POLICY TITLE **Financial Conflicts of Interest in Research**	POLICY NUMBER **NATL.KFRI.001**
ACCOUNTABLE DEPARTMENT **Kaiser Foundation Research Institute**	EFFECTIVE DATE **05/14/2023**
DOCUMENT OWNER **Director, NCRSP**	PAGE **1 of 21**

1.0 Policy Statement

Kaiser Permanente (KP) is committed to conducting research with integrity. KP employees, physicians, and individuals responsible for or essential to the design, conduct, or reporting of research conducted or proposed within KP must promptly disclose significant financial interests that may present a financial conflict of interest (FCOI). KP evaluates and manages these situations to ensure research decisions made are in the best interests of KP, its research participants, patients, and members. KP operates in accordance with federal regulations addressing FCOI in research.

2.0 Purpose

The purpose of this policy is to describe requirements for identifying and managing Investigator and Senior/Key Personnel-related FCOIs in the conduct of research activities.

3.0 Scope/Coverage

This policy applies to all employees, physicians, and dentists, who are employed by or partners of the following entities (collectively referred to as "Kaiser Permanente"):

3.1 Kaiser Foundation Health Plan, Inc. (KFHP);

3.2 Kaiser Foundation Hospitals (KFH);

3.3 KFHP/H subsidiaries;

3.4 Permanente Medical Groups (PMGs); including Colorado Permanente Medical Group (CPMG), Hawaii Permanente Medical Group (HPMG), Mid-Atlantic Permanente Medical Group (MAPMG), Northwest Permanente (NWP), Southern California Permanente Medical Group (SCPMG), The Permanente Medical Group (TPMG), The Southeast Permanente Medical Group (TSPMG), and Washington Permanente Medical Group (WPMG);

3.5 The Permanente Federation (TPF); and

3.6 Permanente Dental Associates (PDA).

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 Investigators/Senior/Key Personnel and either KP or research participants may be a conflict of interest. A potential conflict of interest exists when Investigators or Senior/Key Personnel have 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 (Note that the definition of this term may be different than in other KP policies).

4.2 **Financial Conflict of Interest (FCOI) —** A Significant Financial Interest (SFI) that KP determines could directly and significantly affect the design, conduct or reporting of research. For Public Health Service (PHS) funded research, a FCOI must be reported to the PHS Awarding Component.

4.3 **Financial Interest —** Anything of monetary value, whether or not the value is readily ascertainable, including but not limited to: salary, honoraria, any other compensation for consulting or other similar services; any equity or ownership interest; any rights to intellectual property; or any sponsored travel. A financial interest applies to Investigators or Senior/Key Personnel and those of the Investigators or Senior/Key Personnel's immediate family that reasonably appear to be related to the Investigators or Senior/Key Personnel's institutional responsibilities (Note that the definition of this term may be different than in other KP policies).

4.4 **Investigator —** Any person regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed research. Investigators include: Principal Investigator (PI), Co-Investigators (Co-I), Project Directors (PD), and Co-PIs. An Investigator makes direct and significant contributions to a project by helping to prepare and carry out the protocol (plan) for the study; ensuring data integrity; monitoring the safety of the study, collection and analysis of data; and reporting results of the study. In research subject to Food and Drug Administration (FDA) regulations, an Investigator is the individual who actually conducts a clinical investigation – i.e., under whose immediate direction the test article is administered or dispensed to or used involving a subject. In the event an investigation is conducted by a team of individuals, the Investigator is the responsible leader of the team.

4.5 **Senior/Key Personnel —** Senior/Key Personnel means the PD/PI and any other person identified as Senior/Key Personnel by KP in the grant application, progress report, or any other report KP submitted to the sponsor. For research subject to FDA regulations, such individuals may include, but not be limited to, individuals accountable for (1) making critical decisions regarding eligibility of subjects, (2) obtaining consent for a study, as well as (3) individuals listed on the Form FDA 1572, Study Delegation of Authority Log, or the Investigator Agreement. For sponsored research, the sponsor's guidelines spell out who must be named as Senior/Key Personnel. Sponsor guidelines may use the following terms: Senior Personnel, Non Co-PI, Senior Personnel, Key People, and Senior Key Person. These terms are the same as Key Personnel.

