

Financial Conflict of Interest (FCOI)

**HAWAII'
PACIFIC
HEALTH**

KAPI'OLANI
PALI MOMI
STRAUB
WILCOX

Background

- This tutorial reviews the requirements of and the responsibilities for compliance with the 2011 revised Federal regulation on Financial Conflict of Interest (FCOI) for grants, cooperative agreements, and contracts.
- It does not include all regulatory requirements.

Key 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.

Key Definitions

(continued)

- **Investigator**

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include collaborators or consultants.

- **Institutional Responsibilities**

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, which include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Data and Safety Monitoring Boards.

- **Financial Interest**

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Key Definitions

(continued)

- **Financial Conflict of Interest**

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

- **Key Personnel**

Key personnel means 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.

Key Definitions

(continued)

Significant Financial Interest

Significant financial interest means 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:

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 or an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institution that is affiliated with an Institution of higher education.

Key Definitions

(continued)

Significant Financial Interest *(continued)*

Does not include the following types of financial interests:

1. 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.
2. Any ownership interest in the Institution held by the Investigator if the Institution is a commercial or for-profit organization.
3. 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. 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.
5. 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.

Purpose

- The FCOI regulation was established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest.

Who Must Comply

- Institutions, Investigators and Key Personnel must comply with the regulation and HPH policy.
- This includes:
 - Hawai'i Pacific Health
 - Each investigator or key person who is planning to participate in, or is participating in research.
 - Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or proposed research, including subgrantees, contractors, consortium participants, collaborators, or consultants.

What Types of Research

The regulation applies to:

1. Basic research,
2. Applied research (e.g., a published article, book or book chapter),
3. Product development (e.g., a diagnostic test or drug), and
4. Clinical trials.

Investigator Responsibilities

The Investigator is responsible for:

- Following HPH's policies and procedures;
- Completing FCOI training prior to engaging in research and annually thereafter or immediately if
 1. HPH revises its FCOI policy in a manner that affects Investigator requirements,
 2. an Investigator is new to HPH, or
 3. HPH finds that an Investigator is not in compliance with its policy;

Investigator Responsibilities

(continued)

- Submitting a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appear to be related to his/her institutional responsibilities;
- Submitting reimbursed or sponsored travel related to the Investigator's responsibilities (including investigator meetings); and
- Updating all financial disclosures on an annual basis or within 30 days of the acquisition or discovery of a new Significant Financial Interest.

What Needs to Be Disclosed

- All financial interests related to your responsibilities for HPH are to be disclosed to the Hawai'i Pacific Health Research Institute (HPHRI):
 - Compensation, other than from HPH, received in the last twelve (12) months.
 - Proprietary interest of any amount in the investigational item.
 - 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.
 - 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.
 - Equity interest in a non-publically traded company. This only includes direct holdings and does not include interests in mutual funds.
 - 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.
 - Reimbursed or sponsored travel. Include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip.

What Needs to Be Disclosed

(continued)

- **What about assets by a spouse and dependent children?**

Interests that should be disclosed include the aggregated amounts, values and holdings of financial interests of the Investigator and his/her spouse and dependent children.

What Needs to Be Disclosed

(continued)

- **What about interests in mutual funds?**

Income from investment vehicles, such as mutual funds and retirement accounts is not required as long as the Investigator does not directly control the investment decisions made in these vehicles.

What Needs to Be Disclosed

(continued)

- **What about stocks and stock options?**

Stock option assets are to be reported by the time an application for funding is submitted and then reported annually or as new stock options are obtained, in the same manner as all other assets.

What Needs to Be Disclosed

(continued)

- **What financial instruments do not need to be disclosed?**
 - 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.
 - 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.
 - 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.
 - Salary, royalties, or other remuneration paid by HPH to the Investigator if the Investigator is currently employed or otherwise appointed by HPH. This includes intellectual property rights assigned to HPH and agreements to share in royalties related to such rights.
 - Any ownership interest in the Institution held by the Investigator if the Institution is a commercial or for-profit organization.

When to Disclose

Disclosures are to be made at the following times:

1. When a research project is submitted to HPHRI or at the time of application to a funding organization, whichever is earlier.
2. Annually as requested by HPHRI.
3. Within 30 days of discovery of a new significant financial interest.

How to Disclose

- Disclosures are to be made to HPHRI on the HPHRI specified form.
 - The form is located on the intranet and internet under the Research Institute and is called *Disclosure of Financial Interests Form*.
 - Call HPHRI for a copy of the form.
 - Call HPHRI if there are questions about completing the form.
 - Click the **Resources** button at the top right of the screen to access this form.

Evaluation of FCOI

- HPHRI will review all financial disclosure forms submitted by individuals.
- All financial interests will be tracked in a database.
- HPHRI will determine if any of the disclosed interests represent a significant financial interest.
- For each significant financial interest, HPHRI will determine if it is a FCOI.
- All FCOI will be reported to the Corporate Compliance Officer for development of a management plan for the FCOI.

Management of FCOI

- Conditions or restrictions imposed to manage a FCOI may include, but are not limited to, the following:
 - Public disclosure of the significant financial interest (e.g., when presenting or publishing the research),
 - Disclosure of the FCOI directly to research participants,
 - Monitoring of the research by independent reviewers,
 - Modification of the research plan,
 - Disqualification from participation in all or a portion of the research,
 - Reduction or elimination of the significant financial interest, or
 - Severance of relationships that create actual or potential conflicts.

Disclosure of Policy and FCOI

- The FCOI policy will be posted on the HPH website and HPH intranet.
- For significant financial interests determined to be FCOIs with Public Health Service (PHS) funded research, the following will be available via a written response to a requestor:
 - Investigator's name;
 - Investigator's title and role on the research project;
 - Name of the entity in which the significant financial interest is held;
 - Nature of the significant financial interest; and
 - 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.

Disclosure of Policy and FCOI

(continued)

- The written response will note that the FCOI listing 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. This should be subsequently requested by the requestor.
- The information will remain available for responses to written requests for three (3) years from the date that the information was most recently updated.

Reporting to PHS

- HPHRI will be responsible for required reporting to PHS if an investigator has a FCOI with PHS-funded research.
 - An initial report of any FCOI will be made prior to expenditure of any PHS funds for PHS-funded research.
 - For any significant financial interest that is identified as conflicting subsequent to the initial FCOI report, an FCOI report regarding the FCOI will be provided to PHS within 60 days. HPH will ensure that a management plan has been implemented. A retrospective review must 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.

Reporting to PHS

(continued)

- Each annual report will include the status of the FCOI, changes to the management plan, and if the FCOI is still being managed or if it no longer exists.
- 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.

Disclosure of Financial Interests Form

- Please be sure to **complete and submit** the Disclosure of Financial Interests Form to HPHRI.
 - The form is located on the intranet and internet under the Research Institute and is called *Disclosure of Financial Interests Form*.
 - Click the **Resources** button at the top right of the screen to access this form.

Congratulations!!!

You have successfully completed this course!!

Please click “Exit” to proceed to the post exam so you may receive credit for completing this course.

Reminder: After you complete an exam, you may access the course again at any time from your “Completed tab” in the HPH Learning Center.