



KAPI‘OLANI
PALI MOMI
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WILCOX

Title: Financial Conflicts of Interest
Department: Research Institute
Effective Date: 3/18 **Reviewed:**
Previous Version(s): 8/01, 1/02, 6/06, 1/12, 4/12
Replaces: Disclosure of Conflicts of Interest

Policy & Procedure

The reader is cautioned to refer to the Central Policy Database for the most current version of this document and not rely on any printed version.

Approval Signature: Ray Vara
Name: Raymond P. Vara, Jr. **Title:** President and Chief Executive Officer

Approval Signature: Allison Lopes
Name: Allison Lopes **Title:** Director, HPH Research Institute

Scope:

Applicable to all investigators submitting research protocols to Hawai‘i Pacific Health Research Institute (HPHRI). This policy applies to all investigators’, their spouses’ and dependent children’s’ ownership interests and receipt of payments. It also applies to any key personnel such as HPHRI or other research staff.

Policy Statement:

To ensure that individuals directly involved in the conduct, design, or reporting of research involving human subjects do not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied to ensure the protection of research subjects. A significant financial interest could directly and significantly affect the design, conduct or reporting of research.

Any investigator/key personnel on any research project is to disclose all financial interests to HPHRI for review. HPHRI will determine if there is any financial conflict of interest. This includes financial interests of the individual’s spouse and dependent children.

Definitions:

Conflict of interest: A conflict of interest exists when commitments and obligations to Hawaii Pacific Health or to widely recognized professional norms are likely to be compromised by a person’s other interests or commitments, especially financial, particularly if those interests or commitments are not disclosed. A conflict of interest is any interest, financial or otherwise, direct or indirect; participation in any business transaction or professional activity; or incurring of any obligation of any nature, which is or appears to be in substantial conflict with the proper discharge of an Investigator’s duties in the public interest. This includes disclosure of all financial interests such as salaries, fees, honoraria, or gifts associated with consulting, lectures or speaking engagements; equity (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights, and royalties from the rights); payments for directorships, advisory or executive roles and commitments of financial support unrelated to the research study in question. It also includes any activity for which the Investigator expects to receive any type of remuneration including non-monetary inducements or rewards (e.g., entertainment) to investigators or their spouse or dependent children. A conflict of interest would also exist when clinical referrals are made to a business in which the Investigator or his or her spouse or dependent children has a financial interest.

HPHRI: Financial Conflicts of Interest

Definitions (cont.):

<i>Financial conflict of interest (FCOI):</i>	A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.
<i>Financial interest:</i>	Anything of monetary value, whether or not the value is readily ascertainable.
<i>Institutional responsibilities:</i>	An Investigator's professional responsibilities on behalf of the Institution, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Data and Safety Monitoring Boards.
<i>Investigator:</i>	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 research, which may include collaborators or consultants.
<i>Key personnel:</i>	The project director/principal investigator and any other person identified as key personnel by the Institution in the grant application, contract proposal, contract, progress report, or any other report submitted to the funding agency.
<i>Research:</i>	A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
<i>Significant financial interest:</i>	<p>One or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional responsibilities:</p> <ol style="list-style-type: none">(1) Publicly traded entity – 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, which when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.(2) Non-publicly traded entity – the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, which when aggregated, exceeds \$5,000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).(3) Intellectual property rights and interests (e.g., patents, copyrights) - upon receipt of any income related to such rights and interests.(4) Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. This does not include travel that is reimbursed or sponsored by a 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.

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Definitions (cont.):

- (5) Does not include the following types of financial interests:
- (a) Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution. This includes intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.
 - (b) Any ownership interest in the Institution held by the Investigator if the Institution is a commercial or for-profit organization.
 - (c) 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.
 - (d) Income from seminars, lectures, or teaching engagements sponsored by a 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.
 - (e) Income from service on advisory committees or review panels for a 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.

Sponsor: A pharmaceutical, biotechnology or medical device company or contract research organization that has entered into an agreement with an investigator authorizing that investigator to conduct research studies.

Policy / Procedure:

- I. Investigators and key personnel must disclose all financial interests related to the individual's Institutional responsibilities to HPHRI as follows:**
- A. Compensation, other than from the Institution, received in the last twelve (12) months.
 - B. Proprietary interest of any amount in the investigational item.
 - C. Intellectual property rights of any amount. Notify HPHRI upon the filing of a patent application or the receipt of income related to the intellectual property, whichever is earlier. This does not include unlicensed intellectual property that does not generate income.
 - D. Equity interest in a public company. This only includes direct holdings; it does not include interests in mutual funds and retirement accounts if the investment decisions made are not directly controlled by the individual.
 - E. Equity interest in a non-publically traded company. This only includes direct holdings and does not include interests in mutual funds.
 - F. Payments received from other sources. This does not include income from seminars, lectures, or teaching sponsored by an Institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an Institution of higher education.
 - G. Reimbursed or sponsored travel. Include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip.