For more definitions see *Appendix A — Glossary of Terms.*

5.0 Provisions

5.1 Policy provisions apply to all research being conducted in whole or in part at KP, regardless of the research sponsor, with the following exceptions.

5.1.1 The PHS reporting requirements only apply to research funded by the PHS and Foundations that follow the PHS FCOI regulations and incorporate and expand upon federal regulations designed to promote objectivity in research.

5.1.2 Under FDA regulations and this KP policy, all Investigators and Senior/Key Personnel in clinical research and investigator-sponsored research regulated by the FDA are subject to FDA financial disclosure requirements. Disclosures required by the FDA are forwarded through the sponsor of the investigation who is responsible to maintain record of disclosures.

5.1.3 This policy addresses FCOI requirements specific to research; KP Investigators and Senior/Key Personnel must also follow the KP Principles of Responsibility, *Conflicts of Interest, NATL.EC.007*, and *Vendor Relationship, NATL.EC.016* as applicable.

5.2 **Determination of Significant Financial Interest (SFI).** The Conflict of Interest Officer for Research (CIO-R) determines whether a SFI exists, using the following criteria:

5.2.1 **For any publicly traded entity** a significant financial interest exists for the Investigator, Senior/Key Personnel, and their immediate families if the value of any remuneration received from the entity in the twelve (12) 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.

5.2.2 **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, Senior/Key Personnel or a member of their immediate family holds any equity interest, stock option, or other ownership interest, regardless of value.

5.2.3 **Intellectual property rights and interests** a SFI exists if an Investigator or Senior/Key Personnel or a member or their immediate family receives income related to such rights (e.g., patents, copyrights) regardless of value.

5.2.4 **Sponsored Travel** a SFI exists if the sponsored travel equals or exceeds $5,000, alone or in combination with other remuneration or equity interests. See *Appendix E — Reporting Sponsored Travel* for more information.

5.2.5 An SFI does not include the following types of financial interest:

5.2.5.1 Salary, royalties, or other remuneration, paid by KP from KP funds or from sponsored awards funds managed by KP, to any Investigators or Senior/Key Personnel who are currently employed or otherwise appointed by KP, including intellectual property rights assigned to KP and agreements to share in royalties related to such rights.

5.2.5.2 Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator or Senior/Key Personnel does not directly control the investment decisions made in these vehicles.

5.2.5.3 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.

5.2.5.4 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.

5.2.5.5 Sponsored travel paid for or reimbursed by: KP (e.g., paid from KP funds or from sponsored awards funds managed by KP), 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.

5.2.5.6 Travel to professional meetings in which the Investigator or Senior/Key Personnel pays for themselves and for which the Investigator or Senior/Key Personnel are not reimbursed.

5.3 Determining when a SFI is a FCOI.

5.3.1 It meets the definition for SFI; and

5.3.2 It can be reasonably determined that at least one (1) of the following criteria are met:

5.3.2.1 The SFI could be affected by the funded research;

5.3.2.2 The SFI is with an entity whose financial interest could be affected by the research;

5.3.2.3 The SFI could directly and significantly affect the design, conduct or reporting of the research.

5.4 Disclosure of SFI and FCOIs

5.4.1 Investigators or Senior/Key Personnel are required to disclose SFIs and sponsored travel to the CIO-R, prior to submitting to the Institutional Review Board (IRB), or before applying for funded research, whichever occurs first. The Investigator or Senior/Key Personnel must attest to the accuracy and completeness of the disclosure.

5.4.2 Investigators and Senior/Key Personnel are required to submit an updated disclosure at least annually.

5.4.3 Investigators and Senior/Key Personnel must disclose within ten (10) calendar days any new SFI interests that arise throughout the year. This may occur in situations including, but not limited to, the acquisition of a financial interest through purchase, marriage, or inheritance, or those identified on a project that was transferred from another institution.

5.4.4 All Research Personnel. All research personnel must report all potential FCOI to either the PI for the research project, their direct supervisor (if different), or directly to the CIO-R. PIs must disclose any potential FCOIs on their team to the CIO-R and to the IRB.

