

Section E: Financial Conflict of Interest Policy

The Northwest Portland Area Indian Health Board (NPAIHB) is committed to conducting Research in a manner that ensures the integrity of its Research projects. NPAIHB requires its employees and any other person who is responsible for the design, conduct or reporting of Research being conducted by NPAIHB to promptly disclose significant financial interests and other situations that present a conflict of interest or the appearance of a conflict of interest. NPAIHB operates in accordance with federal regulations addressing Research conflicts of interest, including financial conflict of interest, as required by 42 C.F.R. Part 50, Subpart F (Public Health Service grants and cooperative agreements) and 45 C.F.R. Part 94 (Public Health Service contracts) (hereinafter collectively referred to as “Federal Regulations”).

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 NPAIHB, regardless of the Research Sponsor.

Definitions

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 NPAIHB 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.

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

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Research.

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.

Institution: The entity that receives funding from the Public Health Service of the U.S. Department of Health and Human Services (PHS), meaning NPAIHB or its subcontractors.

Institutional Responsibilities: These include an Investigator’s professional responsibilities on behalf of NPAIHB, including those involving Research and Research consultation.

Investigator: The Investigator means 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.

Key Personnel: The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under a PHS grant, cooperative agreement or contract. Consultants and those with a postdoctoral role also may be considered Key Personnel if they meet this definition.

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).

Significant Financial Interest (SFI): A financial interest of the Investigator and those of the Investigator's Immediate Family that reasonably appears to be related to the Investigator's Institutional Responsibilities. For example, an SFI for any non-publicly traded entity 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 any equity interest; or intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests, regardless of value. The term "SFI" does not include the following types of Financial Interests:

- a) Salary, royalties, or other remuneration paid by NPAIHB to the Investigator if the Investigator is currently employed or otherwise appointed or contracted by NPAIHB, including intellectual property rights assigned to NPAIHB and agreements to share in royalties related to such rights;
- b) 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;
- c) 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
- d) 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.

Provisions

- 1. Enrollment Bonuses and Special Payments.** 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.
- 2. Ownership.** Unless otherwise agreed to in writing by the NPAIHB entity in question, any inventions, intellectual property, or proprietary information developed as a result of Research conducted while on NPAIHB work time, or using NPAIHB information, equipment, or facilities is owned by the NPAIHB entity by which the Investigator is employed.
- 3. Publications.** Investigators may not publish, formally present, or provide expert commentary on Research without disclosing a SFI in any company that sponsored the study being reported.
- 4. Appearance of Conflict.** Investigators must avoid other situations, not specifically described in this policy that may create a FCOI or the appearance of a FCOI.
- 5. In-kind (non-cash) Support.** Investigators may not accept in-kind support from Research Sponsors, with the exception of payment of travel expenses. Immediate Family of Investigators may not accept in-kind support.
- 6. Travel.** Investigators may receive in-kind support from Research Sponsors such as airline tickets, to attend meetings related to the conduct or review of Research. All such in-kind support must be disclosed, which disclosure shall at a minimum include the purpose of the trip, the identity of the sponsor/organization, the destination and duration.
- 7. Education/Information about Conflict of Interest.** NPAIHB provides Investigators and others who participate in Research education about this policy, including what constitutes a FCOI and required reporting of SFIs. NPAIHB must provide this information to Investigators prior to Investigators engaging in Research, every four years thereafter, and immediately when:
 - a) This policy is revised in a manner that affects the requirements for Investigators;
 - b) An Investigator is new to NPAIHB; or
 - c) An Investigator is not in compliance with the policy or in compliance with a plan to manage a FCOI.
- 8. 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 SFI (s) and the nature and scope of those interest(s). If an Investigator has SFIs, the Investigator must declare this in writing. Investigators must disclose all in-kind travel support, regardless of value.
 - a) Investigators must immediately disclose any new SFIs 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.

b) Investigators must submit an updated disclosure of SFIs no less than annually during the course of Research. Such disclosure shall include any information that was not disclosed initially or in a subsequent disclosure of SFIs, and shall include updated information regarding any previously disclosed SFI.

c) 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.

d) 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.