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II. Disclosures of financial interests are to be made to HPHRI on the HPHRI specified form at the following times.

- A. Submission of the research project to HPHRI or at the time of application to a funding organization, whichever is earlier.
- B. Annually as requested by HPHRI. New financial interests must be disclosed and the values of previously disclosed financial interests are to be updated. This disclosure will also include any information that was not initially disclosed or disclosed in a subsequent disclosure.
- C. Within thirty (30) days of discovery or acquisition of a new significant financial interest.
- D. An individual may not work on a research project until this disclosure has been submitted to HPHRI.

III. Disclosure to the designated Institutional Review Board (IRB)

- A. HPHRI will determine which financial interests need to be disclosed to the designated IRB on the IRB application for review.
- B. HPHRI and/or the designated IRB will determine if the financial interest needs to be disclosed directly to human subjects research participants.
- C. HPHRI will report any changes in financial interest holdings to the applicable IRB immediately upon notification by the individual, as required by the applicable IRB

IV. Evaluation of FCOI

- A. HPHRI will review all financial disclosure forms submitted by individuals.
- B. All financial interests will be tracked by individual in a database.
- C. The CMS (Centers for Medicare and Medicaid Services) Open Payments database on the Internet will be checked annually for payments to any individuals submitting an FCOI form to HPHRI. If any interest is found which is not in the HPHRI database, that interest will be added to the HPHRI database.
- D. HPHRI will review and analyze each individual's interests and determine if any of the interests represent a significant financial interest.
- E. If there is a significant financial interest, then a determination will be made if it is a FCOI (see definition of FCOI above). This determination may be made in consultation with the Corporate Compliance Officer and/or General Counsel.
- F. All FCOIs will be reported to the Hawai'i Pacific Health (HPH) Corporate Compliance Officer for development of a management plan for the FCOI. The management plan shall specify the actions that have been, and will be, taken to manage such FCOI. Examples of conditions or restrictions that may be imposed to manage a FCOI include, but are not limited to the following:
 - 1. Public disclosure of the financial conflict of interest (e.g., when presenting or publishing the research),
 - 2. Disclosure of the FCOI directly to research participants,
 - 3. Monitoring of the research by independent reviewers,

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4. Modification of the research plan,
 5. Change of personnel or personnel responsibilities, or disqualification from participation in all or a portion of the research,
 6. Reduction or elimination of the significant financial interest (e.g., sale of equity interest), or
 7. Severance of relationships that create actual or potential conflicts.
- G. HPHRI will determine if a significant financial interest needs to be disclosed, upon written request, based on the (1) continued holding of the significant financial interest, (2) determination that the significant financial interest is related to the research activity, and (3) conclusion that the significant financial interest is a financial conflict of interest.
- H. HPHRI will determine if any FCOI needs to be reported to the Public Health Service (PHS). This only applies to PHS-funded research.
- I. If a new Investigator or an existing Investigator discloses a new significant financial interest, HPHRI will review the significant financial interest within sixty (60) days to determine if a FCOI exists. Any FCOI will be forwarded to the HPH Corporate Compliance Officer for development of a management plan that specifies the actions that have been and will be taken to manage the FCOI.

V. Management of any FCOI

- A. The management plan of any FCOI will be implemented by HPHRI after the plan is developed by the HPH Corporate Compliance Officer.
- B. The management plan may include the following elements:
1. An investigator with a FCOI cannot participate in the informed consent process;
 2. The financial interest is to be disclosed in any abstracts, posters, oral presentations or journal publications;
 3. Request an addendum to previously published presentation;
 4. Other elements as determined by the HPH Corporate Compliance Officer.
- C. Investigator compliance with the management plan will be monitored by HPHRI on an ongoing basis until completion of the research to see if the research was biased in the design, conduct or reporting of the research.
- D. HPHRI will conduct a retrospective review in cases of non-compliance to see if the research was biased in the design, conduct, or reporting of the research.
- E. HPHRI will notify PHS promptly (when applicable) when bias is found and submit a mitigation report which will include the impact of the bias on the research project and the actions the Institution has or will take to eliminate and/or mitigate the effect of the bias.