5.5 Review of SFI Disclosures. The CIO-R receives and reviews disclosure statements via the annual survey process or from the Regional Research Office in accordance with this policy. The CIO-R determines whether there is an FCOI and it can be managed. For new research, this review must occur before IRB approval or the expenditure of any funds under funded research, whichever occurs first. For ongoing research, this is to occur within 60 calendar days of an Investigators or Senior/Key Personnel's disclosure of an SFI. The CIO-R may not review disclosures relating to the CIO-R's own research or those of the CIO-R's spouse and immediate family. The Research Compliance Officer will review disclosures by the CIO-R.

5.6 Management of FCOIs. The CIO-R develops and implements a plan to manage any FCOI. Components of the plan are detailed in *Appendix B — Content Requirements of Plans to Manage Financial Conflicts of Interest*. The CIO-R must develop and implement a management plan for new research; (1) before IRB approval or the expenditure of any funded research; or (2) in ongoing funded research, within 60 calendar days of an Investigators or Senior/Key Personnel's disclosure of a SFI interest.

5.6.1.1 Any identified FCOI is reported to the IRB, KFRI, and if applicable, the appropriate Regional Research Institute. A management plan is provided to the IRB by the CIO-R for review. The IRB determines whether the project, pursuant to the management plan, may proceed in light of the identified FCOI.

5.6.2 Monitoring of FCOIs. The Research Compliance Officer will determine the appropriate functional unit responsible for monitoring adherence with the management plan in consultation with the COI-R.

5.7 Retrospective Review: Investigators and Senior/Key Personnel Non-Compliance

5.7.1 Identification of Retrospective FCOI. If a FCOI is not identified or managed in a timely manner, the CIO-R will complete a retrospective review of the Investigators or Senior/Key Personnel's funded research project to determine whether any funded research, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting of such research.

5.7.1.1 Criteria that would trigger a retrospective review of activities include but are not limited to: Nondisclosure by Investigators or Senior/Key Personnel of a SFI that is subsequently determined by the CIO-R to constitute a FCOI; failure by KP to review or manage such a FCOI; or Investigators or Senior/Key Personnel noncompliance with a FCOI management plan.

5.7.1.2 This review is to be completed within 120 days of determination of noncompliance by the applicable CIO-R.

5.7.1.3 The review will include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) Project Director (PD)/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigators and Senior/Key Personnel with the financial conflict of interest; (5) Name of the entity with which the Investigators and Senior/Key Personnel a FCOI; (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.

5.7.2 Determination of FCOI. If the retrospective review confirms a FCOI, the CIO-R may develop a mitigation plan to eliminate or mitigate the impact of the potential bias on the research project.

5.7.2.1 PHS Funded Activity: If appropriate, KFRI updates the previously submitted FCOI report to PHS, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, KFRI 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, KFRI submits FCOI reports at initiation and annually.

5.7.3 Corrective Action Plan. Depending on the nature of the FCOI, Research Compliance may determine additional interim measures to address the actions that led to noncompliance outside of the mitigation plan.

5.8 Reporting to the Public Health Service (PHS)

5.8.1 Reporting Required. KFRI reports a FCOI if it impacts PHS-funded research.

5.8.1.1 The National Institutes of Health (NIH) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Phase I programs are exempt from reporting requirements.

5.8.2 Timing of Reporting

5.8.2.1 If KP identifies a FCOI during ongoing PHS-funded research, KFRI reports to PHS within 60 calendar days of identification.

5.8.2.2 KFRI may also report a FCOI as part of the annual progress report on the research and as part of any requests for an extension of the award; and following a retrospective review.

5.8.2.3 KFRI reports to PHS before KP's expenditure of any funds under a PHS-funded research project If KP eliminates the FCOI before the expenditure of PHS-awarded funds, KFRI does not submit the FCOI report to PHS.

5.8.2.4 If KP discovers a FCOI after expenditure of any funds under a PHS-funded research project.

5.8.3 Method of Reporting. KFRI provides the FCOI report to a PHS Awarding Component.

5.8.4 Information to Include in Report. KFRI will provide a FCOI report with sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of KP's management plan. The requirements for what the FCOI report must contain are detailed in *Appendix D — Reporting Requirements to U.S. Public Health Service.*

5.8.5 Annual Reporting. KFRI provides to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI for any PHS-related FCOI reported by KFRI, as well as any changes to the

management plan for the duration of the PHS-funded research. The annual FCOI report specifies whether the FCOI is still being managed or explains why the FCOI no longer exists. KFRI provides these annual reports in the time and manner specified by the PHS Awarding Component.

