



Administrative Procedure Chapter 12, Research
Administrative Procedure Section AP 12.304, Procedures for Disclosing and Addressing
Conflicts of Interest Related with Extramurally-Funded Activities

Effective Date: March 1, 2019

Dates Amended: Previously AP 8.956, August 2014, July 2012

Responsible Office: Office of the Vice President for Research and Innovation

Governing Board and/or Executive Policy: EP 12.214, Conflicts of Interest and
Commitment

Review Date: February 2019

I. PURPOSE:

To establish clear guidelines and procedures consistent with applicable university executive policy(ies), governmental regulations and sponsor requirements to ensure that the design, conduct, and reporting of all Extramurally-Funded Activities will be free from bias resulting from Investigator Conflicts of Interest.

NOTE: Until separate administrative procedures are implemented to address organizational/institutional conflicts of interest and conflicts of commitment, this AP 12.304 shall exist concurrently with EP 12.214 and AP 5.504. To the extent that any financial conflict of interest (FCOI) provisions conflict among these policies and procedures, the terms and provisions of this AP 12.304 shall govern.

II. DEFINITIONS

- A. COI – Stands for Conflicts of Interest, and refers to financial or professional/personal interests which may influence, or appear to influence, an Investigator's objectivity or judgment in fulfilling his or her Institutional Responsibilities. "Professional/personal interests" shall refer to interests or activities undertaken outside of an Investigator's Institutional Responsibilities.
- B. COIC – Stands for Conflict of Interest Committee, and refers to a group of individuals appointed by the Deciding Official to review and consult on FCOI/COI matters.
- C. Deciding Official – Unless otherwise designated by the University of Hawai'i (UH) President, the Vice President for Research and Innovation (VPRI) will serve in this capacity.

- D. Disclosure – Refers to:
1. Making known to UH the existence of any Significant Financial Interest;
 2. Making known to UH the existence of any potential or actual FCOI/COI;
 3. Providing a statement as to the existence of any FCOI/COI, such as in public presentations or publications;
 4. Notifying funding agencies of any potential or actual FCOI/COI; and/or
 5. Notifying other individuals involved in Extramurally-Funded Activities of any potential or actual FCOI/COI.
- E. Extramurally-Funded Activity – An activity that is funded by an external, non-UH entity and may include research, instruction, training, public service, or any other scholarly or administrative activity.
- F. FCOI – Stands for Financial Conflicts of Interest, and refers to COI that are specifically financial in nature.
- G. Immediate Family – Includes the Investigator’s spouse, domestic partner/reciprocal beneficiary and dependent children.
- H. Institutional Responsibilities – Refers to an Investigator’s professional responsibilities on behalf of UH, which may include activities such as research, teaching, training, consulting, professional practice and committee memberships or service.
- I. Investigator – May include a Project Director (PD), Principal Investigator (PI), Co-Investigator, Co-PD, Co-PI, key person or any other person who shares responsibility for the design, conduct, or reporting of the Extramurally-Funded Activity. May also include clinical investigators, subrecipients, and students involved in extramurally-funded activities.
- J. Management Plan – A written plan describing the oversight and monitoring activities that will be undertaken to manage and mitigate the FCOI/COI. The Management Plan must be acknowledged and agreed to by Investigators with identified FCOI/COI and those with responsibilities for oversight of the Management Plan.
- K. ORC – Refers to the UH Office of Research Compliance