9. Review of Disclosures. NPAIHB 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 FCOI 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 SFI. Additionally, whenever a FCOI is not identified or managed in a timely manner (including failure by the Investigator to disclose a SFI that is an FCOI, failure by NPAIHB to review or manage such an FCOI, or failure by Investigator to comply with a FCOI management plan), NPAIHB will, within 120 days of determining such non-compliance, complete a retrospective review of the Investigator's activities and the Research to determine whether any Research conducted during the period of non-compliance was biased in the design, conduct or reporting of such Research. Such retrospective review shall comply with the applicable Federal Regulations.

10. Reporting to the Public Health Service NPAIHB reports a FCOI if it 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. A SFI is related to PHS-funded Research if NPAIHB reasonably determines that the SFI could be affected by the PHS-funded Research, or is in an entity whose financial interest is affected by the Research.

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

b) Method of Reporting. NPAIHB provides to the PHS Awarding Component an FCOI Report regarding any Investigator's SFI found by NPAIHB to be a FCOI.

c) 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 FCOI, and to assess the appropriateness of NPAIHB's management plan. The requirements for what the FCOI report must contain are detailed in Appendix 1 of this policy, Reporting Requirements to PHS.

d) Annual Reporting. For any FCOI reported by NPAIHB, with regard to an ongoing PHS-funded Research, NPAIHB provides to the PHS Awarding Component an annual FCOI Report that addresses the status of the FCOI and 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. NPAIHB provides these annual reports in the time and manner specified by the PHS Awarding Component.

e) 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, NPAIHB promptly notifies the PHS Awarding Component of the corrective action taken or to be taken.

f) Management of Financial Conflicts of Interest. The CIO develops and implements a plan to manage (e.g., reduce or eliminate the FCOI; ensure to the extent possible that design, conduct and reporting of Research are free from bias) any FCOI consistent with the applicable Federal Regulations. NPAIHB 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 SFI. NPAIHB monitors the Investigator's compliance with the management plan.

11. Sanctions. Failure to comply with this policy will result in institutional sanctions to the Investigator, which may include loss of Research privileges. Persons who fail to comply with this policy are subject to disciplinary action, up to and including termination.

12. Documentation and Retention of Documentation. NPAIHB maintains records relating to all Investigator disclosures and NPAIHB's review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a FCOI), 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.

13. Posting on a Publicly Accessible Web Site. In accordance with Federal Regulations, this policy is posted on www.NPAIHB.org, which is accessible to the public. In addition, prior to NPAIHB's expenditure of any funds under a PHS-funded Research project, NPAIHB ensures public accessibility, via its website named above, of information concerning any SFI disclosed to NPAIHB that meets the following three criteria: (1) The SFI was disclosed and is still held by the Key Personnel; (2) NPAIHB determines that the SFI is related to PHS-funded Research; and (3) NPAIHB determines that the SFI is a FCOI. NPAIHB maintains this information on the publicly accessible website, consistent with the applicable Federal Regulations, for 4 years from the date the information was most recently updated.

14. Subcontracts. When NPAIHB subcontracts PHS-funded Research to another Institution, NPAIHB 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. NPAIHB includes the following terms in its subcontracts:

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

b) If the subcontractor will not provide such certification, the agreement will state that subcontractor Investigators are subject to NPAIHB's policy for disclosing SFIs that are directly related to the subcontractor's work for NPAIHB. The agreement will specify time period(s) for the subcontractor to submit all Investigator disclosures of SFIs to NPAIHB, and which time period(s) will be sufficient to enable NPAIHB to comply in a timely manner with its review, management, and reporting obligations under the Federal Regulations.

Approval

This policy was approved by the Northwest Portland Area Indian Health Board Delegates at the Quarterly Board Meeting on January 25, 2013.