5.8.6 Monitoring. For PHS funded research, KFRI is responsible for monitoring compliance with the management plans, regardless of the Regional Research Institute performing the research.

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

5.9 Subawards

5.9.1 Subawards Issued by KP Under PHS Funded Prime Awards. When KP issues a subaward to carry out a portion of a PHS funded project, the subawardee must comply with PHS FCOI regulations. KP therefore, will only issue subawards under PHS funded awards to institutions that have FCOI policies that comply with the PHS regulation or institutions that agree to be subject to this policy. KP includes the following terms in its subcontracts:

5.9.1.1 If the subcontractor's Investigators or Senior/Key Personnel will comply with the subcontractor's FCOI policy, the subcontractor will certify as part of the agreement that its policy complies with 42 Code of Federal Regulations Part 50, Subpart F (the "Federal Regulations"). Additionally, the agreement will specify the time period(s) for the subcontractor to report to KP all identified FCOI, as defined by the Federal Regulations, within a sufficient time period(s) to enable KP to provide FCOI reports before the expenditure of funds, and within 60 calendar days of any subsequently identified FCOI.

5.9.1.2 If the subcontractor will not provide such certification, the agreement will state that subcontractor Investigators and Senior/Key Personnel are subject to KP's policy for disclosing SFI that are directly related to the subcontractor's work for KP. The agreement will specify time period(s) for the subcontractor to submit all Investigators and Senior/Key Personnel disclosures of SFIs 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.

5.9.1.3 If a subawardee Investigators and Senior/Key Personnel has a FCOI, KP is responsible for reporting the FCOI to the PHS on

behalf of the subawardee. KFRI will report subawardee FCOI using the same method it uses to disclose its own FCOI and will notify the subawardee of any requests for information. Questions regarding the specifics of subawardee FCOI are directed to the subawardee.

5.9.2 Subawards Issued to KP Under PHS Funded Prime Awards

5.9.2.1 When KP receives a subaward from another organization to carry out a portion of a PHS funded project, KP must comply with the PHS regulations regarding FCOI. KP applies its own policy to these proposals and awards rather than the policies of the subawarding organization. KP provides reports of FCOI to the subawarding organization for reporting to PHS as specified in the PHS regulations.

5.9.2.2 FCOI Reports are provided in the same form and format as KP uses in connection with its direct awards for PHS. KP will make this information available to the public. The subawarding organization is also responsible for public reporting. The subawarding organization may choose to do so either by posting KP's report to a publicly available website or responding to written requests within five (5) business days.

5.10 Documentation and Maintenance of Records

5.10.1 KFRI and the CIO-R maintains records relating to all actions under this policy. Retention includes documents relating to the following subject matter. Covered persons are advised to consult *Business Record Retention, NATL.EC.005*.

5.10.1.1 Investigators and Senior/Key Personnel disclosures.

5.10.1.2 KP's review of such disclosures.

5.10.1.3 KP's response to such disclosures (regardless of any FCOI finding).

5.10.2 Documents must be maintained for at least three (3) years from the date of submission of the final expenditures report unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the three (3) year period, in which case, records will be retained until completion of the action and resolution of all issues. KFH personnel is advised to consult *Business Record Retention, NATL.EC.005*.

5.10.3 In accordance with federal regulations, this policy must be maintained and be made available via a publicly accessible website: about.kaiserpermanente.org/our-story/health-research/about-our-research (see 6.4.1). The information KP provides on the publicly

accessible website is detailed in *Appendix C — FCOI Information Provided on the Publicly Accessible Website*.

5.10.4 Prior to KP's expenditure of any funds under a PHS-funded research project, KFRI ensures public accessibility of information concerning any SFI disclosed to KP on a publicly accessible website that meets the following three (3) criteria: (1) All SFI(s) were disclosed and is/are still held by the Investigators or Senior/Key Personnel; (2) KP determined the SFI is related to PHS-funded Research; and (3) KP determines that the SFI is a FCOI.

5.10.4.1 KP maintains this information on the publicly accessible website for four (4) years from the date the information was most recently updated.

5.10.4.2 The website shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the institution's identification of a new FCOI.

5.11 Training. KP provides training and education about this policy and its contents to Investigators and Senior/Key Personnel and others who participate in research.

