond Baxter	Senior Vice President	Community Benefit Research and Health Policy	August 8, 2012

Name	Title	Organization	Date of Approval
Robert M. Pearl, MD	President and Chief Executive Officer	Mid-Atlantic States Medical Group, P.C.	August 1, 2012
Philip Madvig, MD	Associate Executive Director	The Permanente Medical Group, Inc.	July 11, 2012
Jeffrey Weisz, MD	President and Executive Medical Director	Northwest Permanente P.C.	August 8, 2012
Edward Ellison, MD	Executive Medical Director and Chairman of the Board	Southern California Permanente Medical Group	July 25, 2012
Bill Wright, MD	President and Executive Medical Director	Colorado Permanente Medical Group, P.C.	July 24, 2012
Ronald Copeland, MD, FACS	President and Executive Medical Director	Ohio Permanente Medical Group	July 23, 2012
Rob Schreiner, MD, FACP, FCCP	Executive Medical Director and Chairman of the Board	The Southeast Permanente Medical Group, Inc.	June 15, 2012
Geoffrey Sewell, MD	President and Executive Medical Director	Hawaii Permanente Medical Group, Inc.	July 25, 2012

Policy Life History

Original Approval Date:	Revision Approved Date:	Update Date:
Original Effective Date:	Revision Effective Date:	Update Effective Date:
Original Communicated Date:	Revision Communicated Date:	

Appendix 1: Glossary of Policy Terms

Clinical Research: Research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment.

Conflict of Interest Officer for Research (CIO): The individual with authority to review financial disclosures by investigators and determine whether a conflict of interest exists.

Immediate Family: This includes the following individuals, regardless of whether they are living in the household of the investigator: spouse, domestic partner, minor or dependent children or former spouse for whom financial assistance is provided, and any other related or unrelated individuals living in the household who are financial dependents.

Institutional Responsibilities: These include an investigator's professional responsibilities on behalf of KP, including those involving research, research consultation, teaching, professional practice, KP committee memberships, and services on Kaiser Permanente Institutional Review Boards or Data and Safety Monitoring Boards.

Key Personnel: In research funded by the PHS, this includes the project director/principal investigator and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered key personnel if they meet this definition.

Regional Research Office: The designated office with authority and responsibility to oversee research within a region.

Remuneration: Remuneration includes:

- Salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship);
- Equity interests including any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Research: A systematic investigation, study, or experiment designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social sciences research.

Research Sponsor: Is any entity which provides funding for a research study or an investigational product that is being tested in a study (e.g., pharmaceutical companies, device manufacturers, foundations, academic institutions, or government agencies).

Appendix 2: Reporting Requirements to U.S. Public Health Service

The following are the minimum requirements for information that must be included in a Financial Conflict of Interest Report submitted to the PHS.

The FCOI Report must include at minimum:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the investigator with the financial conflict of interest;
- (iv) Name of the entity with which the investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$0 to \$4,999; \$5,000 to \$9,999; \$10,000 to \$19,999; amounts between \$20,000 to \$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;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for KP's determination of the financial conflict of interest; and

(viii) A description of the key elements of KP's management plan, including

a. Role and principal duties of the conflicted investigator in the research;

b. Conditions of the management plan;

c. How the management plan is designed to safeguard objectivity in the research;

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.

Appendix 3: Content Requirements of Plans to Manage Financial Conflicts of Interest

A plan to manage financial conflicts of interest may include the following:

(i) Public disclosure of the financial conflict of interest (e.g., when presenting or publishing the research);

(ii) For research involving human participants, disclosure of the financial conflict of interest directly to the participants;

(iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias that may result from the financial conflict of interest;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

Appendix 4: FCOI Information Provided on the Publicly Accessible Website

The information that is included on the Kaiser Permanente's publicly accessible Website is:

1. The investigator's name;
2. The investigator's title and role with respect to the research;
3. The name of the entity in which the significant financial interest is held;
4. The nature of the significant financial interest; and
5. The approximate dollar value of the significant financial interest (dollar ranges are permissible):

- \$0 to \$4,999;
- \$5,000 to \$9,999;
- \$10,000 to \$19,999;
- amounts between \$20,000 to \$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.

Reviewed by: Jeffrey P. Braff, DrPH, CIP, Kaiser Permanente Conflict of Interest Officer for Research and Director-Human Research Protections, Kaiser Foundation Research Institute