- L. ORS – Refers to the UH Office of Research Services.
- M. PHS – Stands for Public Health Service, and refers to the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including but not limited to, the National Institutes of Health (NIH). PHS has authority for the administration of 42 CFR § 50 and 45 CFR § 94, as may be amended from time to time. Other funding entities such as private non-profits may have adopted PHS FCOI regulations, and this Administrative Procedure shall also apply to Extramurally-Funded Activities with such entities.
- N. SFI – Stands for Significant Financial Interest, and refers to anything of monetary value or potential monetary value, to Investigators and/or their Immediate Family, received from non-UH entities, which is, or appears to be, reasonably related to the Investigator's Institutional Responsibilities. SFI refers to anything of monetary value received in the past 12 months and includes, but is not necessarily limited to, the following:
1. From publicly traded entities:
 - a) Remuneration in excess of \$5,000, aggregated per entity; or
 - b) Any equity interest (e.g., ownership, stocks) in excess of \$5,000, aggregated per entity
 2. From non-publicly traded entities:
 - a) Remuneration in excess of \$5,000, aggregated per entity; or
 - b) Any equity interest of any value
 3. Intellectual Property: royalties/income from intellectual property (e.g., patents, copyrights and trademarks) not partially licensed to and/or owned by UH.
 4. Sponsored Travel: reimbursement or sponsorship for travel made by a non-UH entity, related to Investigator's Institutional Responsibilities. Applies ONLY to Investigators who receive extramural awards from PHS and any non-PHS agencies who incorporate PHS regulations in their award terms.
- SFI does not include:
- Salary, royalties, or other remuneration paid by UH to its Investigators;

- Equity interests arising solely by reason of investment in a business by a mutual fund, pension, or other institutional investment fund over which the investor does not exercise control;
 - Income from seminars, lectures, or teaching engagements sponsored by federal, state, local government agencies, or U.S. institutions of higher education;
 - Royalties or related compensation paid by UH, such as intellectual property rights assigned to UH and agreements to share royalties related to those rights; or
 - Income from service on advisory committees or review panels for federal, state, or local governmental agencies or U.S. institutions of higher education.
- O. Supervisor – Refers to the immediate supervisor of an Investigator (e.g., Department Chair) who must review and approve Disclosures, as well as the next level in an Investigator’s organization (e.g., Dean, Director, Campus Chancellor, or Vice President, as appropriate) who must provide a second level of approval.

III. **ADMINISTRATIVE PROCEDURE:**

A. Responsibilities

1. Investigators involved in Extramurally-Funded Activities shall be responsible for:
 - a) Complying with applicable governmental regulations and funding agency policies pertaining to FCOI/COI;
 - b) Disclosing the existence of any SFI (see III.B.1 Disclosure);
 - c) Disclosing the existence of any potential or actual FCOI/COI;
 - d) Disclosing the existence of any FCOI/COI in public presentations or publications;
 - e) Disclosing to other individuals involved in Extramurally-Funded Activities any potential or actual FCOI/COI;
 - f) Cooperating with appropriate offices in implementing a Management Plan prior to engaging in Extramurally-Funded Activities, when it is determined that a Management Plan is

required, and complying with the measures described therein (see III.B.2 Management Plan);

- g) Disclosing any changes to previously made Disclosures within 30 days of such a change;
- h) Completing FCOI training, if such training is required by a funding agency, such as PHS (see III.B.6 Training); and
- i) When conducting human subjects research, informing human participants of the presence of an FCOI/COI in compliance with 45 CFR § 46, regardless of the source of funding, and informing the UH Human Studies Program or other Institutional Review Board, as appropriate.

2. ORC shall be responsible for:

- a) Reviewing Disclosures submitted by Investigators and approved by Supervisors for concurrence that the SFI are reasonably related to their Institutional Responsibilities (as defined in II.J.) and/or whether or not an actual or potential FCOI/COI exists;
- b) Notifying an Investigator's Supervisor of the Disclosure of any SFI that may constitute an actual or potential FCOI/COI.
- c) When SFI constitutes an FCOI/COI, assisting an Investigator with drafting a Management Plan for review by the ORS and ORC Directors before final approval by the Deciding Official.
- d) Consulting with the UH Office of Technology Transfer (OTT) on conditions of Management Plans concerning IP disclosure, ownership, royalties, and licenses, when necessary;
- e) Referring cases to the COIC, or through the Deciding Official, when an Investigator and a Supervisor cannot agree whether a SFI does or does not constitute an FCOI/COI;
- f) Referring cases of actual or potential FCOI/COI to the COIC when a Management Plan must be implemented;
- g) Monitoring an Investigator's compliance with an established Management Plan;
- h) Referring cases to the Deciding Official where the Investigator has failed to comply with a Management Plan;