5.11.1 Investigators and Senior/Key Personnel must complete training prior to engaging in research, every four (4) years thereafter, and immediately when:

5.11.1.1 This policy is revised in any manner that affects the requirements for Investigators and Senior/Key Personnel; or

5.11.1.2 An Investigators or Senior/Key Personnel is not in compliance with the policy or in compliance with a plan to manage an FCOI; or

5.11.1.3 An investigator or Senior/Key Personnel are new to KP research.

5.12 Regional Policy and Procedures

5.12.1 Each region and PMG may maintain a written standard operating procedure (SOP) describing its processes for adhering to this policy.

5.12.2 Each region and PMG may adopt a stricter FCOI policy as long as it does not conflict with this policy.

5.13 Sanctions. Failure to comply with this policy will result in institutional sanctions to the Investigator or Senior/Key Personnel, which may include but are not limited to (1) loss of research privileges and disciplinary action and (2) disciplinary action up to and including termination.

6.0 Appendices/References

6.1 Appendices

6.1.1 Appendix A — Glossary of Terms

6.1.2 Appendix B — Content Requirements of Plans to Manage Financial Conflicts of Interest

6.1.3 Appendix C — FCOI Information Provided on the Publicly Accessible Website

6.1.4 Appendix D — Reporting Requirements to U.S. Public Health Service

6.1.5 Appendix E — Reporting Sponsored Travel

6.1.6 Appendix F — NWP Governance

6.2 Attachments

6.2.1 Disclosing and Reporting Financial Conflicts of Interest (FCOI) in Research

6.3 Kaiser Permanente Policies

6.3.1 Business Record Retention, NATL.EC.005

6.3.2 Conflicts of Interest, NATL.EC.007

6.3.3 Conflicts of Interest: Vendor Relationships, NATL.EC.016

6.3.4 KP Principles of Responsibility: KP's Code of Conduct

6.4 Other References

6.4.1 about.kaiserpermanente.org/our-story/health-research/about-our-research

6.4.2 Department of Health and Human Services Records Management Program

6.4.3 https://www.federalregister.gov/agencies/public-health-service

6.4.4 1743-2 - NIH Litigation Hold Policy

6.5 Regulatory Information

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

6.5.2 21 CFR Part 54, Financial Disclosure by Clinical Investigators

6.5.3 42 CFR Part 50, Subpart F Promoting Objectivity in Research

6.5.4 45 CFR Part 94, Responsible Prospective Contractors

7.0 Approval

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

Kaiser Foundation Health Plan/Hospital			
Name	**Title**	**Organization**	**Date**
Elizabeth A. McGlynn	Senior Vice President, Research and Quality Measurement	Kaiser Foundation Health Plan, Inc., and Kaiser Foundation Hospitals	04/14/2023
Permanente Medical Groups			
Name	**Title**	**Organization**	**Date**
Jeff Krawcek, MD	President and Executive Medical Director	Colorado Permanente Medical Group (CPMG)	03/16/2023
John Yang, MD	President and Medical Director	Hawaii Permanente Medical Group (HPMG)	03/01/2023
Richard J. McCarthy, MD	Associate Executive Director of the Mid-Atlantic States, The Permanente Medical Group	Mid-Atlantic Permanente Medical Group (MAPMG)	03/06/2023
Leong Koh, MD	President and Chief Executive Officer	Northwest Permanente (NWP)	04/12/2023
Cyrus Lee, DMD	Chief Executive Officer & Executive Dental Director	Permanente Dental Associates (PDA)	12/30/2022
Ramin Davidoff, MD	Executive Medical Director and Chairman	Southern California Permanente Medical Group (SCPMG)	02/20/2023
Chris Grant	Executive Vice President and Chief Operating Officer	The Permanente Federation, LLC (TPF)	02/21/2023

Yi-Fen Chen, MD	Associate Executive Director	The Permanente Medical Group (TPMG)	01/11/2023
Nkem Chukwumerije, MD, MPH, FACP	President and Executive Medical Director	The Southeast Permanente Medical Group (TSPMG)	02/21/2023
Paul Minardi, MD	President and Executive Medical Director	Washington Permanente Medical Group (WPMG)	02/21/2023

Appendix A — Glossary of Terms

Awarding Component / PHS Awarding Component — The organizational unit of the Public Health Service (PHS) within the U.S. Department of Health and Human Services (HHS) that funds the Investigator and Senior/Key Personnel's research.

