

Prepared by the Office of Research Services
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A8.900 Accounting for Research & Training
Office of Research Services

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A8.956 Financial Conflicts of Interest (FCOI) for Public Health
Services (PHS) Grants, Cooperative Agreements and Contracts

I. Purpose

To establish standards that provide a reasonable expectation that the design, conduct, and reporting of research / non- research activities funded / performed under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator FCOI.

II. Objectives

To provide policies and procedures to comply with the U.S. Department of Health and Human Services (HHS) Final Rule on "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (42 C.F.R. § 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. § 94)" available at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>. The University of Hawaii's (UH) Executive Policy E5.214 entitled "Conflicts of Interest and Commitment" available at <http://www.hawaii.edu/apis/ep/e5/acaf.php> and APM A5.504 "Procedures for Disclosing and Addressing Conflicts of Interest and Commitment" available at <http://www.hawaii.edu/apis/apm/a5000.php> provide the foundation for identifying, reporting, managing or resolving conflicts of interest at UH.

III. Applicability

This HHS Final Rule is applicable to each Institution that is applying for, submits a proposal, or that receives PHS research /non-research funding by means of a grant, cooperative agreement or contract and

each Investigator who is planning to participate in, or is participating in, such activities. However, this rule does not apply to Small Business Innovation Research Program (SBIR) Phase I applications. Refer to http://sites.nationalacademies.org/PGA/fdp/PGA_070596 for a list of PHS and non-PHS Agencies adopting the HHS FCOI regulations.

IV. Definitions

- A. *Conflicts of Interest Committee (COIC)* - faculty, staff and administrators appointed to review and provide advice on how to manage or eliminate cases concerning potential or real Conflicts of Interest. COIC members are appointed by the Deciding Official from nominations submitted from the UH Faculty Senates.
- B. *Deciding Official* - the administrator of Executive Policy E5.214. Unless otherwise designated by the University's President, the Vice President for Research (VPR) will serve in this capacity.
- C. *Entity* - any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and their spouse or dependent children) receives remuneration or in which such person has an ownership or equity interest.
- D. *Financial Interest* - Anything of monetary value (whether or not the value is readily ascertainable), that belongs to the Investigator (and their spouse or dependent children).
- E. *Financial Conflict of Interest (FCOI)* - significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research / non-research activities.
- F. *FCOI report* - an institution's report of FCOI to PHS
- G. *HHS* - U.S. Department of Health and Human Services and any components of the department to which authority may be delegated.
- H. *Institution* - any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, PHS research / non-research funding.

- I. *Institutional responsibilities* - an Investigator's professional responsibilities on behalf of UH, and as defined in UH Executive Policy E5.214 and APM A5.504.
- J. *Investigator* - the Project Director (PD) or Principal Investigator (PI) or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research / non-research activities funded by PHS or proposed for such funding, which may include, for example, collaborators or consultants. UH considers the role, rather than the title, of those involved in research/non-research activities and the degree of independence with which those individuals work. Note: The Investigator's spouse and dependent children have been eliminated from the definition of "Investigator" under the 2011 revised regulation; however, they are referenced in the definition of "Significant Financial Interest" because the Investigator must disclose Significant Financial Interests of his/her spouse and dependent children.
- K. *Senior Administrator* - member of the UH administration above the organizational level of Department Chairperson or the equivalent in non-academic units of UH.
- M. *Senior/key personnel* - PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to PHS.
- N. *Significant Financial Interest (SFI)* - covers all financial interests that have monetary value, whether or not the value is readily ascertainable. 42 C.F.R. § 50, Subpart F; 45 C.F.R. § 94
 - 1. A financial interest consisting of 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:
 - a. With regard to any publicly traded entity, an *SFI* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.

For purposes of this definition, 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;

- b. With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, 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); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel, (as defined in UH APM A8.851, "*Employee Out-of-state and Intra-state Travel*") that is reasonably related to their institutional responsibilities, and when aggregated for each entity exceeds \$5,000. This disclosure requirement applies to Investigators and their immediate family members. Travel that is reimbursed or sponsored by a federal, state, local government agency, or a U.S. 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 a U.S. Institution of higher education, is excluded from this disclosure requirement.
 - 3. *SFI* does not include the following types of financial interests: salary, royalties, or other remuneration paid by UH to the Investigator if the Investigator is currently employed or otherwise appointed by UH, including intellectual property rights assigned to UH and agreements to share in royalties related to such rights; 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 federal, state, or local government agency, U.S. Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, or a research institute that is affiliated with a U.S. Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, a U.S. 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 a U.S. Institution of higher education.