VI. Plan for Untimely Disclosures

- A. Upon identification of a significant financial interest which was not disclosed in a timely manner or was not previously reviewed, HPHRI will, within sixty (60) days, review the significant financial interest to determine if a FCOI exists. If an FCOI exists, HPHRI will

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- contact the Corporate Compliance Officer to implement a management plan that identifies the actions that have been, and will be, taken to manage the FCOI going forward.
- B. Within 120 days of determination of noncompliance, HPHRI will complete a retrospective review of the Investigator's activities and the research project to determine if the research was biased in the design, conduct or reporting of the research during the time period of noncompliance.
1. HPHRI will document the retrospective review as follows:
 - a. Project number;
 - b. Project title;
 - c. Project Director or Principal Investigator;
 - d. Name of the Investigator with the FCOI;
 - e. Name of the entity with which the Investigator has a FCOI;
 - f. Reason(s) for the retrospective review;
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - h. Findings of the review; and
 - i. Conclusions of the review.
 2. Based on the results of the review, HPHRI will update the previously submitted FCOI report if appropriate, and specify the actions that will be taken to manage the FCOI going forward.
 3. If bias is found, the Institution will notify the PHS awarding component promptly, if applicable, and submit a mitigation report to the PHS awarding component. The mitigation report will include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and the Institution'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, and an analysis of whether the research project is salvageable).
- C. HPHRI will monitor Investigator compliance with the management plan on an ongoing basis until completion of the research project.

VII. Training and Education

- A. Initial training on FCOI will be required prior to, or at the time of, submission of a project to HPHRI. Training must be completed before a project is approved. This training may be provided online through the HPH Learning Center (HLC) or via paper or electronic copies of the training. FCOI initial training will include information about the existence of HPH's FCOI policy, Investigator responsibilities regarding disclosure of FCOIs, and information about FCOI regulations.
- B. Annual training may also be completed online via HLC or via paper or electronic copies of the training. Investigators will be notified when the annual training is due.

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- C. Individual training will be provided either online through HLC or by HPHRI in the following circumstances:
 - 1. The FCOI policy changes in a manner that affects the Investigator's disclosure requirements.
 - 2. There is an Investigator new to the institution.
 - 3. An Investigator is noncompliant with this policy or any management plan under this policy.

VIII. Subrecipients of Funds

- A. This policy will apply to any subrecipients of funds received by Hawai'i Pacific Health (HPH) or any of its affiliates.
- B. Adherence to this policy will be included in any applicable subrecipient contract along with specific time periods to report all FCOIs to HPH.

IX. Disclosure on the HPH Website

- A. The FCOI policy will be posted on the Hawai'i Pacific Health website.

X. Public Accessibility Regarding Significant Financial Interests Related to PHS-Funded Research

- A. For significant financial interests determined to be FCOIs with PHS-funded research, the following will be available via a written response to a requestor within 5 business days of a written request:
 - 1. Investigator's name;
 - 2. Investigator's title and role on the research project;
 - 3. Name of the entity in which the significant financial interest is held;
 - 4. Nature of the significant financial interest; and
 - 5. Approximate dollar value of the significant 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 value cannot be readily determined through reference to public prices or other reasonable means of fair market value.
- B. The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of identification of a new FCOI, which should be requested subsequently by the requestor.
- C. The information will remain available for responses to written requests for three (3) years from the date that the information was most recently updated.

XI. FCOI Reporting to the Public Health Service

- A. An initial report is to be made to PHS prior to expenditure of any PHS funds for PHS-funded research. The reported information will include the following:
 - 1. Project number;

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2. Project Director or Principal Investigator;
3. Name of the Investigator with a FCOI;
4. Name of the entity with which the investigator has a FCOI;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the financial interest using ranges (\$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 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;
8. The basis for the Institution's determination that the financial interest conflicts with such research; and
9. A description of the key elements of the Institution's management plan will include the following:
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan;
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - 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.

If a FCOI is eliminated, it will not be reported.

- B. For any significant financial interest that is identified as conflicting subsequent to the initial FCOI report, an FCOI report (including the elements noted in A. above) regarding the FCOI will be provided to PHS within sixty (60) days. HPH will ensure that a management plan has been implemented. For any significant financial interest that was not disclosed timely by an investigator or was not previously reviewed or managed by HPH, a retrospective review will be completed to determine if the PHS funded research, or any portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. If bias is found, HPH will notify the PHS awarding component promptly and submit a mitigation report to it.
- C. Annual reports will include the status of the FCOI, changes to the management plan, and if the FCOI is still being managed or if the FCOI no longer exists. An annual report is to be submitted for the duration of the project period.
- D. A management plan is to be developed and implemented prior to the expenditure of PHS funds and within 60 days of any subsequently identified FCOI.
- E. If the failure of an Investigator to comply with HPH's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or

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reporting of the PHS-funded research, HPH shall promptly notify the PHS Awarding Component of the corrective action to be taken and will comply with any further action required by the PHS Awarding Component.

XII. Retention of Records

HPHRI will retain records for three (3) years from the date the final expense report is submitted. These records will include all disclosures of financial interests, the Institution's review of and response to such disclosures (whether or not a disclosure resulted in the determination of a FCOI), and all actions taken under the Institution's policy or retrospective review.

Standard / Reference & Year:	42 CFR 50, Subpart F and 45 CFR 94
Rationale for Revision:	<input type="checkbox"/> New <input checked="" type="checkbox"/> Update <input type="checkbox"/> Consolidation <input type="checkbox"/> Review
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