Conflict of Interest Officer for Research (CIO-R) — A Research Compliance designated individual with the authority to review financial disclosures by Investigators and Senior/Key Personnel, determine whether a FCOI exists and implements a plan to manage the FCOI. The CIO-R may appoint a designee(s) to assist in carrying out his/her duties and throughout this policy references to the CIO-R shall include the CIO-R's designee(s).

Entity — Any domestic or foreign, public or private, for profit, non-profit or governmental organization, or research sponsor.

Equity Interest — Includes stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity, as determined through reference to public prices or other reasonable measures of fair market value.

FCOI Report — A report submitted to a PHS Awarding Component when a FCOI is related to PHS-funded research and the SFI identified could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Food and Drug Administration (FDA) — The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation as well as tobacco and healthcare innovations. FDA Mission and regulatory authority can be found here ~ https://www.fda.gov/about-fda/what-we-do#mission define similar to PHS.

Immediate Family — Investigator spouse or domestic partner and dependent children. (Note that the definition of this term may be different than in other KP policies.)

In-kind (non-cash) Support — Contributions of goods or services by a research sponsor.

Institution — Kaiser Foundation Research Institute (KFRI), the national KFH office that receives PHS funding on behalf of KP. For non-PHS-funded research, the institution includes other KP legal entities that have research contracting authority to sign research agreements and receive research funding on behalf of KP (e.g., PMGs).

The Institutional Official (IO) for the KP Protection of Human Subjects — The individual delegated the legal authority to represent Kaiser Permanente and to require compliance of all institutional components listed in the Federalwide Assurance (FWA) on matters related to human research. The IO is authorized to act for and on behalf of KP and obligates KP to the terms of the FWA. The IO is authorized to speak for and legally commit the institution to compliance with the requirements of the federal regulations regarding the involvement of human subjects in research.

Institutional Responsibilities — Investigators or Senior/Key Personnel's professional

responsibilities while performing duties on behalf of KP, including: research, research consultation, teaching, professional practice, clinical practice, institutional committee memberships, and service on panels.

Institutional Review Board (IRB) — An administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB is charged with the responsibility of reviewing, prior to its initiation, all research (whether funded or not) involving human participants. The IRB is concerned with protecting the welfare, rights, and privacy of human subjects. The IRB has the authority to approve, disapprove, monitor, and require modifications in all research activities that fall within its jurisdiction as specified by both the federal regulations and institutional policy.

Public Health Service (PHS) — The Public Health Service of the U.S. Department of Health and Human Services, including, but not limited to the National Institutes of Health (NIH), the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, and Substance Abuse and Mental Health Services Administration. The most current list can be found at the PHS website: https://www.federalregister.gov/agencies/public-health-service (see 6.4.3).

Regional Research Institute/Department(s) — The designated KP entity with authority and responsibility to oversee research operations within a region.

Remuneration — Financial compensation including salary and payment for services not otherwise identified as salary, such as consulting fees, honoraria or paid authorship, and in kind (non-cash) gifts from entities for which one provides services and sponsored travel.

Research — Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy.

Research Sponsor – An entity that provides funding for a research study or an investigational product that is being tested in a study. Examples of research sponsors are individuals, pharmaceutical companies, device manufacturers, foundations, academic institutions, governmental agencies, KFHP/H or PMGs.

Significant Financial Interest (SFI) — Financial interest that meets any of the criteria for significance set forth in this policy.

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

Sponsored Travel — Includes: (a) travel expenses paid to Investigators or Senior/Key

Personnel or travel paid on an Investigators or Senior/Key Personnel's behalf, in any twelve (12) month period; and (b) travel reimbursed to or paid on behalf of an Investigators or Senior/Key Personnel's Immediate Family in any twelve (12) month period. See *Appendix E — Reporting Sponsored Travel* for more information.

Subaward — An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of an award received by the pass-through entity. I.e., a subaward is a portion of KP's sponsored project passed to another entity in order to complete a portion of the KP project's scope of work.