V. Responsibilities

A. Investigator

1. Disclose any SFI that reasonably appears to be related to institutional responsibilities by completing either the UH Conflicts of Interest Disclosure Form (Attachment A) per APM A5.504 **or** ORS FCOI-1 Disclosure Form (Attachment B). The disclosure shall be included with the proposal submission packet.
2. PHS-funded Investigators must complete ORS FCOI training at <https://laulima.hawaii.edu/portal> prior to engaging in research / non-research activities related to a PHS- funded grant or contract.
3. If a subaward is issued, incorporate terms into the subaward agreement that establish whether UH's FCOI policy or that of the subrecipient will apply to the subrecipient's

Investigators and disclose subrecipient Investigator's SFI prior to incurring any project expenditures or within 45 days of any subsequently identified FCOI.
4. Comply with FCOI management plan if applicable.

B. Senior Administrators - Chancellors, Deans, Director

1. Perform initial review of all SFIs disclosed by the Investigator, including those not disclosed in a timely manner in accordance with UH policies and procedures.
2. Forward disclosures concerning potential FCOI, and other SFIs for which the Senior Administrator requires assistance to the Office of Research Services (ORS), Compliance Section for possible referral to the COIC or Deciding Official.

Note: Guidelines for reviewing the disclosure statements and COIC responsibilities are outlined in APM A5.504, sections III.B. and IV.

D. Conflict of Interest Committee (COIC)

1. Review and provide advice on elimination or management of potential or actual FCOI.
2. Develop an FCOI management plan per guidelines in APM A5.504 Section X. and monitor Investigator's compliance with such plan.
3. For SFIs not disclosed in a timely manner in accordance with UH policies and procedures, perform a retrospective review of the Investigator's activities and the PHS-funded project within 120 days of determining noncompliance, to determine whether any PHS-funded research, or portion thereof, conducted during the period of noncompliance, was biased in design, conduct, or reporting of such research.
4. Deliberate on allegations of UH Conflict of Interest policy (E5.214) violation and recommend to the Deciding Official conditions or sanctions for resolution.

E. Office of Research Services (ORS)

1. Maintain a policy that complies with the HHS Final Rule and make it available on a publicly accessible UH Web site.

2. Inform each PHS-funded Investigator of the following:
 - a. HHS Final Rule available at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
 - b. This APM A8.956, UH Executive Policy E5.214, available at <http://www.hawaii.edu/apis/ep/e5/acaf.php>, and APM A5.504, " available at <http://www.hawaii.edu/apis/apm/a5000.php>; and
 - c. Investigator's responsibility regarding disclosure of SFI.
3. Require that each PHS-funded Investigator complete ORS FCOI training prior to engaging in research / non-research activities on any PHS-funded project:
 - a. at least every four years, and
 - b. immediately whenever any of the following occur:
 - UH revises its policy
 - An Investigator is new to UH
 - UH finds that the Investigator is not in compliance with the FCOI policy or management plan
4. Perform periodic monitoring of Investigator's completion of required training.
5. Review the subaward agreement to ensure that it incorporates terms that establish whether UH's FCOI policy or that of the subrecipient will apply to the subrecipient's Investigators.
6. Coordinate the review of potential FCOI with COIC or Deciding Official.
7. Assist COIC / Deciding Official in determining whether FCOI exists and monitor Investigator's compliance with FCOI management plan. Examples of conflict resolution are identified in APM A5.504, Section V.

8. If any SFI is determined to be an FCOI:
 - a. Disclose required information on a publicly accessible UH Web site prior to expenditure of funds and update annually and within 60 days of receipt of identification of any additional FCOI. Such information shall remain accessible for at least three years from the date that it was most recently updated.
 - b. Provide a report, including mitigation report to PHS if bias is found for previously undisclosed SFI, PHS prior to expenditure of funds and update annually with progress report and within 60 days of receipt or identification of any additional FCOI.

VI. Procedures

- A. At the time of proposal submission to meet PHS FCOI regulations:
 1. Investigator discloses any SFI related to their UH responsibilities by attaching either the UH Conflict of Interest Disclosure Form (Attachment A) in accordance with APM A5.504 **or** completes and attaches ORS FCOI-1 form (Attachment B).