- i) Referring cases to the Deciding Official where there may have been a violation of UH FCOI/COI policy or procedure, federal regulation, or funding agency policy;
 - j) Notifying the UH Human Studies Program or other Institutional Review Board, as appropriate, of identified FCOI/COI pertaining to human subjects research;
 - k) Providing FCOI/COI training to Investigators and FCOI/COI review training to Supervisors; and
 - l) Keeping records pertaining to Disclosures, Management Plans, Reports, Retrospective Reviews, and Training for a minimum of three (3) years following the date that the final expenditure report or final invoice is submitted to the funding agency.
3. ORS shall be responsible for:
- a) Certifying that UH has an established FCOI/COI policy and procedure and that UH is in full compliance with all of the regulatory requirements by the funding agency, and making the policy available on a publicly accessible Web site;
 - b) Collecting subrecipient FCOI certifications on the Subrecipient Letter of Intent and/or Subrecipient Commitment Form (S-1).
 - c) Providing initial and ongoing (e.g., annual) FCOI reports to funding agencies of any potential or actual FCOI/COI (see III.B.3 Reporting) I, as required by the agencies;
 - d) Notifying funding agencies of FCOI Management Plans as required by the agencies;
4. Supervisors shall be responsible for:
- a) Reviewing Investigators' Disclosures for concurrence that the disclosure is accurate, any disclosed SFI are reasonably related to their Institutional Responsibilities, whether or not an actual or potential FCOI/COI exists, and approving such Disclosures;
 - b) Assisting with the establishment and monitoring of a Management Plan, if one is required.

5. The Deciding Official shall be responsible for:
 - a) Upon referral by ORC, determining whether or not an Investigator's SFI does or does not constitute an FCOI/COI, and when such a determination cannot be made, delegating to the COIC to make such a determination;
 - b) Upon referral by ORC or the COIC, making recommendations for conditions of Management Plans and, reviewing and approving of finalized Management Plans;
 - c) Reviewing determinations made by the COIC as to whether or not a violation of UH FCOI/COI policy or procedure, governmental regulations, or funding agency policy has occurred;
 - d) Initiating a retrospective review when necessary (see III.B.4. Retrospective Review);
 - e) Imposing corrective action requirements or sanctions upon an Investigator for violations of UH policy or procedure, governmental regulation, or funding agency policy (see III.B.5. Sanctions); and
 - f) Appointing of COIC members based on Mānoa and other campus Faculty Senate nominations. COIC investigations of Unit 7 Faculty Members will be conducted in accordance with Article IX, Academic Freedom, Section D. "Procedure for Dealing with Alleged Breach of Professional Ethics and/or Conflicts of Interest in Research or Scholarship" of the Unit 7 Collective Bargaining Agreement.

6. When delegated by the Deciding Official, the COIC shall be responsible for:
 - a) Determining whether an Investigator's SFI does or does not constitute an FCOI/COI;
 - b) Recommending measures for COI Management Plans;
 - c) Assist in monitoring management plan compliance, when agreed upon;
 - d) Conducting a retrospective review when necessary; and

- e) Determining whether or not a violation of UH COI policy or procedure, federal regulation, or funding agency policy has occurred.

B. Procedures

1. Disclosures

Investigators involved in Extramurally-Funded Activities, including those applying for extramural funds, shall disclose any SFI, FCOI/COI. Investigators who have disclosed SFI and/or have received extramurally-funded award(s) shall submit or update their Disclosure no less frequently than annually. Additionally, all Investigators shall review and update their Disclosure, as appropriate, when any of the following actions occur:

- a) Prior to applying for extramural funding,
- b) Within 30 days of receiving an extramurally-funded award if a disclosure has not been completed,
- c) Within 30 days of changes to an Investigator's SFI, FCOI/COI, or
- d) When a new Investigator will participate in an existing Extramurally-Funded Activity.

If an extramural award is received without an application, Investigators must update their Disclosures, as appropriate, at the time the award is received.

Supervisors and ORC will review the Disclosures for concurrence and determination as to whether or not the Investigator's SFI and/or other potential COI could directly and significantly affect the design, conduct, or reporting of the Extramurally-Funded Activity. Prior to allowing any award expenditures, ORC may require the Investigator to implement a Management Plan for any identified actual or potential FCOI/COI. ORS may also be responsible for reporting identified FCOI/COI, as required by regulation or funding agency policy. (See III.B.3. Reporting.)