Appendix B — 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 FCOI 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 FCOI;

(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 C — FCOI Information Provided on the Publicly Accessible Website

The information included on the KP's publicly accessible Website about.kaiserpermanente.org/our-story/health-research/about-our-research (6.4.1) is:

- The Investigators or Senior/Key Personnel's name.
- The Investigators or Senior/Key Personnel's title and role with respect to the research.
- The name of the entity in which the SFI is held.
- The nature of the SFI.
- The approximate dollar value of the SFI.

The following dollar ranges are permissible:

- $0-$4,999
- $5,000-$9,999
- $10,000-$19,999; amount between $20,000-$100,000, in increments of $20,000
- $100,000+, in increments of $50,000

Alternatively, a statement may be made that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new FCOI.

Appendix D — Reporting Requirements to U.S. Public Health Service

The following are the minimum requirements for information that must be included in a FCOI Report submitted to the PHS.

1. Project number.
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used.
3. Name of the Investigators or Senior/Key Personnel with the FCOI.
4. Name of the entity with which the Investigators or Senior/Key Personnel has a FCOI.
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).
6. Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
7. A description of how the financial interest relates to the PHS-funded research and the basis for KP's determination of the FCOI.
8. A description of the key elements of KP's management plan, including:
    a. Role and principal duties of the conflicted Investigators and Senior/Key Personnel 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 Investigators or Senior/Key Personnel agreement to the management plan.
    e. How the management plan will be monitored to ensure Investigators or Senior/Key Personnel compliance.
    f. Other information as needed.

Appendix E — Reporting Sponsored Travel

Sponsored travel is included in the determination of whether the aggregate value of an Investigators and Senior/Key Personnel financial interests rises to the level of a SFI. Sponsored travel includes (a) travel expenses paid to an Investigators and Senior/Key Personnel or travel paid on an Investigators and Senior/Key Personnel behalf, by a single entity in any 12-month period and (b) travel reimbursed to or paid on behalf of an Investigators and Senior/Key Personnel Immediate Family by a single entity in any twelve (12) month period, for the duration of the project.

NIH states that looking back over the previous twelve (12) month period provides baseline information that allows KP to take into account whether Investigators and Senior/Key Personnel have an ongoing financial relationship with an entity providing a payment or reimbursement or whether the payment or reimbursement was limited in duration.

Investigators and Senior/Key Personnel must report sponsored travel if both of the following criteria, A and B, are met:

A. The sponsored travel equals or exceeds $5,000, alone or in combination with other remuneration and equity interests during the following time periods:
   - Within the 12 months prior to the submission of a proposal; and/or
   - Thereafter, within 30 calendar days following reimbursement or within 30 calendar days following the completion of a trip.

B. The sponsored travel is paid for or reimbursed by any party other than:
   - KP (e.g., paid from KP funds or from sponsored awards funds managed at KP).
   - U.S. Federal, state, or local governmental agencies.
   - U.S. institutions of higher education.
   - U.S. Research institutions affiliated with institutions of higher education.
   - U.S. Academic teaching hospitals and medical centers.

The disclosure must include at a minimum, the purpose, cost of the trip (estimate if unknown), the identity of the organization or entity funding the travel, the destination, the duration of the trip (usually days), and the relationship between the trip and the Investigators or Senior/Key Personnel's proposals and awards. The CIO-R may request additional information to determine whether the sponsored travel is related to the Investigators or Senior/Key Personnel's institutional responsibilities and professional expertise.

Appendix F — NWP Governance

- For the purposes of this policy, NWP's Chief Compliance Official (CCO) is designated as NWP's Conflict of Interest Officer for Research (CIO-R) and/or NWP's Research Compliance Officer.
- KFRI, Research Compliance, and CHR will communicate changes in research compliance activities and the designated CIO-R that affects NWP and research programs that NWP employees are involved in.
- Annual research conflict of interest surveys, whether to satisfy section 5.4.2 or otherwise, will be conduct jointly with NWP and the results reviewed jointly.
- All investigations into potential Financial Conflicts of Interest will be jointly conducted by NWP and KPNW. NWP's CCO, or delegate, will be included at the earliest known instance of a potential conflict.
- NWP will be responsible for any sanctions or enforcement actions resulting from this policy involving NWP employees. This includes the determination if an adverse employment action will occur. The results of all sanctions and corrective action plans will remain confidential. No conflict of interest involving a NWP employee will be reported to a regulator or outside of KP without the knowledge and approval of NWP's CCO, except when required by the Institutional Review Board for NWP research studies.