Disclosures should be included with the proposal submission packet.
 2. With each proposal submission, UH certifies that it:
 - a. has an up-to-date process to identify and manage FCOI
 - b. shall promote and enforce Investigator compliance with HHS Final rule, including disclosure of SFI
 - c. shall manage FCOI and provide initial and ongoing FCOI reports to awarding components as necessary

B. Prior to engaging in PHS-funded activities or expending any funds:

1. Investigators must complete ORS FCOI training at <https://laulima.hawaii.edu/portal>.
2. For awards received without a proposal or if changes to SFI have occurred since submission of the proposal, Investigator must disclose SFI in accordance with procedure VI.A.1. above.
3. Senior Administrator will perform an initial review of the Investigator's SFI disclosure to determine whether an FCOI exists. If assistance is required for determination or if an FCOI is identified, Senior Administrator will forward disclosure information to COIC via ORS.
4. COIC will review the Investigator's SFI disclosure and determine if any SFI is related to the PHS-funded research / non-research activities and whether it could directly and significantly affect the design, conduct, or reporting of the PHS-funded project.
5. If an FCOI is identified, COIC will develop a management plan (see APM A5.504 Section V.) and the Deciding Official will review and approve such plan.
6. ORS will report all FCOIs to PHS and post required information to the publicly accessible UH Web site.

C. During the award period:

1. If an Investigator acquires or discovers a new SFI, Investigator must disclose such SFI to ORS within 30 days of identification of the SFI in accordance with procedures outlined in VI.A.1. above.
2. If an Investigator who is new to participating in an existing PHS-funded project discloses an SFI or an existing Investigator identifies a new SFI, Investigator must disclose the SFI in accordance with procedures outlined in VI.A.1. above and the Senior Administrator will perform

a review to determine whether an FCOI exists and if there is a need to manage, reduce or eliminate the conflict. The Senior Administrator may refer to COIC for assistance. The review must be completed within 60 days of identification.

a. If UH determines the SFI to be an FCOI, the COIC will implement a management plan on an interim basis.

b. ORS will submit an FCOI report to PHS within 60 days and ensure that UH has implemented a Management Plan.

3. If UH discovers an undisclosed SFI or a failure by an Investigator to comply with the FCOI management plan, the Senior Administrator performs a retrospective review to determine whether an FCOI exists and if there is a need to manage, reduce or eliminate the conflict. The Senior Administrator may refer to COIC for assistance. Retrospective reviews must be completed within 120 days of identification.

a. If determined to be FCOI, ORS will update the previously submitted FCOI report to PHS, specifying actions to manage the FCOI on a go-forward basis.

b. If bias is found, ORS will notify PHS promptly and submit a mitigation report.

4. ORS will submit an updated annual FCOI report to PHS at the same time as the annual progress or technical report and update the publicly accessible UH Web site for each FCOI.

5. COIC will monitor the Investigator's compliance with the FCOI Management Plan and in accordance with APM A5.504 Section V.D., take corrective action for noncompliance if necessary.

6. If a subaward is issued, Investigator will incorporate as part of a written subaward agreement with the subrecipient, terms that establish whether UH's (awardee institution) FCOI policy or that of the subrecipient will apply to the subrecipient's Investigators.

a. If subrecipient's Investigators must comply with its own FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this HHS Final Rule. If subrecipient cannot provide such certification, the agreement shall state that the subrecipient Investigators are subject to the UH FCOI policy for disclosing SFI that are directly related to the subrecipient's work for UH.

i. The subaward agreement shall specify time periods for the subrecipient to report all identified FCOI to UH. Such time periods shall be sufficient to enable ORS to provide timely FCOI reports to PHS.

b. Alternatively, if the subrecipient's Investigator must comply with UH's FCOI policy, the subaward agreement shall specify time periods for the subrecipient to submit all Investigator disclosures of SFI to UH. Such time periods shall be sufficient to enable UH to comply with its review, management, and reporting obligations.

7. ORS will perform periodic reviews of training logs to ensure that PHS-funded Investigators have completed the required training. ORS may suspend account activity at any time if training is not completed as required.

8. Sanctions against any Investigator who fails to comply with UH's FCOI policy or management plan will be taken in accordance with APM A5.504 Section V.D. ORS shall promptly notify PHS of the corrective action taken or to be taken for any FCOI that appears to have biased the design, conduct, or reporting of PHS funded activities.

D. Post Award Termination

1. UH will maintain records related to SFI disclosures and FCOI determinations in accordance with APM A5.504, Section XI.