2. Management Plans

Management Plans are intended to mitigate or eliminate the potential for bias in an Extramurally-Funded Activity. Management Plans are normally agreed to by Investigators and their Supervisors, with

assistance and input from the COIC/ORC. If a Management Plan cannot be agreed to by the above listed parties, ORC may refer the matter to the Deciding Official. All completed Management Plans will be furnished to ORC for transmittal to the Deciding Official, for approval.

Management Plans, at minimum, will include a description of the potential conflict and criteria that may lead to risk, a justification for proceeding with management (versus eliminating the conflict), and management strategies, including conditions or restrictions that may be imposed to ensure integrity and objectivity, eliminate bias, and protect human subjects in all Extramurally-Funded Activities. Additionally, Management Plans may include, but not necessarily be limited to, the following measures:

- a) Public disclosure of the FCOI:
 - (1) In writing to any requestor within five business days of the request and shall include elements listed in III.B.3. Reporting (a.1-7);
 - (2) In all relevant publications and presentations;
 - (3) To appropriate co-Investigators, members of the laboratory or research group, students or trainees; and/or
 - (4) To the UH Human Studies Program (or other Institutional Review Board).
- b) Monitoring of the Extramurally-Funded Activities by Supervisor or other individual(s) who have agreed to oversee compliance with the management plan.
- c) Review of notebooks, publications and presentations for accurate disclosure and/or data integrity.
- d) Meeting regularly with Supervisor(s), a PD/PI, scientific collaborators, and/or other individuals who will oversee compliance with the Management Plan.
- e) Annual reporting to ORC of the activities undertaken with respect to compliance with the Management Plan.

- f) Reporting any significant concerns to the COIC, ORC or Deciding Official, including recommendations for revisions to the Management Plan or any mitigation concerns.
- g) Modification of the research or extramural activity plan to mitigate or eliminate the FCOI/COI.
- h) Prohibition from contributing to any activity that could be influenced because of SFI (e.g., the Investigator may be prohibited from serving as the PD/PI, analyzing data, determining whether potential subjects are eligible for enrollment, or soliciting consent).
- i) Divestiture of SFI (i.e., allowing work to proceed contingent upon the sale or disposal of specified financial interests).
- j) Severance of relationships that create conflicts (e.g., relinquishing a seat on a board of an outside entity).
- k) Documentation of any exception (i.e., facts that support that an Investigator is uniquely qualified or positioned, and should be permitted to participate in a specific Extramurally-Funded Activity under appropriate management, despite a SFI). In rare cases, the Deciding Official or the COIC may also advise that the potential for significant scientific progress, important technology transfer, benefits to society or public health and welfare outweigh concerns about FCOI/COI. In such cases, the exception shall be documented in an appropriate Management Plan.

3. Reporting

- a) ORS shall submit initial and annually updated FCOI reports to funding agencies, as necessary. Included in the FCOI reports shall be the following:
 - (1) Project/award/grant/contract number, PI/PD name or contact PI/PD name,
 - (2) Name of Investigator with the FCOI,
 - (3) Name of the entity with which the Investigator has a FCOI,
 - (4) Nature of the FCOI (e.g., equity, consulting fees, travel reimbursements, honoraria, etc.),

- (5) Value of the financial interest by range of value as follows:
 - i. \$0 to \$4,999;
 - ii. \$5,000 to \$9,999;
 - iii. \$10,000 to \$19,999;
 - iv. Amounts between \$20,000 and \$100,000 by \$20,000 increments; and
 - v. Amounts above \$100,000 by \$50,000 increments;

or, a statement that a value cannot be determined, and why,
 - (6) A description of how the FCOI relates to the Extramurally-Funded Activity and the basis for determining that the interest conflicts with such activity, and
 - (7) A statement as to whether the FCOI was managed, reduced, or eliminated, and if managed, details of the Management Plan.
- b) ORS shall submit annual update reports to funding agencies, which shall include all of the above, in addition to all of the following:
 - (1) Status of the FCOI,
 - (2) Changes, if any, in the Management Plan, and
 - (3) Other records regarding the FCOI upon request by funding agencies.
 - c) ORS shall report FCOI information required by funding agencies prior to expenditure of extramural funds. The FCOI information shall be reported within 60 days of the date the new SFI was identified and shall be updated annually.
 - d) ORC shall make available FCOI information to the public, upon request within five business days. This information shall be available for three years following the date that the final

expenditure report or final invoice is submitted to the funding agency.

4. Retrospective Review

a) If an Investigator with an active extramurally-funded project fails to disclose timely an SFI that is potentially an FCOI/COI, or if an Investigator fails to comply with a Management Plan, the Deciding Official shall initiate a retrospective review through the COIC to determine whether bias in the Extramurally-Funded Activity exists. Retrospective reviews shall be completed within 120 days of identification of noncompliance, and shall include, at minimum, documentation of the following:

- (1) Project/award/grant/contract number, PI/PD name or contact PI/PD name,
- (2) Name of Investigator with the FCOI,
- (3) Name of the entity with which the Investigator has a FCOI,
- (4) Nature of the FCOI (e.g., equity, consulting fees, travel reimbursements, honoraria, etc.),
- (5) Value of the financial interest by range of value as follows:
 - i. \$0 to \$4,999;
 - ii. \$5,000 to \$9,999;
 - iii. \$10,000 to \$19,999;
 - iv. Amounts between \$20,000 and \$100,000 by \$20,000 increments; and
 - v. Amounts above \$100,000 by \$50,000 increments;

or, a statement that a value cannot be determined, and why,

- (6) Reason(s) for the retrospective review,
 - (7) Details of the retrospective review (e.g., methodology of review process, composition of review panel, documents reviewed, etc.), and
 - (8) Findings and conclusions of the review.
- b) If the retrospective review concludes that bias in the Extramurally-Funded Activity occurred:
- (1) Interim measures shall be implemented immediately by the Deciding Official and/or appropriate Supervisor, and may include suspension of the Extramurally-Funded Activity until an appropriate Management Plan is decided upon;
 - (2) As necessary, ORS shall submit a mitigation report, and/or update any previously submitted FCOI report to the funding agency, specifying actions that eliminate/mitigate the effect of the bias and any interim measures necessary to remove the conflicted investigator from the Extramurally-Funded Activity; and
 - (3) After the initial mitigation report, ORS shall submit updated reports annually to funding agencies, as necessary. (See III.B.3. Reporting.)

5. Sanctions

If an Investigator fails to report SFI, FCOI/COI, comply with this Administrative Procedure, or an established Management Plan, it shall be considered to be a violation of UH policy and may result in suspension or termination of Extramurally-Funded Activities. Funding agencies may also impose restrictions or penalties upon Investigators for non-compliance with their FCOI/COI policies and/or regulations. UH may take further disciplinary action up to and including termination of employment, if appropriate.

6. Training

Some funding agencies, such as PHS, require FCOI training for funded Investigators. FCOI training is available through ORC and PHS-funded Investigators must complete training:

- a) Prior to engaging in any Extramurally-Funded Activity or expending any extramural funds;
- b) Once at least every four years; or
- c) Immediately, whenever UH revises its policy(ies), an Investigator is new to UH or new to the Extramurally-Funded Activity; or if UH finds that an Investigator is not in compliance with UH policy(ies) or an approved Management Plan.

IV. DELEGATIONS OF AUTHORITY:

There is no administrative procedure specific delegation of authority.

V. CONTACT INFORMATION:

The Office of the Vice President for Research and Innovation, telephone number: (808) 956-5006; and email: uhovpri@hawaii.edu may be contacted for information relating to this Administrative Procedure.

VI. REFERENCES:

- Link to superseded procedures: <https://www.hawaii.edu/policy/archives/ap/>
- 42 CFR §§ 50.601-607, Promoting Objectivity in Research
- 45 CFR §§ 94.1-6, Responsible Prospective Contractors
- 45 CFR § 46, Protection of Human Subjects
- See the UH Office of Research Compliance Website -- <https://www.hawaii.edu/researchcompliance/conflicts-interest> for more information.
- See the UH Office of Research Services Website -- <http://www.ors.hawaii.edu/> - for more information.

VII. EXHIBITS AND APPENDIXES:

None

Approved:

Vassilis Syrmos
Vice President for Research and Innovation

Date